THE WHITE HOUSE

WASHINGTON

July 8, 1996

MEMORANDUM FOR **THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS**

FROM: **Elizabeth Drye**
Diane Regas

SUBJECT: **Summary of Meeting (June 28)**

This memorandum summarizes the meeting of the Interagency Working Group on Human Radiation Experiments (IAWG), held on June 28. We had a very productive discussion on issues related to uranium miners, nasopharyngeal radiation and the Marshall Islanders. We expect to come very close to making policy decisions on all outstanding issues related to the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE) recommendations by mid-July. Please review the summary below for accuracy and any information that your agency needs to provide.

At the close of the meeting, the IAWG developed agendas for the next two discussions. We will meet next on July, 9, at 10:30 a.m., in the Eisenhower Room, White House Conference Center. (You do not need to be cleared in to the White House complex for this meeting.) We will discuss the Atomic Veterans (led by VA) and the waivers of consent for classified information (led by HHS). We will meet again, tentatively on July 16 at 10:30 (note the change), to discuss notification (led by DOE) and IRBs (led by HHS).

SUMMARY OF MEETING

I. Public Involvement in follow-up to ACHRE

DPC reported that we have agreed on at least the following steps for public involvement in our ongoing process. When we are ready to propose legislation we will advise stakeholders and listen to any reactions that they may have to our proposals. When we are ready to propose regulations, each Agency will make an extra effort to notify and involve stakeholders in this process--recognizing that many do not regularly scan the Federal Register for notices of relevant changes in the rules. Lastly, when we are ready to announce other executive actions, the DPC staff will give stakeholders notice and a brief, informal opportunity to understand what actions we intend to take.

II. Uranium Miners (Recommendation 7) (DOJ):

a. *Criteria for compensation of lung cancer.* We agreed that new criteria for determining whether uranium miners' lung cancer was caused by exposure in the mines should be added to existing legislation. We agreed that miners who qualify under either set of criteria should be eligible for compensation. DOJ will draft the proposed legislation by the end of July with new criteria, using a 90% level of assurance. OMB will analyze whether new legislation,or other action, is needed to address funding issues.

b. *Non-malignant respiratory disease criteria.* The Radiation Exposure Compensation Act Committee, led by DOJ, will propose revised criteria for compensation of non-malignant diseases. The Committee will have a proposed criteria by the end of the summer, and will draft proposed legislation soon thereafter.

c. *Presumption that members of the Navajo Tribe are non-smokers.* We agreed that there should be a presumption that Navaho were non-smokers based on the information and research that has been developed to date. DOJ will notify the IAWG if it determines that there are equal protection concerns with this decision. DOJ plans to propose changes in the regulations by the end of this summer.

d. *B-readers.* DOJ will propose changes in the regulations to emphasize the use of high resolution CT scans in determining the presence of non-malignant respiratory disease. In addition, DOJ will propose changes to eliminate any appearance of bias in the operation of the B-reader program. Those people who have been denied compensation solely because of a negative chest radiograph will be notified of the new encouragement to use CT scans.

e. *Non-reservation mines.* The Administration will propose legislation that would expand eligibility for compensation under RECA to miners with non malignant respiratory diseases who worked in mines outside of the Reservations.

f. *Smoking cessation.* DOJ will propose to modify its regulations to define non-smokers to include lung cancer claimants who stopped smoking 15 years or more before the date of diagnosis.

g. *Accepting CT scans.* DOJ will propose to modify its regulations to accept high-resolution CT scans as proof of the presence of a compensable non-malignant respiratory disease.

h. *Accepting lung biopsies.* DOJ will propose to modify its regulations to allow lung biopsies to be used as proof of the presence of non-malignant respiratory disease, where there is a medical reason to conduct the biopsy.

i. *Ethno-specific pulmonary function tables.* DOJ will propose to modify its regulations to adopt scientifically supported, ethno-specific pulmonary function tables to be used in judging whether pulmonary function is impaired. DOJ will notify the IAWG if it determines that there are equal protection concerns with this decision.

j. *Definition of Impaired Pulmonary Function.* DOJ will propose to modify its definition of impaired pulmonary function to be consistent with the American Thoracic Society.

III. Nasopharyngeal Radiation Treatments (CDC – DOD):

a. *Military Nasopharyngeal Radiation Treatments*

DOD will continue its efforts to identify members of the military who were treated with nasopharyngeal radiation. Recent new information suggests that as many as one thousand individuals may be identifiable. This information raises the possibility that an epidemiological study of the effects of these treatments could be possible. Neither the feasibility nor the desirability of such a study will be decided upon before the end of the summer.

The appropriateness of notification of affected veterans will be decided in reference to the overall criteria for notification that the IAWG will discuss in a future meeting.

VA is drafting legislation to make veterans treated with nasopharyngeal radiation eligible to participate in the VA's Ionizing Radiation Registry Examination program as well as to have priority eligibility for treatment of radium-related conditions. This legislation will be available for interagency review soon.

b. *Military Experiments involving Nasopharyngeal Radiation and External X-ray treatments*

DOD has found information about 5 – 10 individuals who were the subject of experiments involving nasopharyngeal radiation and external X-rays. The appropriateness of notification of affected veterans will be decided in reference to the overall criteria for notification that the IAWG will discuss in a future meeting.

c. *Risks from Nasopharyngeal Radiation Treatment in the General Public (non-experimental):* The IAWG endorsed CDC's recommendation that efforts to address risks to the general public should focus on education of the medical community. CDC described several efforts underway to ensure that this education is adequate.

IV. Marshall Islanders (DOE):

The IAWG endorsed DOE's recommendation that the federal effort in the Marshall Islands needs to flow from a long-term planning process that supports full involvement of the Marshallese in decisions about how to spend available federal money; how to support improvements in the health care infrastructure; and how to ensure that medical surveillance, and any ongoing studies, reflect the needs of the community.

July 3, 1996

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FROM: **Elizabeth Drye**
Diane Regas

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SUMMARY OF MEETING

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AS SENT

June 25, 1996

MEMORANDUM FOR THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS

FROM: **DIANE REGAS** /s/

SUBJECT: **SUMMARY OF MEETING (JUNE 20)**

This memorandum summarizes the meeting of the Interagency Working Group on Human Radiation Experiments (IAWG), held on June 20. Our goals were to begin making policy decisions on outstanding issues related to the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE) so that the Administration can respond publicly to ACHRE's recommendations by mid-July.

At the June 20 meeting we discussed issues related to the National Bioethics Advisory Commission and related to compensation for uranium miners. Below is a summary of our discussion, including decisions made and outstanding decisions and information that we need. Please read the summary carefully for material that your agency may need to provide. **Our next meeting will be on Friday, June 28 at 10:30-12:30 in OEOB Room 472.** At the meeting we will conclude our discussion on uranium miners (led by DOJ); decide on our course of action related to nasopharyngeal radiation treatments (led by DOD and CDC) and Marshall Islanders (led by DOE). DPC will also report on our discussions regarding public involvement. All materials for the meeting should be delivered to Elly Melamed at DOE by COB Wednesday June 26.

We will not meet during the week of July 1, however **we expect to meet twice during the second week of July (tentatively Tuesday and Friday)** and very frequently thereafter until we have IAWG recommendations on all the outstanding policy issues. We appreciate your dedication to solving the difficult challenges raised by Human Radiation Experiments, and look forward to your help in a strong push to resolve the remaining questions in the next few weeks.

SUMMARY OF MEETING

I. National Bioethics Advisory Commission: We discussed the six tentative issues for referral to NBAC, and made the following decisions (the "recommendation number" refers to the ACHRE report):

Recommendation 9 : (NBAC's role in establishing strategies to ensure the centrality of ethics in human subject research.) We decided it is appropriate to refer this to NBAC, but every agency also needs to explain the efforts underway now to respond. In addition, HHS agreed to work with DOD and VA to resolve the outstanding issue of money for research in this area.

Recommendation 10: (NBAC's role in changing IRB's.) We agreed that we need further discussion of the regulations that set guidelines for IRB's, to be led by HHS (probably July 12). In addition we agreed that we should be more specific in the questions that we ask NBAC on this issue (recognizing that NBAC will set its own priorities).

Recommendation 11 : (Ongoing public forum needed to discuss ethical issues raised by human experimentation.) We agreed that it is misleading to suggest that NBAC is the only ongoing federal public forum to discuss bioethical issues. All agencies need to provide information explaining the public fora that they make available to discuss such issues. We may need to revisit this discussion after we evaluate the agncies' information.

Recommendation 13 : (NBAC's role in improving oversight, sanctions, and scope of human subjects protections.) This referral is within the scope of NBAC. Action is needed to get the reports in response to the executive order from HUD, DOT, DOL, DOI. HHS agreed to follow up with these agencies, with help from DPC if necessary.

Recommendation 14: (NBAC's role in future compensation for research injury.) We agreed that this issue would not be referred to NBAC. Instead DOJ would take the lead in explaining the priniciples behind our belief that the current case-by-case approach is appropriate.

Recommendation 15: (NBAC's role in deciding whether federal rules should be changed to codify "no waivers" of consent.) We agreed that this issue would not be referred to NBAC. Instead, we may recommend that the criteria for waiver of consent in classified and non-classified research will be the same. To decide this issue HHS will outline the criteria and circumstances under which consent may be waived in non-classified research. We will discuss this at a future meeting (probably July 9).

II. Uranium Miners DOJ led a discussion of the technical report from the Radiation Exposure Compensation Act Committee on amending RECA. DOJ distributed material identifiying non-controversial recommendations and those that may need discussion. We plan to complete this discussion on June 28.

With regard to amendments to RECA to change the eligibility requirements for lung cancer compensation, we agreed to consider only those policy options that do not exclude either currently eligible miners or the additional miners that the report identified. DOJ agreed to provide options and lead another discussion on this issue.

We also agreed that the RECA committee should study and recommend changes to RECA to compensate miners who have non-malignant respiratory diseases. We still need to decide how to approach this issue in a public response to ACHRE given that the work of the Committee will not be completed before fall.

CARCINOGENS IN FOOD

- What actions has the Administration taken to enhance/protect the Delaney Clause? What is its current status?

  What specifically does the Delaney Clause do? What does it protect the public from, how many people protected, who is protected, etc.?

June 11, 1996

MEMORANDUM FOR THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS

FROM: **ELIZABETH DRYE**
DIANE REGAS

SUBJECT: **SUMMARY OF MEETING**

This memorandum summarizes the meeting of the Interagency Working Group on Human Radiation Experiments (IAWG), held on June 6. Our goals were to identify what issues need further work before the Administration can respond publicly to each of the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE); to establish a process to resolve those issues; and to prepare to respond to ACHRE's recommendations by mid-July.

At the June 6 meeting we identified the major issues that may need work, described below, and agreed to some next steps towards resolving them. In particular a lead agency for each issue agreed to summarize outstanding decisions needed, and options by June 14, and deliver the material to Elly Melamed at DOE. Please send the material by noon on June 14 so that it can be distributed before the end of the day to the IAWG. **Our next meeting will be on June 20, at 2:30, in Room 472.**

- Compensation: The Department of Justice will review and edit the previous explanation of the Administration's policy on compensation, and determine whether there are outstanding issues that need to be resolved.
- Notification: The Department of Energy (DOE) will outline a response to ACHRE's recommendation. The response will highlight our agreements with the Committee; explain what is or soon will be available to the public; explain what will not be available and why; and explain ongoing efforts by the agencies to respond to inquiries and to find additional relevant information. We recognize that the Administration's ultimate statement on this issue needs to go further than responding to ACHRE.
- Expectations for the National Bioethics Advisory Committee (NBAC): The White House Office of Science and Technology Policy (OSTP) and the National Institutes of Health (NIH) will work together to review references in the "White Paper" to NBAC. Our goals are to ensure that the totality of the issues referred to NBAC from this group is realistic given NBAC's broad charter. We also need to identify alternative ways to respond to the ACHRE's recommendations if referral to NBAC is

inappropriate. Resolution of what issues should be referred to NBAC is a very high priority. Our expectation is that, by June 14, OSTP and NIH staff will recommend what should be referred to NBAC.

- Uranium Miners: The Department of Justice has led a working group to put forward options, which we propose to discuss at the next meeting.
- Marshall Islanders: DOE will work with the Department of Interior to identify outstanding issues and propose options.
- Nasopharyngeal Radiation: The Department of Defense (DOD) will work with the Centers for Disease Control and Prevention (CDC) and the Department of Veterans Affairs (VA) to identify outstanding issues and options. This issue was not discussed at the meeting, but we believe that it would be useful to get CDC's view about an appropriate public health notification for those who underwent this treatment. We recognize that this issue falls outside the scope of ACHRE's charter.
- Atomic Veterans: Although we did not discuss this issue extensively at the meeting, it presents difficult and controversial policy issues. It is important that we spend substantial time on the 20th discussing the pros and cons of the options. DOD agreed to work with the VA to identify outstanding issues and provide options to resolve them.

We look forward to our next meeting on Thursday the 20th. Please call either of us if you have any questions (456-2216). You can also use e-mail: Regas_D@a1.eop.gov.