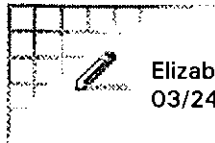


NLWJC - Kagan

DPC - Box 030 - Folder 011

**Health - Radiation
Experiments**

Health - Radiati - Exper.



Elizabeth Drye
03/24/97 06:13:24 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:

Subject: Need for Closure on Radiation Report Release Date

Press (Lori McHugh) advised Friday that they wanted to put the report and EO out this Friday, March 28th, at the top of McCurry's briefing, but now Press office is revisiting. I do not want to sit on this beyond Monday as the main coalition of interest groups -- the Task Force on Radiation and Human Rights -- has asked us to get it out the door before their meeting April 1 (per a letter Diane brought to my attention Friday). DOE and my preference is to release the report, however we can, this week. Pena and key Asst. Secretary are available Friday and MAY be available Thursday. Barry Toiv is now working to get closure in the press office. If this comes up again, please let people know we need to get it out the door. We just need 2 days notice to get to advisory committee members, certain reporters, and key Hill people if we want to get any decent press and not offend anyone. Since 7 agencies are involved, outreach can't be done at very last minute. Thanks for your help.

**The Administration Announces Actions
Responding to President Clinton's Advisory Committee on
Human Radiation Experiments
March 28, 1997**

Background

In January, 1994 President Clinton established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had supported unethical human radiation experiments and releases of radiation during the Cold War. He asked ACHRE to uncover the truth, recommend ways to right past wrongs, and suggest ways to make sure the government will not repeat past mistakes.

In October, 1995 ACHRE issued its report. ACHRE found that the government had conducted several thousand human radiation experiments from 1945 to 1975 and that the majority advanced biomedical research. The Committee found, however, that some were conducted unethically. For example, scientists injected plutonium into 18 patients without their knowledge, and researchers conducted experiments on indigent patients and children. ACHRE made 18 recommendations to open the public record, protect human subjects of future research, and compensate those wronged by the government's actions.

In October, 1995 the President received the Advisory Committee's report and made it clear that the report would "not be left on a shelf to gather dust" He directed his Cabinet to "use and build on these recommendations." Over the past year and a half, the Administration has acted to implement ACHRE's recommendations to improve openness in government, strengthen ethics in human subjects research, and compensate individuals for the government's mistakes.

Today's Announcement

- **The Administration released *Building Public Trust*, outlining its comprehensive response to the President's Advisory Committee on Human Radiation Experiments (ACHRE). The report summarizes actions to address ACHRE's 18 recommendations.**
- **The Departments of Energy and Justice announced that the government has settled compensation claims with families of all of the known individuals ACHRE recommended for compensation. ACHRE recommended the government compensate the families of 18 subjects of plutonium injection experiments. The government has settled with all 16 families that came forward.**
- **President Clinton signed a memorandum to strengthen the rights and protections of people participating in secret, government-supported research. ACHRE recommended that subjects of secret experiments have special protections and information. Acting on that recommendation, the President directed agencies today to propose new rules for secret research that would require scientists to: obtain informed consent from all potential subjects of all secret experiments (current rules allow researchers to waive informed consent in certain cases); disclose the identity of the sponsoring agency to potential subjects; and tell potential subjects that an experiment is classified. The new rules would**

also establish a more independent review process; require the head of the agency conducting secret human research to approve each project; and require permanent records of secret experiments. The President also directed federal agencies to report annually on the number of classified human research projects and the number of subjects in each project. **A preliminary review by the Administration's human radiation Interagency Working Group indicates that the government is not supporting any classified human research at this time;** today's directive initiates a formal, routine accounting of secret human studies.

- The Administration announced proposed **amendments to the Radiation Exposure Compensation Act of 1990 to compensate hundreds of uranium miners who would not be compensated under current law.** ACHRE found that some deserving miners do not qualify for compensation under the Act. The amendments would establish fairer, science-based criteria for compensation. The Administration will also propose regulatory changes to RECA to facilitate claims processing.

Previous and On-going Actions Described in *Building Public Trust* Include:

Actions to Improve Openness in Government.

- ACHRE transferred more than 4,000 cubic feet of documents to the National Archives. The Administration has made 300,000 fully searchable pages of documents available on the Internet, and will add an additional 200,000 pages shortly. The Departments of Energy and Defense have published document search guides.
- The President signed Executive Order 12958 directing Federal agencies to review and declassify thousands of documents, including documents on radiation experiments.

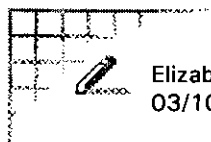
Actions to Protect human subjects in the future.

- President Clinton established the National Bioethics Advisory Commission (NBAC) to examine bioethical issues, including human research issues. A subcommittee of NBAC will address certain broad questions raised by ACHRE, including how to strengthen Institutional Review Boards -- the local ethics panels for Federally-sponsored research.
- In October, 1995 President Clinton directed agencies to develop plans to improve their oversight of ethics rules. The agencies have completed their review and upgraded protections, and NBAC will review agency procedures in the coming months.
- Agencies have undertaken nationwide education efforts to raise the profile of ethical considerations, and are funding research to improve our understanding of informed consent.

Actions to Right Past Wrongs.

- In October, 1995 President Clinton apologized to subjects of radiation experiments and their families on behalf of an earlier generation of American leaders and citizens; former Energy Secretary O'Leary made apologies in certain individual cases.
- The Administration will propose legislation to make veterans treated with nasopharyngeal radiation eligible for health care services under the Veteran's Administration's Ionizing Radiation Program.

File -
Radhak



Elizabeth Drye
03/10/97 07:11:04 PM

Record Type: Record

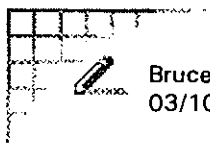
To: Bruce N. Reed/OPD/EOP

cc: Diane C. Regas/OPD/EOP, Elena Kagan/OPD/EOP

Subject: Re: ACHRE EO

No problem getting this done by the 25th. We will have the report responding to all 18 recommendations and uranium miner legislation done too. We'll get back to you with suggestions on briefing -- as you know, O'Leary wanted to be involved in any announcement.

File -
Radiation



Bruce N. Reed
03/10/97 07:01:17 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP, Diane C. Regas/OPD/EOP
cc: Elena Kagan/OPD/EOP
Subject: ACHRE EO

We have tentatively put the ACHRE EO on the schedule for Tues March 25. This is the Pres's day off, so his only involvement would be to make sure the e.o. got signed sometime that day. Perhaps Pena could go to the WH briefing room to explain the details (unless there's someone better to do it).

One issue is not resolved -- how to make sure the Tuskegee folks don't feel slighted. I argued that since this wasn't a POTUS event, that shouldn't be as difficult -- but we'll have to deal with that issue with Ann Lewis somehow. Maybe a stmt goes out on that sometime too (not same day).

Can you get everything wrapped and ready? It may fall off and on the schedule a few more times, but the odds look pretty good.

THE WHITE HOUSE

WASHINGTON

In January 1994, after accounts of Cold War-era experiments involving the effects of radiation on humans came to light, I established an independent Advisory Committee on Human Radiation Experiments to investigate these reports. I asked the Committee to determine the truth about this dark chapter in our nation's history.

After taking extensive testimony and conducting numerous public hearings, the Advisory Committee issued its report in October, 1995. The Committee's report included recommendations to make the record of these experiments open to the public, improve ethics in human research today, and right the wrongs of the past inflicted on unknowing citizens. In my remarks when I accepted the report, I promised that it would not be left on the shelf to gather dust. I made a commitment that we would learn from the lessons that the Committee's report offered and use it as a road map to lead us to better choices in the future.

This document -- my Administration's response to the Advisory Committee's report -- is a milestone in meeting that commitment. We have actively worked to respond to the important recommendations made by the Advisory Committee through a special interagency working group. This group includes representatives from the Executive Office of the President, the Departments of Energy, Defense, Health and Human Services, Justice, Veterans Affairs, the National Aeronautics and Space Administration, and the Central Intelligence Agency. The Environmental Protection Agency has also joined the effort. This report reflects the joint progress of these agencies to address the Advisory Committee's recommendations.

My Administration has made significant achievements in opening government and making information more easily available to the citizens to whom it belongs. Agencies have also improved the protections in place for subjects of future human research. Finally, the Federal government is providing redress to those who have suffered from radiation experiments, as recommended by the Advisory Committee.

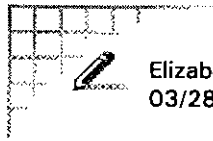
I emphasize that this document is by no means the end of the journey. Much work remains to be done. I am confident that all of us -- the eminent committee that produced the original report, the Federal officials who worked so hard to support the Committee's efforts and now are implementing its recommendations, and most importantly, the citizens of this great country from whose experiences we have learned so much -- can together help ensure a better world for our children.

My thanks to all of you for a job well done, I pledge my strong support for your continued efforts.

Bill Clinton

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PHOTOCOPY

Health - Radiation



Elizabeth Drye
03/28/97 05:54:25 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc:

Subject: CLINTON TOUGHENS FEDERAL PROTECTIONS FOR HUMAN GUINEA PIGS

FYI -- early AP story.

----- Forwarded by Elizabeth Drye/OPD/EOP on 03/28/97 05:54 PM -----



SHIMABUKUR L @ A1
03/28/97 02:43:00 PM

Record Type: Record

To: Elizabeth Drye

cc:

Subject: CLINTON TOUGHENS FEDERAL PROTECTIONS FOR HUMAN GUINEA PIGS

Date: 03/28/97 Time: 12:27

RCClinton toughens federal protections for human guinea pigs

WASHINGTON (AP) President Clinton took steps today to protect those who participate in secret, government-sponsored experiments from mistreatment and assure they are fully informed of the risks.

The administration also said it has settled the last of a number of claims, totalling \$6.5 million, from families of civilians who were injected with plutonium or uranium as part of secret experiments in the 1940s.

The actions are "designed to increase public trust ... and make our government accountable to the American people," said Energy Secretary Federico Pena, whose department has spearheaded the public review of past radiation experiments.

Pena said the administration also will ask Congress to expand a program that provides compensation to uranium miners who were exposed to radiation as part of the government nuclear weapons program. He said up to 600 additional miners would be compensated at a cost of about \$50 million.

The plans for giving greater protection to research participants were prompted by recommendations more than a year ago by a presidential commission that investigated the government's use of humans in radiation research during the Cold War years.

The advisory panel warned that past excesses might be repeated unless there are new safeguards.

The White House said today that Clinton had signed a memorandum

strengthening the rights and protections afforded individuals who agree to be subjects of secret, government-supported research.

The White House said a review by an interagency task force uncovered no government-supported classified human research at this time. But officials acknowledged that formal accounting for such research needs to be improved.

Meanwhile, the White House said it had settled claims with four additional families of 18 individuals who were given plutonium injections as part of 1940s experiments. One victim has not been located and the family of another does not want compensation, said Tara O'Toole, DOE's assistant secretary for environment, safety and health.

Associate Attorney General John Dwyer said the 16 claims 12 of which totalling \$4.8 million were made public last November total \$6.5 million.

The government has said it is prepared to provide compensation to the families of 52 other individuals who the advisory commission said were believed to be subjected to improper radiation experiments. The identity of those 52 are not known, and so far no families have come forward, according to the White House.

Under the new presidential directive on human research, agencies must develop new rules that clearly require scientists to obtain informed consent from all potential subjects of secret experiments. Currently, such consent may be waived under some circumstances.

The president also ordered that any research subject be told the identity of the sponsoring agency and whether the experimentation is classified. The new rules also would require the head of the agency to approve such research and develop a more independent review process than currently provided.

Also in response to the October 1995 findings by the Advisory Committee on Human Radiation Experiments, the president said he will:

Ask Congress to broaden a 1990 law that allows compensation to underground uranium miners who became ill because of exposure to radiation. Under current law, hundreds of miners are ineligible for compensation.

Will propose legislation to make veterans' health care benefits available to airmen and sailors who were subjects of radioactive nasal treatments more than 50 years ago. The treatments were to prevent broken eardrums during flight or in submarines.

Will seek broader epidemiological studies to determine the long-term health impact of nuclear bomb testing during the Cold War to military personnel and civilian populations near the test areas.

APNP-03-28-97 1237EST

Health-Radiation

**ACTIONS TO RESPOND TO THE PRESIDENT'S ADVISORY COMMITTEE ON
HUMAN RADIATION EXPERIMENTS
QUESTIONS AND ANSWERS (NOT FOR DISTRIBUTION)**

April 28, 1997

Overview of Advisory Committee Scope, Findings, and Recommendations

Q: What is the universe of experiments studied by the Advisory Committee?

A: The President directed the Advisory Committee on Human Radiation Experiments (ACHRE) to review government sponsored biomedical experiments on individuals involving intentional exposure to ionizing radiation, focusing on the period from 1944 until 1974. The Committee did not consider common clinical practices that involved incidental exposures to ionizing radiation (e.g. x-rays).

The President's charge also covered intentional releases of ionizing radiation designed to test human health effects or to measure the extent of human exposure. The Committee studied a number of populations exposed to radiation during the government's Cold War activities, including veterans of atomic test blasts, western uranium miners, and residents of the Marshall Islands.

Q: How many experiments does this include?

A: No one knows exactly how many experiments this includes. The Advisory Committee reported that the government had sponsored several thousand human radiation experiments between 1945 and 1974.

Q: How many people were involved in these experiments?

A: Because only fragmentary information has survived about many of these experiments it was not possible for the Advisory Committee to estimate how many people were involved.

Q: How many people were harmed in the experiments?

A: The Advisory Committee was not in a position to answer this question completely. In general, the Committee found that the majority of experiments they studied involved trace amounts of radiation given to adults, similar to those used in research today. These were unlikely to have caused physical harm. The Committee identified several groups of experiments that may have increased individuals' risks, including total body irradiation experiments on ill patients and iodine-131 experiments involving children.

Q: How many people were not informed in advance that they were the subject of an experiment?

A: Only very limited documentation about consent in individual experiments has survived and no estimates can be made. Generally, the Committee found that researchers obtained consent from healthy subjects, but not from patient-subjects. The Advisory Committee did look more broadly at issues of informed consent across the government and found that the government did not have comprehensive policies in place before 1974. Although the government has strengthen informed consent procedures significantly since 1974, the Committee recommended -- and the Administration is taking -- additional steps to improve informed consent, including requiring informed consent in all classified research (eliminating a current waiver provision) and studying further the informed consent process.

Q: What did the Advisory Committee recommend?

A: The Committee made 18 recommendations to open the record to the public, compensate those who were wronged, and protect human subjects of future research.

Q: What has the Administration done to respond?

A: The Administration has already taken steps in each of these areas. For example, to open up the record, the Administration has put thousands of pages of documents on the Internet and in the National Archives, and has developed document search guides. To better protect human subjects in the future, the President established the National Bioethics Advisory Committee (NBAC) and asked NBAC to examine many of the questions raised by ACHRE. To redress the wrongs of the past, the President apologized to subjects of radiation experiments and their families, and agencies have worked hard to settle compensation claims. These and many other actions responding to the Committee's recommendations are outlined in the report released today.

Today the Administration also announced two new actions -- the President is issuing a directive strengthening protections for subjects of classified research, and the Administration is proposing legislation to improve compensation for uranium miners.

Q: Are current protections for subjects of human research inadequate?

A: A strong system of Federal oversight, education, and sanctions is currently in place to ensure the protection of the subjects of government sponsored human research. The Administration has taken a number of steps to further strengthen

protections for human subjects based on the Advisory Committee's recommendations. For example, the National Bioethics Advisory Commission is reviewing Institutional Review Board policies -- IRBs are the local boards that review the ethics of individual research projects. And today the President signed a directive to protect subjects of classified research.

The Administration is also working to improve the informed consent process. Despite the vigor with which all parties embrace the informed consent process, the Advisory Committee found that little is actually known about the effectiveness of this transaction between researcher and prospective subject. In response, the NIH and the Departments of Energy and Veterans Affairs are initiating research to develop new knowledge about the informed consent process.

Q: Now that the National Bioethics Advisory Commission has been given a special assignment on cloning, does this mean that there will be a delay in addressing protection of human research subjects.

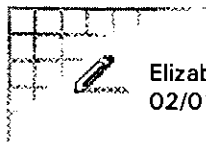
A: No. the National Bioethics Advisory Commission has already established an ambitious plan of work to address the current status of Federal protection for human research subjects. The work will proceed in parallel with the special assignment on cloning. NBAC is planning to issue a report to the President and to Congress in October and hopes that little or no delay will be incurred as a result of the additional work.

Q: What is being done to provide compensation in connection with the human radiation experiments?

A: The Advisory Committee recommended the government compensate or consider compensate subjects of certain biomedical experiments. The Department of Justice has worked closely with other Departments to resolve individual claims. As announced today, the Administration has resolved all claims brought forward for experiments the Advisory Committee specifically identified for compensation. The Administration has settled with families of 16 plutonium injection subjects. The plutonium injection cases were singled out by the Advisory Committee as being particularly troubling ethically and deserving of compensation because efforts were made by the government to keep information secret from the subjects or their families to avoid government liabilities or embarrassment. The Advisory Committee also identified two other experiments for compensation (see Recommendation 1), but the subjects of those experiments are unknown.

Several other experiments were identified by the Advisory Committee for consideration for possible compensation, subject to further development of the facts surrounding the experiments. That fact-finding continues in a number of these cases. [Refer detailed questions to DoJ].

Some populations exposed to radiation releases studied by the Committee are already eligible for compensation under existing law, including atomic vets and uranium miners. The Committee recommended certain changes to these programs. The Administration has reviewed and acted on those recommendations. For example, today we are announcing new legislation to improve compensation for uranium miners.



Elizabeth Drye
02/01/97 02:56:15 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elena Kagan/OPD/EOP

Subject: More Interviews

I will be out of the office most of Monday, Feb. 3 (10:30-4:30), and all of Monday, Feb. 10 for medical school interviews. Mike and I think the Wed. educ. roundtable is in good shape, so I don't anticipate any conflicts with these dates. Any idea when/if you will want to resurrect radiation report/eo on classified research?



REGAS_D @ A1
01/09/97 11:38:00 PM

Record Type: Record

To: Elena Kagan, REED_B @ A1@CD@LNGTWY
cc: DRYE_E @ A1@CD@LNGTWY
Subject: TIME SENSITIVE - Radiation Report update

Thanks for you help on the radiation issue. Your thoughts helped to stimulate a productive discussion with DOJ on alternative approaches.

DOJ and I are planning to put a revised proposal into OMB review on Friday. The new approach quantifies uncertainties in the claims process, and proposes to give the miners the benefit of the doubt in resolving the uncertainties. This approach avoids the precedential issue that DOJ was concerned about, while expanding the number of miners eligible for compensation. (Miners who fall within this approach would still get partial compensation.)

Please let me know if you wish to discuss this. We are still planning a Tuesday press conference.

file



White House Press Release

In Acceptance Of Human Radiation Final Report

The White House

Office of the Press Secretary

For Immediate Release

October 3, 1995

Remarks By The President
In Acceptance Of Human Radiation Final Report

Old Executive Office Building

11:07 P.M. Edt

The President: Let me begin with a simple thank you to everyone who participated in this extraordinary project and to everyone who supported them.

I am especially glad to see here today Senator Glenn, who's been so active in working on medical ethics issue, Congressman Markey, who's worked on this issue for a very long time, Congressman Frost, Secretary Shalala, Deputy Secretary of Veterans Affairs Herschel Gober, and of course, the Attorney General who basically tries to get us all to do the right thing all the time. (Laughter.)

I want to thank Secretary O'Leary for her extraordinary devotion to this cause. And you heard in her remarks basically the way that she views this. It's a part of her ongoing commitment to finish the end of the Cold War. And perhaps no Energy Secretary has ever done as much as she has to be an advocate, whether it is for continued reforms within the Energy Department or her outspoken endorsement of the strongest possible commitment on the part of the United States to a Comprehensive Test Ban Treaty, which I believe we will achieve next year in no small measure thanks to the support of the Secretary of Energy.

And, of course, I want to thank Dr. Ruth Faden for her extraordinary commitment of about a year and a half of her life to this unusual but important task.

And all of you who served on the committee -- I remember the first time we put this committee together. I looked -- I said, that's a pretty distinguished outfit. I wish I could give them five or six jobs to do. (Laughter.) I'll expect you back next Monday and then we'll -- (laughter). I do thank you so much for the work you have done.

Let me tell you that, just as this is an important part of the efforts that Secretary O'Leary outlined, I saw this committee as an indispensable part of our effort to restore the confidence of the American people in the integrity of their government. All of these political reform issues to me are integrated. When I became the President, I realized we had great new economic challenges, we had profound social problems, that a lot of these things had to be done by an energized American citizenry, but that our national government had a role to play in moving our country through this period of transition. And in order to do it, we needed to increase the capacity of the government to do it through political reform, but we also needed, as much as anything else, to increase the confidence of the American people that, at the very least, they could trust the United States government to tell the truth and to do the right things.

So you have to understand that, for me, one reason this is so important is that I see it as part of our ongoing effort to give this government back to the American people -- Senator Glenn's long effort to get Congress to apply to itself the same laws it

imposes on the private sector; the restrictions that I imposed on members of my administration in high positions for lobbying for foreign governments; and when the lobby bill failed in the Congress, I just imposed it by executive order on members of the Executive Branch. All these efforts at political reform, it seems to me, are important.

But none of these efforts can succeed unless people believe that they can rely on their government to tell them the truth and to do the right thing. We have declassified thousands of government documents, files from second world war, the Cold War, President Kennedy's assassination. These actions are not only consistent with our national security, they are essential to advance our values.

So, to me, that's what this is all about. And to all those who represent the families who have been involved in these incidents, let me say to you, I hope you feel that your government has kept its commitment to the American people to tell the truth and to do the right thing.

We discovered soon after I entered office that with the

specter of an atomic war looming like Armageddon far nearer than it does today, the United States government actually did carry out on our citizens experiments involving radiation. That's when I ordered the creation of this committee. Dr. Faden and the others did a superb job. They enlisted many of our nation's most significant and important medical and scientific ethicists. They had to determine first whether experiments conducted or sponsored by our government between 1944 and 1974 met the ethical and scientific standards of that time and of our time. And then they had to see to it that our research today lives up to nothing less than our highest values and our most deeply-held beliefs.

From the beginning, it was obvious to me that this energetic committee was prepared to do its part. We declassified thousands of pages of documents. We gave committee members the keys to the government's doors, file cabinets and safes. For the last year and a half, the only thing that stood between them and the truth were all the late nights and hard work they had to put in.

This report I received today is a monumental document -- (laughter) -- in more ways than one. But it is a very, very-important piece of America's history, and it will shape America's future in ways that will make us a more honorable, more successful and more ethical country.

What this committee learned I would like to review today with a little more detail than Dr. Faden said, because I think it must be engraved on our national memory. Thousands of government-sponsored experiments did take place at hospitals, universities and military bases around our nation. The goal was to understand the effects of radiation exposure on the human body.

While most of the tests were ethical by any standards, some were unethical, not only by today's standards, but by the standards of the time in which they were conducted. They failed both the test of our national values and the test of humanity.

In one experience, scientists -- experiment -- scientists injected plutonium into 18 patients without their knowledge. In another, doctors exposed indigent cancer patients to excessive doses of radiation, a treatment from which it is virtually impossible that they could ever benefit.

The report also demonstrates that these and other experiments were carried out on precisely those citizens who count most on the government for its help -- the destitute and the gravely ill. But the dispossessed were not alone. Members of the military -- precisely those on whom we and our government count most -- they were also test subjects.

Informed consent means your doctor tells you the risk of the treatment you are about to undergo. In too many cases, informed consent was withheld. Americans were kept in the dark about the effects of what was being done to them. The deception extended beyond the test subjects themselves to encompass their families and

the American people as a whole, for these experiments were kept secret. And they were shrouded not for a compelling reason of national security, but for the simple fear of embarrassment, and that was wrong.

Those who led the government when these decisions were made are no longer here to take responsibility for what they did. They are not here to apologize to the survivors, the family members or the communities who's lives were darkened by the shadow of the atom and these choices.

So today, on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subjected to these experiments, to their families, and to their communities.

When the government does wrong, we have a moral responsibility to admit it. The duty we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is one we can never walk away from. Our government failed in that duty, and it offers an apology to the survivors and their families and to all the American people who must -- who must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing.

We know there are moments when words alone are not enough. That's why I am instructing my Cabinet to use and build on these recommendations, to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience.

When called for, we will work with Congress to serve the best needs of those who were harmed. Make no mistake, as the committee report says, there are circumstances where compensation is appropriate as a matter of ethics and principle. I am committed to seeing to it that the United States of America lives up to its responsibility.

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

That's why this morning, I signed an executive order instructing every arm and agency of our government that conducts, supports or regulates research involving human beings to review immediately their procedures, in light of the recommendations of this report, and the best knowledge and standards available today, and to report back to me by Christmas.

I have also created a Bioethics Advisory Commission to supervise the process, to watch over all such research, and to see to it that never again do we stray from the basic values of protecting our people and being straight with them.

The report I received today will not be left on a shelf to gather dust. Every one of its pages offers a lesson, and every lesson will be learned from these good people who put a year and a half of their lives into the effort to set America straight.

Medical and scientific progress depends upon learning about people's responses to new medicines, to new cutting-edge treatments. Without this kind of research, our children would still be dying from polio and other killers. Without responsible radiation research, we wouldn't be making the progress we are in the war on cancer. We have to continue to research, but there is a right way and a wrong way to do it.

There are local citizens' review boards, there are regulations that establish proper informed consent and ensure that experiments are conducted ethically. But in overseeing this necessary research, we must never relax our vigilance.

The breathtaking advances in science and technology demand that we always keep our ethical watchlight burning. No matter how rapid the pace of change, it can never outrun our core convictions that have stood us so well as a nation for more than 200 years now, through many different scientific revolutions.

I believe we will meet the test of our times -- that as science and technology evolve, our ethical conscience will grow, not shrink. Informed consent, community right-to-know, our entire battery of essential human protections -- all these grew up in response to the health and humanitarian crises of this 20th century. They are proof that we are equal to our challenges.

Science is not ever simply objective. It emerges from the crucible of historical circumstances and personal experience. Times of crisis and fear can call forth bad science, even science we know in retrospect to be unethical. Let us remember the difficult years chronicled in this report, and think about how good people could have done things that we know were wrong.

Let these pages serve as an internal reminder to hold humility and moral accountability in higher esteem than we do the latest development in technology. Let us remember, too, that cynicism about government has roots in historical circumstances. Because of stonewallings and evasions in the past, times when a family member or a neighbor suffered an injustice and had nowhere to turn and couldn't even get the facts, some Americans lost faith in the promise of our democracy. Government was very powerful, but very far away and not trusted to be ethical.

So today, by making ourselves accountable for the sins of the past, I hope more than anything else, we are laying the foundation stone for a new era. Good people, like these members of Congress who have labored on this issue for a long time, and have

devoted their careers to trying to do the right thing, and having people justifiably feel confidence in the work of their representatives. They will continue to work to see that we implement these recommendations.

And under our watch, we will no longer hide the truth from our citizens. We will act as if all that we do will see the light of day. Nothing that happens in Washington will ever be more important in anyone's life affected by these experiments, perhaps, than these reports we issue today. But all of us as Americans will be better off because of the larger lesson we learned in this exercise and because of our continuing effort to demonstrate to our people that we can be faithful to their values.

Thank you very much. (Applause.)

End

11:23 A.M. Edt



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THE WHITE HOUSE
WASHINGTON

January 6, 1997

MEMORANDUM FOR BRUCE REED

FROM:

DIANE REGAS

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.

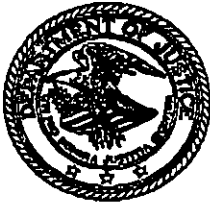
PUBLIC REACTION: Stuart Udall, former Secretary of the Interior and his clients, mostly Navaho, are likely to react strongly if the Administration does not propose some compensation for most miners with lung cancer. I expect they will have some success in the New Mexico Congressional Delegation and with 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

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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.

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.