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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Ron Peterson to Legislative Liaison Officer [partial] (1 page)	10/08/1996	P3/b(3)

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

FOLDER TITLE:
RECA [Radiation Exposure Compensation Act] [Folder 1]

2014-0046-S
rc1437

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]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
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Freedom of Information Act - [5 U.S.C. 552(b)]

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b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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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]

THE WHITE HOUSE

WASHINGTON

December 12, 1996

MEMORANDUM FOR GEORGE PHILLIPS

FROM: DIANE REGAS
Domestic Policy Council

SUBJECT: Proposed Changes to RECA

Attached are the materials that we discussed suggesting a modification to the RECA language that OMB circulated a couple of weeks ago.

The intention of the language is to provide partial compensation to miners for whom the probability is between 20% and 50% that their lung cancer was caused by exposure to radiation in mines. As you can see in the attached table provided by NCI, approximately 25-30% of the miners in this category are already eligible for compensation under the current RECA standards.

Our current best estimate of the total additional cost of this proposal *combined with the changes to RECA that we have already agree upon* is between $13 and $14 million over the next 20 years.

You and I discussed some of the reasons for this proposed addition, including: treating similarly situated miners similarly; minimizing some of the existing inequities in RECA between downwinders and miners; and recognizing that the public and policy-makers strongly believe that the government's Cold War actions in exposing people to radiation were contrary to deeply-held values.

If you, or anyone in your office, would like to discuss this further, I would be happy to meet with you here or in your offices. Please call me at 456-5589 or page me when you are ready to discuss this.

cc: Elizabeth Drye
T J Glauthier

Attachments (Table 5; proposed statutory language)

Table 5: Estimated numbers of lung cancer deaths in the Colorado and New Mexico study populations in the 20 years after end of follow-up by current RECA criteria and by interval of probability of causation.

	Eligible under RECA		
PC	No	Yes	Total
	Based on model with WLM exposure		
<0.2	209.4	0.1	209.5
0.2-	189.9	83.5	273.4
≥0.5	8.3	99.3	107.6
Total	407.6	182.9	590.5
	Based on maximum PC from WLM model and duration/year of first exposed model[a]		
<0.2	92.3	0.0	92.3
0.2-	152.6	56.2	208.8
≥0.5	162.7	126.7	289.4
Total	407.6	182.9	590.5

[a] Estimates for miners in the New Mexico study are subject to additional uncertainty since data on duration of exposure were not available. Exposure of one year assumed in any year a miner was exposed.

(c) CLAIMS RELATING TO URANIUM MINING.--(1) Section 5 of the Act is amended by deletion in its entirety and insertion of the following in its place:

(a) Eligibility of Individuals for Full Compensation. -- Any individual who was employed in a uranium mine located in one of the specified states at any time during the designated time period, shall receive $100,000 if he/she --

(1) submits written medical documentation that he or she developed lung cancer, and

(A) if a nonsmoker,

(i) was exposed to 200 or more working level months of radon progeny; or

(ii) was exposed to at least the amount of radon progeny in working level months prescribed in Table NS1, based on the individual's age at date of cancer incidence and the number of years since his or her last exposure to radon progeny in the designated time period; or,

(iii) was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NS2, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period; or

(B) if a smoker,

(i) submits written documentation that he or she was exposed to 300 or more working level months of radon progeny and cancer incidence occurred before age 45, or was exposed to 500 or more working level months of radon progeny, regardless of age of cancer incidence; or

(ii) submits written documentation that he or she was exposed to at least the amount of radon progeny in working level months prescribed in Table S1, based on the individual's age at date of cancer incidence and number of years since last exposure to

radon progeny during the designated time period, or

(iii) submits written documentation that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table S2, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period;

(2) submits written medical documentation that he or she developed a nonmalignant respiratory disease, and that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NMD;

and is NOT eligible for compensation under paragraph (a)

(b) Eligibility of Individuals for Partial Compensation -- Any individual who was employed in a uranium mine located in one of the specified states at any time during the designated time period, shall receive $50,000 if he/she submits written medical documentation that he or she developed lung cancer, and

(1) if a nonsmoker,

(i) was exposed to at least the amount of radon progeny in working level months prescribed in Table PC1, based on the individual's age at date of cancer incidence and the number of years since his or her last exposure to radon progeny in the designated time period; or,

(ii) was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table PC2, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period; or

(2) if a smoker,

(i) submits written documentation that he or she was exposed to at least the amount of radon progeny in working level months prescribed in Table PC3, based on the individual's age at date

of cancer incidence and number of years since last exposure to radon progeny during the designated time period, or

(ii) submits written documentation that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table PC4, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period;

(c) Any individual eligible for full or partial compensation under subsections (a) or (b) shall receive payment if --

(1) a claim for payment is filed with the Attorney General by or on behalf of such individual, and,

(2) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act.

(3) payment can be made in accordance with section 6.

(d) Definitions -- For purposes of this section --

(1) the term "working level month of radiation" means radiation exposure at the level of one working level every work day for a month, or an equivalent exposure over a greater or lesser amount of time;

(2) the term "working level" means the concentration of the short half-life daughters of radon that will release 1.3 x 10^5 million electron volts of alpha energy per liter of air;

(3) the term "nonmalignant respiratory disease" means pulmonary fibrosis, cor pulmonale related to pulmonary fibrosis, and moderate or severe silicosis or pneumoconiosis;

(4) the term "Indian tribe" means any Indian tribe, band, nation, pueblo, or other organized group of rcommunity, that is recognized as eligible for special programs and services provided by the United States to Indian tribes because of their status as Indians.

(5) the term "specified states" means Arizona, Colorado, New Mexico, Utah, or Wyoming; and

(6) the term "designated time period" means the period beginning January 1, 1947 and ending on December 31, 1971.

U.S. Department of Justice

Civil Division, Torts Branch

Environmental Torts
Post Office Box 340
Washington, D.C. 20044

Telephone: (202) 616-4448
Telecopier: (202) 616-4989

August 2, 1996

TO: Human Radiation Interagency
Working Group

Enclosed please find a copy of the Final Report of the Radiation Exposure Compensation Act Committee. On behalf of the Committee, I would like to express my appreciation for the opportunity we were provided, and the support of the IAWG throughout the process. As you know, we are continuing to examine the possibility of proposing new threshold criteria for the nonmalignant diseases specified in the statute, and we will report to the IAWG as soon as we have completed our investigation.

If you need any additional copies of the Final Report, please feel free to contact me at 616-4448 at your convenience.

Once again, thank you for your support and patience.

Sincerely,

Paul Yanowitch
for the Committee

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

LRM NO: 5739

FILE NO: 2926

10/8/96

LEGISLATIVE REFERRAL MEMORANDUM

Total Page(s): 17

TO: Legislative Liaison Officer - See Distribution below:

FROM: Ron PETERSON Ron Peterson (for) Assistant Director for Legislative Reference

OMB CONTACT: Holly FITTER 395-3233 Legislative Assistant's Line: 395-6194
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fitter_e@a1.eop.gov
Eric MACRIS 395-4706

SUBJECT: JUSTICE Proposed Draft Bill: Radiation Exposure Compensation Act Amendments Act

DEADLINE: 10:00 AM Tuesday, October 15,1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **5739**

FILE NO: **2926**

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet.
If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.
You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Holly FITTER 395-3233
Office of Management and Budget
Fax Number: 395-5691
Branch-Wide Line (to reach legislative assistant): 395-6194

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: JUSTICE Proposed Draft Bill: Radiation Exposure Compensation Act Amendments Act

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

U. S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

Honorable Albert Gore
President
United States Senate
Washington, D.C. 20510

Dear Mr. President:

Enclosed is a draft bill entitled the "Radiation Exposure Compensation Act Amendments Act of 1996." We are forwarding an identical proposal to the Speaker of the House of Representatives.

This draft bill would amend various provisions of the Radiation Exposure Compensation Act of 1990, 42 U.S.C. § 2210 note ("the Act" or "RECA"), to ensure that the criteria for compensation are consistent with the latest scientific data and analytical methods. The draft bill would incorporate new eligibility criteria for uranium miners seeking compensation for lung cancer and specified nonmalignant respiratory diseases, and expand existing eligibility criteria for downwind and onsite participant claimants. The draft bill would also clarify the circumstances under which an award due to an onsite participant under the Act must be offset by payments from third parties or the Federal Government, and would extend the period of time in which claims for compensation may be filed and payments awarded. The proposed legislation is designed to remedy a series of perceived shortcomings in the Act that may be frustrating congressional intent to provide compassionate payments to individuals who suffer or have suffered from diseases presumably resulting from exposure to radiation in connection with the Federal Government's nuclear weapons testing program.

BACKGROUND

On October 15, 1990, the President signed into law P.L. 101-426, the Radiation Exposure Compensation Act of 1990. The Act established a procedure to make partial restitution to three classes of individuals who were put at serious risk by the Federal Government's nuclear weapons testing program during the Cold War era and who, presumably as a result of exposure to radiation, developed certain diseases. The three classes of eligible claimants recognized in the Act are: 1) individuals who lived a specified duration in certain counties downwind of the Nevada Test Site during defined time periods when above-ground

nuclear tests were conducted, and who suffer or suffered from any of thirteen radiogenic malignant diseases; 2) Department of Defense and Department of Energy personnel and contractors physically present at one of the Federal Government's nuclear weapons testing sites during an atmospheric detonation of a nuclear device, and who suffer or suffered from any of thirteen radiogenic malignant diseases; and 3) individuals employed in underground uranium mines in the states of Arizona, Colorado, New Mexico, Utah and Wyoming during the period January 1, 1947 through December 31, 1971, and who suffer or suffered from either lung cancer or one of several nonmalignant respiratory diseases. The statute requires uranium miner claimants to prove that they were exposed to specified minimum levels of radiation in the course of their employment in underground uranium mines. The prescribed minimum exposure level varies depending on a claimant's smoking status and age at the time of onset of the disease.

The Act provides a set level of compensation to an eligible claimant in each class (defined to include the exposed individual or specified surviving beneficiaries): a "downwinder" receives $50,000; an "on-site participant" receives $75,000; and a uranium miner receives $100,000. The Department of Justice administers the RECA through the Radiation Exposure Compensation Program ("Program").

The provisions of the RECA defining the eligibility criteria for uranium miner claimants have increasingly been the subject of criticism by scientists, claimants and interested parties in the affected areas. The principal criticism has been that the threshold radiation exposure criteria are inconsistent with the latest scientific information. Most recently, the Act's provisions relating to uranium miners (and the Department of Justice's implementing regulations) were reviewed by the President's Advisory Committee on Human Radiation Experiments, charged with investigating the history of human radiation experimentation conducted by the federal government during the Cold War period. In its Final Report, the Advisory Committee concluded that much of the criticism of the Act was justified. It recommended that the Administration undertake a review of the provisions of RECA governing compensation for uranium miners to ensure that they are fair, consistent with current scientific evidence, and compatible with the objectives of the Act.

In response to this recommendation, the Administration created a committee of experts to review the provisions relating to uranium miners in light of the latest epidemiological data and analytical methods. The Committee concluded, among other things, that the present exposure criteria are problematic in a number of ways. First, the latest data indicate that the exposure minimum misrepresents the risk of lung cancer for many miners. As a consequence, the present criteria have the unfortunate and unjust

effect of denying compensation to many miners who were subject to a considerable risk of lung cancer from exposure to radon progeny, and who later developed lung cancer. Second, the data at present do not support the statutory connection between exposure to radiation and the development of the specified nonmalignant respiratory diseases. These nonmalignant lung disorders are most likely caused by silica and other toxic agents in the mining environment, not radiation.

Third, through its experience administering the Act, the Department of Justice has identified a number of statutory provisions relating to the downwind and onsite participant populations that should be modified to promote just compensation to deserving claimants. The Department believes that a number of these provisions have caused claimants undue hardship. In particular, leading scientists at the National Cancer Institute (NCI) now inform the Department that the list of compensable radiogenic diseases for the downwind and onsite participant populations is no longer comprehensive, and, further, that some of the lifestyle conditions identified in the Act as precluding recovery for an otherwise compensable disease are no longer accurate. The Department has had to deny compensation to a number of claimants who, based on the information provided by the NCI, should be eligible. In addition, through what is plainly an oversight in the original Act, onsite participants are not entitled to recover for childhood leukemia. While Congress, quite understandably, did not anticipate that any children would be present at a nuclear weapons testing facility during a detonation, the original Act defines "childhood," for purposes of this section, as exposure before the age of 21. The Department of Justice has denied claims, albeit a small number, from otherwise eligible veterans and government contractors who were in fact present at a designated testing facility during an official test prior to age 21, and who later contracted childhood leukemia. Under current law, these individuals are not eligible for payments.

Fourth, the statute presently requires the Department to offset any award to an otherwise eligible claimant by any payments the claimant has received from some other source related to injuries covered by the Act. The Act specifically provides, however, that an award to downwinders or uranium miners not be offset by any payments received on a claim for workers compensation benefits. The offset provisions for onsite participants differ: they do not make explicit that workers compensation benefits are excluded from offset, and they require the offset of any payments to the claimant from the Federal Government based on injuries covered by the Act. This lack of parity has proved particularly frustrating to claimants and the Department. Under the explicit direction of the Act, the Department has had to offset awards to onsite participant claimants by Social Security disability payments. The Department

does not, however, offset awards to downwinders and uranium miners for similar disability payments.

PROPOSED LEGISLATION

The proposed bill would attempt to remedy the shortcomings in the Act relating to uranium miners by incorporating new eligibility criteria for both lung cancer and nonmalignant respiratory disorders based on the latest epidemiological data and analytical methods. The proposed amendments would add two additional sets of eligibility criteria to the existing exposure criteria for lung cancer, one based on minimum radiation exposure levels, the other on minimum duration of employment. These new criteria more accurately reflect the risk of lung cancer from uranium mining, and, therefore, more accurately provide for compensation to claimants whose lung cancer more likely than not was caused by their exposure to radon in uranium mines. The draft bill would allow a claimant to qualify by meeting <u>either</u> the existing exposure-based criteria, or <u>one</u> of the two new alternative criteria.

The proposed bill would also establish separate threshold eligibility criteria for claimants seeking compensation for a nonmalignant respiratory disorder. These threshold criteria would be based on duration of employment in uranium mines, a surrogate for exposure to the toxic agents in the mining environment known to significantly affect miners' risk of these diseases. The proposed bill would also eliminate some redundancy in the list of compensable nonmalignant respiratory disorders, and eliminate the statutory language limiting compensation for silicosis or pneumoconiosis to claimants employed in uranium mines located on an Indian Reservation.

Additionally, the bill would expand the list of compensable diseases for the downwind and onsite participant populations to be consistent with the latest scientific information that we have. The bill would add to the list of compensable diseases primary cancer of the salivary gland, if the claimant was not a smoker, and primary cancer of the male breast. It would also modify the list of lifestyle conditions that exclude otherwise eligible claimants by eliminating the requirement that claimants seeking compensation for pancreatic cancer not have a history of heavy coffee drinking.

The proposed bill would also correct an oversight in the initial Act: it would expand the eligible population for childhood leukemia to include any onsite participant first exposed to radiation at one of the designated nuclear weapon detonation sites prior to age 21, and who meets the remaining statutory medical criteria.

Additionally, the proposed bill would modify the offset provisions relating to onsite participants. The bill would specifically exclude from offset, as it does for downwinders and uranium miners, any payments an onsite participant receives on a claim for workers compensation benefits based on injuries covered by the Act. The bill would also specifically limit the offset for payments by the Federal Government to payments made by the Department of Veterans Affairs. This would include amounts paid to the onsite participant under the Radiation Exposed Veteran's Compensation Act, but exclude benefits paid under Social Security disability programs for the same compensable illness. These proposed amendments would put onsite participants on an equal footing with downwinders and uranium miners with respect to federal disability payments.

Finally, the proposed bill would make some technical amendments. The bill would amend the provision setting a twelve-month limit on the time within which the Department of Justice must process a claim. The bill would clarify that where the Department seeks necessary documentation from the claimant or some third-party, the limitations period is tolled. The bill would amend the statutory provisions defining the period of time in which claims will be accepted and the Trust Fund available for payments.

The Administration believes that the changes proposed to the eligibility criteria in this bill will enfranchise many claimants previously denied compensation, as well as some unknown number of claimants who have not submitted claims believing themselves ineligible under the existing criteria. The proposed amendments would give all future potential claimants the 20 years initially envisioned by Congress to file a claim under the amended Act.

We believe that the enactment of the draft bill would be the best way to promote the congressional objectives stated in the Radiation Exposure Compensation Act of 1990. The proposed bill will ensure that individuals presumably injured as a result of the Federal Government's nuclear weapons testing program are justly compensated.

Thank you for your consideration of this important matter. The Office of Management and Budget advises that there is no objection to the presentation of this draft bill from the standpoint of the Administration's program.

Sincerely,

Andrew Fois
Assistant Attorney General

A BILL

To amend the eligibility criteria of the Radiation Exposure Compensation Act (42 U.S.C. § 2210 note (Supp. 1995)), and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Radiation Exposure Compensation Act Amendments Act of 1996".

SEC. 2. TRUST FUND.

Section 3(d) of the Radiation Exposure Compensation Act (42 U.S.C. § 2210 note (Supp. 1995)) (cited hereinafter as "the Act") is amended by striking "the enactment of the Act [Oct. 15, 1990]" and inserting "this amendment of the Act".

SEC. 3. CLAIMS RELATING TO ATMOSPHERIC NUCLEAR TESTING.

(a) Section 4(a)(1) of the Act is amended to read as follows:

"(1) Claims relating to childhood leukemia - Any individual who --

"(A) was physically present in an affected area for a period of at least 1 year during the period beginning on January 21, 1951, and ending on October 31, 1958;

"(B) was physically present in the affected area for the period beginning on June 30, 1962, and ending on July 31, 1962; or

"(C) participated onsite in a test involving the atmospheric detonation of a nuclear device,

and who submits written medical documentation that he or she, after such period of physical presence or such onsite participation (as the case may be), and between 2 and 30 years after first exposure to fallout, contracted leukemia (other then chronic lymphocytic leukemia), shall receive $50,000 (in the case of an individual described in subparagraphs (A) or (B)) or $75,000 (in the case of an individual described in subparagraph (C)), if --

"(i) initial exposure occurred prior to age 21;

"(ii) the claim for such payment is filed with the Attorney General by or on behalf of such individual; and

"(iii) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act.".

(b) Section 4(b)(2) of the Act is amended --

(1) by inserting "male and" before "female breast";

(2) by striking "and low coffee consumption"; and

(3) by inserting "salivary gland (provided not a heavy smoker)," after "gall bladder,".

SEC. 4. CLAIMS RELATING TO URANIUM MINING.

(a) Section 5(a) of the Act is amended to read as follows:

"(a) Eligibility of Individuals.-- Any individual who was employed in a uranium mine located in one of the specified states at any time during the designated time period, and who--

"(1) submits written medical documentation that he or she developed lung cancer, and

"(A) if a nonsmoker,

"(i) was exposed to 200 or more working level months of radon progeny; or

"(ii) was exposed to at least the amount of radon progeny in working level months prescribed in Table NS1, based on the individual's age at date of cancer incidence and the number of years since his or her last exposure to radon progeny in the designated time period; or,

"(iii) was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NS2, based on the individual's age at date of

cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period; or

"(B) if a smoker,

"(i) submits written documentation that he or she was exposed to 300 or more working level months of radon progeny and cancer incidence occurred before age 45, or was exposed to 500 or more working level months of radon progeny, regardless of age of cancer incidence; or

"(ii) submits written documentation that he or she was exposed to at least the amount of radon progeny in working level months prescribed in Table S1, based on the individual's age at date of cancer incidence and number of years since last exposure to radon progeny during the designated time period, or

"(iii) submits written documentation that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table

S2, based on the individual's age at date of cancer incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period;

"(2) submits written medical documentation that he or she developed a nonmalignant respiratory disease, and that he or she was employed in an underground uranium mine or mines in the specified states and during the designated time period for at least the amount of time prescribed in Table NMD,

"shall receive $100,000, if --

"(A) the claim for such payment is filed with the Attorney General by or on behalf of such individual, and

"(B) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act.

"(3) Payments under this section may be made only in accordance with section 6 of the Act.".

(b) Section 5(b)(3) of the Act is amended to read as follows:

"(3) the term 'nonmalignant respiratory disease' means pulmonary fibrosis, corpulmonale related to pulmonary fibrosis, and moderate or severe silicosis or pneumoconiosis;".

(c) Section 5(b)(4) of the Act is amended --

(1) by striking the period at the end of the paragraph and inserting ";" and

(2) by inserting the following at the end:

"(5) the term 'specified states' means Arizona, Colorado, New Mexico, Utah, or Wyoming; and

"(6) the term 'designated time period' means the period beginning January 1, 1947 and ending on December 31, 1971.".

SEC. 5. DETERMINATION AND PAYMENT OF CLAIMS.

(a) Section 6(c)(2)(B) of the Act is amended --

(1) in clause (i) by inserting "(other than a claim for workers compensation)" after "claim"; and

(2) in clause (ii) by striking "Federal Government" and inserting "Department of Veteran Affairs".

(b) Section 6(d) of the Act is amended by inserting at the end the following:

"The Attorney General may request from any claimant, or from any individual or entity on behalf of any claimant, any additional information or documentation reasonably necessary to complete the determination on the claim in accordance with the procedures established under subsection (a). The period of time from the Attorney General's request for additional information or documentation until the time such is provided, or the requested party informs the Attorney

General the information or documentation cannot or will not be provided, will not be counted toward the twelve month limit established in this subsection.".

SEC. 6. LIMITATION ON CLAIMS AND TRUST FUND.

(a) Section 8 of the Act is amended to read, as follows:

"A claim to which this Act applies shall be barred unless the claim is filed within 20 years after the date of enactment of the Radiation Exposure Compensation Act Amendments Act of 1996.".

(b) The first sentence of section 3(d) of the Act is amended to read, as follows:

"(d) Termination.-- The Fund shall terminate 22 years after the date of enactment of the Radiation Exposure Compensation Act Amendments Act of 1996.".

reca.1
9/17/96

SECTION-BY-SECTION ANALYSIS

Section 1 states short title of the legislation, the "Radiation Exposure Compensation Act Amendments Act of 1996."

Section 2 would amend section 3(d) of the Radiation Exposure Compensation Act ("the Act") to extend the date for termination and dissolution of the Radiation Exposure Compensation Trust Fund consistent with the proposed amendment to section 8 of the Act extending the time period for filing claims.

Section 3 would amend section 4 of the Act by expanding the eligibility criteria for downwinder and onsite participant claimants.

Subsection (a) would amend section 4(a)(1) of the Act by expanding the class of claimants eligible for compensation for childhood leukemia. The amendment would add onsite participants who were exposed to radiation before the age of 21 while participating onsite in a test involving the atmospheric detonation of a nuclear device.

Subsection (b) would amend the list of compensable diseases in section 4(b) of the Act to account for the latest scientific findings regarding the effects of radiation exposure. The amendment would add two new diseases that have now been associated with exposure to radiation -- primary cancers of the male breast and salivary gland -- and eliminate the requirement that claimants seeking compensation for pancreatic cancer not have a history of heavy coffee drinking. The bill would limit compensation for salivary gland cancer to claimants who were not heavy smokers.

Section 4 would amend the provisions of the Act defining the eligibility criteria for uranium miner claimants.

Subsection (a) would amend section 5(a) of the Act by deleting the present exposure criteria that uranium miners must satisfy to be eligible for compensation for either lung cancer or a nonmalignant respiratory disease, and replacing in lieu thereof separate eligibility criteria for each disease condition. This provision would amend the existing exposure criteria for lung cancer by adding two additional sets of criteria -- one also based on exposure to radiation, and one based on duration of employment -- and allow claimants to meet either the existing exposure standards or either of the two new alternative standards. These new sets of criteria were developed by the Administration utilizing the latest epidemiological data and analytical methods, to ensure that the eligibility criteria accurately reflect the risk of lung cancer from uranium mining, and thus provide compensation to deserving claimants. This subsection would also add new eligibility criteria for the compensable nonmalignant respiratory diseases, based on duration

of employment. These new criteria are designed to incorporate the latest scientific data indicating that the most likely cause of these diseases is not exposure to radiation, but exposure to silica, dust and other toxic agents in the mining environment.

Subsection (b) would amend section 5(b)(3) of the Act by eliminating the redundant reference to pulmonary fibrosis in the list of compensable nonmalignant respiratory disorders. It would also eliminate the limitation on compensation for silicosis and pneumoconiosis to uranium mines on Indian Reservations. This would ensure that miners employed in uranium mines off Indian Reservations (yet within one of the specified mining states) are compensated on the same conditions as miners employed in mines on Indian Reservations; the risk of silicosis due to uranium mining was not restricted to mines on Indian Reservations.

Subsection (c) would amend section 5(b) of the Act by adding two new phrases employed in section 5(a) as shorthand for temporal and geographic eligibility criteria. These new phrases are designed to aid the clarity of the eligibility criteria.

Section 5 would amend the provisions of section 6(c)(2) of the Act defining the circumstances in which awards to onsite participants must be offset by payments received to from other parties.

Subsection (a) would amend section 6(c)(2)(B)(i) to clarify that awards under the Act to on-site participants should not be offset by payments to the claimant based on a workers compensation claim for the same injuries. It would also amend section 6(c)(2)(B)(ii) to clarify that an award under the Act should be offset only by payments from the Department of Veteran's Affairs, and not by disability payments from other federal agencies, such as Social Security. These amendments are designed to enhance parity among the eligible populations by ensuring that payments to onsite participants are offset on the same terms as payments to downwinders and uranium miners.

Subsection (b) would amend section 6(d) of the Act by adding explicit authorization for the Attorney General to seek and obtain from claimants, or from any individual or private or public entity on behalf of claimants, any documentation or information necessary to determine eligibility. This provision also provides that the time period during which the Attorney General is awaiting the requested information shall not count toward the twelve-month statutory limit on processing claims.

Section 6 would amend section 8 of the Act by extending the period of time in which a claimant could file a claim for compensation. The amendment would allow claims to be filed within 20 years of the date of enactment of the proposed amendments, to ensure that all prospective claimants eligible for

compensation under the new proposed criteria would have time to file a claim. Similarly, section 3 of the Act would be amended to extend the date of termination of the Trust Fund to 22 years after the date of enactment of the draft bill.

reca.3
9/17/96

URANIUM MINERS: ISSUES FOR DECISION

The Radiation Exposure Compensation Act (RECA) Committee recommended changes to the statute and implementing regulations in its Final Report to the IAWG. The recommendations that raise the more difficult issues or are likely to be controversial are listed below, with salient pro and con points to aid the IAWG in reaching a final decision. The recommendations that are more straightforward and are likely to be widely accepted are listed at the end without additional comment; the explanation in the Executive Summary should prove sufficient.

1. Should the Administration propose legislation amending the RECA by adopting the threshold exposure criteria for lung cancer cases proposed by the Committee?

   - the exposure criteria generated and proposed by the Committee reflect the latest credible evidence and scientific methodology;
   - the proposed exposure criteria will compensate some miners denied compensation under the present statutory criteria;
   - the proposed criteria will significantly raise the exposure criteria for some miners over the current RECA criteria, making it more difficult for these claimants to receive compensation; the affected miners would be those who get lung cancer at age sixty or older, and whose last exposure to radon progeny was more than twenty years ago;
   - the Department of Justice will know by the end of the month the approximate percentage of miners who will be newly enfranchised and newly disenfranchised by the Committee's recommended criteria;

   Subissue 1(a): Should the Administration propose threshold criteria based on radon progeny exposure (WLMs) or duration of employment?

   - employment data is likely to be more accurate than historical mine radon measurements;
   - concern about limited historical mine radon measurements led Advisory Committee to recommend use of employment-based criteria;
   - radon progeny exposure criteria are more "accurate" -- they better fit the observed data;

- Committee recommends that if duration of employment criteria are proposed by Administration, exposure criteria also be adopted (i.e., a claimant would qualify under either set of criteria);

Subissue 1(b): What "level of assurance" should the Administration require for proposed criteria?

- "levels of assurance" is a crude relative of statistical confidence intervals, and accounts for uncertainty inherent in the statistical process; it denotes the range of values within which, to the defined degree of assurance, the true criterion lies;

- the higher the level of assurance demanded, the lower the resulting criteria imposed on the claimants, and, consequently, the more claimants eligible;

- the Committee generated three sets of criteria for IAWG consideration: without any added level of assurance, with an 80% level of assurance, and with a 90% level of assurance;

- if criteria unmodified for any level of assurance are used, 83% of lung cancer cases in the known study cohorts are eligible; if the 80% level of assurance criteria are used, 85% of lung cancer cases are eligible; if the 90% level of assurance criteria are used, 86% of lung cancer cases are eligible;

- Committee made no recommendation because the selection of the appropriate set of criteria is a policy choice.

2. Should the Administration propose legislation amending RECA by incorporating new threshold exposure criteria for nonmalignant respiratory disorders unrelated to radon progeny exposure?

- Committee concluded that the evidence linking radon exposure and NMRDs is ambiguous and insufficiently persuasive, at best; NMRDs most likely related to dust and agents in mining environment;

- it may be possible to generate more accurate and "fair" criteria based on employment duration;

- Committee recommended that the IAWG task some qualified body or agency to attempt to generate new criteria;

- legislation proposing new criteria for NMRDs based on duration of employment may have collateral political effect; underground hard rock miners, other than uranium miners, also at risk for NMRDs.

3. Should the Attorney General modify the regulations to create a rebuttable presumption that all Navajo miners were nonsmokers?

   - nonsmokers have to meet significantly lower threshold exposure criteria than smokers; rebuttable presumption would aid many Navajo now probably misclassified as smokers;

   - evidence indicating most Navajo smoked at rate less than minimum set in regulations for definition of smoker (one pack-year) comes from wide range of credible sources, including scientific studies performed prior to 1980;

   - use of ethnic-based classifications could pose legal (equal protection problem); could also create political problems among White miners who were light smokers.

4. Should the Attorney General modify in some fashion the regulations that require claimants to submit radiological proof of the presence of a compensable NMRD read by two NIOSH-certified"B"-readers?

   (a) Objections to present regulatory scheme

      (1) the interpretation of chest radiographs for pneumoconiosis is very subjective, and there is reasonable interreader variability, even among "B"-readers;

      (2) the requirement that claimants have the chest radiograph read by "B"-readers is unnecessarily burdensome and oppressive;

      (3) the Program's practice of selectively auditing certain "B"-readers, and having their interpretations reevaluated by NIOSH-selected "B"-readers, is unfair and unwarranted;

(b) Potential alternative procedures

(1) Do away with requirement of radiological proof of disease process entirely; require only proof of functional impairment;

- eliminates ambiguous, problematic means of proof, and minimizes burdens on claimants;
- Committee strongly opposes a scheme relying solely on functional impairment as proof of compensable disease
  - tests for functional impairment are not specific to the compensable NMRDs -- if functional impairment alone is required, will compensate many miners with noncompensable restrictive lung diseases and obstructive lung diseases (COPD, emphysema);
  - although radiographic interpretation is subjective and variable, can protect claimants from principal danger -- false negative interpretations -- by allowing claimants with functional impairment to submit high-resolution CT scans;

(2) Do away with requirement that chest radiographs be interpreted by "B"-readers only; accept interpretations of any radiologist or treating physician

- minimizes the burden on claimants
- if physician treating patient for compensable NMRD, should be sufficiently reliable diagnosis
- Committee supports continued exclusive use of "B"-readers to interpret radiographs
  - diagnosis by treating physician insufficient; standard treatment minimal, and difficult to devise effective check to eliminate insufficiently credible relationships
  - subjectivity and interreader variability significant where interpretations are by non-"B"-readers; these drawbacks and dangers of false negatives/positives

minimized where interpretation is by "B"-readers;

- limited number of "B"-readers submitting interpretations allows for some check on quality and potential fraud; allowing interpretations by any physician or radiologist would make any auditing process minimally effective, it at all;

- burdens on claimants minimal; can send chest radiographs through mail, and many claimants represented by attorneys

(3) Retain requirement of radiological proof of disease, but require HRCTs instead of chest radiographs

- HRCTs much more selective and sensitive than chest radiographs; significantly decrease the rate of false negative/positive interpretations;

- Committee recommends retaining chest radiograph requirement <u>in first instance</u>:

  - HRCTs expensive ($600) and appreciable (and potentially unnecessary) dose of radiation

  - can insure against risk of false negative by allowing claimants with functional impairment and negative chest radiograph to submit HRCTs; gives claimants benefit of false positives;

(4) Accept diagnosis of compensable NMRD if made by federal physician (i.e., IHS radiologist)

- where diagnosis by federal physician, little risk of fraud;

- meets Program concern with fraudulent or unprofessional interpretations, but does not meet concern that difficulty of interpretation requires experts -- "B"-readers;

- will help only claimants with access to federal medical facilities (Navajo, veterans); will not solve problem for most miner-claimants;

- could impose severe strain on limited federal resources in affected communities -- i.e., one radiologist for all IHS facilities on Navajo reservation

(5) Modify Program audit procedure to bar selective auditing of specific "B"-readers; instead, have all "B"-readers regularly audited to ensure readings are within the bounds of reasonable professional interpretation

- Committee recommendation
- selective auditing and rereading by Program consultants has resulted in perception in affected community that Program biased against compensation;
- selective audit procedure does not eliminate problematic or biased readers from submitting additional readings;
- modifying audit procedure in tandem with acceptance of HRCTs (if functional impairment and negative chest radiograph) would meet most of claimants' objections to "B"-reader requirement;
- deferential standard of review on audit would allow claimants to continue to choose "B"-readers whose interpretations fall in more "liberal" end of spectrum of acceptable, reasonable interpretations.

Non-controversial Recommendations

5. Should the Administration propose an amendment to the RECA to broaden coverage for silicosis and pneumoconiosis to all miners covered by the statute, not just miners who mined on Indian Reservations?

6. Should the Attorney General be requested to modify the regulations to define the term nonsmoker to include lung cancer claimants who stopped smoking 15 years or more before the date of diagnosis?

7. Should the Attorney General be requested to modify the regulations to accept high-resolution CT scans as proof of the presence of a compensable NMRD?

8. Should the Attorney General be requested to modify the regulations to accept as proof of a compensable disease the results of a lung biopsy?

9. Should the Attorney General be requested to modify the regulations to adopt ethnic-specific pulmonary function

standards to determine functional impairment in NMRD claimants?

10. Should the Attorney General be requested to modify the regulations to define functional impairment for NMRD claimants consistent with the American Thoracic Society recommended definition of impairment?

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- call CHR first as
-

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: 1/10/97 ✓ 456-5581 7028

TO: ELIZABETH DAY / DIANE REGAS

FROM: ELLY MELAMED

No. of Pages To Follow: 1

COMMENTS: I AM O'TOOLE'S COMMENTS ON URANIUM MINERS LEGISLATION

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

THANK YOU

Tara O'Toole 1/10/97 4PM

To: OMB
From: Tara O'Toole, Assistant Secretary of Environment Safety and Health
Department of Energy
Subject: DOJ Proposal for Uranium Miner Compensation in RECA Legislation

I note for the record that the widespread practice of using population based statistical data - i.e. cancer doubling doses - to predict the probability of cancer amongst a population is not, from a strictly scientific standpoint, directly applicable to the calculations of a particular individual's chances of getting cancer from a given dose. Given our ignorance about why one person gets cancer and another (with same exposures) does not, it is a reasonable framework as a rule of thumb, but it is NOT SCIENCE.

Nonetheless, I understand DoJ's concerns about setting unexplored new legal precedents for compensation due to government wrongdoing.

We can retain the 50% probability threshold criterion for compensation among Uranium miners and still be generous and compassionate if we make the following adjustment to the current proposal:

Suggest that the proposed confidence interval (CI) of 80% to calculate error adjustment in miner radiation exposures is technically not easily defended and results in minimal additional miners receiving compensation. Usual practice in peer-reviewed science journals is to apply CIs of 90 or 95%. Given the considerable uncertainties in reconstruction of individual dose data, the more conventional allowance for error would seem justified. Use of a 95% CI (i.e. we accept a range of possible dose calculations that will encompass 95% of the person's "true" dose) yields an exposure error correction factor of 3.82.

It is my understanding that using a CI of 80% (correction factor = 2.85) will result in only an additional handful of miners receiving compensation. This leaves the Administration in the position of being stingiest with those people (Uranium miners) who:

a) received (by far) the highest doses of anyone in the entire universe of Human radiation subjects

b) did suffer real harm (lung cancer) - as opposed to the Plutonium injection subjects who were ethically "wronged" by the government but suffered no injury.

Note also that the historical record clearly documents that the government knew miners were exposed to unsafe Radon levels and did nothing for years - the ethical wrong done the miners is at least as egregious as that suffered by plutonium subjects.

The political consequences of the current proposed compensation scheme - significant inequities in how the Administration compensates (mostly Native American) uranium miners with deadly diseases and high doses v. media famous plutonium subjects without obvious health effects could be significant.

Estimated Number of Uranium Miners With Lung Cancer Eligible for Full or Partial Compensation Over Twenty Year Period

1. Number of Lung Cancers

- 7,475 miners in Colorado Plateau and New Mexico cohorts; combined cohort represents approximately 42% of total mining population eligible under RECA[1]
- 5,155 (69%) miners alive as of date of last follow-up (1991)
- 425 (8%) lung cancers expected in non-exposed population of 5,155 white men in 20 year period following 1991[2]
- 590 (11%) lung cancers expected in 5,155 miners in 20 year period; 165 additional lung cancer deaths due to effects of radon exposure in mines
- 1416 lung cancers expected in total mining population

2. Full Compensation

- 184 of 590 expected lung cancers (31%) are eligible for full compensation under present RECA criteria (see Table 7b); *this forecasts 442 lung cancers in the total mining population eligible for full compensation under present RECA criteria*
- IAWG has approved use of criteria that represent 50% probability of causation (PC) adjusted for error due to statistical variability at 90% level of assurance; see Table 7b
    - 148 lung cancers (25%) would qualify for full compensation under WLM model; *this forecasts 355 cases in the total mining population eligible for full compensation*
    - suggests 54 miners (50.8 + 3.4) in combined cohort (130 in total mining population) inappropriately compensated under RECA

3. Partial Compensation

- Using criteria that represent 50% PC adjusted for error due to statistical variability at 90% level of assurance and uncertainties in WLM measurements **at 80% level of assurance**: see Table 7c

  - 257 of 590 total lung cancers (44%) are eligible for either full or partial compensation under the WLM model

  - 109 (257-148) lung cancers (18%) are eligible for partial compensation; forecasts 262 cases in total mining population eligible for partial compensation

- Using criteria that represent 50% PC adjusted for error due to statistical variability at 90% level of assurance and uncertainties in WLM measurements **at 90% level of assurance**: see Table 7d

  - 311 of 590 lung cancers (53%) are eligible for either full or partial compensation under the WLM model

  - 163 (311-148) cases are eligible for partial compensation; forecasts 391 cases in the total mining population eligible for partial compensation

- Using criteria that represent 50% PC adjusted for error due to statistical variability at 90% level of assurance and uncertainties in WLM measurements **at 95% level of assurance**: see Table 7e

  - 362 of 590 lung cancers (61%) are eligible for either full or partial compensation under the WLM model

  - 214 (362-148) cases (36%) are eligible for partial compensation; forecasts 514 cases in the total mining population eligible for partial compensation

Full compensation 80% 109

TOTAL 262

90% 163
391

95% 514

4. Compensation Based on Maximum of WLM or Duration of Employment Models

- IAWG has approved recommendation of Radiation Committee that claimants be allowed to qualify for compensation under either WLM or duration of employment model, whichever maximizes claimant's PC

- Duration of employment model can be adjusted for error due to statistical variability; no adjustment need be made for uncertainty in WLM data because it is not used in this model

- Accurate data on duration of employment for the New Mexico cohort was not available; it was assumed,therefore, that a miner employed in any given year was exposed for the full year. This introduces considerable additional uncertainty to estimates of eligibility for this cohort. To eliminate this additional error, estimates of the effect of the duration of employment model are based on the Colorado Plateau cohort, only.[3]

- Full Compensation

  - Using maximum of WLM/duration models, adjusted for statistical uncertainty at 90% level of assurance (Table 7b), 185 of 334 lung cancers (55%) in Colorado Plateau cohort eligible for full compensation; *this forecasts 833 cases eligible for full compensation in total mining population*

    - estimated number of lung cancers eligible under WLM model is 122; duration model adds 63 cases (19%)

    - 63 additional cases in Colorado Plateau cohort forecasts 284 additional cases in total mining population eligible for full compensation

- Partial Compensation
  - Using maximum of WLM/duration models, adjusted for error due to statistical variability at 90% level of assurance and uncertainties in WLM measurements **at 80% level of assurance** (Table 7c), 215 of 334 lung cancers (64%) are eligible for either full or partial compensation
    - estimated number eligible for either full or partial compensation under WLM model is 189; duration model adds 27 cases; this forecasts 122 additional cases in total mining population eligible for either full or partial compensation
    - 31 of 216 lung cancers (216-185; 9% of lung cancers in Colorado Plateau cohort) are eligible for partial compensation; forecasts 140 cases eligible for partial compensation in total mining population
  - Using maximum of WLM/duration models, adjusted for error due to statistical variability at 90% level of assurance and uncertainties in WLM measurements **at 90% level of assurance** (Table 7d), 234 of 334 lung cancers (70%) are eligible for either full or partial compensation
    - estimated number eligible for either full or partial compensation under WLM model is 217; duration model adds 17 cases; this forecasts 77 additional cases in total mining population eligible for either full or partial compensation
    - 49 of 234 lung cancers (234-185; 15% of lung cancers in Colorado Plateau cohort) are eligible for partial compensation; this forecasts 221 cases eligible for partial compensation in total mining population

- Using maximum of WLM/duration models, adjusted for error due to statistical variability at 90% level of assurance and uncertainties in WLM measurements **at 95% level of assurance** (Table 7e), 252 of 334 lung cancers (75%) are eligible for either full or partial compensation

    - estimated number eligible for either full or partial compensation under WLM model is 244; duration model adds 8 cases; this forecasts 36 additional cases in total mining population eligible for either full or partial compensation

    - 67 of 252 lung cancers (252-185; 20% of lung cancers in Colorado Plateau cohort) are eligible for partial compensation; this forecasts 302 cases eligible for partial compensation in total mining population

1. With the exception of section 4 or as specifically noted, all the computations below are based on the estimated lung cancers in the combined cohort.

2. Expected mortality rates in a non-exposed population are based on U.S. rates in White males. This will distort the numbers slightly, for two reasons. First, the lung cancer mortality rate among men in the mining areas may be slightly different (probably lower) than the U.S. average. Second, a sizeable portion of the combined cohort (approximately 15%) are Navajo men, who have a much lower rate of lung cancer incidence/mortality than Whites.

3. The Colorado Plateau cohort is about 22% of the estimated total mining population eligible under RECA. Using the Colorado Plateau data as a basis for extrapolation will likely <u>seriously</u> overestimate the approximate number of eligible cases in the total mining population. The Colorado Plateau cohort has a much higher average cumulative radon progeny dose than the New Mexico cohort, and for the "average" miner in the total eligible population. For example: 37% (122) of expected lung cancers in the Colorado Plateau cohort would be eligible for full compensation under the criteria in Table 7b; only 11% (27) of expected lung cancers in the New Mexico cohort would be eligible.

Table 7a: Estimated numbers of lung cancer deaths in the 20 years after end of follow-up by current RECA criteria and by interval of probability of causation for the Colorado and New Mexico studies. No adjustment made for statistical variability in exposure-response. (Same as Table 6 in 12/9/96 memo.)

	Colorado Study			New Mexico Study		
	Eligible under RECA			Eligible under RECA		
PC	No	Yes	Total	No	Yes	Total
	Based on model with WLM exposure					
<0.2	88.2	0.1	88.3	121.2	0.0	121.2
0.2-	76.2	78.8	155.1	113.7	4.7	118.3
≥0.5	0.3	90.6	91.0	7.3	9.3	16.6
Total	164.8	169.6	334.4	242.2	14.0	256.1
	Based on maximum PC from WLM model and duration/year of first exposed model[a]					
<0.2	60.7	0.0	60.7	31.7	0.0	31.7
0.2-	91.9	55.5	147.4	60.7	0.7	61.4
≥0.5	12.2	114.1	126.3	149.8	13.3	163.1
Total	164.8	169.6	334.4	242.2	14.0	256.1

[a] Estimates for miners in the New Mexico study are subject to additional uncertainty since data on duration of exposure were not available. Exposure of one year assumed in any year a miner was exposed.

Table 7b: Estimated numbers of lung cancer deaths in the 20 years after end of follow-up by current RECA criteria and by interval of probability of causation for the Colorado and New Mexico studies. Adjustment made for statistical variability in exposure-response (90%).

	Colorado Study			New Mexico Study		
	Eligible under RECA			Eligible under RECA		
PC	No	Yes	Total	No	Yes	Total
Based on model with WLM exposure						
<0.2	67.9	0.1	68.0	100.5	0	100.5
0.2-	93.9	50.8	144.7	125.5	3.4	128.9
≥0.5	3.0	118.6	121.6	16.2	10.6	26.8
Total	164.8	169.6	334.4	242.2	14.0	256.1
Based on maximum PC from WLM model and duration/year of first exposed model[a]						
<0.2	41.3	0	41.3	25.4	0	25.4
0.2-	84.3	23.4	107.7	38.9	0	38.9
≥0.5	39.2	146.2	185.4	177.8	14.0	191.8
Total	164.8	169.6	334.4	242.2	14.0	256.1

[a] Estimates for miners in the New Mexico study are subject to additional uncertainty since data on duration of exposure were not available. Exposure of one year assumed in any year a miner was exposed.

Those that

Table 7c: Estimated numbers of lung cancer deaths in the 20 years after end of follow-up by current RECA criteria and by interval of probability of causation for the Colorado and New Mexico studies. Adjustment made for statistical variability in exposure-response (90%) and uncertainty in WLM (80%).

	Colorado Study			New Mexico Study		
	Eligible under RECA			Eligible under RECA		
PC	No	Yes	Total	No	Yes	Total
Based on model with WLM exposure						
<0.2	41.1	0.2	41.3	70.4	0	70.4
0.2-	56.8	47.6	104.4	105.6	12.3	117.9
≥0.5	2.6	186.1	188.7	25.9	41.9	67.9
Total	100.6	233.8	334.4	201.9	54.2	256.1
Based on maximum PC from WLM model and duration/year of first exposed model[a]						
<0.2	30.6	0	30.6	25.4	0	25.4
0.2-	56.8	11.1	87.9	38.0	0.8	38.8
≥0.5	13.1	202.7	215.8	138.6	53.4	191.9
Total	100.6	233.8	334.4	201.9	54.2	256.1

[a] Estimates for miners in the New Mexico study are subject to additional uncertainty since data on duration of exposure were not available. Exposure of one year assumed in any year a miner was exposed.

Table 7d: Estimated numbers of lung cancer deaths in the 20 years after end of follow-up by current RECA criteria and by interval of probability of causation for the Colorado and New Mexico studies. Adjustment made for statistical variability in exposure-response (90%) and uncertainty in WLM (90%).

	Colorado Study			New Mexico Study		
	Eligible under RECA			Eligible under RECA		
PC	No	Yes	Total	No	Yes	Total
Based on model with WLM exposure						
<0.2	30.4	0.1	30.5	58.2	0	58.2
0.2-	42.7	44.0	86.7	86.9	17.2	104.1
≥0.5	2.5	214.7	217.2	21.2	72.6	93.8
Total	75.6	258.7	334.4	166.3	89.8	256.1
Based on maximum PC from WLM model and duration/year of first exposed model[a]						
<0.2	24.4	0	24.4	25.3	0	25.3
0.2-	45.4	30.7	76.1	35.7	2.4	38.1
≥0.5	5.9	228.0	233.9	105.4	87.4	192.8
Total	75.6	258.7	334.4	166.3	89.8	256.1

[a] Estimates for miners in the New Mexico study are subject to additional uncertainty since data on duration of exposure were not available. Exposure of one year assumed in any year a miner was exposed.

Table 7e: Estimated numbers of lung cancer deaths in the 20 years after end of follow-up by current RECA criteria and by interval of probability of causation for the Colorado and New Mexico studies. Adjustment made for statistical variability in exposure-response (90%) and uncertainty in WLM (95%).

	Colorado Study			New Mexico Study		
	Eligible under RECA			Eligible under RECA		
PC	No	Yes	Total	No	Yes	Total
Based on model with WLM exposure						
<0.2	24.0	0.1	24.1	49.4	0	49.4
0.2-	34.9	31.9	66.8	72.5	16.0	88.5
≥0.5	1.5	242.0	243.5	20.7	97.5	118.2
Total	60.4	273.9	334.4	142.6	113.5	256.1
Based on maximum PC from WLM model and duration/year of first exposed model[a]						
<0.2	20.7	0	20.7	25.3	0	25.3
0.2-	36.8	24.8	61.6	32.2	4.0	36.2
≥0.5	2.9	249.2	252.1	85.2	109.5	194.5
Total	60.4	273.9	334.4	142.6	113.5	256.1

[a] Estimates for miners in the New Mexico study are subject to additional uncertainty since data on duration of exposure were not available. Exposure of one year assumed in any year a miner was exposed.

TABLE 1-A
Minimum Radiation Exposure Levels for Full Compensation for Lung Cancer (in Working Level Months)
Nonsmokers

	Years since last radon progeny exposure		
Age at disease	<10	10-19	≥20
<50	1	2	9
50-59	4	8	33
60-69	16	45	141
≥70	24	50	203

TABLE 1-B
Minimum Radiation Exposure Levels for Full Compensation for Lung Cancer (in Working Level Months)
Smokers

	Years since last radon progeny exposure		
Age at date of diagnosis	<10	10-19	≥20
<50	5	11	46
50-59	19	40	163
60-69	81	174	703
≥70	117	250	1,010

TABLE 2-A
Minimum Duration of Employment
for Full Compensation For Lung Cancer
(in Years)
Nonsmokers

Age at disease	Years since last radon progeny exposure <10	10-19	≥20
	First exposed: <1955		
<50	0.0[a]	0.0	0.0
50-59	0.1	0.2	0.3
60-69	0.5	0.7	1.5
≥70	0.7	1.1	2.4
	First exposed: 1955-59		
<50	0.0	0.0	0.0
50-59	0.1	0.2	0.3
60-69	0.6	0.9	1.9
≥70	0.9	1.4	3.0
	First exposed: ≥1960		
<50	0.0	0.0	0.1
50-59	0.3	0.4	0.8
60-69	1.6	2.4	5.0
≥70	2.5	3.8	8.0

[a] A value of 0.0 years denotes employment in an underground uranium mine for at least 1 day but less than 18 days (.05 years or 102 working hours).

TABLE 2-B
Minimum Duration of Employment
For Full Compensation for Lung Cancer
(in Years)
Smokers

Age at disease	Years since last radon progeny exposure <10	10-19	≥20
	First exposed: <1955		
<50	0.0[a]	0.0	0.0
50-59	0.2	0.3	0.6
60-69	1.1	1.6	3.4
≥70	1.7	2.6	5.5
	First exposed: 1955-59		
<50	0.0	0.0	0.1
50-59	0.2	0.4	0.7
60-69	1.4	2.1	4.3
≥70	2.2	3.3	7.0
	First exposed: ≥1960		
<50	0.0	0.1	0.1
50-59	0.6	0.9	1.9
60-69	3.6	5.5	11.5
≥70	5.8	8.8	18.5

[a] A value of 0.0 years denotes employment in an underground uranium mine for at least 1 day but less than 18 days (.05 years or 102 working hours).

TABLE 3-A
Minimum Radiation Exposure Levels
For Partial Compensation For Lung Cancer
(in Working Level Months)
MEASUREMENT ERROR @ 80% CI
Nonsmokers

	Years since last radon progeny exposure		
Age at disease	<10	10-19	≥20
<50	0.5	1	5
50-59	2	4	17
60-69	8	23	71
≥70	12	25	103

TABLE 3-B
Minimum Radiation Exposure Levels
For Partial Compensation For Lung Cancer
(in Working Level Months)
Smokers

	Years since last radon progeny exposure		
Age at disease	<10	10-19	≥20
<50	3	6	23
50-59	10	20	82
60-69	41	88	355
≥70	59	126	510

TABLE 3-A
Minimum Radiation Exposure Levels
For Partial Compensation For Lung Cancer
(in Working Level Months)
MEASUREMENT ERROR @ 90% / 95% CI
Nonsmokers

	Years since last radon progeny exposure		
Age at disease	<10	10-19	≥20
<50	0.4/0.3	0.7/0.5	3/2
50-59	1/1	3/2	12/9
60-69	5/4	16/12	50/37
≥70	9/6	18/13	72/53

TABLE 3-B
Minimum Radiation Exposure Levels
For Partial Compensation For Lung Cancer
(in Working Level Months)
MEASUREMENT ERROR @ 90% / 95% CI
Smokers

	Years since last radon progeny exposure		
Age at disease	<10	10-19	≥20
<50	2/1	4/3	16/12
50-59	7/5	14/10	57/43
60-69	29/21	61/46	248/184
≥70	41/31	88/65	356/264

Table 1: WLM values for which a lung cancer case has a probability of causation exceeding 0.2 due to radon progeny exposure[a].

Age at disease	Years since last radon progeny exposure					
	Smokers			Non-smokers		
	<10	10-19	≥20	<10	10-19	≥20
<50	2	3	13	0.3	1	3
50-59	6	12	47	1	2	10
60-69	24	50	204	5	10	43
≥70	34	71	292	7	15	61

[a] Model used to compute PC=0.5, $RR = 1 + \beta \times w^{\kappa} \times \phi_{tsle} \times \theta_{age}$ with time since last exposure and age defined by categories. Parameters from Model A in Table 1 of the Committee's Report with β replaced by β_{smk} or β_{ns} as described in the report text.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

Route Slip

To: Elizabeth Drye, Diane Regas	Take necessary action	
	Approval or signature	
	Comment	
	Prepare reply	
	Discuss with me	
	For your information	
	See remarks below	x
From: Victoria Baecher Wassmer VBW	Date: March 19, 1997	

Remarks:
I understand that you both were interested in taking a look at this rule on Radiation Exposure Compensation when it arrived at OIRA from Justice. Justice has asked us for a very quick turnaround because of an expected news conference early next week. I would appreciate it if you would call me by Friday if have any comments/concerns. Thanks for the quick review.

Did you see this?

D

BILLING CODE: _____

DEPARTMENT OF JUSTICE

Civil Division

28 CFR Part 79

RIN 1105-AA49

Radiation Exposure Compensation Act: Evidentiary Requirements; Definitions and Number of Claims Filed

AGENCY: Department of Justice

ACTION: Proposed Rule.

SUMMARY: The Department of Justice ("the Department") proposes to amend its existing regulations implementing the Radiation Exposure Compensation Act ("RECA" or "Act"), 42 U.S.C. § 2210 note (1994). The proposed rule would: (1) allow claimants to submit affidavits or declarations in support of a claim under certain circumstances; (2) allow the use of high resolution computed tomography reports and pathology reports of tissue biopsies as additional means by which claimants can present evidence of a compensable non-malignant respiratory disease; (3) amend the definitions of "smoker" and "non-smoker;" (4) include *in situ* lung cancers under the definition of primary cancers of the lung; and (5) allow claimants, who have filed claims prior to the implementation of these proposed regulations and have been denied compensation to file another three times.

DATES: Written comments must be submitted on or before [insert date 60 days after date of publication in the Federal Register].

ADDRESS: Please submit written comments to Gerard W. Fischer, Assistant Director, U.S. Department of Justice, Civil Division, P.O. Box 146, Ben Franklin Station, Washington, D.C. 20044-0146.

FOR FURTHER INFORMATION CONTACT: Gerard W. Fischer (Assistant Director), 202/616-4090 and Lori Beg (Attorney), 202/616-4377.

SUPPLEMENTARY INFORMATION: At the recommendation of the President's Advisory Committee on Human Radiation Experiments, the Administration empaneled the Radiation Exposure Compensation Act Committee (the "Radiation Committee") to re-evaluate the provisions in the Act and the Department's implementing regulations relating to uranium miners. In July, 1996, after extensive investigation, the Radiation Committee submitted a Final Report detailing its findings and recommendations. In addition to recommending changes to the eligibility criteria in the Act, the Radiation Committee recommended that the Department modify some of the regulations governing proof of medical, smoking and exposure criteria. Based upon this report and the Department's own evaluation of the regulations, this rule is proposed.

This proposed rule would expand the set of circumstances in which claimants are allowed to submit affidavits or declarations in support of a claim. Sworn statements are presently permitted to establish identity of family members, prior receipt of other compensation, coffee consumption and employment information. As modified by this rule, claimants will now be allowed to submit sworn statements to establish smoking and alcohol consumption

histories where no other records exist. This action is needed because relevant records are not available to some claimants due to the passage of time. Therefore, this modification represents only a minor expansion of an existing regulation.

The rule would also allow the use of high resolution computed tomography ("HRCT") reports and pathology reports of tissue biopsies as additional means by which claimants can present evidence of a compensable non-malignant respiratory disease. HRCT is increasingly being used by physicians to diagnose pneumoconioses because it is often a more sensitive diagnostic tool than standard chest x-rays. Accepting HRCT findings will assist many claimants who cannot prove they have developed a compensable non-malignant respiratory disease through standard chest x-rays. Additionally, pathology reports of tissue biopsies are considered a highly reliable basis for diagnosis of disease by the medical community.

The rule would amend the definitions of "heavy smoker" and "non-smoker" to exclude claimants who stopped smoking for at least fifteen years prior to the date of diagnosis of specific diseases. It is now accepted by experts in the medical community that smoking cessation leads to a significant reduction in relative risk of developing certain cancers. Another proposed change would include *in situ* lung cancers under the definition of primary cancers of the lung, based upon expert opinion from the National Cancer Institute.

Finally, the rule would allow claimants who have filed claims prior to the implementation of these proposed regulations and have been denied compensation to file another three times. This action would allow denied claimants to take advantage of changes in the regulations that liberalize documentation requirements. The Department anticipates that much of the information in refiled claims will have been previously verified. Accordingly, the internal administrative processing costs of refiled cases will be minimal. Presently, the regulations permit three attempts at establishing eligibility, so this proposal simply continues that process.

While the practical effect of the proposed rule will likely be to increase the number of claimants eligible for compensation, the extent of that increase is not entirely clear. Presently, RECA has been appropriated $30 million for FY 1997. In addition, because the proposed rule expands the type of evidence that will be considered, it is not anticipated that the proposed rule will generate any significant controversy.

In accordance with 5 U.S.C. § 605(b), the Attorney General has reviewed this regulation and certifies that this rule affects only individuals filing claims under RECA. Therefore, this rule does not have a significant economic impact on a substantial number of small entities. This rule, however, is a significant regulatory action under Executive Order 12866 and, accordingly, has been reviewed by the Office of Management and Budget. The rule is not a major rule as defined by 5 U.S.C. § 804(2) nor is

it a rule having federalism implications warranting assessment in accordance with section 6 of Executive Order 12612. In addition, this rule is in full compliance with the Paperwork Reduction Act.

List of Subjects

28 CFR Part 79

Administrative practice and procedure, Cancer, Delegation of authority (Government agencies), Leukemia, Radiation Exposure Compensation Act, Tort Claims, Underground mining, Uranium.

Accordingly, part 79 of chapter I of title 28 of the Code of Federal Regulations is proposed to be amended as follows:

PART 79 -- CLAIMS UNDER THE RADIATION EXPOSURE COMPENSATION ACT

Subpart A -- General.

Sec.

79.4 Burden of proof, production of documents, presumptions, and affidavits.

79.5 Requirements for written medical documentation, contemporaneous records, and other records or documents.

Subpart C -- Eligibility Criteria for Claims Relating to Certain Specified Diseases.

Sec.

79.21 Definitions.

79.27 Proof of no heavy smoking, no heavy drinking, no heavy coffee drinking and no indication of hepatitis B and cirrhosis.

Subpart D -- Uranium Miners

Sec.

79.31 Definitions.

79.36 Proof of non-malignant respiratory disease.

79.37 Proof of non-smoker.

Subpart F -- Procedures

Sec.

79.51 Filing of claims.

79.55 Procedures for payment of claims.

1. The authority citation for part 79 continues to read as follows:

Authority: Sec. 6(b) and (j), 42 U.S.C. § 2210 note (1994).

2. Section 79.4(c) is amended by redesignating subparagraphs 3 and 4 as subparagraphs 4 and 5, adding new subparagraph (3) and revising new subparagraph (4) as follows:

(c) * * * * *

(1) Eligibility of family members as set forth in Subpart F, section 79.51(e), (f), (g), (h) or (i);

(2) Other compensation received as set forth in Subpart F, section 79.55 (c) or (d);

(3) Smoking and/or drinking history and/or age at diagnosis as set forth in Subpart C, section 79.27(d), and Subpart D, section 79.37(d);

(4) The amount of coffee consumed as set forth in Subpart C, section 79.27(d); or

(5) Mining information as set forth in Subpart D, section 79.33(b)(2).

3. Section 79.5(c) is amended by adding new paragraph (c).

(c) To establish eligibility the claimant or eligible surviving beneficiary may be required to provide, where appropriate, additional contemporaneous records to the extent they exist or an authorization to release additional contemporaneous records or a statement by the custodian(s) of the records certifying that the requested record(s) no longer exist. Nothing in these regulations shall be construed to limit the Assistant Director's ability to require additional documentation.

4. In § 79.21, paragraph (d) is amended by adding one new sentence after the second sentence to read as follows:

(d) * * * The term excludes an individual who smoked more than 20 pack years, but who can establish in accordance with § 79.27 that he or she stopped smoking at least fifteen (15) years prior to the diagnosis of primary cancer of the esophagus, pharynx, or pancreas, and did not resume smoking at any time thereafter.

5. Section 79.27 is amended by revising the heading, redesignating paragraph (c) as new paragraph (e), adding new paragraphs (c) and (d), and revising paragraphs (a) and (b) and new paragraphs (c) and (d), to read as follows:

§ 79.27 Proof of no heavy smoking, no heavy drinking, no heavy coffee drinking and no indication of the presence of hepatitis B and cirrhosis.

(a) If the claimant or eligible surviving beneficiary is claiming eligibility under this Subpart for primary cancer of the

esophagus, pharynx, pancreas or liver, the claimant or eligible surviving beneficiary must submit in addition to proof of the disease, all medical records listed below from any hospital, medical facility, or health care provider that were created within the period six (6) months before and six (6) months after the date of diagnosis of primary cancer of the esophagus, pharynx, pancreas or liver:

(1) * * *

(2) all operative and consultation reports;

(3) * * *

(4) all physician, hospital and health care facility admission and discharge summaries.

In the event that any of the above records no longer exist, the claimant or eligible surviving beneficiary must submit a certified statement by the custodian(s) of those records to that effect.

(b) If the medical records listed in paragraph (a) of this section, or information possessed by the state cancer or tumor registries reflects that the claimant was a heavy smoker or a heavy drinker or indicates the presence of hepatitis B and/or cirrhosis, the Radiation Exposure Compensation Unit will notify the claimant or eligible surviving beneficiary and afford that individual the opportunity to submit other written medical documentation or contemporaneous records in accordance with § 79.52(b) to establish that the claimant was not a heavy smoker or

heavy drinker or that there was no indication of hepatitis B and/or cirrhosis.

(c) The Unit may also require that the claimant or eligible surviving beneficiary provide additional medical records or other contemporaneous records and/or an authorization to release such additional medical and contemporaneous records as may be needed to make a determination regarding the indication of the presence of hepatitis B and/or cirrhosis and the claimant's history of smoking and alcohol-consumption.

(d) If the custodian(s) of the records listed in paragraph (a) of this section and records requested in accordance with paragraph (c) of this section certifies that a claimant's records no longer exist, and if the state cancer or tumor registries do not contain information concerning the claimant's history of smoking or alcohol-consumption, the Assistant Director may require that the claimant or eligible surviving beneficiary submit an affidavit (or declaration) made under penalty of perjury detailing the histories or lack thereof and the basis for such knowledge (if the eligible surviving beneficiary). This affidavit (or declaration) will be considered by the Assistant Director in making a determination concerning the claimant's history of smoking and alcohol-consumption.

(e) * * *

6. In § 79.31, paragraph (e) is revised to read as follows:

(e) *Non-smoker* means an individual who never smoked tobacco cigarette products or smoked less than the amount defined in

paragraph (f), below and includes an individual who smoked at least one (1) pack year but whose acceptable documentation as set forth in 79.37 establishes that he or she stopped smoking at least fifteen (15) years prior to the diagnosis of primary cancer of the lung and did not resume smoking at any time thereafter.

7. In § 79.31, paragraph (h) is revised and new paragraphs (s) and (t) are added to read as follows:

(h) * * * The term includes cancers *in situ*.

* * *

(s) *High resolution computed tomography* (HRCT) means a computed tomograph (CT) of the chest which utilizes thin collimation, image reconstruction with a high-spatial frequency algorithm, increased kVp or mA technique, and the use of a large matrix size.

(t) *HRCT Reader* means a physician who is board-certified in radiology and who devotes at least thirty (30) percent of his or her practice to thoracic radiology or is a member of the Society of Thoracic Radiology. An affidavit (or declaration) made under penalty of perjury must be submitted by the HRCT reader to establish the above qualifications.

8. Section 79.36 is revised as follows:

(a) Written medical documentation is required in all cases to prove that the claimant developed a non-malignant respiratory disease. * * *

(d) * * *

(1) * * *

(i) * * *

(ii) If the claimant is alive,

One or more of the following:

(A) *Chest x-rays and two "B" reader interpretations.* A chest x-ray administered in accordance with standard techniques on full size film at quality 1 or 2, and interpretative reports of the x-ray by two certified "B" readers classifying the existence of fibrosis of category 1/0 or higher according to the ILO 1980, or subsequent revisions;

(B) *High resolution computed tomography scans and interpretation.* An HRCT scan administered in accordance with Tables 5a and 5b in Appendix D of this part, and an interpretative reading by one HRCT reader showing:

(*1*) Honeycombing, bilaterally at two or more levels; or

(*2*) Any two of the findings listed below, visible bilaterally at two or more HRCT levels in a non-dependent lung:

(*A*) Intralobular interstitial thickening;

(*B*) Irregular interlobular septal thickening;

(*C*) Parenchymal bands unassociated with pleural thickening;

(*D*) Subpleural lines or subpleural nodules (1 to 5 mm in diameter);

(*E*) Architectural distortion;

(*F*) Pulmonary nodules (1 to 10 mm. in diameter); or

(*G*) Cicatricial emphysema.

(*3*) *Pathology reports of tissue biopsies.* A pathology report of a tissue biopsy shall be considered as documentation to

establish a compensable non-malignant respiratory disease when performed for medically-justified reasons.

The Radiation Exposure Compensation Unit may seek qualified medical review of HRCT, "B" reader interpretations, and pathology reports of tissue biopsies submitted by a claimant or eligible surviving beneficiary or obtain additional HRCT and "B" reader interpretations or pathology reports of tissue biopsies at any time to ensure that appropriate weight is given to this evidence and to guarantee uniformity and reliability.

One or more of the following:

(C) *Pulmonary function tests.* Pulmonary function tests consisting of three tracings recording the results of the forced expiratory volume in one second (FEV1) and the forced vital capacity (FVC) administered and reported in accordance with the Standardization of Spirometry - 1987 Update by the American Thoracic Society, and reflecting values for FEV1 or FVC that are equal to or less than 80% of the predicted value for an individual of the claimant's age, sex, and height, as set forth in the Tables in Appendix A; or

(D) *Arterial blood-gas studies.* An arterial blood-gas study administered at rest in a sitting position, or an exercise arterial blood-gas test, reflecting values equal to or less than the values set forth in the Tables in Appendix B.

9. Section 79.37 is amended by revising the part heading, adding new paragraphs (c) and (d) and revising paragraphs (a) and (b) to read as follows:

§ 79.37 Proof of non-smoker and diagnosis prior to age 45

(a) In order to prove a history of non-smoking for purposes of section 79.32(c)(1), and/or diagnosis of a compensable disease prior to age 45 for purposes of section 79.32(c)(2)(i), the claimant or eligible surviving beneficiary must submit all medical records listed below from any hospital, medical facility, or health care provider that were created within the period six (6) months before and six (6) months after the date of diagnosis of primary lung cancer or a compensable nonmalignant respiratory disease:

(1) * * *

(2) all operative and consultation reports;

(3) * * *

(4) all physician, hospital and health care facility admission and discharge summaries.

In the event that any of the above records no longer exist, the claimant or eligible surviving beneficiary must submit a certified statement by the custodian(s) of those records to that effect.

(b) If, after a review of the records listed in paragraphs (a) above, and/or the information possessed by the PHS, NIOSH, state cancer or tumor registries, state authorities, or the custodian of a federally supported health-related study, the Assistant Director finds that the claimant was a smoker, and/or that the claimant was diagnosed with a compensable disease after age 45, the Unit will notify the claimant or eligible surviving

beneficiary and afford that individual the opportunity to submit other written medical documentation in accordance with § 79.52(b) to establish that the claimant was a non-smoker and/or was diagnosed with a compensable disease prior to age 45.

(c) The Unit may also require that the claimant or eligible surviving beneficiary provide additional medical records or other contemporaneous records and/or an authorization to release such additional medical and contemporaneous records as may be needed to make a determination regarding the claimant's smoking history and/or age at diagnosis with a compensable disease.

(d) If the custodian(s) of the records listed in paragraph (a) of this section and the records requested in accordance with paragraph (c) of this section certifies that a claimant's records no longer exist, and information possessed by the PHS, NIOSH, state cancer or tumor registries, state authorities, or the custodian of a federally supported health-related study do not contain information pertaining to the claimant's smoking history, the Assistant Director may require that the claimant or eligible surviving beneficiary submit an affidavit (or declaration) made under penalty of perjury detailing the claimant's smoking history or lack thereof and the basis for such knowledge (if the eligible surviving beneficiary). This affidavit (or declaration) will be considered by the Assistant Director in making a determination concerning the claimant's history of smoking.

10. In § 79.51, paragraph (j) is amended by revising subsection (3) and (4), adding subsection (5) and adding a sentence after the last sentence as follows:

(j) * * *

(1) * * *

(2) * * *

(3) Onsite participation in a nuclear test,

(4) Exposure to a defined minimum level or radiation in a uranium mine or mines during a designated time period, or

(5) The identity of the claimant and/or surviving beneficiary.

* * * Claims filed prior to the date of implementation of these amending regulations will not be included in determining the number of claims filed.

11. In § 79.55, paragraph (d)(1) is revised to read as follows:

(d) * * *

(1) * * *

(i) Any disability payments or compensation benefits paid to the claimant and his/her dependents while the claimant is alive; and

(ii) Any Dependency and Indemnity Compensation payments made to survivors due to death related to the illness for which the claim under the Act is submitted.

APPENDIX D TO PART 79 - HRCT TECHNIQUE

Table 5a: Summary of HRCT technique

Essential scanner settings

1. Collimation: Thinnest available collimation (1-1.5 mm).
2. Reconstruction algorithm: High-spatial frequency or "sharp" algorithm
3. Scan time: 1-2 seconds
4. kVp; mA; mAs: Routine settings for chest CT
5. Matrix size: Largest available (512 x 512).
6. Window level: -600 to -700 HU
   Window width: 1000 HU to 1500 HU
7. Photography: 12 on 1.
8. Field of view: As small as possible to incorporate both lungs (30-40 cm.)

Table 5b: Scanning protocol and procedure

HRCT technique: scan protocol for suspected silicosis or fibrotic lung disease

Chest radiograph normal or minimally abnormal:

Full inspiration with prone and supine scans using 2-cm spacing from lung apices to bases

Dated:

Janet Reno,

Attorney General.

THE WHITE HOUSE

WASHINGTON

January 6, 1997

MEMORANDUM FOR BRUCE REED

FROM: DIANE REGAS Diane R.
Domestic Policy Council

SUBJECT: Proposed Changes to RECA – Decision Needed by January 7

We expect to announce the Administration's response to the Presidential Advisory Committee on Human Radiation Experiments next week. As part of that announcement, the staff is recommending legislation to amend the Radiation Exposure and Compensation Act of 1990 (RECA). There is one outstanding issue with respect to the Administration's bill and, on Friday, the Department of Justice (DOJ) asked us to seek your view of the change before going ahead.

ISSUE: Should the Administration propose any compensation for uranium miners with lung cancer where the probability is between 20%–50% that their cancer was caused by government's failure to appropriately ventilate the mines?

BACKGROUND: From the 1940s to the 1960s the United States' nuclear weapons program relied on uranium from mines in the Southwestern United States. Miners working in those mines were exposed to levels of radiation known to be dangerous because the United States did not ensure that the mines were adequately ventilated. As a result hundreds of miners contracted or will contract fatal lung cancer.

The Radiation Exposure and Compensation Act of 1990 (RECA) provides for compensation of some miners, as well as those living downwind of nuclear test sites. Uranium miners qualify for $100,000 compensation if they were exposed to a certain amount of radiation and they contract lung cancer (almost always fatal).

The Advisory Committee on Human Radiation Experiments (ACHRE) recommended that the President seek legislation that would "provide compensation to *all* miners who develop lung cancer after some minimal duration of employment underground..." Their recommendation was based, in part, on the conclusion that the actions of the United States with respect to the miners was egregious. The government knowingly allowed the miners to work under conditions likely to cause fatal cancers and neither warned the miners nor took action to mitigate the danger. *See* ACHRE Final Report, pages 565–582.

The Inter-Agency Working Group on Human Radiation (IAWG), chaired by DPC staff, has developed proposed legislation to respond to the ACHRE recommendations on RECA. Different aspects of the proposal would address two different populations:

1. Miners for whom the probability is greater than 50% that exposure in the mines caused their disease. (The calculated probability is population-based and does not account for individual susceptibility.) All agencies in the IAWG support proposing legislation that would affect these miners.

2. Miners for whom the population analysis suggests that the probability is less than 50% that mining exposure caused the disease. DOJ has expressed concern about proposing legislation that would compensate these miners.

1. Miners with a Probability of Causation of Greater than 50%

The legislative history suggests that Congress intended RECA to provide compensation to uranium miners for whom the probability that their illness was caused by radiation exposure while mining is greater than 50 percent. In these cases, RECA provides $100,000 in compensation per uranium miner. In practice, RECA does not accomplish this goal because documenting exact exposures is too difficult and because the scientific premises underlying RECA are not accurate. Therefore the current law denies compensation to some miners who clearly should be eligible.

A working group of the Department of Justice and the National Cancer Institute analyzed the current compensation scheme and recommended changes to ensure that miners are eligible for compensation if it is more likely than not (probability >50%) that their lung cancer was caused by exposure in the mines. The proposed measures provide new, less burdensome methods for miners to establish that radiation caused their illness. The measures also expand the list of compensable diseases, based on new scientific evidence.

All departments in the IAWG agree that the Administration should propose these changes.

2. Miners with a Probability of Causation of Less than 50%

The IAWG has also been considering a proposal to provide partial compensation to miners for whom there is a significant probability that their lung cancer was caused by exposure in the mines, but the probability is less than 50%. DOJ has voiced concerns about this proposal.

OPTIONS

Option A: Propose legislation to provide at least partial compensation ($50,000) to all miners for whom the probability is between 20% and 50% that their lung cancer was caused by exposure to radiation in uranium mines. This approach would also include proposing the measures outlined in Section 1, above, for miners with greater than 50% probability.

Option B: Limit the Administration's proposed legislation to compensation of miners with lung cancer for whom it is more probable than not that the cancer was caused by exposure to radiation in uranium mines (*i.e.* only propose measures outlined in Section 1 above).

DISCUSSION

OPTION A: Expanding compensation to miners should be viewed in the context of the Administration's response to ACHRE more generally. In responding to ACHRE, the Administration's policy has been to be as generous as is reasonable because the government's actions in these cases denied fair protection to individuals, and undermined democratic control over the government. According to ACHRE's chair, Dr. Ruth Faden, expanded compensation for uranium miners is one of the most strongly-felt of ACHRE's recommendations.

ACHRE's recommendation to expand compensation without requiring individualized proof of causation is appropriate because of the egregiousness of the government's conduct, the impact of the increased cancer rates in these communities and the government's support for studying the miners without taking reasonable steps to reduce the known risk.

Without a change, uranium miners who are not now compensated under RECA will continue to be held to a higher standard of causation than others who are compensated under RECA. Under RECA, people living downwind of certain areas are compensated ($50,000) if they get a radiogenic disease--even though the probability is very low (<10%) that the disease was caused by the government's action. In addition, because RECA is not currently based on a probabilistic standard, a significant number of uranium miners who fall within the 20%-50% probability range in Option A are already eligible for compensation. Option A would overcome some of these inequities.

The Clinton Administration has, in certain cases, advocated compensation where there is less than a 50% probability that physical harm was caused by the government's action. First, within the last two months, the government has compensated 13 experimental subjects, as recommended by ACHRE, without any causal link to physical disease. Second, the President announced that children of veterans exposed to agent orange will be compensated with medical care if they are born with spina bifida. This decision was made despite the extremely low probability of a connection and in the absence of biological plausibility.

Our current best estimate of the total additional cost of this proposal *combined with the changes to RECA that we have already agreed upon* is between $13 and $14 million over the next 20 years. The expected cost of option A is only a fraction of this amount.

Outside of the DPC staff, this option is strongly supported by DOE. I expect that OSTP will also support this option, and OMB will express a view within the next day or so.

OPTION B: [A memo from DOJ making a full argument on this point is attached.]

The general rule in litigation should remain that the government will only pay compensation

if it is more likely than not that the government's action caused the harm. Any decision to expand the government's liability to other cases is setting a bad precedent. The possible result will be further expansion of the government's liability within RECA--possibly to new populations--and the creation of a model that may be used in entirely different circumstances.

This option is supported by DOJ.

PUBLIC REACTION: Stuart Udall, former Secretary of the Interior and his clients, mostly Navaho, are likely to react strongly if the Administration does not propose some compensation for most miners with lung cancer. I expect they will have some success in the New Mexico Congressional Delegation and with the Governor. The decision on this issue, however, is unlikely to affect the overall reception of the Administration's response to ACHRE.

RECOMMENDATION AND NEXT STEPS

I recommend that you support Option A. Whatever your decision, OMB will inform key Departments to determine whether any Department wishes to request a principals meeting to discuss this issue further.

cc: Jack Gibbons
T J Glauthier
Elena Kagan

Attachment

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 3, 1997

MEMORANDUM

TO: Greg Jones
Office of Legislative Affairs

SUBJECT: Proposed Amendments to RECA to Provide Partial Compensation to Uranium Miners

This responds to your request for the views of the Civil Division on the amendments to the Radiation Exposure Compensation Act (RECA) which would authorize the payment of partial compensation to uranium miners for whom the probability is 50% or less that their lung cancer was caused by exposure to radiation in the mines.

First, we support the other proposed amendments to RECA because we believe they will result in a fairer program for the claimants. We helped to develop many of these proposals based on our experience in administering the program. We have worked hard to improve the administration of the program and are proud of what we have achieved and fully support the bulk of what has been proposed. We feel, however, that we must object to one of the proposals.

The current RECA provisions authorize the payment of $100,000 in compensation to miners who demonstrate that they were exposed to defined minimum levels of radiation. The legislative history of RECA indicates that Congress set the minimum exposure levels to approximate the point where, on average, it was more likely than not the miner's exposure caused his lung cancer; i.e., where the probability of causation was greater than 50%.[1]

RECA also authorizes the payment of compensation in the amount $50,000 to downwinders, i.e., persons who demonstrate that they were physically present in certain specified counties or geographic areas in the States of Arizona, Nevada, and Utah

[1] We understand that because the minimum exposure levels currently specified in the statute do not accurately reflect a 50% probability of causation for most miners, the Department has proposed legislation to amend RECA to incorporate new, more accurate criteria. We support these proposals.

during periods when atmospheric testing was carried out at the Nevada Test Site, and who suffer from certain statutorily specified radiogenic cancers.

One of the proposed amendments to RECA would add provisions authorizing the payment of compensation in the amount of $50,000 to uranium miners who demonstrate that they were exposed to levels of radiation in the mines at which the probability is only between 20% and 50% that their lung cancer was caused by exposure to radiation in the mines.

It is our understanding that the rationale for these proposed amendments is to more nearly equalize the treatment of uranium miners and downwinders. Scientific evidence indicates that downwinders were exposed to much lower levels of radiation and, therefore, a much smaller increased risk of cancer, than were uranium miners. Therefore, the argument goes, it is unfair to allow downwinders whose probability of causation is below 50% to recover compensation while denying such recovery to uranium miners.

We believe this reasoning is flawed. If the current scheme is providing payments to individuals whose illnesses more likely than not were not caused by radiation does not justify expanding payments to other individuals whose illnesses were not likely caused by radiation. We do not believe the case has adequately been made to overcompensate the miners which would be favored by the proposed legislation.

Our main concern is that if this legislation is enacted, it can be anticipated that other groups will seek to be included in a similar way. For example, the geographical limits on the downwinder population will be subject to expansion. The counties and geographic areas currently specified in the statute exclude persons in adjacent counties and geographic areas where they were exposed to comparable levels of radiation from the nuclear testing program. Moreover, the costs of an expanding program are difficult to predict. For instance, the initial assessment of the cost of the Black Lung Program proved to be dramatically low.

Very importantly, expansion of the precedent for paying individuals compensation for injuries which, more likely than not, were not caused by the events triggering the compensation program is a profound policy decision. We would draw the policy line short of providing recovery for persons who probably were not injured by the government activities involved. The rule in litigation is that those who sue the government for injuries caused by governmental action must prove that the injuries were caused by the governmental action. [This standard is encompassed in 28 USC 1346(b)] In many of these cases the plaintiffs may have a sympathetic case but lack the evidence to prove causation by the preponderance standard. Once the precedent is established

that in some "exceptionable" cases the government, although not legally liable, is willing to legislatively compensate claimants, it will be hard to justify denying compensation to one group of citizens having granted it to others.

Moreover, reducing the level of compensation does not derogate from the adverse consequences. The issue remains whether an individual should receive compensation for injuries most likely unrelated to the activities giving rise to the compensation. The bottom line is the same, the government would provide compensation even though most of the claimants receiving compensation would be compensated for injuries unrelated to the government's conduct. We believe the dangers of allowing compensation in these instances will invite many more such requests.

Having raised these concerns, we recognize that the decision of whether to bestow a new entitlement on a favored group is a policy call and acknowledge that this proposal will be considered by Congress which can weigh these risks in their consideration of the amendment. In administering many of these compensation programs and in generally defending the government against claims of aggrieved citizens, however, we believe that such an extension should not be proposed by the Administration.

We do not believe it is good public policy because it creates a new standard of compensation for one specific, favored group of citizens, which is not generally available to others whose claims may, in some instances, be equally or even more compelling. By making exceptions to certain favored groups rather than adhering to requirements equally applicable to everyone injured by the government, we will open a process in which groups may obtain relief more on the basis of their political ability than on the basis of an easily understood and accepted "more likely than not" standard. Once this policy Rubicon is crossed it will be easier for each successive group to muster its arguments that it is also deserving of a special exception. Ultimately, such deviation from the standard for "favored" groups may undermine the public's faith in the government's commitment to treating all of its citizens equally and undermine the public's support of such compensation programs.

<u>The bottom line is we think it is bad policy to pay taxpayer funds for a condition which is not likely caused by government conduct</u>.

RECA Questions for Eric Morris

RECA has already ~~spent~~ $200 million in last 4 years —
(as of 9/96) — $13-14 million not significant — Paid
for in discretion — appropriated annually depends on
what Justice requests to cover claims

2000 people
180 people more under our charges —
50 - 150 (790 miners)
15 Future 79 million no charge
13-14 million w/all charges

TO DO Paperwork -

- OMB can clear by noon on Thursday -

- Bruce — I go with greener compensation
  - omb
  - noon Thursday deadline for comment
- Circulate first - get back to us.

Bob Damus - OGC General Counsel (generally opposed to everything).

THE WHITE HOUSE

WASHINGTON

January 6, 1997

MEMORANDUM FOR BRUCE REED

FROM: DIANE REGAS Diane R.
Domestic Policy Council

SUBJECT: Proposed Changes to RECA – Decision Needed by January 7

We expect to announce the Administration's response to the Presidential Advisory Committee on Human Radiation Experiments next week. As part of that announcement, the staff is recommending legislation to amend the Radiation Exposure and Compensation Act of 1990 (RECA). There is one outstanding issue with respect to the Administration's bill and, on Friday, the Department of Justice (DOJ) asked us to seek your view of the change before going ahead.

ISSUE: Should the Administration propose any compensation for uranium miners with lung cancer where the probability is between 20%–50% that their cancer was caused by government's failure to appropriately ventilate the mines?

BACKGROUND: From the 1940s to the 1960s the United States' nuclear weapons program relied on uranium from mines in the Southwestern United States. Miners working in those mines were exposed to levels of radiation known to be dangerous because the United States did not ensure that the mines were adequately ventilated. As a result hundreds of miners contracted or will contract fatal lung cancer.

The Radiation Exposure and Compensation Act of 1990 (RECA) provides for compensation of some miners, as well as those living downwind of nuclear test sites. Uranium miners qualify for $100,000 compensation if they were exposed to a certain amount of radiation and they contract lung cancer (almost always fatal).

The Advisory Committee on Human Radiation Experiments (ACHRE) recommended that the President seek legislation that would "provide compensation to *all* miners who develop lung cancer after some minimal duration of employment underground..." Their recommendation was based, in part, on the conclusion that the actions of the United States with respect to the miners was egregious. The government knowingly allowed the miners to work under conditions likely to cause fatal cancers and neither warned the miners nor took action to mitigate the danger. *See* ACHRE Final Report, pages 565–582.

The Inter-Agency Working Group on Human Radiation (IAWG), chaired by DPC staff, has developed proposed legislation to respond to the ACHRE recommendations on RECA. Different aspects of the proposal would address two different populations:

1. Miners for whom the probability is greater than 50% that exposure in the mines caused their disease. (The calculated probability is population-based and does not account for individual susceptibility.) All agencies in the IAWG support proposing legislation that would affect these miners.

2. Miners for whom the population analysis suggests that the probability is less than 50% that mining exposure caused the disease. DOJ has expressed concern about proposing legislation that would compensate these miners.

1. Miners with a Probability of Causation of Greater than 50%

The legislative history suggests that Congress intended RECA to provide compensation to uranium miners for whom the probability that their illness was caused by radiation exposure while mining is greater than 50 percent. In these cases, RECA provides $100,000 in compensation per uranium miner. In practice, RECA does not accomplish this goal because documenting exact exposures is too difficult and because the scientific premises underlying RECA are not accurate. Therefore the current law denies compensation to some miners who clearly should be eligible.

A working group of the Department of Justice and the National Cancer Institute analyzed the current compensation scheme and recommended changes to ensure that miners are eligible for compensation if it is more likely than not (probability >50%) that their lung cancer was caused by exposure in the mines. The proposed measures provide new, less burdensome methods for miners to establish that radiation caused their illness. The measures also expand the list of compensable diseases, based on new scientific evidence.

All departments in the IAWG agree that the Administration should propose these changes.

2. Miners with a Probability of Causation of Less than 50%

The IAWG has also been considering a proposal to provide partial compensation to miners for whom there is a significant probability that their lung cancer was caused by exposure in the mines, but the probability is less than 50%. DOJ has voiced concerns about this proposal.

OPTIONS

Option A: Propose legislation to provide at least partial compensation ($50,000) to all miners for whom the probability is between 20% and 50% that their lung cancer was caused by exposure to radiation in uranium mines. This approach would also include proposing the measures outlined in Section 1, above, for miners with greater than 50% probability.

Option B: Limit the Administration's proposed legislation to compensation of miners with lung cancer for whom it is more probable than not that the cancer was caused by exposure to radiation in uranium mines (*i.e.* only propose measures outlined in Section 1 above).

DISCUSSION

OPTION A: Expanding compensation to miners should be viewed in the context of the Administration's response to ACHRE more generally. In responding to ACHRE, the Administration's policy has been to be as generous as is reasonable because the government's actions in these cases denied fair protection to individuals, and undermined democratic control over the government. According to ACHRE's chair, Dr. Ruth Faden, expanded compensation for uranium miners is one of the most strongly-felt of ACHRE's recommendations.

ACHRE's recommendation to expand compensation without requiring individualized proof of causation is appropriate because of the egregiousness of the government's conduct, the impact of the increased cancer rates in these communities and the government's support for studying the miners without taking reasonable steps to reduce the known risk.

Without a change, uranium miners who are not now compensated under RECA will continue to be held to a higher standard of causation than others who are compensated under RECA. Under RECA, people living downwind of certain areas are compensated ($50,000) if they get a radiogenic disease--even though the probability is very low (<10%) that the disease was caused by the government's action. In addition, because RECA is not currently based on a probabilistic standard, a significant number of uranium miners who fall within the 20%-50% probability range in Option A are already eligible for compensation. Option A would overcome some of these inequities.

The Clinton Administration has, in certain cases, advocated compensation where there is less than a 50% probability that physical harm was caused by the government's action. First, within the last two months, the government has compensated 13 experimental subjects, as recommended by ACHRE, without any causal link to physical disease. Second, the President announced that children of veterans exposed to agent orange will be compensated with medical care if they are born with spina bifida. This decision was made despite the extremely low probability of a connection and in the absence of biological plausibility.

Our current best estimate of the total additional cost of this proposal *combined with the changes to RECA that we have already agreed upon* is between $13 and $14 million over the next 20 years. The expected cost of option A is only a fraction of this amount.

Outside of the DPC staff, this option is strongly supported by DOE. I expect that OSTP will also support this option, and OMB will express a view within the next day or so.

OPTION B: [A memo from DOJ making a full argument on this point is attached.]

The general rule in litigation should remain that the government will only pay compensation

if it is more likely than not that the government's action caused the harm. Any decision to expand the government's liability to other cases is setting a bad precedent. The possible result will be further expansion of the government's liability within RECA--possibly to new populations--and the creation of a model that may be used in entirely different circumstances.

This option is supported by DOJ.

PUBLIC REACTION: Stuart Udall, former Secretary of the Interior and his clients, mostly Navaho, are likely to react strongly if the Administration does not propose some compensation for most miners with lung cancer. I expect they will have some success in the New Mexico Congressional Delegation and with the Governor. The decision on this issue, however, is unlikely to affect the overall reception of the Administration's response to ACHRE.

RECOMMENDATION AND NEXT STEPS

I recommend that you support Option A. Whatever your decision, OMB will inform key Departments to determine whether any Department wishes to request a principals meeting to discuss this issue further.

cc: Jack Gibbons
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<u>The bottom line is we think it is bad policy to pay taxpayer funds for a condition which is not likely caused by government conduct</u>.

Tara O'Toole 1/10/97 4PM

To: OMB
From: Tara O'Toole, Assistant Secretary of Environment Safety and Health
Department of Energy
Subject: DOJ Proposal for Uranium Miner Compensation in RECA Legislation

I note for the record that the widespread practice of using population based statistical data - i.e. cancer doubling doses - to predict the probability of cancer amongst a population is not, from a strictly scientific standpoint, directly applicable to the calculations of a particular individual's chances of getting cancer from a given dose. Given our ignorance about why one person gets cancer and another (with same exposures) does not, it is a reasonable framework as a rule of thumb, but it is NOT SCIENCE.

Nonetheless, I understand DoJ's concerns about setting unexplored new legal precedents for compensation due to government wrongdoing.

We can retain the 50% probability threshold criterion for compensation among Uranium miners and still be generous and compassionate if we make the following adjustment to the current proposal:

Suggest that the proposed confidence interval (CI) of 80% to calculate error adjustment in miner radiation exposures is technically not easily defended and results in minimal additional miners receiving compensation. Usual practice in peer-reviewed science journals is to apply CIs of 90 or 95%. Given the considerable uncertainties in reconstruction of individual dose data, the more conventional allowance for error would seem justified. Use of a 95% CI (i.e. we accept a range of possible dose calculations that will encompass 95% of the person's "true" dose) yields an exposure error correction factor of 3.82.

It is my understanding that using a CI of 80% (correction factor = 2.85) will result in only an additional handful of miners receiving compensation. This leaves the Administration in the position of being stingiest with those people (Uranium miners) who:

a) received (by far) the highest doses of anyone in the entire universe of Human radiation subjects

b) did suffer real harm (lung cancer) - as opposed to the Plutonium injection subjects who were ethically "wronged" by the government but suffered no injury.

Note also that the historical record clearly documents that the government knew miners were exposed to unsafe Radon levels and did nothing for years - the ethical wrong done the miners is at least as egregious as that suffered by plutonium subjects.

The political consequences of the current proposed compensation scheme - significant inequities in how the Administration compensates (mostly Native American) uranium miners with deadly diseases and high doses v. media famous plutonium subjects without obvious health effects could be significant.