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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: Comments [partial] (1 page)	12/31/1996	P3/b(3)
002. fax	Andrea Razzaghi to Distribution re: call for papers [partial] (1 page)	01/07/1997	P3/b(3)

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

FOLDER TITLE:
Comments on Report [1]

2014-0046-S
rc1436

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

U.S. Department of Justice
Office of the Assistant Attorney General
Civil Division

George Jordan Phillips
Counselor to the Assistant Attorney General

950 Pennsylvania Ave., N.W., Room 3143
Washington, D.C. 20530
(202) 514-5713 Fax (202) 514-8071

January 31, 1997

HAND DELIVERY

Diane Regas
Senior Policy Analyst
Domestic Policy Council
Old Executive Office Bldg.; Rm. 222
Washington, D.C. 20502

Dear Diane:

AAG Hunger is still very uncomfortable with any partial compensation proposal, but if the Administration is determined to put one forth, he would feel more comfortable if the 80% confidence interval were utilized because it appears that the measure of the uncertainty of the underlying data we are utilizing may overstate the amount of error. He still strongly questions the wisdom of the partial compensation proposal because such a proposal will likely result in miners being compensated for cancers which were in all probability not related to the exposure in the mines.

Beyond the factor of the exaggeration of the error present in the underlying data, basing the eligibility criteria on the lower limit of the 80% confidence interval would in reality result in a 90% confidence level that all the miners whose cancers are related to the exposure are compensated, for the reasons explained below. Likewise, the utilization of the lower bound of a 90% confidence interval results in a 95% confidence level that all miners whose cancers were caused by the exposure would be compensated. If there is a decision made to put a partial compensation proposal forward, AAG Hunger would like the opportunity to discuss his concerns with Bruce Reed if a confidence level exceeding 90% is chosen.

We believe that the amount of uncertainty in the underlying data is overstated for the miners as a whole, which implies that we are actually achieving a higher degree of confidence that we will be compensating all miners whose exposure to radiation is the likely cause of their cancer.

The newly proposed full compensation criteria (both WLM and duration of employment) have already been adjusted for the

uncertainty associated with the statistical sampling process, at a 90% level of assurance. There are at least two reasons why adjusting the WLM criteria for the additional uncertainty associated with WLM measurements at a 90% or 95% level of assurance may overestimate the effect of error (i.e., overcompensate some miners).

First, the new exposure criteria were derived by combining data from two relatively equal-sized cohorts of miners: the Colorado Plateau cohort and New Mexico cohort. The error associated with WLM measurements has been calculated for the Colorado Plateau mining cohort only; a similar analysis has never been done on the New Mexico cohort. For purposes of adjusting eligibility criteria, we assumed that the magnitude of the measurement error is the same in both cohorts. This assumption, however, probably overestimates the effect of the error in the combined cohort.

It is widely believed that the measurement error for the Colorado Plateau data is greater than the measurement error for the New Mexico data. The WLM measurements for the Colorado Plateau cohort are relatively sparse for many mines and many years; consequently, miners' exposures are often estimates based on interpolations and extrapolations from other mines and other years. The New Mexico study, on the other hand, covers later years, when the sampling techniques were more accurate and actual measurements more plentiful.

Because an error analysis has never been done on the New Mexico cohort, we do not know precisely how much our assumption overestimates the error in the combined cohort. According to one of the scientists on the Radiation Committee familiar with the cohorts, a very, very, very rough estimate of the measurement error for the New Mexico cohort is 60%. Thus, the average error for the two cohorts, perhaps more representative of the error for the total mining population, could be in the area of 80%. Regardless, adjusting for the WLM measurement error by using the highest confidence intervals (90% or 95%) will surely exaggerate the impact of the error.

Second, the criteria for partial compensation are created by lowering the eligibility criteria for full compensation to account for the estimated WLM measurement error. The amount by which the criteria are lowered will depend upon the confidence

interval one chooses to apply: that is, how sure one wants to be that the effect of the error is captured.[1]

For our purposes -- generating minimum eligibility criteria -- we are concerned only with the bottom half of the confidence interval. We want to make sure that the claimant's probability of causation is above the lowest point defined by the confidence interval; we do not care if the claimant's actual probability is above the upper end of the confidence interval, for then the claimant is surely entitled to compensation.

Because we are looking only at the lower bound, when we select as the eligibility criteria one bound of the 90% confidence interval we get the effect of a 95% confidence interval: there is only a 5% possibility that the true value is below the adjusted criterion. Though a level of 95% probability is the norm in most scientific fields, we can effectively achieve that level by using the 90% plan. Using the 95% plan, however, would account for more error than is the norm in the scientific community.

Additionally, the estimated error associated with the WLM measurements in the Colorado Plateau cohort (about 97%) represents the uncertainty associated with the calculation of the cumulative exposure history of the average miner in the cohort. Because we use the average miner, the estimated error will be lower than the true error for some miners employed in the earlier years (e.g., 1951 to 1955), and will be greater than the true error for some miners employed in the later years (e.g., 1965 to 1968).[2]

I have enclosed the memorandum I received from Paul Yanowitch concerning the budget estimates for the proposed RECA amendments including estimates concerning the partial compensation proposal.

---

[1] A "confidence interval" of "x" percent implies that one is "x" percent sure that, accounting for the uncertainty, the true value (in our case, the 50% probability of causation criterion) is within that interval. The interval is centered around the best estimate of the criterion. The probability that the true value lies outside the confidence interval is equal to 100% minus "x". One-half of this probability is below the lowest point of the confidence interval; one-half is above the highest point of the interval.

[2] The Colorado Plateau study is based on mine measurements from 1951 to 1968. It is technically feasible to calculate the error associated with the WLM measurements in specific time periods within this larger time frame. However, this task would likely take a biostatistician a few months to complete.

Please let me know if you need anything else.

Sincerely,

George J. Phillips

cc: Elizabeth Drye (OEOB, Rm 222)
Enclosure

U.S. Department of Justice

Washington, D.C. 20530

January 21, 1997

TO: George Phillips
Counselor to the
Assistant Attorney General

FROM: Gerard W. Fischer
Assistant Director
Torts Branch, Civil Division

Paul Yanowitch
Trial Attorney
Torts Branch, Civil Division

Subject: Budget Estimates for RECA Amendments

Set out below are our best estimates of the cumulative cost of the amendments to RECA currently under consideration. These "bottom line" estimates include costs associated with previously denied claims refiled under the newly proposed criteria, and the cost of claims expected over the 20-year term of the compensation program. We believe that our estimates are based on a number of assumptions that will overestimate the actual costs of the program. An Attachment to this memorandum contains a detailed explanation how we calculated these cost estimates.

We recognize that the cumulative financial impact of the amendments is somewhat larger than we had previously anticipated. This is due principally to (1) new information which has allowed us to calculate the number of additional claims eligible under the duration of employment standard; (2) the inclusion of previously denied claims now eligible for compensation; and (3) a correction to our estimate of the cost of the RECA program if it was not amended, which we had previously overestimated. Our prior estimates did not sufficiently highlight the absence of these additional costs.

It is important to note, however, that the bulk of the additional costs are due to proposed amendments to the full compensation criteria. The new criteria for full compensation were developed by the Radiation Committee, and have been approved by the IAWG without dissent. These new criteria are estimated to add approximately $30 million over the next 20 years.

This figure is larger than we may have suggested in the past because, as noted above, we overestimated the cost of an unamended RECA Program. Our original estimate for an unamended RECA Program was based on an extrapolation from the Colorado Plateau cohort, which has the highest average radon exposure of any uranium mining group. This group, therefore, is at the highest risk of lung cancer. We have since combined that cohort with a second cohort of lower-exposed miners to create a composite group that we believe better reflects the average risk of lung cancer in the total mining population eligible for compensation under RECA.

The estimates below also indicate that the costs of the various partial compensation schemes vary only minimally, when viewed over the 20 year program period. The difference between the least expensive partial compensation scheme -- 80% plan that adds $6.7 million -- and the most expensive scheme -- 95% plan, that adds $17.4 million -- is under 10 million dollars.

We must also emphasize that the figures below are estimates of the cumulative impact of the proposed changes, only. We have made no attempt to estimate the impact of the changes on any specific fiscal year budget.

cc: J. Patrick Glynn
J. Euler
L. Liner
M. Schrader

	Unamended RECA	Amended RECA
No. of Miners		
No. Eligible Full Comp.	441	776
No. Eligible Partial Comp.	0	134 (80% plan) 238 (90% plan) 348 (95% plan)
Cost (in millions of dollars)		
Full Comp.	44.1	77.6
Prior Denials	0.0	17.7
Future Claims	44.1	59.9
Partial Comp.	0.0	6.7 (80% plan)
Prior Denials		1.35
Future Claims		5.35
	0.0	11.9 (90% plan)
Prior Denials		1.65
Future Claims		10.25
	0.0	17.4 (95% plan)
Prior Denials		2.4
Future Claims		15.0

TOTAL BUDGET IMPACT:
(in millions of dollars)

Unamended RECA	$44.1
Amended RECA	
	$84.3 (80% plan) [$40.2 additional]
	$89.5 (90% plan) [$45.4 additional]
	$95.0 (95% plan) [$50.9 additional]

ATTACHMENT

I. **Costs of RECA If NOT Amended**

A. Claims Eligible for Full Compensation

1. Use Table 7b: estimated number of miners in Colorado Plateau and New Mexico cohorts who will die of lung cancer over next twenty years, and be eligible for compensation under present RECA criteria

   (a) 50% probability of causation adjusted for uncertainty associated with statistical sampling process

   (b) IAWG approved adjustment for statistical sampling uncertainty at 90%

2. Estimated number of lung cancer deaths in combined cohort eligible under RECA = 184 (169.9 + 14.0)

3. Combined cohort is approximately 42% of estimated total mining population eligible under RECA temporal/geographic criteria; estimates from combined cohort must therefore be multiplied by 2.4 (1/.42) to forecast impact in total minimg population

4. 184 estimated eligible lung cancer deaths in combined cohort forecasts 441 eligible cases in total mining population

5. 441 cases eligible for full compensation ($100,000) = $44.1 million

B. Claims Eligible for Partial Compensation

1. Under present statutory scheme, claimants are not eligible for partial compensation

2. 0 cases eligible for partial compensation = $0.0

II. **Costs if RECA Amended**

A. Prior Denials Eligible For Compensation Under Amended Statute

1. Prior Denials Eligible for Full Compensation

(a) Total of 352 denied lung cancer claims to date; 238 denied because of insufficient exposure (too few WLMs); 188 of these analyzed under the newly proposed WLM and duration of employment criteria

(b) 112 of 188 (60%) previously denied claims are now eligible under newly proposed WLM (82 eligible) or duration of employment (additional 30 eligible) criteria

(1) 46 of 188 cases are "certain" denials

(2) 30 of 188 are "uncertain" denials; insufficient information on claimants' exposure history to determine eligibility confidently

(c) Assuming this 60% rate of eligibility applies as well to 50 prior denials not analyzed (238-188), an additional 30 prior denials are eligible for full compensation

(d) Minimum of 142 (112 + 30) cases eligible for full compensation = $14.2 million; assuming worst case that all 30 "uncertain" denials are approvals, maximum of 172 prior denials eligible for full compensation = $17.2 million

2. Prior Denials Eligible For Partial Compensation

(a) 77 of 188 previously denied claims analyzed still ineligible for full compensation under proposed amendments; these claims analyzed to determine if eligible for partial compensation under various proposed schemes

(b) If statute amended to account for WLM measurement uncertainty at 80% level of assurance

(1) 6 of 76 (8%) claims ineligible for full compensation would be eligible for partial compensation

(2) 51 of 76 are "sure" denials

(3) 19 of 76 (25%) are "uncertain" denials; insufficient information on claimant's exposure history to determine eligibility confidently

(4) Assuming 8% rate of eligibility from analyzed denials, 2 of 20 unanalyzed cases ineligible for full compensation now eligible for partial compensation

(5) Minimum of 8 prior denials eligible for partial compensation = $.4 million; assuming worst case that all "uncertain" denials are approvals, maximum of 27 (8 + 19) prior denials eligible for partial compensation = $1.35 million

(c) If statute amended to account for WLM measurement uncertainty at 90% level of assurance

(1) Prior denials not analyzed by Program under 90% level of assurance scheme; estimates based on averages of prior denials under 80% and 95% schemes

(2) estimated 15 of 76 (20%) claims ineligible for full compensation would be eligible for partial compensation

(3) estimated 44 of 76 would be "sure" denials

(4) estimated 18 of 76 (24%) are "uncertain" denials; insufficient information on claimant's exposure history to determine eligibility confidently

(5) Assuming estimated 20% rate of eligibility based on analyzed denials, 4 of 20 unanalyzed cases ineligible for full compensation now eligible for partial compensation

(6) Estimated minimum of 19 prior denials eligible for partial compensation = $.95 million; assuming worst case that all "uncertain" denials are approvals, maximum of 33 (15 + 18) prior denials eligible for partial compensation = $1.65 million

(d) If statute amended to account for WLM measurement uncertainty at 95% level of assurance, Table 7e:

(1) 24 of 76 (32%) claims ineligible for full compensation would be eligible for partial compensation

(2) 34 of 76 ineligible for partial compensation are "sure" denials

(3) 18 of 76 (24%) are "unsure" denials; are insufficient information on claimant's exposure history to determine eligibility confidently

(4) Assuming 32% rate of eligibility from analyzed denials, 6 of 20 unanalyzed cases ineligible for full compensation now eligible for partial compensation

(5) Minimum of 30 (24 + 6) prior denials eligible for partial compensation = $1.5 million; assuming worst case that all "uncertain" denials are approvals, maximum of 48 (30 + 18) prior denials eligible for partial compensation = $2.4 million

B. Future Cases Eligible For Compensation Under Amended Statute

1. Future Cases Eligible for Full Compensation

(a) Per IAWG, proposed amendments would allow a claimant to qualify under either newly devised WLM criteria, newly devised duration of employment citeria, or present RECA criteria

(b) Use Table 7b: estimated number of miners in Colorado Plateau and New Mexico cohorts who will die of lung cancer over next twenty years, and be eligible for compensation under 50% probability of causation adjusted for uncertainty associated with statistical sampling process at 90%

(c) Computed number of cases eligible under either WLM or duration of employment models is subject to significant error; alternative method used to compute eligible cases

(1) Precise data on duration of employment in New Mexico cohort unavailable; assumed that miner employed for full year for each year employed; assumption likely overestimates duration for many miners, underestimating risk

(2) Error due to assumption regarding duration of employment likely sufficiently significant that computed number of cases in New Mexico eligible under duration of employment model not reliable

(3) Algorithm to estimate number of cases eligible under either WLM or duration of employment models in New Mexico:

-- Proportional increase in eligible cases in Colorado Plateau cohort due to addition of duration of employment model computed; (# eligible under either WLM or duration model) - (# eligible under WLM model)/# eligible under WLM model

-- Assumed that proportional increase in eligible cases due to adding duration of employment model equivalent in two cohorts; proportional increase applied to known number of cases eligible in New Mexico cohort under WLM model, and added to number of cases eligible under WLM model

-- Radon progeny levels in Colorado Plateau cohort significantly higher than in New Mexico cohort; implies that average exposure (WLMs) per duration higher in Colorado -- so using Colorado rate of increase will overestimate risk in New Mexico cohort

(d) Number of cases eligible in combined cohorts under either WLM or duration model = 226.3

-- 226.3 = 185.4 (CO) + 40.86(NM)

-- 40.86 = (((185.4-121.6)/121.6) x 26.8) + 26.8

(e) 226.3 estimated lung cancer deaths in combined cohort eligible under either model forecasts 543 (226.3 x 2.4) eligible cases in total mining population

(f) According to Table 7b, 23.4 lung cancers in combined cohorts will not qualify under either WLM or duration models, but will qualify under RECA; forecasts 56 (23.4 x 2.4) additional cases in total mining population eligible under statute if amended as proposed

(g) Total cases eligible for full compensation = 599 (543 + 56); 599 cases = $59.9 million

2. Future Cases Eligible For Partial Compensation

(a) 80% Level of Assurance: Table 7c

(1) Table 7c shows estimated number of miners in Colorado Plateau and New Mexico cohorts who will die of lung cancer over next twenty years, and be eligible for compensation under 50% probability of causation adjusted for statistical sampling uncertainty at 90% and WLM measurement uncertainty at 80%

(2) Number of cases eligible for either full or partial compensation in combined cohorts under either WLM or duration model = 294

-- 294 = 215.8 (CO) + 77.7(NM)

-- 77.7 = (((215.8-188.7)/188.7) x 67.9) + 67.9

(3) 294 estimated lung cancer deaths in combined cohort eligible under either model forecasts 706 (294 x 2.4) eligible cases in total mining population

(4) Of 706 cases eligible for some compensation, 599 meet eligibility criteria in Table 7b for full compensation

(5) Total cases eligible for partial compensation = 107 (706 - 599); 107 cases = $5.35 million

(b) 90% Level of Assurance: Table 7d

(1) Table 7d shows estimated number of miners in Colorado Plateau and New Mexico cohorts who will die of lung cancer over next twenty years, and be eligible for compensation under 50% probability of causation adjusted for statistical sampling uncertainty at 90% and WLM measurement uncertainty at 90%

(2) Number of cases eligible for either full or partial compensation in combined cohorts under either WLM or duration model = 335

-- 335 = 233.9 (CO) + 101 (NM)

-- 101 = (((233.9-217.2)/217.2) x 93.8) + 93.8

(3) 335 estimated lung cancer deaths in combined cohort eligible under either model forecasts 804 (335 x 2.4) eligible cases in total mining population

(4) Of 804 cases eligible for some compensation, 599 meet eligibility criteria in Table 7b for full compensation

(5) Total cases eligible for partial compensation = 205 (804 - 599); 205 cases = $10.25 million

(c) 95% Level of Assurance: Table 7e

(1) Table 7e shows estimated number of miners in Colorado Plateau and New Mexico cohorts who will die of lung cancer over next twenty years, and be eligible for compensation under 50% probability of causation adjusted for statistical sampling uncertainty at 90% and WLM measurement uncertainty at 95%

(2) Number of cases eligible for either full or partial compensation in combined cohorts under either WLM or duration model = 374.5

-- 374.5 = 252.1 (CO) + 122.4 (NM)

-- 122.4 = (((252.1-243.5)/243.5) x 118.2) + 118.2

(3) 374.5 estimated lung cancer deaths in combined cohort eligible under either model forecasts 899 (374.5 x 2.4) eligible cases in total mining population

(4) Of 899 cases eligible for some compensation, 599 meet eligibility criteria in Table 7b for full compensation

(5) Total cases eligible for partial compensation = 300 (899 - 599); 300 cases = $15 million

C. **Total Compensation**

1. Full Compensation

a. Maximum total number of cases eligible for full compensation under newly proposed criteria = 177 prior denials plus 599 future claims = 776

b. 771 cases at full compensation = $77.6 million

2. Partial Compensation

a. 80% Level of Assurance

1. Maximum total number of cases eligible for partial compensation under 80% level of assurance scheme = 27 prior denials plus 107 future claims = 134

2. 134 cases at partial compensation = $6.7 million

3. Total cost of 80% scheme, full and partial compensation = $77.6 + $6.7 = $84.3 million

b. 90% Level of Assurance

1. Maximum total number of cases eligible for partial compensation under 90% level of assurance scheme = 33 prior denials plus 205 future claims = 238

2. 238 cases at partial compensation = $11.9 million

3. Total cost of 90% scheme, full and partial compensation = $77.6 + $11.9 = $89.5 million

c. 95% Level of Assurance

1. Maximum total number of cases eligible for partial compensation under 95% level of assurance scheme = 48 prior denials plus 300 future claims = 348

2. 348 cases at partial compensation = $17.4 million

3. Total cost of 95% scheme, full and partial compensation = $77.6 + $17.4 = $95.0 million

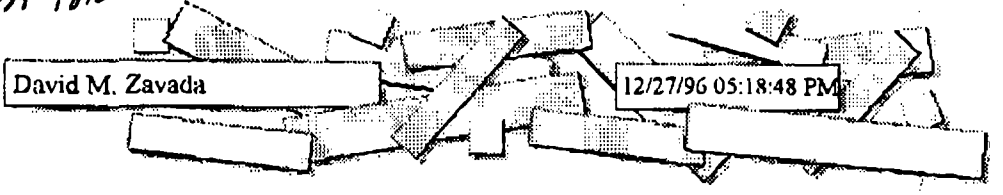
3. Additional Cost of Amendments Over Twenty Year Period

a. 80% Level of Assurance: $84.3 - $44.1 = $40.2 million

b. 90% Level of Assurance: $89.5 - $44.1 = $45.4 million

c. 95% Level of Assurance: $95.0 - $44.1 = $50.9 million

To: D. Regan/E. Drye
Fr: Hitt.
VA Branch + CIA comments on Radiation Rpt



Record Type: Record

To: Elyse H. Fitter/OMB/EOP

cc: Alexandra Lehr/OMB/EOP, Alexander S. Keenan/OMB/EOP, Toni S. Hustead/OMB/EOP
Subject: Irm: EHF7 Report on Human Radiation Experiments

The VA Branch has the following comments on the Commission's report:

1. Epidemiological tables are currently used by VA to relate dose exposure levels to cancer to establish service-connection for the condition. Onco service-connection is established, monthly cash benefits are awarded. Consequently, revisions to the epidemiological tables may result in changes in benefit levels which may include PAYGO costs.

2. Remove any reference to the Administration proposing legisation to qualify veterans, exposed to nasopharyngeal radiation in service, for VA health screening and care. This is an issue with cost and policy implications that needs to be further examined by OMB and the agency. We will explore this issue with the agency more in-depth over the next few months in order to make an informed decision.

The following changes should be made to reflect this change: 1) On page iii of the Executive Summary remove the fourth bullet. 2) On page 24 in second paragraph remove everything below the first sentence. (The first sentence about the VA and CDC teleconference can be merged with the paragraph above).

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Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

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rc1436

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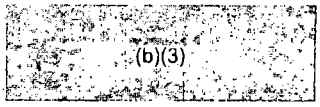

[001]

CIA Comments re: LRM EHF7 *(Proposed Report on Actions to Respond to the Advisory Committee on Human Radiation Experiments)*

- Although CIA agrees with many of the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE), CIA has concerns regarding ACHRE's Recommendation #15 (p. 16), which would require: researchers to identify an agency sponsoring classified research projects, and agency heads to approve all human subjects research involving classified information.

- As CIA noted in its letter to Robert Dumas, dated 11 December 1996, identification of an agency sponsoring classified human research could, in rare cases, jeopardize national security, while adding little, if any, additional protection to research subjects. **The proposed Presidential Memorandum, which will implement ACHRE's recommendations, should be modified to provide an exemption from the requirement to identify an agency sponsoring classified research if the head of the agency determines that such an exemption is necessary for national security purposes. The proposed report's description of the actions directed by the Presidential Memorandum concerning this matter should be changed to reflect this modification.**

- The proposed requirement that all classified human subjects research be approved by the head of the agency is not required under existing rules. It is burdensome and unnecessary for those categories of research that pose a minimal risk. **The proposed Presidential Memorandum should be amended so that heads of agencies sponsoring classified research would not be required to approve research that is exempt from coverage under existing rules or which can be approved under an expedited review procedure. The proposed report's description of the actions directed by the Presidential Memorandum concerning this matter should also be changed to reflect this modification.**

- CIA is concerned with imprecise language in the last draft of the proposed Presidential Memorandum that it reviewed concerning the composition of the Institutional Review Board (IRB). The proposed Presidential Memorandum that CIA reviewed would require each IRB to include a "non-governmental member". However, the term "non-governmental member" is not clearly defined, leaving a question as to whether a person who receives grants or other funding from the government may serve on a panel as the "non-governmental member." This point should be clarified.

File - Comments on "Buddy"

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

31-Dec-1996 09:55am

TO: REGAS_D
TO: DRYE_E

FROM: Elyse H. Fitter

SUBJECT: lrm: EHF7 Report on Human Radiation Experiments

Message Creation Date was at 31-DEC-1996 09:48:00

---------- Forwarded by Elyse H. Fitter/OMB/EOP on 12/31/96 09:45 AM ----------

David M. Zavada
12/27/96 05:18:48 PM
Record Type: Record

To: Elyse H. Fitter/OMB/EOP
cc: Alexandra Lehr/OMB/EOP, Alexander S. Keenan/OMB/EOP, Toni S. Hustead/OMB/EOP
Subject: lrm: EHF7 Report on Human Radiation Experiments

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Let us know if you have any questions.

THE 53RD PRESIDENTIAL INAUGURAL
THE PRESIDENTIAL INAUGURAL COMMITTEE
801 I STREET, NORTHWEST
WASHINGTON, DC 20599-0002
202-222-1600

OPENING DAY OPERATIONS

FAX COVER SHEET

To: Elizabeth Drye Fax No. _____

From: MARK BENOIT SCOTT BERTONE ALEXA BIRDSONG GAIL BOWER PHILIP COBB KATHY ANNE COHEN JENNIFER CURLEY CHRIS CYCMANICK QUINT DAVIS (MICHAEL GORDON) LEO GAMBACORTA MICHAEL DUGA ATIF HARDEN BRIDGET HARTIGAN CATHY KENNY JASON KRUGER DANA LEWIS MARISSA LUZZATTO REBECCA McKENZI NATHAN NAYLOR NAN PARATI MORRIS REID KATE RICHARDSON TAGUE RICHARDSON NANCY ROCHA DIXIE RUBIN RON SALEH ADAM SITKOFF KERI SMITH ERIC STERN REGENA THOMAS GUS WEST

Date: 12-30 96 No of Pages: 3

Message: _____

1601 18th Street, NW, #608
Washington, DC 20009

December 30, 1996

Elizabeth Drye
Domestic Policy Council
The White House
Washington, DC

Dear Elizabeth:

Thank you for talking to me earlier today. As discussed, attached please find a copy of my resume.

As I mentioned in our conversation, I wrote the Manual on School Uniforms and the Manual to Combat Truancy and worked on many other issues at the Department of Education. While I did not work with Mike Cohen when we were at the Department, I have worked with Rahm Emanuel, Steve Neuwirth, Jeremy Ben-Ami, Molly Brostrom and Dennis Burke, among many others at the White House. References from the Department include Governor Kunin, Frank Holleman (ED's chief of staff) and, of course, Secretary Riley himself.

You should know that currently I am working at the Presidential Inaugural Committee as Communications Director for "An American Journey," the Inaugural events on the Mall. My phone number there is 222-1860.

Per your suggestion, I will call next week. I look forward to meeting with you in the new year.

Very Truly Yours,

Michael L. Gordon

MICHAEL L. GORDON
1601 18th Street, NW, #608
Washington, DC 20009
(202) 462-0141

EXPERIENCE

MICHIGAN COORDINATED CAMPAIGN, Detroit, MI (June 1996-November 1996)
Communications Director: Coordinated statewide press, research and monitoring efforts for Clinton-Gore '96 and Michigan's Democratic ticket. Served as campaign liaison and spokesperson to statewide media. Devised and implemented rapid response communications plan to counter state visits and major announcements by Dole, Kemp and leading Republican surrogates. Worked with constituency groups in developing message and press strategy for all state campaigns. Scheduled Clinton-Gore surrogates for press events and interviews. Planned and coordinated Clinton-Gore constituency roll-outs. Managed staff of 10.

U.S. DEPARTMENT OF EDUCATION, Washington, DC (1994-96)
Special Assistant, Deputy Secretary Madeleine Kunin: Functioned as Deputy Chief of Staff. Developed Administration policy on school uniforms and student truancy; drafted President Clinton's Manual on School Uniforms and Manual to Combat Truancy. Represented Deputy Secretary to constituency groups on equity issues. Coordinated education policy and press for White House Conference on Youth Drug Use and Violence. Devised and implemented Department's "Good News in Education" communications campaign. Served as Acting Chief of Staff.

CLINTON-GORE PRESIDENTIAL TRANSITION, Washington, DC (1992-93)
Associate Counsel, Personnel Department: Served on vetting team, providing research and analysis of candidates for Cabinet and Sub-cabinet level positions.

CLINTON-GORE '92, Little Rock, AR (1991-92)
National Advance Staff: Served as lead or press lead on advance teams throughout country. Managed all aspects of traveling and local press operations. Organized free and paid media campaigns. As Deputy Press Desk, trained and advised advance staff.

EDUCATION

COLUMBIA UNIVERSITY SCHOOL OF LAW/GRADUATE SCHOOL OF BUSINESS
Joint Degree Program: Juris Doctorate/Master of Business Administration, 1991
Honors and Activities:
- Harlan Fiske Stone Scholar (Law School Dean's List)
- Business School Dean's List

UNIVERSITY OF PENNSYLVANIA
Bachelor of Arts, cum laude, 1987, with honors
Honors and Activities:
- President, Penn Student Body
- Spoon Award 1987: Penn's highest undergraduate honor
- Dean's List

LEGAL EXPERIENCE

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, New York, NY (1993-94)
Associate: Worked in banking and real estate departments.

To: E. Bryen / D. Regas

From H. Fitts

DoD comts on Rad Rept.

DoJ likely to have no comments

will confirm today 1/2/97

pages iii, 5, 7, 14, 19, 21, 22, 24, 33, appendix

compensate certain subjects, and consider modifying the Radiation Exposure Compensation Act, and its regulations, to compensate additional uranium miners.

Key Actions

- The President apologized to all subjects on behalf of the government; Energy Secretary O'Leary has made apologies in certain individual cases.
- The federal government has paid compensation to 13 of the 18 known subjects ACHRE recommended be compensated, ~~and is in negotiations with others~~ ALL 18 HAVE DIED.
- The Administration will propose legislative and regulatory changes to the Radiation Exposure Compensation Act to incorporate the latest science and better compensate affected miners.
- The Administration has prepared legislation to make veterans treated with nasopharyngeal radiation eligible for health screening under the Veteran's Administration's Ionizing Radiation Program.

In summary, the actions and policies described in this report will bring justice to those harmed by the mistakes of the Cold War and will prevent the recurrence of past wrongs.

ensure that records are accessible upon legitimate request from the public or governmental sources. The Advisory Committee further recommended that all records of the CIA bearing on programs of secret human research from the late 1940s through the early 1970s be reviewed for declassification. ACHRE expressed their expectation that most, if not all, of these CIA documents would be declassified and made public.

Response to Recommendations on Openness

ACHRE's recommendations are intended to ensure that the records of the Human Radiation experiments are organized and accessible and to promote better access to government records. This section responds to those specific recommendations. The next section more fully describes actions that individual agencies have taken to make records more fully open to public scrutiny.

ACHRE identified the National Archives as the appropriate repository for many of the documents related to human radiation experiments. The Administration agrees. All the Advisory Committee's records have been transferred to the Archives and the principle Departments are also transferring large quantities of records to the Archives. DOE is transferring over five million pages of historically valuable documents; DOD is transferring approximately one hundred thousand pages of documents; the CIA is transferring one thousand pages of documents; and HHS is transferring approximately thirty thousand pages of documents.

ACHRE recommended that the Departments make all finding aids more readily accessible. The government supports this recommendation and has taken steps to implement it. The Departments involved in radiation experiments have a tremendous volume of records. This volume makes providing tools to find specific information as critical as allowing access to files. The vast majority of relevant documents are DOE or DOD records. DOE is putting aids to historical records still in agency custody in public reading rooms and on the Internet. DOD has also taken steps to simplify the research process and provide staff support for individuals who wish to search relevant documents.

ACHRE recommended that the government take steps to improve public access to records that remain in the Departments' custody. Part of ACHRE's concern focuses on those records and collections that needlessly remain classified and that would be of significant interest to the public. President Clinton's Executive Order 12958 of April 17, 1995 addresses this concern. The Order automatically declassifies most old records that are determined to be of permanent historical value five years from the date of the Order. The Order applies to all records, not just those related to human radiation experiments. Agencies are actively reviewing their records and releasing those that are not exempt on a regular schedule to comply with the order. Although the Executive Order does not include restricted data (atomic energy information) DOE is actively reviewing this material as well.

are at the Coordination and Information Center (CIC) in Nevada.

Making records accessible: DOE has summarized how to find its records in the publication, "Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records," published in February 1995. The list of experiments in that volume is updated and expanded in, "Human Radiation Experiments Associated with the U.S. Department of Energy and its Predecessors." The text of these documents is also available via the OHRE Homepage (http://www.ohre.doe.gov). DOE also has developed a one-day course on how and where to locate human radiation experiment and related historical records.

Understanding the record: DOE staff interviewed researchers and others possessing first-hand knowledge of the human radiation experimentation and therapy that occurred during World War II and the Cold War. The result is "Human Radiation Studies: Remembering the Early Years." This 29-part series comprises some 1,350 pages of transcripts. This series offers scholars and interested lay persons a vivid glimpse inside one of the most controversial chapters in our nation's postwar history.

The Department is currently developing a plan to fund an oral history project, conducted by a non-Federal institution, which will allow the subjects and their families to tell the story from their perspective. This project will provide a reminder of the importance of protecting individual rights, even in times of national security crisis.

The Department of Defense

Identifying Subjects: The Department of Defense (DOD) is searching records for members of the armed services who may have been experimental subjects. In particular DOD is seeking rosters of those who were treated experimentally or therapeutically with nasopharyngeal radiation. This effort is similar to an effort several years ago to identify those service members who were present at above-ground nuclear tests. (The full story of that effort was chronicled by the Defense Special Weapons Agency in DNA 6041F, "For the Record--A History of the Nuclear Test Personnel Review Program, 1978-1993," March, 1996, which supersedes DNA 6041F, August 1986.)

Making records accessible: DOD is preparing a guide, similar to the DOE *Roadmap*, ~~that summarizes DOD involvement in human radiation experiments~~, describes the search process for the records of those experiments, and provides the result of the search. "The Department of Defense Report on the Search for Human Radiation Experiments Records ~~Search~~, 1944-1994" is planned for release in December 1996.

The National Aeronautics and Space Administration

National database: The National Aeronautics and Space Administration (NASA) has established a permanent collection of human radiation experiment

ACHRE Findings and Recommendations on the Protection of Military Personnel (Recommendation # 12) :
ACHRE found that it is often difficult, in a military setting, to distinguish requests for volunteers from orders. "The military setting, with its strict hierarchical authority structure and pervasive presence in the lives of its members, poses special problems for ensuring the voluntariness of participation in research activities. Thus, although the DOD has adopted and implemented the consent requirements of the Common Rule, additional procedural safeguards and educational activities for officers may be warranted to counteract the generalized deference to authority inherent in military culture. Also, because the opportunity to serve the nation as subjects in defense-oriented research projects is closely akin to the demands placed on members of the military in their routine duties, it is desirable to emphasize the distinction between research and course-of-duty risks both in consent procedures and in officer training programs."

ACHRE recommended that the military better ensure the protection of rights and interests of military personnel who are involved in human subjects research by reviewing general policies and procedures, educating officers and investigators, implementing policies and practices that make certain participation is genuinely voluntary, and maintaining a registry of volunteers. (Recommendation # 12.)

Response: The Administration agrees that extraordinary steps are needed to protect military personnel, and DOD is implementing ACHRE's recommendations. Among other steps, DOD is revising directives and Military Department regulations, and incorporating needed training into courses for commanders, senior leadership, and those involved in human subjects research. In the summer of 1997, DOD published a revised human subjects protection regulation that includes policy changes recommended by the Advisory Committee. For example, the new policy will preclude officers and non-commissioned officers from playing a role in selecting volunteers for military tests to avoid undue command influence (see Appendix B for more details).

ACHRE Findings and Recommendation on the Federal Oversight of Research (Recommendation # 13):
ACHRE found that oversight of human subjects research is limited and is constrained by practical considerations. ACHRE found that the "current mechanisms for oversight . . . do not provide a sufficient basis for ensuring that the current system is working properly."

ACHRE found that sanctions may be inadequate for violations of human subjects research protections. For example failure to obtain consent from subjects (who are not physically injured) is generally punishable only by the withdrawal of research funding.

. ACHRE also found that "there is a need to assess the level of research performed outside [the Common Rule] and to consider action to ensure that all

Part 3: Righting Past Wrongs

Overview

The ACHRE report reviewed in detail several case studies of government-supported human radiation research including: the injections of plutonium into 18 hospital patients during and after World War II; research with prisoners; and research on patients who had previously been exposed to total body irradiation in clinical settings.

The Advisory Committee also considered issues related to certain radiation exposures associated with government activities that the Advisory Committee concluded should not be considered "experiments". These exposures were sustained as a result of government activity undertaken for purposes other than human radiation research. The exposed populations include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

The Committee recommended several steps that the government should take to make amends for the specific wrongs for which the government bears moral responsibility.

This section of the report discusses ACHRE's findings and recommendations in the areas of notification, apology, and compensation and presents the Administration's response. Within the discussion of compensation, the report addresses individual cases, uranium miners, other populations covered under the Radiation Exposure Compensation Act, veterans, and Marshall Islanders.

Notification

ACHRE Finding on Notification

The Advisory Committee found "no subjects of biomedical experiments for whom there is a need to provide notification and medical follow-up for the purpose of protecting their health." In addition, the Committee found no evidence that descendants of subjects of human radiation experiments have a greater likelihood of inheriting genetic effects. (Recommendation # 4.)

ACHRE Recommendations on Notification (Recommendation # 4):

The Advisory Committee recommended that:

- For any newly-discovered experiments the government should notify participants and provide medical follow-up for "those subjects for whom there is a significant risk of developing a radiation-related disease that has not yet occurred, or has occurred but may still be undetected or

THIS IS CORRECT BUT QUOTE NOT A RECOMMENDATION

Discussion

Many of the wrongs in experimentation involved failure to provide subjects with a full and fair disclosure of the risks and benefits (or lack of benefits). At first impression the solution to this lack of disclosure seems evident--namely disclose now what was not disclosed in the past. After careful consideration, however, ACHRE recommended that decisions about notification be based on "evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals." In discussing this recommendation, ACHRE observed that notification can impose new burdens on subjects, including anxiety; medical harm,; inconvenience; possible stigmatization by friends, family, employers, or insurance carriers; and cost of seeking medical testing or follow-up. In light of these considerations, and the difficulty in tracing subjects, ACHRE recommended notification in the limited circumstances where the individual desires notification or where the notification would be of medical benefit to the individual.

This recommendation has generated controversy among stakeholders, including those who participated in the Stakeholders Workshop of February 26, and 27, 1996, held by the federal departments. Some stakeholders believe the government has a responsibility to notify and provide medical follow-up to all who were wronged by the government--not only those who were physically harmed by the government's conduct. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally advocated that the government pursue some form of notification, and provide medical care by physicians of their own choice. Many subjects or families of subjects do not have confidence that the government can honestly make a judgment about notification, or that the government can, without bias or intimidation of subjects, implement any needed medical follow-up. Others have also suggested that subjects would want notification whether or not they were harmed. *See* Hearings on Human Radiation Experiments, Senate Committee on Governmental Affairs, March 12, 1996, remarks of Senator Glenn.

The Administration agrees that the decision of when and how to notify experimental subjects requires a judgment about whether individuals would want to be notified of the government's potentially wrongful act to them, even if there is no expectation of physical harm, or no possibility to detect or treat an expected disease.

Where records become available that would allow notification, the Administration notify subjects that meet the ACHRE criteria and will also notify those that meet any one of three additional criteria. The criteria are intended to shed light on the non-medical benefits that may accrue to those potentially being notified. As noted above, subjects will be notified if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about

In the event that the departments uncover additional forgotten experiments, the decision to notify any newly-discovered subjects will be made by the Department that sponsored the research, based on the criteria discussed above.

the effects of the experiment and notification is necessary to understand whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that these other benefits—where they are present—would cause most subjects to prefer notification.

Information Requests: Potential experimental subjects will be given information if they ask for it. Further the government will keep and search records that will help potential subjects find answers about their own history. In addition the government will use all reasonable means to let potential subjects know that they have the opportunity to ask questions about their own history and a choice about whether to pursue the information.

To make the choice meaningful, the government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research. Publicity about the existence of experiments, and the widespread availability of a general description of the research has successfully generated tens of thousands of inquiries from those who want to know whether they were experimental subjects. This large response suggests that the government's outreach efforts have provided an opportunity for a significant portion of potential subjects to choose whether to seek more information.

Based on the response so far, the Administration believes that continued publication of general information and aggressive follow-up of individual inquiries satisfies much of the government's obligation to notify those who potentially were subjects of experiments.

Additional Research: In the event that the departments uncover additional forgotten experiments, any newly-discovered subjects will be notified made by the Department that sponsored the research, based on the criteria discussed above.

As experiments are identified there may be uncertainty about whether initial exposures to radiation significantly increased the risk to subjects. In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be enough identifiable subjects to allow for a follow-up study. The follow-up study would be designed to identify any risk to subjects and whether medical follow up could be beneficial. The Administration's policy does not preclude conducting such a study—even though the government cannot answer with certainty what level of risk is faced by former subjects and whether there is any prospect of medical or other benefit to subjects from a follow-up study. Any follow-up study should move forward only under the following conditions: 1) All care has been taken to minimize any harmful effects of participating in a study; 2) non-governmental experts, including ethicists, have been consulted regarding the study and its fairness to individuals who will be notified of their prior participation in an experimental treatment.

Actions to Date

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 asymptomatic individuals but recommended that individuals treated with NP radium inform their health care providers for consideration when they are examined or evaluated. VA officials have published information on NP irradiation treatments in medical journals and provided it to veterans' newsletters.

The VA and CDC held 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. The Administration has proposed legislation that would make veterans treated with NP radium eligible for the VA's Ionizing Radiation Program. The Administration will be resubmitting this legislative proposal in its 1997 legislative package for consideration during the first session of the 105th Congress.

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 and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM concerning the Iodine-131 experiments involving Native Alaskans as set forth in its recent report. Efforts are ongoing with representatives of the Native Alaskans to determine appropriate follow-up remedies.

Identifying Additional Subjects: DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located. In addition DOE asked all its facilities at which human radiation experiments were identified to provide detailed information about the availability of data, if any, relating to individual subjects, the feasibility of notification, and whether any notification process had occurred. Where employees or former employees had been involved in experiments, notification generally had taken place. Otherwise, it was determined that the available data did not warrant notification in light of the criteria outlined above. If new information or experiments come to light, the Department will review these according to the Advisory Committee criteria.

Remedies

ACHRE Findings Regarding Compensation

The Advisory Committee found that:

1) "[T]he government sponsored . . . several thousand human radiation

Exposure Compensation Standards Act. This Act requires the claimant to show that the disease is both radiogenic (can be caused by radiation) and connected to the type and amount of radiation the veteran was exposed to during service. The implementing regulations include a list of diseases for which claimants do not have to prove, as a general matter, that radiation can cause the disease. HHS' epidemiological tables then provide additional information to help VA adjudicate claims, and provide some measure of predictability for claimants. This approach has the potential to be scientifically more accurate in determining service connection. It has, however, been criticized for a variety of reasons, including that the epidemiological tables are out of date, the system creates a difficult burden of proof and the process is expensive for claimants and the government.

The Administration has taken steps to make this claims process work better. In September of 1996 the Department of Veterans Affairs proposed to include all forms of cancer in the list of diseases recognized as radiogenic. This proposal would mean that each claim will be evaluated based on an individual's estimated dose and will no longer require a showing that the cancer is radiogenic. In addition, the Administration has worked with the Veterans Advisory Committee on Environmental Hazards (VACEH), an independent panel that reviews the scientific issues related to radiation-induced disease, to determine whether other diseases should be added to the list of diseases under the second approach to compensation. Transcripts of VACEH's discussions and citations to the scientific papers they considered are available from the VA. As new information becomes available, the VACEH will review it carefully and advise the Secretary if changes in the VA's regulations are warranted.

ACHRE noted that many have raised questions about the level of investment in dose reconstruction and scientific investigation compared to the amount invested in compensation of veterans. The Administration's view is that we owe veterans both -- a complete look at the facts and compensation for service-connected disease. The VA and DOD have invested heavily in making sure that full and fair information is available for every veteran who may have been exposed to radiation during service. The dose reconstructions, including their methodology, have been independently peer-reviewed. Every veteran who seeks compensation needs this information, and it can be enormously frustrating for veterans when the information is incomplete or indeterminate. The principle reason that dose reconstruction has cost more than claims is that the dose reconstruction has suggested that most veterans were exposed to levels not expected to cause a significant increase in risk. Unfortunately, there is no shortcut to this information, and it has been expensive to develop.

ACHRE noted that complaints have been raised about the appeals process for radiation-related claims. VA recognizes it must do a better job at meeting veterans' needs, and is taking steps to improve

from DOE's Office of Public Inquiries at 202 586-5575. The report is also available on the World Wide Web (www.ohre.doe.gov).

4. *Human Radiation Experiments Associated with the United States Department of Energy and its Predecessors*, released in July 1995 by OHRE, contains a listing, description, and selected references for 435 documented human radiation studies dating back to World War II. Hard copies of this report (DOE-EH-0491) are available from DOE's Office of Public Inquiries at 202 586-5575. The report is also available on the World Wide Web (www.ohre.doe.gov).

5. *Human Radiation Studies: Remembering the Early Years*, completed November 1995 by OHRE, consists of a 29-part series of oral histories whose purpose is to enrich the documentary record, provide missing information, and allow an opportunity for the researchers to provide their perspective. A descriptive brochure, which lists all of the subjects of the oral histories and provides brief background on each, as well as copies of the individual oral histories, are available from OHRE at 202 586-0858. The oral histories are also available on the World Wide Web (www.ohre.doe.gov).

6. *Radiation Protection and the Human Radiation Experiments*, Los Alamos Science, Number 23, 1995, is a special issue of this journal which discusses the work and the findings of the Laboratory's Human Studies Project Team. The team was formed to address questions concerning the ethics and conduct of human radiation experiments that were carried out by Los Alamos researchers from the Manhattan Project days through the 1960s. The report is available from Los Alamos Science, Mail Stop M708, Los Alamos National Laboratory, Los Alamos, NM 87545.

7. *The Department of Defense Report on* the Search for Human Radiation Experiment Records, 1944-1994, has a planned release date of December, 1996. It will be published by the Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs.

ITALICS ALL THE WAY TO THE X

w/ Dr. Faden's comments

Building Public Trust:

Actions to Respond to
The Advisory Committee on Human Radiation Experiments

R. F. — research on outcomes. —

Actions — anything in agency plans?

What to do about expectations

Table of Contents

Executive Summary

"Our greatness is measured not only in how we . . . do right but also [in] how we act when we know we've done the wrong thing; how we confront our mistakes, make our apologies, and take action."

-- President Clinton
October 3, 1995

In January, 1994 President Clinton established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had funded and conducted unethical human radiation experiments and releases of radiation during the Cold War. The President directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. The Committee published its findings and recommendations in October, 1995.

This report presents the Administration's actions to respond to ACHRE's findings and recommendations. The Committee found that the government had conducted ~~unethical experiments and identified changes to ensure~~ the ~~government does not repeat past mistakes.~~ ACHRE made 18 specific recommendations to improve openness in government, protect human subjects in the future, and compensate those who were wronged. The Administration has adopted most of ACHRE's recommendations and has acted throughout the government to implement them.

Opening the Record

ACHRE recommended that the government take a number of steps to organize the historical records of human radiation experiments and to give the public access to these records. ACHRE identified the National Archives as the appropriate repository for documents. The Committee also recommended an independent review of the CIA's record-keeping system and all documents related to human radiation experiments.

Key Actions

- The Administration has invested heavily in making documents accessible. ACHRE transferred more than one million pages of documents to the National Archives. The Administration has made 300,000 fully searchable pages of documents available on the Internet, and will add an additional 200,000 pages shortly. The Departments of Energy and Defense are publishing document search guides.
- The President signed Executive Order 12958 directing Federal agencies to review and declassify thousands of documents, including documents on radiation experiments.
- The National Records and Archives Administration is conducting an independent review of the CIA's record-keeping system.
- The CIA's Inspector General reviewed and reported on the CIA's human experiments. The report is on the Internet.

Protecting Human Subjects in the Future

The Advisory Committee recommended steps to strengthen protections for human subjects and ensure the government does not repeat past mistakes.

Key Actions

- President Clinton ~~issued a~~ directive to strengthen protections for subjects of classified (secret) research. Agencies will propose new rules to eliminate waiver of informed consent; disclose the identity of the sponsoring agency; ensure a more independent review process; and require permanent records. Agencies will also report annually on the number of ~~human~~ subjects involved in ~~classified~~ research.
- President Clinton established the National Bioethics Advisory Committee (NBAC) to examine bioethical issues, including human research issues. A subcommittee of NBAC will address certain broad questions raised by ACHRE, including how to strengthen Institutional Review Boards -- the local ethics panels for federally-sponsored research.
- President Clinton directed agencies to develop plans to improve oversight of ethics rules. NBAC will review these plans in the coming months.
- Agencies have undertaken nationwide education efforts to raise the profile of ethical considerations, and are funding research to improve our understanding of ethical issues.

Righting Past Wrongs

The Advisory Committee recommended, among other things, that the government apologize to all subjects,

compensate certain subjects, and consider modifying the Radiation Exposure Compensation Act, and its regulations, to compensate additional uranium miners.

Key Actions

- The President apologized to all subjects on behalf of the government; Energy Secretary O'Leary has made apologies in certain individual cases.
- The federal government has paid compensation to 13 of the 18 known subjects ACHRE recommended be compensated, and is in negotiations with others.
- The Administration will propose legislative and regulatory changes to the Radiation Exposure Compensation Act to incorporate the latest science and better compensate affected miners.
- The Administration has prepared legislation to make veterans treated with nasopharyngeal radiation eligible for health screening under the Veteran's Administration's Ionizing Radiation Program.

In summary, the actions and policies described in this report will bring justice to those harmed by the mistakes of the Cold War and prevent the recurrence of past wrongs.

Elly Melamed
586-2268

Introduction

Democratic government requires trust: people need to know and believe that the government is telling the truth. Without information about what the government is doing and why, citizens cannot exercise democratic control over government institutions.

The Clinton Administration's efforts to allow public scrutiny of government-sponsored human radiation experiments has been an important part of the effort to expand openness in government. President Clinton facilitated public scrutiny of the human radiation experiments and other records with Executive Order 12958, which automatically declassifies most old classified information. Thousands of documents are newly-available so the public can examine our history, particularly the history of the Cold War and the human radiation experiments that are the subject of this report.

In January 1994 President Clinton appointed the Advisory Committee on Human Radiation Experiments (ACHRE) chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University. The President also directed all Federal agencies to search for records related to human subjects radiation research and provide them to the Advisory Committee. The Committee's charge was to review this information and provide advice regarding scientific and ethical issues related to biomedical experiments that involved ionizing radiation and certain intentional releases of radiation. The President directed the Committee to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted). The Advisory Committee published an interim report in 1994, and a final report in October of 1995. Two years of work culminated with a final report containing twenty-three findings and eighteen specific recommendations.

After the Advisory Committee made its recommendations, federal agencies sponsored a two-day workshop for members of the public concerned about these issues. The workshop gave private citizens with an interest in human radiation experiments an opportunity to provide input into the government response to the recommendations of the Advisory Committee. The Administration has considered the views of the stakeholders in responding to ACHRE's recommendations. The full transcript of this workshop is available on the Internet.

This report presents the Administration's actions to respond to ACHRE's

recommendations. The Administration has adopted most of the Committee's recommendations, has done more than the Committee recommended in a few instances, and has not accepted a few of the Committee's recommendations. This report explains these decisions.

This report is divided into three sections: Secrecy and Openness, Protecting Future Human Subjects, and Righting Past Wrongs. The report presents those actions that are completed or underway. The Administration will continue to take steps to open the government's records, raise ethical standards and right the wrongs of the past.

Part 1: Openness in Government

Overview

Throughout our nation's history secrecy has been needed to protect our nation's security. At the same time, Americans have recognized that the government's power to act in secret conflicts with core democratic principles. Misuse of secrecy feeds a sense of mistrust in government that can undermine our cohesion as a nation.

During the Cold War, the government funded secret human radiation experiments; the mistrust created by these experiments makes it imperative that public have access to the record of the government's activities. The Administration opened the record, as discussed below, and changed rules that kept documents secret for many years after it was necessary. These changes, along with other safeguards in place already, will help to ensure that the government does not repeat the wrongs of the human radiation experiments.

Actions to Open the Record

When the Advisory Committee on Human Radiation Experiments (ACHRE) began its work, it found that there was no complete and accurate history of the government's actions. Moreover, the records of what had happened were dispersed and difficult to access, and some records were classified. The Administration mobilized all key Departments to examine, declassify where necessary, and bring together the documents that ACHRE needed. Only after these documents became available could ACHRE fully examine and evaluate the government's conduct and make recommendations for the future. ACHRE collected and transferred to the Archives over a million pages of documents. The Agencies are supplementing that material with over 5 million more pages of documents from the Department of Energy (DOE), the Department of Defense (DOD), the Central Intelligence Agency (CIA), the Department of Veteran Affairs (VA), and the Department of Health and Human Services (HHS).

A large and growing body of documents collected by the Federal agencies is available for online searching through the Internet's World Wide Web at the Human Radiation Experiments Interagency Home Page (http://hrex.dis.anl.gov). This site allows

citizens to examine close to ~~three hundred thousand~~ 300,000 pages of material, and will soon contain approximately half a million pages. The database provides both document images and sophisticated full-text searching capabilities. Many of these documents were originally unclassified but approximately 7,000 documents were specifically declassified for this project.

The general availability of information about human radiation experiments has alerted citizens to wonder about their own role in this history. As a result, tens of thousands have sought personal information about their potential participation in human radiation experiments. To protect individual privacy personal information is not publicly available. However individuals can obtain information on their potential personal involvement through the Helpline at (202)586-8539.

ACHRE Finding on Openness

The Advisory Committee found "that the government did not routinely undertake to create records needed to ensure that secret programs could be understood and accounted for in later years, and that it did not adequately maintain such records where they were created." Further, "many important record collections (including records that were not initially classified) have been maintained in a manner that renders them practically inaccessible to those who need them, thereby limiting the utility of the records to the government itself, as well as the public's rights under the Freedom of Information Act." (Finding # 19.)

ACHRE Recommendations on Openness
(Recommendation # 17 and # 18)

The Advisory Committee recommended that the government take the following steps to organize the historical records of human radiation experiments and to give access to the public, and to the government itself.

- The most important historical collections should be entrusted to the National Archives.
- Agencies should make readily available all existing inventories, indexes, folder listings, and other finding aids to record collections now under agency control. Classified finding aids should undergo declassification review, and declassified versions of these finding aids should also be made available.
- The government should ensure the development of policies to improve public access to records held by agencies or deposited in federal records centers.
- Agencies should maintain complete records, available to the public, of document destruction.
- The government should review and develop policies concerning public access to records generated or being held by private contractors and institutions receiving federal funding.

The Advisory Committee also recommended that the CIA's record-keeping system be reviewed to

ensure that records are accessible upon legitimate request from the public or governmental sources. The Advisory Committee further recommended that all records of the CIA bearing on programs of secret human research from the late 1940s through the early 1970s be reviewed for declassification. ACHRE expressed their expectation that most, if not all, of these CIA documents would be declassified and made public.

Response to Recommendations on Openness

ACHRE's recommendations are intended to ensure that the records of the Human Radiation experiments are organized and accessible and to promote better access to government records. This section responds to those specific recommendations. The next section more fully describes actions that individual agencies have taken to make records more fully open to public scrutiny.

ACHRE identified the National Archives as the appropriate repository for many of the documents related to human radiation experiments. The Administration agrees. All the Advisory Committee's records have been transferred to the Archives and the principle Departments are also transferring large quantities of records to the Archives. DOE is transferring over five million pages of historically valuable documents; DOD is transferring approximately ~~one hundred thousand~~ 100,000 pages of documents; the CIA is transferring one thousand pages of documents; and HHS is transferring approximately thirty thousand pages of documents.

ACHRE recommended that the Departments make all finding aids more readily accessible. The government supports this recommendation and has taken steps to implement it. The Departments involved in radiation experiments have a tremendous volume of records. This volume makes providing tools to find specific information as critical as allowing access to files. The vast majority of relevant documents are DOE or DOD records. DOE is putting aids to historical records still in agency custody in public reading rooms and on the Internet. DOD has also taken steps to simplify the research process and provide staff support for individuals who wish to search relevant documents.

ACHRE recommended that the government take steps to improve public access to records that remain in the Departments' custody. Part of ACHRE's concern focuses on those records and collections that needlessly remain classified and that would be of significant interest to the public. President Clinton's Executive Order 12958 of April 17, 1995 addresses this concern. The Order automatically declassifies most old records that are determined to be of permanent historical value five years from the date of the Order. The Order applies to all records, not just those related to human radiation experiments. Agencies are actively reviewing their records and releasing those that are not exempt on a regular schedule to comply with the order. Although the Executive Order does not include restricted data (atomic energy information) DOE is actively reviewing this material as well.

let's be consistent in using numbers or text for numbers ≥ 1 million, ≤ 1 million

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b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
National Science and Technology Council

Telephone (202) 456-6104 FAX (202) 456-6026

TO: DISTRIBUTION **FROM: Andrea Razzaghi**

Pages: = Cover +1 **DATE: January 7, 1997**

Message:

The following is a call for papers to be presented at a workshop sponsored by the Application Council of the NSTC Committee on Computing, Information, and Communications, May 13-15, 1997. Please note that papers will be accepted starting in January and are due no later than March 3, 1997.

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A. Ladwig, NASA, 202-358-4336
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J. Toole, NCO, 703-306-4727
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D. Robyn, NEC, 202-456-2223
T. J. Glauthier, OMB, 202-395-4639
J. Fellows, OMB, 202-395-4817
G. Reed, OVP, 202-456-9500
G. Simon, OVP, 202-456-6231
B. Starr, ACDA, 202-736-4472
(b)(3) [002]
✓ E. Drye, DPC, 202-456-7028
J. Dale, USDA, 202-690-2842

To: See the distribution list at the bottom of this message
cc: lindam @ isi.edu, cthomas @ isi.edu
Subject: Call for White Papers - R&D opportunities in Federal Information Services

Colleagues,

As most of you know, a workshop on R&D Opportunities in Federal Information Services is being sponsored by the Applications Council of the National Science and Technology Council's Committee on Computing, Information, and Communications and is being coordinated by the Information Sciences Institute of the University of Southern California. Funding for conducting the workshop has been provided by the National Science Foundation's Directorate for Computer and Information Science and Engineering, the President's Government Information Technology Services Board, and National Institutes of Health's National Center for Research Resources. The workshop is scheduled for May 13-15, 1997 to be held at a location to be determined in or near Washington, D.C.

As a result of the first meeting (December 3-4) of the organizing committee for the workshop, a Call for White Papers has been developed. The Call and additional information on the workshop process can be found at URL http://www.isi.edu/nsf/ . This URL will be kept live and dynamic as more information is available, and will serve as the entry point for on-line submission of White Papers beginning in mid-January 1997. Papers are due no later than March 3, 1997.

All sectors and interested parties are encouraged to submit Papers for review. Please forward this message to any interested individuals or organizations.

Thank you.

Lawrence E. Brandt
Program Manager for Advanced Information Systems
Division of Advanced Scientific Computing, Room 1122
National Science Foundation
4201 Wilson Blvd.
Arlington VA 22230

Phone - 703/306-1963
Fax - 703/306-0632
Internet - lbrandt@nsf.gov
Home page - http://www.cise.nsf.gov/asc/lbrandt/

DOE is also reviewing and updating its classification authorities and guidelines.

ACHRE came across references to some records that they could neither find nor confirm destroyed. As a result, the Committee recommended that the Federal government permanently maintain copies of all records destruction notices. The federal government generates an enormous number of records, many of which are of no long term interest. These records are routinely destroyed. It would be impractical to retain records destruction notices of all of these records, so the Administration does not fully accept this recommendation. However, to meet the Committee's concerns, the President is directing agencies to permanently retain records relating to classified human subject experiments.

ACHRE recommended that citizens' right to know about the activities undertaken by the government should not depend on whether government employees or contractors carried out the activities. Thus, ACHRE recommended reviewing policies governing access to records of grantees and contractors. Federal records regulations (36 CFR 1222.48) already specify that data created for Federal government use by contractors are Federal records if they are delivered to, or fall under the legal control of, the Government. All federal records must be managed according to rules that provide for appropriate access. Administration policy requires each agency to use contract provisions or other mechanisms to assert ownership of, or appropriate access to, contractor records.

ACHRE recommended review and declassification of CIA historical records and a review of CIA's recordkeeping system. The CIA recognizes the special scrutiny that is given information about CIA-sponsored human subjects research. The National Archives and Records Administration (NARA) has undertaken an independent review of the CIA's records management program that will be completed in the spring of 1997. In addition, the CIA is reviewing for declassification a few documents relevant to the MKULTRA program that have not been previously declassified and released. The CIA has already transferred approximately 1,000 pages of declassified documents, and a CIA Inspector General report on human subjects research to the National Archives. The documents are also available on the Internet.

Steps Toward Achieving Openness

Below is a more detailed listing of some of the steps agencies have taken to achieve the goal of opening the historical record. In addition, Appendix 1 summarizes sources of more information, including a list of record sources, Internet sites and publications related to human radiation experiments.

The Department of Energy

Making records available: DOE has posted over 250,000 pages of historical documents on the Internet, making the documents available in libraries, community centers, schools, and around the world. Paper copies of all documents

are at the Coordination and Information Center (CIC) in Nevada.

Making records accessible: DOE has summarized how to find its records in the publication, "Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records," published in February 1995. The list of experiments in that volume is updated and expanded in, "Human Radiation Experiments Associated with the U.S. Department of Energy and its Predecessors." The text of these documents is also available via the OHRE Homepage (http://www.ohre.doe.gov). DOE also has developed a one-day course on how and where to locate human radiation experiment and related historical records.

Understanding the record: DOE staff interviewed researchers and others possessing first-hand knowledge of the human radiation experimentation and therapy that occurred during World War II and the Cold War. The result is "Human Radiation Studies: Remembering the Early Years." This 29-part series comprises some 1,350 pages of transcripts. This series offers scholars and interested lay persons a vivid glimpse inside one of the most controversial chapters in our nation's postwar history.

The Department is currently developing a plan to fund an oral history project, conducted by a non-Federal institution, which will allow the subjects and their families to tell the story from their perspective. This project will provide a reminder of the importance of protecting individual rights, even in times of national security crisis.

The Department of Defense

Identifying Subjects: The Department of Defense (DOD) is searching records for members of the armed services who may have been experimental subjects. In particular DOD is seeking rosters of those who were treated experimentally or therapeutically with nasopharyngeal radiation. This effort is similar to an effort several years ago to identify those service members who were present at above-ground nuclear tests. (The full story of that effort was chronicled by the Defense Special Weapons Agency in DNA 6041F, "For the Record--A History of the Nuclear Test Personnel Review Program, 1978-1993," March, 1996, which supersedes DNA 6041F, August 1986.)

Making records accessible: DOD is preparing a guide, similar to the DOE *Roadmap*, that summarizes DOD involvement in human radiation experiments, describes the search process for the records of those experiments, and provides the result of the search. "The Department of Defense Report on the Human Radiation Experiments Records Search, 1944-1994" is planned for release in December 1996.

The National Aeronautics and Space Administration

National database: The National Aeronautics and Space Administration (NASA) has established a permanent collection of human radiation experiment

records and a database at Johnson Space Center. For the first time, these records will be organized, accessible, and available by request from the collection and on the Internet.

Part 2: Protecting Future Human Subjects

Overview

The success of the effort to open the historical record will be measured, in part, by whether we avoid repeating past mistakes. ACHRE's review of human radiation experiments raised questions of whether the current system of protection is adequate for all types of human subjects research. The measures described below will strengthen the protection of human subjects and address ACHRE's findings.

Federal responsibilities for maintaining ethics in human subjects research is dispersed in several agencies and committees in the government. First, each agency is responsible for the ethical administration of its programs, including grants and contracts. Second, the President's Office of Science and Technology Policy has a statutory oversight role, and will continue to monitor and address issues of science and ethics. Third, the Department of Health and Human Services has a convening role among Agencies that are bound by the Common Rule--the Federal Policy for the Protection of Human Subjects that governs all federally conducted, funded, or regulated research. (56 *Federal Register* 28010, June 18, 1991.) Finally, the National Bioethics Advisory Commission (NBAC), an independent body recently established by the President, will take up some of the most pressing ethical issues that we face. (For a description of NBAC see page 10.)

The Interagency Working Group on Human Radiation Experiments (IAWG), is a temporary collaboration among several federal agencies. The IAWG has worked to support ACHRE and to respond to its recommendations. The policies in this report seek to ensure appropriate follow-up on ACHRE recommendations by more permanent bodies.

ACHRE Findings on Protecting Human Subjects in the Future

Based on its review of current human subject protections, the Advisory Committee found, among other things, that:

"[H]uman research involving radioisotopes is currently subjected to more safeguards and levels of review than most other areas of research involving human subjects. The Advisory Committee further finds that there are no apparent differences between the treatment of human subjects of radiation research and human subjects of other biomedical

research." (Finding # 20.)

"[T]oday research involving human subjects sponsored by the government may be classified and conducted in secret, but it must comply with the provisions of the Common Rule." (Finding # 21.)

"[I]n comparison with the practices and policies of the 1940s and 1950s, there have been significant advances in the protection of the rights and interests of human subjects of biomedical research. However, we also find that there is evidence of serious deficiencies in some parts of the current system for the protection of the rights and interests of human subjects." (Finding # 22.)

ACHRE Recommendations on Protecting Human Subjects in the Future

ACHRE Recommendation on the Centrality of Ethics

(Recommendation # 9): ACHRE recommended that active efforts on a national scale be made to ensure that human subjects researchers fully understand the ethical implications and responsibilities of their work, and the centrality of ethical decisions.

Response: Responsibility for ethical conduct of research begins with researchers and extends to their institutions and other supporters. The Administration has multiple efforts underway to reach, educate, oversee and hold accountable each layer of the research system. The Administration is also taking steps to further understanding of and consensus about ethical issues.

National Bioethics Advisory Commission

NBAC was established by the President to provide guidance to all Federal agencies on the ethical conduct of human behavioral and clinical research, and the applications of that research. NBAC 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. NBAC was established in part to respond to ACHRE, and the Administration expects NBAC will choose to address the key issues identified in ACHRE's recommendations. NBAC can not be expected to review all issues raised by ACHRE. The Administration has been careful to ensure that issues not taken up by NBAC will be addressed elsewhere.

As a first priority, NBAC will seek to improve protection of the rights and welfare of human research subjects. The Executive Order establishing NBAC required each agency to review its current human subjects research in light of the Advisory Committee recommendations and report the results to NBAC. NBAC is currently reviewing these documents. Appendix B details specific activities currently being carried out by the agencies as a result of their reviews.

NBAC's meetings are public and provide a forum for dialogue on ethics issues. At its inaugural meeting, held on October 4, 1996, NBAC heard

presentations on issues related to genetic research as well as the broader area of human subjects research. Members of Congress and representatives from diverse organizations including the Task Force on Radiation and Human Rights, the College of American Pathologists, the Biotechnology Industry Organization and the Atomic Veterans Working Group testified on ethics issues and on NBAC's mission.

Education

ACHRE's report made clear that a key to preventing the repetition of past mistakes is constant and thorough education about ethics and how they apply to current human subjects research. The Administration is responding to ACHRE's specific recommendations by co-sponsoring educational programs with external groups such as medical schools, universities, and scientific societies. The goals of these educational efforts are, first, to strengthen human subjects protection. The second goal is to provide a forum for addressing ongoing as well as emerging issues in human subjects research. The third goal of educational efforts is to familiarize professionals engaged in non-Federally funded human subjects research with the relevant ethical considerations .

Part of the ongoing educational process is a reinforcement of the importance of Institutional Review Boards (IRBs) at institutions conducting Federally funded research. These IRBs are local groups whose membership and responsibilities are regulated by the Federal government. They are responsible for reviewing and approving the ethical content of all proposed human subjects research projects. IRB's are a linchpin in the protection of human subjects, and their credibility and effectiveness depend on adequate awareness of basic ethical topics. At a minimum, these topics include the fundamental general principles of ethics in research and practical application of those principles to particular projects.

Another important target of education is the government employees who have responsibility for supporting or overseeing human subjects research. Thus, Departments are implementing training programs within Federal agencies to educate senior level officials on regulations and policies governing human subjects research. For example NASA is working with international research partners to develop common ethical principles and to ensure the rights of human subjects are protected.

Information Gathering

ACHRE's report highlighted the limited state of knowledge regarding some key issues in human subjects research. Most importantly, NBAC will be reviewing and evaluating the IRB process.

In addition, Departments have pooled resources to sponsor research on the informed consent process. The informed consent process is intended to help each potential research subject decide whether to participate in research by providing advance information about the research. Information includes a description of the nature of the research, the subject's role

and potential risks, and the subject's rights and responsibilities. Despite the vigor with which all parties embrace the informed consent process, it is not well understood. Much of the Advisory Committee's commentary on current human subjects research was centered on informed consent, and the NIH, VA, DOE, and DOD are committed to supporting research that will more fully illuminate the process. A Request for Applications (RFA) was published in the fall of 1996, and Fiscal Year 1997 monies are earmarked to support this RFA.

ACHRE Recommendation on Institutional Review Boards (Recommendation # 10): ACHRE recommended specific changes to IRBs in five critical areas: mechanisms to ensure a stronger focus on studies that pose more than minimal risk to subjects; better means of explaining to potential subjects the distinction between research and treatment, the realistic likelihood of medical benefit to the subject from participation, and the potential for discomfort and pain; ensuring that potential subjects fully understand the sponsors and purposes of the research; ensuring that potential subjects fully understand the financial implications of participation; and recognition that the IRBs must decide if the quality of the science justifies the risk to the subjects.

Response: The Administration agrees that there are indications that the IRB system is not always adequate to ensure protection of human subjects. However, neither the expertise of the agencies involved in this effort, nor the record before us, is sufficient to conclude that a particular solution will effectively and comprehensively reform the system. NBAC has undertaken to review the current IRB system and intends to finish that project within a year. The Administration anticipates specific recommendations from NBAC regarding reform of IRBs, including recommendations that address ACHRE's concerns.

In the interim, agencies are informing IRBs of ACHRE's recommendations, and are working to improve IRBs.

For example, the Office of Protection from Research Risks (OPRR), part of NIH, is leading a national effort to educate the research community about ACHRE's recommendations. OPRR stages an annual public meeting for individuals interested in the governance of human subjects research. The meeting is produced in close collaboration with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization. In addition, OPRR has led discussions of the recommendations at national workshops in Atlanta, Oklahoma City, Honolulu, Peoria, Houston, and San Diego.

OPRR and the Food and Drug Administration (FDA) make extensive use of public meetings, forums, hearings, and electronic media to address evolving issues on human subject protection. OPRR and FDA also regularly mail information directly to IRBs and other interested parties. In October, 1995 FDA issued a

major revision of its "Information Sheets for Institutional Review Boards and Clinical Investigators," to take into account the latest thinking and to provide guidance to IRBs.

As noted above, ACHRE recommended that IRBs focus the bulk of their time on studies that present more than minimal risk to subjects. To educate the research community about the importance of this recommendation, OPRR sent information to 5,500 addresses in the worldwide. The information highlighted regulatory provisions for (1) exemption from IRB review of six categories of low-risk research, and (2) expedited IRB review of 10 other kinds of research when it is judged by IRBs to be of minimal risk. Proper use of these time-saving mechanisms permits IRBs to devote greater effort to the areas of concern to ACHRE.

ACHRE Recommendation on Maintaining an Open Public Forum (Recommendation # 11):
ACHRE recommended the creation of a mechanism to provide for continuing public discussion and interpretation of ethical rules and principles that govern human subjects research.

Response: The Administration agrees that continuing discussion of ethical rules is vital to protection of human subjects in government-sponsored and privately-sponsored research. Both the government and private institutions have key roles in ensuring that this debate continues. The National Bioethics Advisory Commission (NBAC) will provide an opportunity for public participation in the continuing review and interpretation of ethical rules.

Private organizations and periodicals also serve an important role in the continuing interpretation of ethical rules in public.

The Administration also agrees that there is a need for a mechanism to interpret existing rules that apply to government-sponsored research. Within the Department of Health and Human Services, the Office of Protection from Research Risks provides information and interpretations of the regulations for protection of human subjects. OPRR also maintains an information-by-FAX service and a World Wide Web site to distribute information, and responds to inquiries by mail.

Individual agencies are also promoting public discussion of current ethical issues. For example, DOE's Ethical, Legal, and Social Issues (ELSI) program sponsors a wide variety of educational programs, including meetings and seminars. DOE has recently sponsored two highly acclaimed public television programs on the human genome program. DOE has also sponsored a judges workshop for trial judges to receive information on and discuss the use of DNA evidence in the courtroom. The genome program has also sponsored conferences to discuss genetics in light of religion, and discrimination and other ethical issues.

ACHRE Findings and Recommendations on the Protection of Military Personnel (Recommendation # 12) :
ACHRE found that it is often difficult, in a military setting, to distinguish requests for volunteers from orders. "The military setting, with its strict hierarchical authority structure and pervasive presence in the lives of its members, poses special problems for ensuring the voluntariness of participation in research activities. Thus, although the DOD has adopted and implemented the consent requirements of the Common Rule, additional procedural safeguards and educational activities for officers may be warranted to counteract the generalized deference to authority inherent in military culture. Also, because the opportunity to serve the nation as subjects in defense-oriented research projects is closely akin to the demands placed on members of the military in their routine duties, it is desirable to emphasize the distinction between research and course-of-duty risks both in consent procedures and in officer training programs."

ACHRE recommended that the military better ensure the protection of rights and interests of military personnel who are involved in human subjects research by reviewing general policies and procedures, educating officers and investigators, implementing policies and practices that make certain participation is genuinely voluntary, and maintaining a registry of volunteers. (Recommendation # 12.)

Response: The Administration agrees that extraordinary steps are needed to protect military personnel, and DOD is implementing ACHRE's recommendations. Among other steps, DOD is revising directives and Military Department regulations, and incorporating needed training into courses for commanders, senior leadership, and those involved in human subjects research. In the summer of 1996, DOD published a revised human subjects protection regulation that includes policy changes recommended by the Advisory Committee. For example, the new policy will preclude officers and non-commissioned officers from playing a role in selecting volunteers for military tests to avoid undue command influence (see Appendix B for more details).

ACHRE Findings and Recommendation on the Federal Oversight of Research (Recommendation # 13):
ACHRE found that oversight of human subjects research is limited and is constrained by practical considerations. ACHRE found that the "current mechanisms for oversight . . . do not provide a sufficient basis for ensuring that the current system is working properly."

ACHRE found that sanctions may be inadequate for violations of human subjects research protections. For example failure to obtain consent from subjects (who are not physically injured) is generally punishable only by the withdrawal of research funding.

ACHRE also found that "there is a need to assess the level of research performed outside [the Common Rule] and to consider action to ensure that all

subjects are afforded the protections it offers." (Recommendation # 13.)

ACHRE recommended the improvement of three parts of the current Federal system for human research subject protection: oversight of the research process; sanctions for violations of human subjects protections; and protections for subjects of non-federally-funded research.

Response: The Administration agrees that there are important gaps in the current system of human subjects protection, and has identified, in testimony before Congress, examples of research that does not fall within the ambit of federal protection. The Administration will encourage the Congress to explore whether federal legislation is needed to ensure that all human subjects are adequately protected. The Administration believes that Congress is also the appropriate place to consider whether additional civil or criminal sanctions for the violation of human subject protections are necessary and desirable. Any legislation would need to protect research subjects and avoid deterring needed research.

In addition to exploring legislation, federal agencies are undertaking specific activities to strengthen oversight, some of which are described in Appendix B. The Administration expects that NBAC will recommend additional actions to improve oversight of federal research, and will identify the highest priority steps.

ACHRE Findings and Recommendation on the Compensation of Subjects in the Future (Recommendation # 14):

ACHRE found that the federal government lacks a "policy or guide for a fair system of compensation of research subjects."

ACHRE recommended that the Government resolve the longstanding issue of whether and how all persons injured in the future from Federally-funded human subjects research should be compensated.

ACHRE recommended that the federal government consider a system of compensation for research subjects who suffer physical injury or dignitary harm as a result of federally funded research.

Summary Response: In the absence of a finding that a significant number of modern research subjects are unfairly denied compensation, the Administration is not convinced that a system, outside the existing network of federal and state liability and insurance systems, is necessary.

ACHRE cites the need to spread the cost of research injury as a reason to consider a compensation scheme. However, the current tort system, though imperfect, provides a mechanism to seek compensation for injuries that arise from research. In addition, the tort system provides a powerful incentive to researchers to observe appropriate standards of care in conducting the research. These standards generally include providing for informed consent and

exercising care in the conduct of research.

ACHRE Recommendation Regarding Consent in Classified Research (Recommendation # 15): ACHRE recommended, because of its concerns about past use of secret research that (a) there be a formal policy which establishes that there can be no waiver of informed consent for classified research and that potential subjects of this research must be informed about the identity of the sponsoring agency whenever classified research is involved. ACHRE also recommended that (b) for classified research, an independent panel be established to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance. The records of this panel would be permanent.

Response: ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct classified research using human subjects where such research serves important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." ACHRE recommend that all classified research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research; and
- be approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances." (Recommendations 15a and 15b)
- do audio tapes of the panel's deliberations

The Administration agrees with the first three recommendations. To implement these changes, Federal agencies will jointly propose modifications to the Federal Policy for the Protection of Human Subjects ("Common Rule") as it applies to classified research. The Administration also agrees with ACHRE's call for a special review process for classified research. The Federal agencies will jointly propose amending the common rule to (1) require that institutional review boards for secret projects include a non-governmental member; and to establish an appeals process so that any member of a review board that believes a project should not go forward can appeal the board's decision to approve it; This approach is less burdensome than that recommended by ACHRE but addresses ACHRE's underlying concerns. (2) require retired boards of the sponsoring agencies to keep permanent records of their deliberations and to declassify such records as soon as

The Administration is taking two additional steps to ensure that classified human subjects research remains rare. The President will direct the heads of Federal agencies to disclose annually the number of secret human subjects research projects undertaken by the agency. The President will also prohibit agencies from conducting secret human subjects research without first

~~issuing~~ the ~~Federal Policy for the Protection of Human Subjects~~.

These steps will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

ACHRE Findings and Recommendations Regarding Secret Environmental Releases (Recommendation # 16): The Advisory Committee found that events that raise the same concerns as the intentional environmental releases of radiation in 1948–1952 "could still take place in secret under current environmental laws and regulations."

The Advisory Committee further noted that "Today the law provides that environmental reviews may be conducted in part or even in whole in secret, thereby eliminating provision for public notice and comment. In classified programs, the government must still comply with environmental standards, and the Environmental Protection Agency must oversee and review environmental compliance. However, the EPA has not maintained records of environmental releases where the reviews were conducted in whole or in part in secret." (Finding # 23.)

The Advisory Committee recommended that (a) there be review by an independent panel of any planned environmental release where any aspect involves secrecy and that (b) environmental oversight of classified programs, now done by the Environmental Protection Agency (EPA), should include keeping review records permanently and reporting to Congress.

Response: The Administration agrees that the framework for oversight and recordkeeping of reviews of secret environmental releases needs to be improved.

EPA, in conjunction with Federal agencies conducting classified programs, is taking steps to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. This improved oversight will streamline the process of getting information about environmental activities to enforcement authorities. This effort will give environmental enforcement authorities the information they need to appropriately review secret environmental releases. The information will build upon existing institutional independence and expertise to ensure aggressive review of any secret releases. It would be difficult, if not impossible, to create similar institutional capabilities in a new regulatory entity, such as an independent review panel, that focusses only on these extremely rare occurrences. In addition a new entity would add to the bureaucratic complexities of ensuring environmental safety and would not necessarily increase public protection.

EPA will establish and maintain a permanent file to document EPA's classified reviews under the National Environmental Policy Act (NEPA). The

EPA policy establishing this permanent file will address issues including transport, storage, review, and permanent recordkeeping of classified NEPA documents and EPA review comments. EPA will notify all Federal Agencies of its new classified filing and review procedures and will provide Congress with information on request.

Part 3: Righting Past Wrongs

Overview

The ACHRE report reviewed in detail several case studies of government-supported human radiation research including: the injections of plutonium into 18 hospital patients during and after World War II; research with prisoners; and research on patients who had previously been exposed to total body irradiation in clinical settings.

The Advisory Committee also considered issues related to certain radiation exposures associated with government activities that the Advisory Committee concluded should not be considered "experiments". These exposures were sustained as a result of government activity undertaken for purposes other than human radiation research. The exposed populations include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

The Committee recommended several steps that the government should take to make amends for the specific wrongs for which the government bears moral responsibility.

This section of the report discusses ACHRE's findings and recommendations in the areas of notification, apology, and compensation and presents the Administration's response. Within the discussion of compensation, the report addresses individual cases, uranium miners, other populations covered under the Radiation Exposure Compensation Act, veterans, and Marshall Islanders.

Notification

ACHRE Finding on Notification

The Advisory Committee found "no subjects of biomedical experiments for whom there is a need to provide notification and medical follow-up for the purpose of protecting their health." In addition, the Committee found no evidence that descendants of subjects of human radiation experiments have a greater likelihood of inheriting genetic effects. (Recommendation # 4.)

ACHRE Recommendations on Notification (Recommendation # 4):

The Advisory Committee recommended that:

- For any newly-discovered experiments the government should notify participants and provide medical follow-up for "those subjects for whom there is a significant risk of developing a radiation-related disease that has not yet occurred, or has occurred but may still be undetected or

untreated, and in whom there might be an opportunity to prevent or minimize potential health risks through detection and treatment."

- The government need not notify subjects of experiments reviewed by ACHRE because they did not meet the recommended criteria for notification.

Response

The Administration's view is that, *in general* ACHRE's recommendation is correct. The government will notify any identified subjects who meet the criteria in the ACHRE report. These include any subjects placed at a significant risk for development of a radiation-induced malignancy, where there is a recognized medical benefit from early detection and treatment of the malignancy.

There are other situations, however where the government will also notify an identified experimental subject: if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about the effects of the experiment and notification is necessary to investigate whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that this approach fulfills the government's grave responsibility to inform subjects while maintaining respect for the privacy interests of those who would not want information that has no tangible benefit.

It is important to be clear that notification is not simply the process of taking a list of names, current addresses and phone numbers which are in the possession of Federal agencies and contacting people. For most experiments, no names are available. Much information about past experiments came from the published literature and does not generally include names. Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts. Another barrier to identifying individuals is that much of the information is in the records of private hospitals and universities where confidentiality and privacy rules prohibit government access.

For all of these reasons, the process of locating individuals or next of kin many years after the experiments took place is difficult, time consuming, costly to the taxpayer, and likely to have limited success. Where individuals can be found, it is difficult to assess their exposure and risk given the limited data available.

Notwithstanding the difficulties of undertaking individual notification, the government reaffirms its continuing commitment to openness. Where the government does not undertake individual notification it will continue to make public all material relating to human radiation experiments, to respond to individual inquiries relating to these experiments, and to carefully review any newly-identified experiments in the light of the Advisory Committee notification criteria.

Discussion

Many of the wrongs in experimentation involved failure to provide subjects with a full and fair disclosure of the risks and benefits (or lack of benefits). At first impression the solution to this lack of disclosure seems evident--namely disclose now what was not disclosed in the past. After careful consideration, however, ACHRE recommended that decisions about notification be based on "evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals." In discussing this recommendation, ACHRE observed that notification can impose new burdens on subjects, including anxiety; medical harm,; inconvenience; possible stigmatization by friends, family, employers, or insurance carriers; and cost of seeking medical testing or follow-up. In light of these considerations, and the difficulty in tracing subjects, ACHRE recommended notification in the limited circumstances where the individual desires notification or where the notification would be of medical benefit to the individual.

This recommendation has generated controversy among stakeholders, including those who participated in the Stakeholders Workshop of February 26, and 27, 1996, held by the federal departments. Some stakeholders believe the government has a responsibility to notify and provide medical follow-up to all who were wronged by the government--not only those who were physically harmed by the government's conduct. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally advocated that the government pursue some form of notification, and provide medical care by physicians of their own choice. Many subjects or families of subjects do not have confidence that the government can honestly make a judgment about notification, or that the government can, without bias or intimidation of subjects, implement any needed medical follow-up. Others have also suggested that subjects would want notification whether or not they were harmed. *See* Hearings on Human Radiation Experiments, Senate Committee on Governmental Affairs, March 12, 1996, remarks of Senator Glenn.

The Administration agrees that the decision of when and how to notify experimental subjects requires a judgment about whether individuals would want to be notified of the government's potentially wrongful act to them, even if there is no expectation of physical harm, or no possibility to detect or treat an expected disease.

Where records become available that would allow notification, the Administration notify subjects that meet the ACHRE criteria and will also notify those that meet any one of three additional criteria. The criteria are intended to shed light on the non-medical benefits that may accrue to those potentially being notified. As noted above, subjects will be notified if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about

See Notes

the effects of the experiment and notification is necessary to understand whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that these other benefits--where they are present--would cause most subjects to prefer notification.

Information Requests: Potential experimental subjects will be given information if they ask for it. Further the government will keep and search records that will help potential subjects find answers about their own history. In addition the government will use all reasonable means to let potential subjects know that they have the opportunity to ask questions about their own history and a choice about whether to pursue the information.

To make the choice meaningful, the government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research. Publicity about the existence of experiments, and the widespread availability of a general description of the research has successfully generated tens of thousands of inquiries from those who want to know whether they were experimental subjects. This large response suggests that the government's outreach efforts have provided an opportunity for a significant portion of potential subjects to choose whether to seek more information.

Based on the response so far, the Administration believes that continued publication of general information and aggressive follow-up of individual inquiries satisfies much of the government's obligation to notify those who potentially were subjects of experiments.

Additional Research: In the event that the departments uncover additional forgotten experiments, any newly-discovered subjects will be notified made by the Department that sponsored the research, based on the criteria discussed above.

As experiments are identified there may be uncertainty about whether initial exposures to radiation significantly increased the risk to subjects. In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be enough identifiable subjects to allow for a follow-up study. The follow-up study would be designed to identify any risk to subjects and whether medical follow up could be beneficial. The Administration's policy does not preclude conducting such a study--even though the government cannot answer with certainty what level of risk is faced by former subjects and whether there is any prospect of medical or other benefit to subjects from a follow-up study. Any follow-up study should move forward only under the following conditions: 1) All care has been taken to minimize any harmful effects of participating in a study; 2) non-governmental experts, including ethicists, have been consulted regarding the study and its fairness to individuals who will be notified of their prior participation in an experimental treatment.

Actions to Date

The most important actions the government has taken to notify potential human subjects are the actions described above in the section on openness. This widespread public availability of information has given individuals the opportunity to choose whether they will seek additional information about their own possible involvement in experiments.

Individual Inquiries: Those who would like more information about their individual records can obtain assistance by a simple phone call (the current number to call is 202–586–8539). By calling this number, individuals who think they may have been involved in experiments can get their cases reviewed by the appropriate agency. As of December 1, 1996 DOE has answered over 20,000 information requests, and researched 3,000 cases; DOD has responded to approximately 7,000 case inquiries of which approximately 800 are currently undergoing active research; VA has responded to approximately 1750 inquiries and HHS to approximately 90.

Notification of NASA employees: Consistent with the effort to provide general information to the widest possible groups of people, the National Aeronautics and Space Administration (NASA) has notified approximately 110,000 current and former NASA employees, contractors and grantees about the human radiation research review. This notification included those universities and institutions at which human radiation research was performed through NASA grants.

Notification of Veterans: VA convened an expert committee including specialists in nuclear medicine, radiation oncology, health physics, and radiation dosimetry to review information about certain projects, and to determine whether notification of known subjects is warranted. The VA focused its attention on early radiation research projects for which at least some of the names of research subject were known. These studies were chosen because of the possibility of contacting veterans or family members to encourage medical surveillance or submission of a compensation claim, if warranted. The expert committee did not identify any veterans who warranted special follow–up actions specifically because of their radiation exposure.

Nasopharyngeal Irradiation with Radium (NP) during Military Service: DOD and VA are reviewing the records of hundreds of Service members who received NP irradiation during and immediately following World War II. In April 1996, DOD discovered a Navy medical log book which lists the names of submariners who were given the NP treatment in 1945–1946 under an experimental protocol. Using the log book as the focal point, DOD and VA are conducting intensive research at the National Records Center and other repositories to identify other Service members who received NP treatment and, if feasible, retrieve medical data for possible cohort or epidemiological studies and to notify individuals as appropriate. NP treatment was a widely used conventional therapy, particularly for children, during the 1940s and 1950s. Therefore a study could be valuable to many civilians as well as veterans.

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 asymptomatic individuals but recommended that individuals treated with NP radium inform their health care providers for consideration when they are examined or evaluated. VA officials have published information on NP irradiation treatments in medical journals and provided it to veterans' newsletters.

The VA and CDC held 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. The Administration has proposed legislation that would make veterans treated with NP radium eligible for the VA's Ionizing Radiation Program. The Administration will be resubmitting this legislative proposal in its 1997 legislative package for consideration during the first session of the 105th Congress.

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 and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM concerning the Iodine-131 experiments involving Native Alaskans as set forth in its recent report. Efforts are ongoing with representatives of the Native Alaskans to determine appropriate follow-up remedies.

Identifying Additional Subjects: DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located. In addition DOE asked all its facilities at which human radiation experiments were identified to provide detailed information about the availability of data, if any, relating to individual subjects, the feasibility of notification, and whether any notification process had occurred. Where employees or former employees had been involved in experiments, notification generally had taken place. Otherwise, it was determined that the available data did not warrant notification in light of the criteria outlined above. If new information or experiments come to light, the Department will review these according to the Advisory Committee criteria.

Remedies

ACHRE Findings Regarding Compensation

The Advisory Committee found that:

1) "[T]he government sponsored . . . several thousand human radiation

expectations

experiments. In the great majority of cases, the experiments were conducted to advance biomedical science; some experiments were conducted to advance national interests in defense of space exploration; and some experiments served both biomedical and defense or space exploration purposes." (Finding # 1.)

2) "[P]eople who were used as research subjects without their consent were wronged even if they were not harmed." In addition, the Committee was "not persuaded that even where the facts are clear and the identities of subjects known, financial compensation is necessarily a fitting remedy when people have been used as subjects without their knowledge or consent but suffered no material harm as a consequence." (Recommendation # 3.)

3) "[S]ome government agencies required the consent of some research subjects well before 1944 . . . [and] government agencies did not generally take effective measures to implement their requirements and policies on consent to human radiation research." (Findings # 4 and # 5.)

4) "[T]he government and government officials are morally responsible in cases in which they did not take effective measures to implement the government's policies and requirements. . . ."

"[G]overnment officials and investigators are blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects who were used in research from which the subjects could not possibly derive medical benefits (nontherapeutic research in the strict sense). By contrast, to the extent that there was reason to believe that research might provide a direct medical benefit to subjects, government officials and biomedical professionals are less blameworthy for not having had such protections and practices." (Findings # 11a and 11c.)

5) "[S]ince the end of the Manhattan Project in 1946 human radiation experiments (even where expressly conducted for military purposes) have typically not been classified as secret by the government. Nonetheless, important discussions of human experimentation took place in secret, and information was kept secret out of concern for embarrassment to the government, potential legal liability, and concern that public misunderstanding would jeopardize government programs. In some cases, deception was employed. In the case of the plutonium injection experiments, government officials and government-sponsored researchers continued to keep information secret from the subjects of several human radiation experiments and their families, including the fact that they had been used as subjects of such research. Some information about the plutonium injections, including documentation showing that data on these and related human experiments were kept secret out of concern for embarrassment and legal liability, was declassified and made public only during the life of the Advisory Committee." (Finding # 17.)

ACHRE Recommendations on Apology (Recommendation # 3):

The Advisory Committee recommended:

> "[F]or subjects who were used in experiments for which there was no prospect of medical benefit to them and there is evidence specific to the experiment in which the subjects were involved that (1) no consent, or inadequate consent, was obtained, or (2) their selection as subjects constituted an injustice, or both, the government should offer a personal, individualized apology to each subject."

Response

The Administration agrees that the subjects identified by the Committee were owed an apology by the government. 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. He said,

> "So today, on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subject to these experiments, to their families, and to their communities.
>
> "When the government does wrong, we have a moral responsibility to admit it. The duty we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is one we can never walk away from. Our government failed in that duty, and it offers an apology to the survivors and their families and to all the American people who must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing."

In addition, the Secretary of Energy has apologized on behalf of the government as part of the settlements of individual cases. The Administration will continue to apologize to subjects and their families in appropriate cases as they are considered and settled.

At the same time, the Administration believes that for most subjects the President's apology on behalf of the government to all subjects of human radiation experiments is preferable to pursuing an individualized evidentiary investigation to fulfill the committees admonition that "an apology should be offered only where there is evidence specific to an experiment or subject that no consent, or inadequate consent, was obtained, or the subject's selection constituted an injustice, or both." (Recommendation #3.)

ACHRE Recommendations on Financial Compensation (Recommendations # 1 and # 2):

The Advisory Committee recommended that the government provide financial compensation to subjects of

human radiation experiments in two cases. First, those cases "in which efforts were made by the government to keep information secret from these individuals or their families, or from the public, for the purpose of avoiding embarrassment or potential legal liability, or both, and where this secrecy had the effect of denying individuals the opportunity to pursue potential grievances." Second, those experiments, "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 Advisory Committee identified three sets of subjects that fit the first class of cases: one set of eighteen whose identity is known, and two sets, totalling fifty-two people, whose identity is not known. The Advisory Committee did not make conclusive findings about which subjects fit the second class of cases. Instead, the committee identified several experiments that might fit the second class of cases, with the expectation that the government would consider the Committee's recommendation in deciding whether to compensate individuals.

Response

The Administration agrees with the Advisory Committee's recommendation, and the Department of Justice (DOJ) will, to the extent permitted by law, offer reasonable financial compensation for human radiation experiments in which a government agency was responsible for falling within the Advisory Committee criteria. If compensation cannot be offered under existing law in any case under the stated criteria, the Administration will work with Congress to seek appropriate legislative relief. To date, thirteen claims have been settled, providing a total of over $5 million in compensation. DOJ and the relevant departments continue negotiations on other claims.

DOJ is using a streamlined administrative process, based on Federal Tort Claims Act procedures or other applicable law, to consider compensation as part of a settlement of relevant claims. DOJ and the relevant agencies are seeking to avoid unnecessary litigation, including use of alternate dispute resolution, such as mediation, where appropriate. In considering the issue of compensation, the critical factors are the extent of physical injury to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies seek expert advice on scientific and medical issues.

ACHRE Finding on Compensation of Uranium Miners

The Advisory Committee found that "as a consequence of exposure to radon and its daughter products in underground uranium mines, at least several hundred miners died of lung cancer and surviving miners remain at elevated risk." (Finding # 16.)

ACHRE Recommendations on Compensation of Uranium Miners (Recommendation # 7):

The Advisory Committee recommended that the Administration, "together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners in order to provide compensation to *all* miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be reviewed to determine whether the documentation standards for compensation should be liberalized."

Response

The Administration agrees that the Radiation Exposure Compensation Act of 1990 (RECA) should be amended to ensure that all uranium miners who suffered from lung cancer as a result of their mining employment receive compensation. The Administration is proposing a bill that would make significant and substantial modifications to the statutory compensation criteria for lung cancer. The bill will bring the law into line with current science, and will address some of the issues of fairness that have been raised about the Act's coverage. The Administration will strongly urge the 105th Congress to enact this bill.

Proposed Legislative Changes to RECA: Congress enacted RECA to provide compensation to certain groups of people exposed to radiation as a result of the government's nuclear program during the Cold War and who sustained a radiation-related disease. In particular the Act recognizes the tragedy created by the government's failure to use available resources to ensure that the companies and individuals operating uranium mines in Arizona, Colorado, New Mexico, Utah and Wyoming between 1947-1971 provided adequate ventilation in the mines. The Act provides for compensation to some affected uranium miners, but ACHRE questioned whether the eligibility requirements for compensation were fair and reflected our present scientific knowledge about the effects of radon.

The Administration's proposed changes in RECA are supported by analysis undertaken by an ad hoc committee of government scientists and attorneys with experience in radiation exposure and claims. Their analysis is available in a report, "Final Report of the Radiation Exposure Act Committee" which was submitted to the Human Radiation Interagency Working Group in July of 1996, and is available on the Internet.

The Administration's bill proposes amendments in four key areas.

First, current law requires miners to show that they were exposed to a threshold of 200 working level months of radiation (for nonsmokers) and 300 to 500 working level months (for smokers, depending on the miner's age at the date of diagnosis of disease). The Administration bill would substitute new criteria for compensation based on a scientific analysis of risk factors for lung cancer from uranium

mining. Specifically the criteria include: cumulative exposure, age at which the miner developed cancer, and time since last exposure. The Administration bill proposes to apply these new criteria to provide full compensation for lung cancer in cases where it is more probable than not that the miner's exposure to radiation in underground uranium mines is the cause of the lung cancer. In addition, the Administration proposes to provide partial compensation to those miners for whom there is a lower but significant probability that their lung cancer was caused by exposure in the mines. Specifically the Administration proposes to provide 50% compensation to miners for whom the probability is between 20% and 50% that the lung cancer was caused by their work as miners.

The second major change in the Administration's bill responds to ACHRE's concern that conditioning compensation based on specific radiation exposure levels is too burdensome for some miners and the historical exposure data is too uncertain a base for compensation decisions. Under current law compensation is based in part on cumulative exposure to radon; the Administration's proposal would continue to allow miners to qualify in this manner, albeit under new, fairer exposure criteria. The Administration bill would also allow the amount of time in the mines to be used as a surrogate for exposure in determining whether a miner qualifies for compensation. This change reflects the reality that accurate measurements of radon levels do not exist for many mines, and that the measurements that do exist do not adequately record the miners' actual daily exposures.

Third, the bill would initiate a study to generate new criteria for the compensation of the nonmalignant respiratory diseases specified in the Act. The Act at present conditions compensation for these nonmalignancies on the same radiation exposure criteria that govern compensation for lung cancer. Recent scientific data, however, suggest that the present exposure-based criteria do not accurately represent the risks of developing these nonmalignancies. Criteria based on factors other than radiation exposure, such as duration of employment or exposure to other harmful agents in the mine environment, will likely be more scientifically accurate and better ensure compensation to miners whose nonmalignant disease is the probable consequence of mining. The bill provides for DOJ, in consultation with HHS, to promulgate new, more accurate criteria when warranted.

Lastly, the proposed bill expands the list of compensable diseases for the downwind and on-site participants to reflect current science. The text of the Administration's proposed bill and an analysis of it are attached to this report in Appendix C.

Proposed Regulatory Changes to RECA

ACHRE documented concerns from many citizens regarding the administration of RECA. These concerns focussed on the difficulty of the documentation

requirements and other burdens on those who seek compensation under the Act. The Administration has undertaken a thorough review of the regulations with the intention of making them fairer and more straightforward. While these are the paramount goals, the regulations must also effectively implement the limitations and requirements in RECA. The result of these efforts is a set of proposed changes to the rules, reproduced in Appendix C, that are designed to relieve some of the burden of seeking compensation without sacrificing the accuracy of the decision of whether particular claimants qualify for compensation. The Department of Justice will take comments on this proposal until ***.

The Administration expects that, as a result of these legislative and regulatory changes, additional uranium miners will qualify for compensation.

ACHRE Finding on Compensation of Other Exposed Populations

The Advisory Committee found "that for both the Green Run (at Hanford) and the RaLa tests (at Los Alamos), where dose reconstructions have been undertaken, it is unlikely that members of the public were directly harmed solely as a consequence of these tests." (Finding # 14.)

ACHRE Recommendations on Compensation of Other Exposed Populations (Recommendation # 5):

The Advisory Committee recommended that the Administration "together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in populations currently covered by the law may have resulted."

Response

The Administration agrees with the Advisory Committee's concern for treating exposed populations fairly. DOE has undertaken studies to look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge to determine whether there is any increase in cancer resulting from the operation of DOE facilities. If these studies conclude that there is an increase in cancer, the government will work with Congress to amend existing laws to cover those affected. DOE has provided the General Accounting Office with a list of all studies currently in process, and an estimated schedule for their completion.

ACHRE Finding on Compensation of Veterans

The Advisory Committee found that "some service personnel were used in human experiments in connection with tests of atomic bombs. The Committee finds that such personnel were typically exposed to no greater risks than the far greater number of service personnel

engaged in similar activities for training or other purposes. The Committee further finds that there is little evidence that the 1953 secretary of defense Nuremberg Code memorandum was transmitted to those involved with human experiments conducted in conjunction with atomic testing. However, some of the requirements contained in the memorandum were implemented in the case of a few experiments, apparently independently of the memorandum. The Committee also finds that the government did not create or maintain adequate records for both experimental and nonexperimental participants." (Finding # 12.)

The Advisory Committee also concluded that "although there was a real possibility that human subjects research had been conducted in conjunction with the bomb tests, the tests were not themselves experiments involving human subjects." The Advisory Committee further noted that "while the studies all took place in the context of the atomic bomb, and therefore involved some potential exposure to radiation, none of them were designed to measure the biological effects of radiation itself (as opposed to the levels of exposure)."

ACHRE Recommendation on Compensation of Veterans (Recommendation # 6):

The Advisory Committee recommended that the Administration, "together with Congress, give serious consideration to reviewing and updating epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing so that all cancers or other diseases for which there is a reasonable probability of causation by radiation exposure during active military service are clearly and unequivocally covered by the statutes." (The Radiation-Exposed Veterans Compensation Act of 1988 and the Veterans Dioxin and Radiation Exposure Compensation Standards Act.)

"The Advisory Committee further recommends to the Human Radiation Interagency Working Group that it review whether existing laws governing the compensation of atomic veterans are now administered in ways that best balance allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including the costs and scientific credibility of dose reconstruction."

Response

The Administration agrees with these recommendations and has undertaken to update the epidemiological tables and has reviewed the implementation of these programs to seek ways to make them fairer and more efficient.

Hundreds of thousands of veterans were exposed to radiation--those who were present at atomic tests, those who were part of the American occupation of Hiroshima and Nagasaki, and many who were otherwise exposed to radiation in the course of their duties. The President has recognized the special obligation that we owe the men and women who have served

their country in the Armed Forces. The President recently said

> ...[O]ur country can face up to the consequences of our actions; ... we will bear responsibility for the harm we do, even when the harm is unintended; ... we will continue to honor those who served our country and gave so much.
>
> Nothing we can do will ever fully repay the . . . veterans for all they gave and all they lost, . . . But we must never stop trying.

It is in this spirit that the Administration has considered human radiation issues. related to veterans.

Veterans are eligible for benefits based on their radiation exposure during their service if they have radiogenic diseases and the claims otherwise meet the criteria for benefits. The VA considers claims for compensation and uses radioepidemiological tables to determine whether individual veterans qualify for benefits. The Advisory Committee recommended that those epidemiological tables that govern relief for veterans be updated to reflect the latest scientific information. The government will contract with preeminent scientists to update the tables. The project is expected to take approximately two and one-half years. The Departments are considering a proposal from the Institute of Medicine, part of the National Academy of Sciences to accomplish this update. The updated tables will more accurately identify whether there is a reasonable probability that certain diseases were caused by radiation exposure.

Implementing Existing Law: The Advisory Committee also recommended that the Administration examine and respond to the criticisms that have been made of VA's implementation of the existing compensation laws. The Advisory Committee noted numerous concerns voiced about the claims process. The Administration takes these concerns seriously, and has taken several steps that respond to the concerns. At the same time, in some cases the Administration has found that the system strikes a reasonable balance among the legitimate goals of fairness, speed and accuracy in the decisions made by VA.

First, reported concerns included whether the list of diseases for which compensation is available is fair. The VA currently provides benefits for veterans exposed to radiation based on two separate statutory schemes. The Radiation-Exposed Veterans Compensation Act of 1988 provides that if a veteran has a disease listed in the statute, and meets the criteria for exposure, the veteran is entitled to benefits. Thus, for qualified veterans, the list of compensable diseases establishes a conclusive presumption of a service connection. This approach has the advantage of simplicity, and goes as far as possible toward providing the benefit of doubt to the claimant. It does, however, qualify some people for benefits for whom there is a low probability of a connection between their in-service exposure to radiation and their disease.

The other method for radiation-exposed veterans to obtain benefits is under the Veterans Dioxin and Radiation

Exposure Compensation Standards Act. This Act requires the claimant to show that the disease is both radiogenic (can be caused by radiation) and connected to the type and amount of radiation the veteran was exposed to during service. The implementing regulations include a list of diseases for which claimants do not have to prove, as a general matter, that radiation can cause the disease. HHS' epidemiological tables then provide additional information to help VA adjudicate claims, and provide some measure of predictability for claimants. This approach has the potential to be scientifically more accurate in determining service connection. It has, however, been criticized for a variety of reasons, including that the epidemiological tables are out of date, the system creates a difficult burden of proof and the process is expensive for claimants and the government.

The Administration has taken steps to make this claims process work better. In September of 1996 the Department of Veterans Affairs proposed to include all forms of cancer in the list of diseases recognized as radiogenic. This proposal would mean that each claim will be evaluated based on an individual's estimated dose and will no longer require a showing that the cancer is radiogenic. In addition, the Administration has worked with the Veterans Advisory Committee on Environmental Hazards (VACEH), an independent panel that reviews the scientific issues related to radiation-induced disease, to determine whether other diseases should be added to the list of diseases under the second approach to compensation. Transcripts of VACEH's discussions and citations to the scientific papers they considered are available from the VA. As new information becomes available, the VACEH will review it carefully and advise the Secretary if changes in the VA's regulations are warranted.

ACHRE noted that many have raised questions about the level of investment in dose reconstruction and scientific investigation compared to the amount invested in compensation of veterans. The Administration's view is that we owe veterans both -- a complete look at the facts and compensation for service-connected disease. The VA and DOD have invested heavily in making sure that full and fair information is available for every veteran who may have been exposed to radiation during service. The dose reconstructions, including their methodology, have been independently peer-reviewed. Every veteran who seeks compensation needs this information, and it can be enormously frustrating for veterans when the information is incomplete or indeterminate. The principle reason that dose reconstruction has cost more than claims is that the dose reconstruction has suggested that most veterans were exposed to levels not expected to cause a significant increase in risk. Unfortunately, there is no shortcut to this information, and it has been expensive to develop.

ACHRE noted that complaints have been raised about the appeals process for radiation-related claims. VA recognizes it must do a better job at meeting veterans' needs, and is taking steps to improve

compensation claims processing. For example, VA is redesigning the claims process to provide a partnership among the veteran making a claim, the veteran's representative and the VA employee processing the claim. The VA will discuss the claim, issues that arise and evidence needed. Once a decision is made, the VA will discuss it with the veteran and the veteran's representative and provide help framing the claim for any appellate review. VA believes that this personal interaction will lead to better and faster decisions and will provide a transparent claims process.

The VA remains open to other reforms that will make the process of deciding claims fairer and more streamlined.

ACHRE Finding on Compensation of Marshall Islanders

The Advisory Committee found that "[a]s a consequence of a U.S. hydrogen bomb test conducted in 1954, several hundred residents of the Marshall Islands and the crew of a Japanese fishing boat developed acute radiation effects. Some of the Marshall Islanders subsequently developed benign thyroid disorders and thyroid cancer as a result of the radiation exposure. Surviving Marshallese also may remain at elevated risk of thyroid abnormalities." (Finding # 16.)

ACHRE Recommendation on Compensation of Marshall Islanders (Recommendation # 8):

The Advisory Committee recommended that the U.S. government should continue 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, ACHRE recommended that the Administration consider adding the populations of other exposed atolls to the south and east; that the Administration involve the Marshall Islanders in the design of any further medical research conducted on them; and that the Administration establish an independent panel to review the adequacy of the current monitoring and treatment program.

Response

The Administration recognizes the difficulties and inequities in the current program of medical care for the Marshall Islands and fundamentally agrees with ACHRE's recommendations. The recommendations address the scope and effectiveness of programs designed to provide some benefits to citizens of the Marshall Islands because of their exposure to radioactive fallout from atmospheric tests. Before discussing the particular recommendations that ACHRE put forward, it is appropriate to set out the Administration's vision of the implementation of these programs. DOE has undertaken a reorientation of the Republic of the Marshall Islands (RMI) programs to support more local involvement and control over the resources that have been or will be made available as a part of this program. At base, this

reorientation means open discussion between the U.S. Government and the Marshallese regarding resources available and realistic goals of this program and better coordination of DOE and DOI programs. These tasks are underway.

The heads of delegations of the Government of the Republic of the Marshall Islands (RMI), the Department of Energy (DOE), and the United States (US) Departments of State and Interior held a meeting in May 1996. A Joint Communiqué was signed that outlined a path forward to address the basic ACHRE issues of concern to the Marshall Islands people.

At a subsequent meeting on June 7, 1996, a 30 day action plan was mutually agreed upon. This action plan establishes objectives for eight working groups and a time table for achieving these defined objectives. These include how best to include RMI in decision making on future direction of programs, and evaluate the DOE Marshall Islands medical program.

The Republic of the Marshall Islands has decided recently to address all eight working group issues by hosting a meeting of these working groups in Majuro, Marshall Islands on January 27–31, 1997. These working group meetings will be conducted as bilateral discussions with decisions reached, successes achieved and forward actions identified to meet working group objectives. The meeting will be attended by the leaders of the RMI government and the Local Atoll Government Councils. The U.S. government will be represented by the Department of Energy and their contractors, the Department of State, the Department of the Interior and the Department of Defense.

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 need and to fully involve them in the process of rethinking the program. DOE is also working with the RMI to systematically review and collect historical documents which will help to complete the record of U.S. atmospheric testing in the Marshall Islands and the impact on its people. As part of this effort, DOE is also providing support to facilitate Marshall Island's access to these and previously collected documents. Documents are being scanned into an electronic retrieval system available via the Internet that

makes it possible to key word search many documents of direct pertinence to the RMI concerns.

As ACHRE recommended the Administration plans to continue to support the current monitoring and treatment program. This program is an important element of our nation's commitment to compensate those who were harmed by the atomic testing program.

As ACHRE recommended, the Administration has considered whether additional populations should be included in this program. 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 difference in dose is large enough that the Administration does not conclude that additional populations should necessarily be added to the medical surveillance program. Instead, the connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by CDC. If these or other studies reveal new data to indicate that residents of atolls south and east of Bikini, other than Rongelap and Utirik, are at a significantly increased health risk, DOE will propose any needed expansion of the current medical surveillance program.

APPENDIX A
ACCESS TO RECORDS AND INFORMATION RELATING TO HUMAN RADIATION EXPERIMENTS

Advisory Committee on Human Radiation Experiments (ACHRE) Collection at the National Archives, College Park

Overview. 665 cubic feet of records from the Advisory Committee on Human Radiation Experiments have been deposited at the National Archives and made part of Record Group 220, Presidential Committees, Commissions and Boards. The collection can be accessed through the Archive's Textual Reference Branch located at Archives II, 8601 Adelphi Road, College Park, Maryland. The phone number is 301 713-7250.

The collection consists primarily of documents collected from Federal agencies and other sources during the Committee's research process, but also includes the Committee's administrative files, meeting documentation, notes and other records generated by the staff.

Organization. The ACHRE collection is broken into 12 major series. The series of primary interest to most researchers is the **Research Collection Series**, which consists of two major components, the **Archives** file and the **Library** file. The Archives file represents the primary documents collected from agencies and other sources; the Library file encompasses secondary sources, such as journal articles and published reports. The Archives file is organized by accession number. Each deposit of records to ACHRE was assigned an accession number which consists of an acronym for the document source, the deposit date, and an alpha designator which represents the sequence of deposits from that source on that date. (i.e. DOD-062194-C represents the third Defense Department deposit of June 21, 1994). One accession may consist of one document or several boxes of documents.

Finding Aids at the Archives. Paper copy finding aids are found in five binders at the National Archives. The finding aids provide basic access to the twelve records series. The finding aid for the Archives file identifies the current box number for each accession number. Copies of the ACHRE Final Report and supplemental volumes are also available. Supplemental Volume 2A includes a complete listing of all accessions in the Archives collection, of all publications in the Library collection, of all experiments identified by ACHRE, and of individual documents within each accession which were specifically described, including those cited in the Final Report. Volume 2A also includes indexes of this data sorted in several ways, such as by subject. The electronic index to the collection is not available to researchers at NARA.

Other Finding Aids to the ACHRE Collection. The Lotus Notes database created by the Advisory Committee is available to researchers at the National Security Archive, a private, non-profit organization, located in the Gelman Library at George Washington University, 202 994-7000. However, some familiarity with Lotus Notes may be necessary for a researcher to search the databases.

The National Security Archive also maintains a Web site for ACHRE information (www.seas.gwu.edu/nsarchive/radiation/). The site includes information such as transcripts and related materials for Committee meetings, the text of the Final Report, and the complete listing of the Research Document (Archives) collection, Publications (Library) collection, and experiments. Word searches can be performed using the capabilities of the Internet browser (such as Netscape).

Barriers to Access. ACHRE collection at the National Archives has Privacy Act material interspersed throughout. As a result, most boxes of records must be screened and redacted by Archives staff to remove privacy material prior to being provided to researchers. The Archives has indicated that it needs at least a week of lead time for any requests which involve more than a few folders, to allow time to review the requested material. Researchers are asked to be as specific as possible in their requests.

Please note that it may be difficult to locate a specific document within an accession, because the documents have not been assigned individual document identifiers (i.e. a document number). It may be necessary to review an entire accession to locate the desired document.

Other Resources

DOE Office of Human Radiation Experiments Homepage (http://www.ohre.doe.gov). OHRE created a Web site in early 1995 to make its human radiation experiment document collection and other important information readily available to the public. The **Human Radiation Experiments Information Management System (HREX)** was developed to provide users with the ability to conduct full-text searches of the historical document collection and to retrieve images of those documents. Over 250,000 pages of material are available.

In addition to the historical document collection, the site also provides access to the text of OHRE's publications – the *Roadmap*, the *Experiment List*, and a series of oral histories conducted by OHRE (see publications, below) – as well as other material of interest such as the transcript of a stakeholder's workshop held in February 1996. The text of the Advisory Committee Report is also accessible from this Homepage. This site also provides links to other relevant sites. All documents placed on the Web have been screened for Privacy Act material and personal identifiers removed (redacted). Each document in the collection has been assigned a unique document number and identified with provenance (source) information. The original copy of the document is maintained by the facility or institution identified in the provenance information. Please note that most, but not all, of the documents provided to the Advisory Committee are in HREX. The exceptions are a small number of documents retrieved by Committee staff directly from DOE sites and not processed through OHRE.

Interagency HREX (http://www.hrex.dis.anl.gov). Historical documents collected by other agencies involved in the Interagency Working Group (Department of Defense, Department of Health and Human Services, Department of Veterans' Affairs, Central Intelligence Agency, and the National Aeronautics and Space Administration) are currently being processed for

inclusion with the DOE collection in an enhanced version of the HREX system. This site also provides links to other relevant sites, such as the OHRE Homepage. As above, all documents placed in the Interagency HREX are screened for Privacy Act material and personal identifiers removed (redacted). Interagency HREX is now available to the public although not all documents have as yet been processed for inclusion. It currently has approximately 300,000 pages of documents and when completed will have approximately 500,000 pages.

The Coordination and Information Center (CIC). Paper copies of all DOE documents found in HREX are stored at the CIC in Las Vegas, NV. Paper copies of all DoD's documents have recently been transferred there, as well. In addition to its holdings related to human radiation experiments, the CIC possesses a large collection of documents from the era of atmospheric atomic weapons testing. The CIC may be contacted in writing at P.O. Box 98521, Las Vegas, NV 89193-8521 or by phone at 702-295-0731 to request documents. Small numbers of documents can be printed off the Web, but large volume requests for paper documents are better directed to the CIC. Individuals may access unredacted documents about themselves or about their next-of-kin from the CIC if they provide proof of identity.

The complete index of DOE holdings at the CIC (including the human radiation experiments collection) is available on the Internet via **OpenNet (apollo.osti.gov/html/opennet/opennet1.html).** OpenNet, sponsored by the DOE Office of Declassification, also provides bibliographic information on recently declassified DOE documents.

DOE Public Reading Rooms. Redacted paper copies of all documents located by DOE facilities as part of the human radiation experiments search and included in HREX have also been deposited in the public reading room for that facility.

List of Publications

1. *Final Report: Advisory Committee on Human Radiation Experiments* was released in October 1995, and includes the text of the report (over 900 pages) plus three supplemental volumes. Copies can be obtained from the U.S. Government Printing Office, 202 512-1800. The text of the report is also accessible on the Internet.

2. *The Human Radiation Experiments: Final Report of the President's Advisory Committee* was also published in one volume by Oxford University Press in 1996. This book does not include the supplemental volumes. It does contain President Clinton's remarks on accepting the final report of the Committee and a very useful index. Copies can be obtained in bookstores or directly from Oxford University Press.

3. *Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records*, released in February 1995 by DOE's Office of Human Radiation Experiments, includes project background, site histories, records series descriptions, topical essays, and a preliminary list of experiments. Hard copies of this report (DOE-EH-0445) are available

from DOE's Office of Public Inquiries at 202 586-5575. The report is also available on the World Wide Web (www.ohre.doe.gov).

4. *Human Radiation Experiments Associated with the United States Department of Energy and its Predecessors*, released in July 1995 by OHRE, contains a listing, description, and selected references for 435 documented human radiation studies dating back to World War II. Hard copies of this report (DOE-EH-0491) are available from DOE's Office of Public Inquiries at 202 586-5575. The report is also available on the World Wide Web (www.ohre.doe.gov).

5. *Human Radiation Studies: Remembering the Early Years*, completed November 1995 by OHRE, consists of a 29-part series of oral histories whose purpose is to enrich the documentary record, provide missing information, and allow an opportunity for the researchers to provide their perspective. A descriptive brochure, which lists all of the subjects of the oral histories and provides brief background on each, as well as copies of the individual oral histories, are available from OHRE at 202 586-0858. The oral histories are also available on the World Wide Web (www.ohre.doe.gov).

6. *Radiation Protection and the Human Radiation Experiments,* Los Alamos Science, Number 23, 1995, is a special issue of this journal which discusses the work and the findings of the Laboratory's Human Studies Project Team. The team was formed to address questions concerning the ethics and conduct of human radiation experiments that were carried out by Los Alamos researchers from the Manhattan Project days through the 1960s. The report is available from Los Alamos Science, Mail Stop M708, Los Alamos National Laboratory, los Alamos, NM 87545.

7. *The Department of Defense Report on the* Search for Human Radiation Experiment Records, 1944-1994, has a planned release date of December, 1996. It will be published by the Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs.

APPENDIX B
CURRENT AGENCY ACTIVITIES RELATING TO IMPROVING
HUMAN SUBJECTS RESEARCH PROTECTIONS

The following are specific activities that have been undertaken by agencies involved in the human radiation experiments effort in relation to, or as a result of, their review of current human research in light of the Advisory Committee recommendations.

The Department of Energy:

- Revised and updated the DOE Resource Manual on protecting human subjects. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research as well as all other areas of human subjects protections and provides regulations, resources and models.

- 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. Five laboratories and three field offices were visited by a team in 1996.

- Requested all DOE laboratories to provide a sample of current informed consent documents. These are being reviewed to improve and monitor the quality of these documents.

- Has begun drafting three model informed consent documents that will be sent to all sites to adapt and use, one for genetic research, one for biomedical research, and one for engineering research..

- Requested all laboratories to provide plans that detail local education activities to improve the human subjects research review system.

- Put DOE's FY 95 Human Subjects Database on the Internet.

- Updated the DOE Human Subjects Research Homepage with access to all DOE information, contacts, and resources. These include information about educational workshops and conferences related to generic human subjects research issues. (http//www.er.doe.gov/production/oher/humsubj/index.html)

- Continued the twice yearly meetings of DOE-wide human subjects working group.

- Sponsored a large, interagency human subjects workshop to highlight the ACHRE report and other bioethical issues. This ongoing series is undertaken every other year.

The Department of Defense:

- Reviewed in detail DOD existing policies and procedures for the protection of human research subjects and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."

- Implemented changes to current policies that:

  - 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 at 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.

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 Jawarski 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. An Agency Authorizing Official has been named for the authorization of human research and the protection of human subjects. Documentation of assurance of human subjects protection is required every five years, from all nine NASA Field Installations and the Jet Propulsion Laboratory, if the Center is conducting human subjects research. Centers not conducting such research must recertify by letter every year.

- 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.

- 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 subjects 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; 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 subjects 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 subjects research.

The Department of Health and Human Services:

- Coordinates interagency Request for Applications from researchers, to develop new knowledge related to the informed consent process.

- Expanded technical assistance to IRBs at institutions receiving DHHS research funds, by means of 12 to 24 site visits per year.

- 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.

- Provides administrative support for NBAC.

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.

APPENDIX C

PROPOSED LEGISLATION TO AMEND THE RADIATION EXPOSURE AND COMPENSATION ACT.

This legislation will be cleared separately through OMB review.

APPENDIX D

DIRECTIVE FROM THE PRESIDENT REGARDING CLASSIFIED RESEARCH

This directive will be cleared separately through OMB review.

U. S. DEPARTMENT OF ENERGY

Office of Environment, Safety and Health
1000 Independence Avenue, SW, EH-1
Washington, DC 20585

UNCLASSIFIED FACSIMILE MESSAGE
Office Fax : (202) 586-2268
Verify Fax: (202) 586-0858

Date: Jan 7, 1997

TO: Elizabeth Drye & Diane Regas @(202)456-5581

FROM: Elly Melamed

No. of Pages To Follow: 10

COMMENTS:

Tara wanted you to have these.

PLEASE TELEPHONE_____, AT THE NUMBER ABOVE TO VERIFY RECEIPT OF THIS FAX.....

THANK YOU

1ST ARTICLE of Level 1 printed in FULL format.

N Engl J Med 1996; 335: 1850-1851

December 12, 1996

SECTION: BOOK REVIEWS

LENGTH: 944 words

TITLE: Final Report of the Advisory Committee on **Human Radiation Experiments**. 620 pp. New York, Oxford University Press, 1996. $ 39.95. ISBN 0-19-510792-6.

AUTHOR: Adelstein, S. **James**.

TEXT:

The last time I devoted my summer holiday reading to a single book was when War and Peace was assigned in high school. In addition to bulk, the similarities between the Final Report of the Advisory Committee on **Human Radiation Experiments** and Tolstoy's classic include a large cast of characters and a more than occasional tone of moral indignation. The action in both takes place in war and peace.

The Final Report is the work of a distinguished panel appointed by President Bill Clinton in 1994, mostly comprising academics in the medical and radiation sciences, law, ethics, and other disciplines and chaired by Ruth Faden, director of the Bioethics Institute at Johns Hopkins University. Some 50 staff members assisted the panel. It reviewed experiments conducted between 1944 and 1974 that involved exposing humans to ionizing radiation from various sources. The experiments, some intentional and some accidental, had a wide range of formats and covered a variety of research topics, medical and nonmedical.

The report begins with a primer on radiation, radioactivity, and effects of radiation and a historical perspective on the ethics of research on human subjects. It proceeds with case studies that I would group in three categories: studies of the health effects of the Manhattan Project, assessments of the psychological and somatic effects of putative nuclear warfare, and clinical investigations involving radionuclides. The panel distinguishes among these categories, but grouping them all under the rubric of "**human radiation experiments**" has some confounding consequences. In the case of the Manhattan Project and nuclear warfare, the chief concern should be acts committed in the name of national security, with their attendant secrecy; as for clinical investigation, the principal interests are parity in the patient-doctor relationship, experimentation on vulnerable populations, and informed consent.

The book has a central premise, perhaps a dogma -- that certain ethical principles are so basic that they are not temporally limited and should have been applied throughout the period under study, independently of evolving standards. These principles are the six "one oughts": not to treat people as mere means to an end, not to deceive others, not to inflict harm or a risk of harm, to promote welfare and prevent harm, to treat people fairly and with equal respect, and to respect others' right to self-determination. Judged against these six principles, many of the experiments described in the Final Report fail or falter.

Yet, except for the most egregious examples, the authors do not unduly castigate and seem more intent on informing than on scolding. And they provide considerable information, including oddments such as the informed-consent requirements laid down by the Weimar Republic's Ministry of the Interior in 1931 for therapeutic and nontherapeutic medical research and the 1953 top-secret memorandum of Secretary of Defense Charles Wilson, reiterating the Nuremberg Code and requiring that informed consent be written and witnessed. A copy of Wilson's memorandum was sent to the Joint Chiefs of Staff, but initially it was disseminated no lower than the three secretaries of the armed services because of its security classification. Informed consent is the banner held aloft throughout the Final Report and reemphasized by Jay Katz, a panel member who keenly believes that the matter has not been sufficiently addressed in evaluating current behavior. Katz also points out that the dignity of the subjects, rather than physical injury, should be our principal concern in reviewing past practices. Indeed, most instances cited in the Final Report seem to have caused little physical harm.

The panel's staff members themselves conducted two experiments. In the first they examined contemporary proposals for research (using radiation or not) with regard to the level of risk, the degree to which the subjects understood the research, the factors likely to affect their voluntary participation, and the inclusion of those with a limited ability to make decisions. All these were issues in experiments conducted between 1944 and 1974. Among the panel's findings was that research using radiation is not more risky or ethically problematic than research that does not use radiation; actually, research using radiation may be controlled more strictly than other research, because of the double review by institutional review boards and radiation-safety committees. But the panel also found substantial deficiencies in the current system with regard to the protection of human subjects. In the second study by the panel, 1900 patients were interviewed. Among the conclusions was the following:... nearly 40 percent of the patients we talked with either believed they were or had been subjects of research... almost all of these patients said they had enrolled in research because they thought it was their best chance of personal medical benefit -- but many patients also said that they had participated in research to help others.

The panel concludes with 23 findings and 18 recommendations. Some are technical, and others are general and not beyond contention. But whether one

agrees with all of them or not, this thick book tells a cautionary tale. The great knowledge of disease processes, powerful diagnostic methods, and useful treatments derived from the radioactive materials that became available after World War II came at a price that with greater wisdom and thoughtfulness might have been avoided.S. James Adelstein, M.D., Ph.D.Harvard Medical SchoolBoston, MA 02115

Hastings Center Report, September-October 1996

Adding to the Canon

The Final Report

by Eric M. Meslin

Final Report: White House Advisory Committee on Human Radiation Experiments. (061-000-00-848-9). Washington, D.C.: U.S. Government Printing Office, 1995. 925 pp.

When the first stories of the plutonium experiments, conducted on eighteen hospital patients between 1945 and 1947, were revealed in Eileen Welsome's stories in the *Albuquerque Tribune*, it appeared that another story was to be added to the research ethics curriculum and to our list of "classic cases." When President Clinton announced the formation of the Advisory Committee on Human Radiation Experiments the status of this case was upgraded from one of an interesting footnote to one that gained the attention of the executive branch of the U.S. government, a status achieved only by a select group of previous national advisory committees and commissions.[1] The resulting 925-page report, produced after eighteen months of work by a fourteen-person committee (including one "citizen" member) and a staff of fifty-six is now in the public domain for review and study.[2]

The committee was charged with the following tasks in an executive order by President Clinton: (1) learn and explain the history of human radiation experiments between 1944 and 1974; (2) examine specific cases of known research involving the exposure of humans to radiation (both of environmental releases of radiation and ionizing radiation to their bodies); (3) evaluate the degree to which these experiments were ethically acceptable and scientifically valid; and (4) make specific recommendations for improving (if necessary) the current system for protecting human subjects in research. The resulting document is an intriguing read: part cold war history, part careful review of voluminous files, part commentary on the status of human subjects research historically and in the contemporary period, and part illustration of the state of bioethics research methodology as applied to public policy.

The report is divided into four parts, the first of which provides a historical perspective on radiation experimentation conducted and/or funded by the U.S. government between 1944 and 1974. One is immediately struck not so much by the extent to which ethical issues were discussed in research at that time, but rather how easy it was to administratively dismiss the moral (if not legal) requirements for obtaining informed consent from individuals. Although the historical accounts are the most gripping, the most challenging chapter of Part I is the last, "Ethics Standards in Retrospect." This chapter carefully addresses a problem readily appreciated by anyone who is asked to discuss the ethical integrity of an activity that pre-dates one's experience, or more specifically, the legal and ethical standards enjoyed at the moment.

The committee is able to make its case for the validity of this activity by describing an ethical framework consisting of two types of moral judgments: those that examine the "moral quality of actions, policies, practices, institutions and organizations" and those that examine the "praiseworthiness or blameworthiness of individual agents" (pp. 198-99). The framework describes three kinds of ethical standards: basic ethical principles, government policies, and professional rules (pp. 199-200), which the committee applies retrospectively to the 1944-74 period and demonstrates that some of the research was unethically conducted and some government agencies blameworthy. The grounds for these assertions lie in the presence of certain government and/or department policies relating to the conduct of research and to existing professional guidelines regarding the care of patients. The case for retrospective judgment is made more forcefully using these standards,[3] however, than using the principle-based standards. Of particular interest to those protagonists in the now tiresome debate about the place of ethical principles in bioethical deliberation, this is a sensible, albeit conservative use of the several tools of applied ethics available to scholars. For example, the committee adopts the somewhat mainstream approach that "there is broad agreement about and acceptance of basic ethical principles . . . such as principles that enjoin us to promote welfare and to respect self-determination."[4] But it also recognizes the all-too-obvious point that ethical pluralism is based not only on these principles alone (or at all), but rather on other sources of moral norms including government policies and professional norms and practices.

The committee found that the history is complex and detailed, weaving through various branches of the U.S. government. It traces, as best as possible, the standards used to assess human experimentation. But, like any story, it was incomplete. Documents were missing, old, or occasionally inaccessible. Still, approximately 4,000 instances of human radiation experiments were identified. The committee could not review all of these experiments; instead it identified eight case studies that were representative of the studies conducted. Part II reviews the types of experiments conducted. This casuistic exercise serves two purposes: it provides the content for understanding the general categories of radiation experiments examined by the committee and it focuses the reader's attention in a way that would never be accomplished by the (no doubt) monotonous review of all 4,000 studies. For example, the committee found that the plutonium infusion experiments described by Welsome may very well have been the most egregious examples of unethical research uncovered; had these experiments been treated alongside thousands of others some of the important and perhaps subtler messages might have been lost.

Individual chapters in the report are devoted to each case study. Chapter 5 examines experiments in which sick patients were injected with plutonium as part of the Manhattan Project; Chapter 6 examines the Atomic Energy Commission's system for distributing radioisotopes used in human research. As the committee notes, "in studying [this area] . . . we sought to learn the ground rules that governed the conduct of the majority of human radiation experiments, most of which have received little or no public attention" (p. 229). Chapter 7 describes twenty-one cases of research on children, including the studies co-sponsored by the Quaker Oats Company at the Fernald School in Massachusetts where mentally retarded boys were given oatmeal containing radioactive iron and calcium. In another study at the Wrentham State School, mentally retarded children were administered radioactive iodine. Chapter 8 focuses on total-body irradiation studies, partially sparked by the studies that raised some controversy at the University of Cincinnati. Chapter 9 reviews research conducted on prisoners, one notable example being the research on the effect of ionizing radiation on testicular function.

Chapter 10 describes the use of human subjects in a different context: research done in connection with the testing of nuclear weapons. Although the current research ethics lexicon might exclude these participants from a list of research subjects, this case study convincingly argues for revising what we commonly hold to be a straightforward definition of a "subject" or "participant," and what ought to count as "research" or "experimentation." Complicating this issue is the fact that the "participants" were members of the military. As the committee noted, "having heard from many atomic vets and their family members . . . the real offense to many is the belief the risk was unacceptable and that they or their loved ones may suffer illness unnecessarily as a consequence" (p. 487).

Chapter 11 focuses on another type of "experiment" not typically discussed in research ethics circles: the intentional release of radioactive material into the air to determine how radioactive gases resulting from the production of atomic weapons behave in the atmosphere. The final case study (Chapter 12) relates the committee's assessment of observational research conducted by the U.S. government on three different populations exposed to radiation hazards: uranium miners in the western United States who worked in underground mines with inadequate ventilation; the inhabitants of the Marshall Islands in the South Pacific who were prematurely returned to their island following the detonation of nuclear weapons at Bikini Atoll between 1946 and 1954; and a group of Alaskans (Caucasians, Eskimo, and Indians) who, between 1956 and 1957, were subjects of a study in which iodine[131] was administered to determine the effect on the thyroid gland of extreme cold. The committee concluded that, of the three groups discussed in this chapter, the uranium miners were "the single group that was put most seriously at risk of harm, with inadequate disclosure and with often-fatal consequences" (p. 604).

The committee's historical research is soberingly placed in the context of secrecy. In Chapter 13, we are reminded that the committee knows what they know because they obtained access to some, but not all, files:

> The story we have told in this report could not have been told if the government did not keep records that could be retrieved. By the same token, the story is often disturbingly fragmentary; seemingly contradictory statements of principle or policy abound, and the trail from policy to practice is often hard to discern. The story is complex, but it is also hard to reconstruct because . . . many documents appear to have been long since lost or destroyed. (p. 646)

Following its historical review, Part III details a set of contemporary projects the committee conducted to determine how the current system of protecting human subjects is working. The scope of these three projects was considerable and is discussed in Chapters 14 through 16: a review of current guidelines and policies governing human subjects research to determine whether the problems identified between 1944 and 1974 had been remedied; a mock review of selected contemporary research protocols (the Research Proposal Review Project) to determine the extent to which subjects are currently being protected; and the Subject Interview Study, which insightfully shares the experiences of participants and their families involved in radiation experiments. This latter project is emotionally moving, particularly when you take the time to read the endnotes, which contain more interview data.

Part IV summarizes the committee's findings and recommendations. Seventeen findings and eighteen recommendations are discussed at length in Chapters 17 and 18, respectively.

One of the difficulties in preparing this review was trying to keep separate the various accounts of the committee's work as a *product* of bioethics scholarship from the final report as a piece of scholarship itself. One cannot help but blur these. With this caveat, there are several (potentially) enduring outcomes of this report. I have described these "legacies" in metaphorical terms: architectural renovation, updated cartography, and evolutionary branching.

Architectural Renovation. The history of research ethics in the United States has been updated, refurbished, and remodelled as a result of the committee's work. By dusting off the records, we can now see that several of the most important stories in contemporary research ethics continue to have explanatory and heuristic power. Adding the cold war radiation experiments to Nuremberg, Tuskegee, and Willowbrook adds a brick to the edifice that philosophers, theologians, lawyers, health care professionals, and historians have constructed to inform and warn about opportunities and dangers in science. In addition to reinforcing the power of these stories, there is an opportunity to repair some well-worn steps in the research ethics structure: the standard story that informed consent came into the lexicon in 1957 following *Salgo* must now be revised. Veatch, writing recently in the *Hastings Center Report*, and citing his and others' work, reflected that the history of consent reveals that it

is a relatively recent phenomenon.[5] Indeed, Faden and Beauchamp's seminal work on the history and theory of informed consent[6] takes the cold war period to be the origin of consent. The committee confirmed that consent was discussed as early as 1944.

If the National Commission provided the foundation for two decades of discussion ranging from theoretical questions involving the proper role of ethical principles in debate to more practical problems of involving persons incapable of consent in research, the Advisory Committee report constructs an edifice on that foundation that will surely support fruitful debate for another two decades.

Updated Cartography. Many bioethics reports exist. The report on bioethics in public policy of the now-defunct OTA noted in 1993 that nearly forty national commissions in almost thirty countries had produced reports on a variety of bioethics topics. Rarely do these commissions thoroughly describe the method used to fulfill their mandate and construct a road map for obtaining the original sources and documents used to develop their reports.[7] Unlike the *Belmont Report* (or any of the major bioethics public policy deliberative bodies in the United States since 1974), the Advisory Committee not only constructed the map describing where and how it was going to go (methodologically), it left enough breadcrumbs on the path to allow others to follow and find their way. For example, the final appendix, "A Citizen's Guide to the Nation's Archives—Where the Records Are and How to Find Them," is very helpful.

Not only is this evidence of scientific integrity (since sharing of primary research data is an obligation binding on all researchers), it is also evidence of concern and care for those individuals and families who wish to bring closure to events in their lives. By archiving materials and making them accessible in either hard copy or through various websites on the Internet, the committee has made a positive contribution to the cartographic project.

Evolution of Bioethics Methodology. The methods used to conduct the research in this report reflect the evolution of bioethics scholarship. In one report, we see conceptual, public policy, and jurisprudential analysis. Perhaps most interestingly, we see in-depth use of various quantitative and qualitative empirical methods. Casuistic and narrative methods are used with success. It is probably the most comprehensive use to date by a federal commission of the multiple methods bioethics has to offer to investigate and analyze moral problems in health care. As such, the report is itself a case study.

The history of human research ethics in North America has some familiar stories that the community now recites as comfortably as a storyteller in passing an oral history on to the next generation. It has followed a path that travels past familiar signposts that flag certain seminal documents (Nuremberg, Helsinki), regulatory initiatives (the U.S. *National Research Act*; 45 CFR 46, the Federal Common Rule), and cases (Willowbrook, Tuskegee, the Jewish Chronic Disease Hospital). The pedagogy used to teach about this history tends to be equally well-worn: a comprehensive documentation of the cases of abuse, with the assumption that we can learn from history by simply avoiding past injustices. Although genetic research may ultimately force a rethinking of the way we review, conduct, oversee, and report on human subjects research, the stories emerging from the human radiation experiments conducted in the United States, Canada, and Europe may also play a role in research ethics reform.

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3. A somewhat more elegant argument is made by Allen Buchanan in his recent article "Judging the Past: The Case of the Human Radiation Experiments," *Hastings Center Report* 26, no. 3 (1996): 25-30.

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5. Robert M. Veatch, "Abandoning Informed Consent," *Hastings Center Report* 25, no. 2 (1995): 5-12.

6. Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986).

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8. The Department of Energy produced a comprehensive listing of the DOE records of this research in *Human Radiation Experiments: The Department of Energy Road Map to the Story and the Records* (Washington, D.C.: Department of Energy, February 1995).

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Radiation (ARTICLE)

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Advisory Committee on Human Radiation Experiments: Final Report, October 1995, by Ruth R. Faden, chair, and Kenneth R. Feinberg, Eli Glatstein, and Jay Katz, et al, 925 pp, paper, $44, stock No. 061-000-00-848-9, Washington, DC, US Government Printing Office, 1995(telephone orders: Superintendent of Documents, US Government Printing Office, 202-512-1800, fax 202-512-2250; mail orders: US Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954).

The Human Radiation Experiments: Final Report of the President's Advisory Committee, by Ruth R. Faden, chair, and Kenneth R. Feinberg,Eli Glatstein, and Jay Katz, et al, 620 pp, $39.95, ISBN 0-19-510792-6, New York, NY, Oxford University Press, 1996. (This is the same report as above; it also includes an index.)

Executive Summary of Final Report of the Advisory Committee on Human Radiation Experiments, Ruth R. Faden, chair, 38 pp, paper, $2.75, stock No. 061-000-00849-7, Washington, DC, US Government Printing Office, 1995 (telephone orders: Superintendent of Documents, US Government Printing Office, 202-512-1800, fax 202-512-2250; mail orders: US Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954).

When the Advisory Committee on Human Radiation Experiments was created by President Clinton in January 1994, commentators posed three critical questions. First, was there sufficient surviving documentary evidence to enable the committee to analyze the radiationresearch conducted in the United States between 1942 and 1974; would the record be complete enough to enable it to determine the ethical and scientific standards by which to evaluate the pre-1974 experiments and the extent to which these experiments were consistentwith such standards'? Second, was it worth the expenditure of millions of dollars to uncover and analyze the record? Third, would acommittee appointed by the White House with a membership that was almost evenly divided between bioethicists and physician-scientists inevitably issue a final report that reflected political and intellectual compromise; would the report recount the history in compelling detail and then offer conclusions that blurred the lessonsto be learned? Now that the report has been issued, it is apparent that the answer to all three questions, with appropriate qualifications, is yes.

With the cooperation of many government agencies, particularly the Department of Energy, the advisory committee collected and examined several thousand research protocols. The roster includes the experiments involving plutonium (mainly on patients with a diagnosis of terminal illness); radioisotopes (particularly on children); totalbody irradiation (on advanced cancer patients); testes radiation (on prisoners); and intentional releases into the environment of radiation (in various communities). The

evidentiary record now available is, from the vantage point of historians accustomed to working with lacunae, remarkably complete and filled with surprises. Historians and public policy analysts owe an enormous debt to the archivists, agency administrators, and advisory committee members andstaff for their exceptional diligence.

What do we know that we did not know before? Perhaps the single most important and unexpected finding is just how aware government officials and researchers were in the 1950s and 1960s of the Nuremberg Code in particular and of the principles of research ethics, including informed consent, in general. Although the attention that the public and medical press had paid to the NurembergCode was minimal, leaders in the Department of Defense (DOD), the Armed Forces, and the Atomic Energy Commission (AEC) were fully cognizant of both its specific provisions and broader implications. In fact, their very sensitivity suggests that the provisions of the code were not so much a novel departure as a restatement of long-established and recognized precepts in medical ethics. The report puts to rest the dubious but often-heard claim that research ethics in the 1950s and 1960s were substantially different from thoseof the 1980s and 1990s.

As early as 1947 the AEC appreciated that human radiation experiments had to have a potential therapeutic effect' in order to be ethical, and they had to be susceptible of proof that, prior to treatment, each individual patient, being in an understanding state of mind, was clearly informed of the nature of the treatment, and itspossible effects, and expressed his willingness to receive the treatment.' Thus, when the AEC and the DOD were concerned about the risk to airplane crews posed by nuclear-powered engines and considered using prisoners to test effects of exposure levels, Shields Warren of the AEC commented: It's not very long since we gotthrough trying Germans for doing exactly the same thing.' Another investigator, Joseph Hamilton, remarked that the proposed research would have a little of the Buchenwald touch.' Such expressions prevented the research from being conducted. Moreover, the documentary record reveals that a large number of administrators insisted that investigators obtain consent from subjects and that at least some researchers followed this practice. In all, the Nuremberg Code was not as obscure as many of us had believed, and the idea of informed consent, as many of us had heretofore insisted, had a secureplace in the ethics of human experimentation well before the 1970s.

Because of the advisory committee efforts we also know how large the gap was between ideas and practices, between stated principle andactual deed. The report is replete with dispiriting examples of administrators failing to implement the ethics they espoused. The DOD, for example, incorporated the Nuremberg Code into its regulations and then, amazingly, proceeded to classify the document top secret' and not distribute it within its own network. Yes, the AEC ruled out nontherapeutic radiation research, but it did nothing to enforce the standard even among its contract research organizations.

By the same token, officials resisted suggestions, generally emanating from agency lawyers, on the need for congressional legislation on the conduct of human experimentation. Some were fearful of unfavorable publicity'; others worried that [t]o commit to writing a policy on human experimentation would focus unnecessary attention on the legal aspects of the subject' and narrow the discretion that researchers enjoyed.

Perhaps most disheartening, the advisory commission report sets forth the details of clinical research that patently sacrificed the well-being of its subjects and illuminates the lengths to which researchers and government officials were willing to go in order to maintain secrecy. Thus,

Ebb Cade, a 53-year-old colored male' who was hospitalized following an auto accident but was otherwise in goodhealth, was injected with 5 ug of plutonium at the Oak Ridge Army Hospital; he was, without his knowledge or consent, part of a research project to study the effects of plutonium on workers. Cade, the report documents, was one of at least twenty-two patients [who] were administered long-lived isotopes in experiments.' Nor were all of these subjects terminally ill, a criterion invoked to justify the research on the grounds that they would not be harmed by long-term negative effects. The advisory committee properly notes that terminalillness does not bring with it a waiver of rights.

When the AEC considered declassifying some of these research reports, its declassification officer concluded that such a step was unthinkable:

The document appears to be most dangerous since it describes experiments performed on human subjects, including the actual injection of plutonium into the body. . . . It is unlikely that thesetests were made without the consent of the subjects, but no statementis made to that effect and the coldly scientific manner in which the results are tabulated and discussed would have a very poor effect on the public.

The advisory committee could find no justification for the officer's assumption that consent had actually been obtained. Further, all of the plutonium protocols violated the AEC prohibition on nontherapeutic research. As the report aptly concludes: Concerns about adverse public relations and legal liability do not justify deceiving subjects, their families, and the public.'

Having documented the widespread knowledge of ethical principles and standards in research among agency directors and investigators, the inadequate efforts to distribute, let alone to enforce, these standards, the many experiments that violated the basic rights and well-being of subjects, and the systematic and extensive efforts at cover-up to avoid liability or censure, the advisory committee goes on to place these stunning findings in a frame that is often lackluster and lifeless. In the detailed analyses and case studies ofparticular protocols, its language and judgments are forthright. But the summary statements back off from a resolute declaration of findings. The tone is one of excessive caution, complicating issues that are really not so complicated.

Much of it is a matter of style. The language of the report is unusually arid. Nothing uncovered seems to shock the conscience, provoke dismay, or threaten democratic principles. Whether the case is that of retarded children at Fernald State School, Waltham, Mass, being fed radioisotopes under protocols that lied to their parents, or AEC officials hiding information to protect themselves and their investigators from well-deserved public criticism, the report all tootypically adopts a posture of disengagement, distance, almost abstraction.

But there are also matters of interpretation. The report is most critical of research of a nontherapeutic character conducted without subjects' knowledge or consent. However, it suggests that failures torespect subjects' autonomy are less reprehensible when the research had a prospect, however faint, of therapeutic benefit. To justify this conclusion, it notes that many investigators followed this practice and that medical paternalism and discretion was more entrenched then than now. But such arguments ignore the fact that most of the normative statements on research ethics did not distinguish in principle between therapeutic and nontherapeutic experiments. Although, as one commentator suggested, it might be moredifficult to get consent from sick patients, that does not make it any the less necessary. Nor is it right to reduce culpability becauseof the number of people who violated the precepts.

In this same compromising spirit, the report totters on the verge of allowing ends to justify means. Although explicitly disavowing such a proposition, it is too eager to remind readers that the research, however ethically dubious, produced important findings. Allthe while, the report does not hold up to embarrassment or consider what might be appropriate censure for a researcher or government official who had breached ethical principles or public trust. To be sure, this charge was not part of the advisory committee mandate; however, a more forceful report might have discussed the admittedly complex question of whether or how to respond to past transgressions.Acts are dubbed wrongful, but actors are never implicated.

These criticisms notwithstanding, the advisory committee efforts have much to commend them. The committee has built an archive that will be of invaluable use to anyone concerned with the past or futureof human experimentation, indeed, to anyone intent on keeping government responsive to its citizens. So too, the advisory committeerecommendations on compensation are persuasive: where harms occurred and consent was ignored, as was the case with plutonium, uranium, andtestes and total body irradiation experiments, the government should deliver a personal and individualized apology' and provide financialcompensation. Where no material harms occurred but individual rights were violated, the committee insists on formal government apologies. The advisory committee also suggests a number of reforms for the current system of research oversight, and, although they lack daring and imagination, they make clear that abuse in human experimentation is not a thing of the past.

Finally, and perhaps most important, the work of the advisory committee demonstrates that truth will eventually out. Sooner or later secrets will be revealed; those who abuse power will be identified even if they do not suffer personal consequences. This is no trivial precedent, and it may help to shield us from future transgressions.David J. Rothman, PhDColumbia College of Physicians and SurgeonsNew York, NY