ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM: ARE WE FULFILL-ING THE PROMISE WE MADE TO THESE COLD WAR VETERANS WHEN WE CREATED THIS PROGRAM? (PART I)

HEARING

BEFORE THE

SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

MARCH 1, 2006

Serial No. 109-110

Printed for the use of the Committee on the Judiciary



Available via the World Wide Web: http://judiciary.house.gov

U.S. GOVERNMENT PRINTING OFFICE

26-290 PDF

WASHINGTON: 2006

COMMITTEE ON THE JUDICIARY

F. JAMES SENSENBRENNER, Jr., Wisconsin, Chairman

HENRY J. HYDE, Illinois HOWARD COBLE, North Carolina LAMAR SMITH, Texas ELTON GALLEGLY, California BOB GOODLATTE, Virginia STEVE CHABOT, Ohio DANIEL E. LUNGREN, California WILLIAM L. JENKINS, Tennessee CHRIS CANNON, Utah SPENCER BACHUS, Alabama BOB INGLIS, South Carolina JOHN N. HOSTETTLER, Indiana MARK GREEN, Wisconsin RIC KELLER, Florida DARRELL ISSA, California JEFF FLAKE, Arizona MIKE PENCE, Indiana J. RANDY FORBES, Virginia STEVE KING, Iowa TOM FEENEY, Florida TRENT FRANKS, Arizona LOUIE GOHMERT, Texas

JOHN CONYERS, JR., Michigan
HOWARD L. BERMAN, California
RICK BOUCHER, Virginia
JERROLD NADLER, New York
ROBERT C. SCOTT, Virginia
MELVIN L. WATT, North Carolina
ZOE LOFGREN, California
SHEILA JACKSON LEE, Texas
MAXINE WATERS, California
MARTIN T. MEEHAN, Massachusetts
WILLIAM D. DELAHUNT, Massachusetts
ROBERT WEXLER, Florida
ANTHONY D. WEINER, New York
ADAM B. SCHIFF, California
LINDA T. SÁNCHEZ, California
CHRIS VAN HOLLEN, Maryland
DEBBIE WASSERMAN SCHULTZ, Florida

PHILIP G. KIKO, General Counsel-Chief of Staff PERRY H. APELBAUM, Minority Chief Counsel

SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS

JOHN N. HOSTETTLER, Indiana, Chairman

STEVE KING, Iowa LOUIE GOHMERT, Texas LAMAR SMITH, Texas ELTON GALLEGLY, California BOB GOODLATTE, Virginia DANIEL E. LUNGREN, California JEFF FLAKE, Arizona BOB INGLIS, South Carolina DARRELL ISSA, California SHEILA JACKSON LEE, Texas HOWARD L. BERMAN, California ZOE LOFGREN, California LINDA T. SÁNCHEZ, California MAXINE WATERS, California MARTIN T. MEEHAN, Massachusetts

George Fishman, Chief Counsel Art Arthur, Counsel Allison Beach, Counsel Cindy Blackston, Professional Staff Nolan Rappaport, Minority Counsel

CONTENTS

MARCH 1, 2006

OPENING STATEMENT

	Page
The Honorable John N. Hostettler, a Representative in Congress from the State of Indiana, and Chairman, Subcommittee on Immigration, Border	
Security, and Claims	1
der Security, and Claims	5
and Claims The Honorable Elton Gallegly, a Representative in Congress from the State of California, and Member, Subcommittee on Immigration, Border Security, and Claims	8
	0
WITNESSES	
Mr. Shelby Hallmark, Director, Office of Workers Compensation Programs, U.S. Department of Labor	
Oral Testimony	10
Prepared Statement	11
John Howard, M.D., M.P.H., Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. De- partment of Health and Human Services	
Oral Testimony	19
Prepared Statement	20
James Melius, M.D., DRPH, Administrator, New York State Laborers Health and Safety Trust Fund, Member of the Advisory Board on Radiation and Worker Health	
Oral Testimony	25
Prepared Statement	26
Mr. Richard D. Miller, Senior Policy Analyst, Government Accountability Project	_0
Oral Testimony	29
Prepared Statement	32
APPENDIX	
AFFENDIA	
MATERIAL SUBMITTED FOR THE HEARING RECORD	
Prepared Statement of the Honorable Sheila Jackson Lee, a Representative	
in Congress from the State of Texas, and Ranking Member, Subcommittee	
on Immigration, Border Security, and Claims	67
Prepared Statement of John Mauro, Ph.D., CHP, Project Manager, S. Cohen	
& Associates (SC&A, Inc.)	68
Programs, U.S. Department of Labor, to post-hearing questions from the	73
Honorable John N. Hostettler	13
questions from the Honorable John N. Hostettler	81

	Page
Responses of James Melius, M.D., DRPH, Administrator, New York State	
Laborers Health and Safety Trust Fund, Member of the Advisory Board	
on Radiation and Worker Health, to post-hearing questions from the Honor-	
able John N. Hostettler	90
Responses of Richard D. Miller, Senior Policy Analyst, Government Account-	
ability Project, to post-hearing questions from the Honorable John N.	
Hostettler	94
Letter from Sanford Cohen, President, S. Cohen Associates, Inc.	104

ENERGY EMPLOYEES OCCUPATIONAL II.I.-NESS COMPENSATION PROGRAM: ARE WE FULFILLING THE PROMISE WE MADE TO THESE COLD WAR VETERANS WHEN WE CREATED THIS PROGRAM? (PART I)

WEDNESDAY, MARCH 1, 2006

House of Representatives. SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS, COMMITTEE ON THE JUDICIARY,

Washington, DC.

The Subcommittee met, pursuant to notice, at 4:10 p.m., in Room 2141, Rayburn House Office Building, the Honorable John N. Hostettler (Chairman of the Subcommittee) presiding.

Mr. Hostetler. The Subcommittee will come to order.

Today's hearing is the first in a series of oversight hearings the Subcommittee will be holding on the Energy Employees Occupational Illness Compensation Program Act. The focus of today's hearing is twofold. The immediate issue at hand is an OMB internal document brought to the Subcommittee's attention concerning the granting of special exposure cohort status to groups of sick cold war workers.

The Department of Energy, or DOE, or its contractors often either did not properly monitor workers' radiation exposures or there are no existing records. So in these cases, this nuclear worker compensation program directs the Department of Health and Human Services, or HHS, after review and a recommendation by the Advisory Board on Radiation and Worker Health, the Board, to make such workers members of the Special Exposure Cohort, or SEC.

Under the SEC, benefits are paid to workers with on-the-job radiation exposures of at least a year and development of cancer after at least 5 years. If designated an SEC member, a \$150,000 lump sum payment plus medical benefits are provided to that member if diagnosed with one of 22 radio-sensitive cancers. The lack of legitimate records of exposure to radiation is, unfortunately, relatively common for these workers, especially in the earlier years of the DOE weapons complex. OMB's list of possible actions to be taken to minimize costs in this area of the program needs to be dissected carefully to determine its potential impact on the Government promise made to these veterans of the Cold War in creating

Additionally, strengths, weaknesses, problems and improvements in the program will be discussed today. Hopefully we will all be better educated about this program by the end of the hearing as well as know clearly what the priority issues are that need to be

addressed in subsequent hearings.

The findings in the law as enacted state in part that, "since the inception of the nuclear weapons program, a large number of nuclear weapons workers at sites at the Department of Energy and at sites of vendors who supplied the cold war effort were put at risk without their knowledge and consent for reasons that, documents reveal, were driven by fears of adverse publicity, liability, and employee demands for hazardous duty pay. To ensure fairness and equity, the civilian men and women who over the past 50 years have performed duties uniquely related to the nuclear weapons production and testing programs should have efficient, uniform, and adequate compensation for beryllium-related health conditions and radiation-related health conditions." That, in fact, was and still is congressional intent. This intent was not created out of speculation, but out of documented proof of the Government's attempt to hide the truth from workers.

For example, the 1947 Atomic Energy or AEC Director of Oak Ridge Operations' memo to the AEC general manager stated, "Papers referring to levels of soil and water contamination surrounding Atomic Energy Commission installations, idol speculation on future genetic effects of radiation, and papers dealing with potential process hazards to employees are definitely prejudicial to the best interests of the Government. Every such release is reflected in an increase of insurance claims, increased difficulty in

labor relations, and adverse public sentiment."

Later that year, Oak Ridge recommended that the AEC Insurance Branch review declassification decisions for liability concerns. Their recommendation stated, "following consultation with the Atomic Energy Commission Insurance Branch, the following declassification criteria appears desirable: If specific locations or activities of the Atomic Energy Commission and/or its contractors are closely associated with statements and information which would invite or tend to encourage claims against the Atomic Energy Commission or its contractors, such portions of articles to be published should be reworded or deleted. The effective establishment of this policy necessitates review by the Insurance Branch as well as the Medical Division prior to declassification."

In 1948, the AEC Declassification Branch found that a study of Los Alamos workers could be declassified as, "open research." The Insurance Branch called for very careful study before making the report public and wrote, "We can see the possibility of a shattering effect on the morale of the employees if they become aware that there were substantial reasons to question the standards of safety under which they are working. In the hands of labor unions, the results of this study would add substance to demands for extra hazardous duty pay. Knowledge of the results of this study might increase the number of claims of occupational injury due to radiation and place a powerful weapon in the hands of a plaintiff's attorney."

This secrecy policy was documented again in 1960 by AEC biomedical officials where they recognized that, "possibly 300 people at Paducah should be checked out" for neptunium contamination,

but that there was hesitation to, "proceed to intensive studies because of the union's use of this as an excuse for hazard pay."

The OMB document sent to the Labor Department sets out a plan to effect the current decision-making process and independent review on the basis of SEC status of approvals on budget concerns rather than on the scientific basis mandated by the law. The document commends DOL for informing OMB of a potentially large expansion of benefits due to designation of SECs and states that a White House-led interagency working group will be convened to come up with options to administratively contain growth in the cost of benefits paid out by the program. It then lists five options for discussion in that regard.

The first option is to require the Administration clearance of SEC determinations. This option appears to place budget examiners with only a budget focus in the role of making the final decisions on approving SEC status for recommended groups of claimants without regard for actual health determinations on the adequacy or inadequacy of radiation records made for that purpose.

The second option is to, "address any imbalance in membership of the President's Advisory Board on radiation and worker health." This seems to imply that OMB believes the current presidentially-appointed Board has been unbalanced. Scientific integrity and processing claims has been maintained by this nuclear worker compensation program's requirement that the Board be balanced in medical, scientific, and worker perspectives and independent in their review process. As a result, the Board has been well-balanced; however, when a Board member died last year whose voting record favored the position of DOL and NIOSH officials responsible for the program, two Board members not so predisposed in their voting were removed. The reason for their removal was stated to be that their term limits had expired; however, other members with the identical tenure were not removed, rendering this explanation hollow.

The Judiciary Committee encouraged the White House to maintain balance in the Board's composition and preserve the institutional knowledge. The Committee urged that these Board members be retained to sustain the Board's independence and decision-making quality. The concerns were dismissed and three new Board members were recommended by officials running the program that is subject to Board review, and were placed on the Board. It appears that the balanced Board OMB contemplates may be one that will determine the scientific evidence available is sufficient to justify denial of the majority of SECs in order to contain growth of benefit payment costs. This does not coincide with balancing the Board or ensuring independence as contemplated in the law passed by Congress.

Option three calls for an expedited review of SEC recommendations by outside experts. The law states, "the President shall establish an independent review process using the Advisory Board on Radiation and Worker Health," thus creating and tasking the Board with providing independent review of science used for claims processing. If OMB's concern is with costs, adding another layer of costly review makes no sense. The indication is OMB doesn't trust the Board which the President appointed nor its team of expert health physicists to provide cost-containing results. The Committee has yet to find evidence during the existence of the current review procedure that the Board's advice has been unsound or led to un-

warranted approvals.

Option four questions the credibility of the Board's audit contractor. This contractor's conflict of interest restrictions are more stringent than the restrictions on NIOSH, its contractors, or the Board members. Contrary to OMB's view, the Committee's review of conflict of interest concerns has found that significant conflicts of interest center on individuals employed by Oak Ridge Associated Universities, or ORAU, the contractor hired by NIOSH to perform dose reconstructions and not the Board's contractor hired to review NIOSH and ORAU's work.

The final option is to require that NIOSH demonstrate that its site profiles and other dose reconstruction guidances are balanced. Again, it is unclear what they mean by balanced. Both site profiles and dose reconstructions are to be based on data and facts. Data and facts are not a perspective. They are either valid, comprehensive, and able to withstand public scrutiny, or they are not. One question that must be answered is the meaning of the term "balance" in this context. Hopefully our witnesses will enlighten the

Subcommittee in this regard.

OMB's plan to address imbalances in the Board and conflicts of interest with the audit contractor seems to be an attempt to deny claims based on false realities and accusations. These options seem to attempt to replace a statutorily-mandated independent review process with a behind-closed-door process to cut benefit payments to the claimants who had the least knowledge of how hazardous their work conditions really were because of the lack of exposure information in their cases. If that is the case, their goal to cut costs would override the honest validation of a claim due to credible scientific evidence or lack thereof, the core purpose of the program.

Unlike the majority of claims programs administered by the Labor Department, compensation provided by this nuclear worker compensation program addresses purposeful harm perpetrated on innocent employees without their knowledge. That dynamic of this program adds a much higher presumption that claims should be paid without hesitation or resistance than does a broken bone from a fall at the office. This is not the Federal Employees Compensa-

tion Act or the Longshore Compensation Program.

It is troubling that the document thanks the DOL office that administers its nuclear worker compensation program for notifying them of the potential increased costs from SECs. That coupled with statements by DOL officials on the public record and in documents provided to the Committee expressing annoyance with the depth of review conducted on NIOSH scientific findings and the view that the Advisory Board needs to be brought under control by NIOSH on their decisions don't reflect well on the underlying attitude of some key officials involved with the running of this program.

DOL was tasked with running a non-adversarial claims process here, but at a minimum this document raises questions about DOL's objectivity and neutrality as the claims administrator. It does not seem to lie in line, once again, with the spirit of the law. This plan to override science to meet OMB's budget priorities is inappropriate and speaks to an institutional mind set at odds with congressional intent. It does a disservice to these Cold War veterans. Unless we root out this problem, it will undermine Government credibility with claimants and the public. Unfortunately this behavior by Government officials could, due to reactive demands for Congress to legislatively mandate more SECs, potentially by this Chairman, be more costly to the Government coffers than allowing the independent process originally established by Congress to proceed unhindered.

I hope our witnesses today can speak to each of these proposed actions and calm the furor this document has created within the claimant community. The purpose of this nuclear worker compensation program is as stated in the statute, to provide for timely, uniform, and adequate compensation of covered employees and, where applicable, survivors of such employees. That should be the Government's guiding principle, not undermining legitimate claims processing to save what in reality is a minuscule fraction of the entire Federal budget.

At this time, I would like to recognize the gentlewoman from Texas, the Ranking Member of the Subcommittee, Ms. Jackson Lee

for an opening statement.

Ms. Jackson Lee. Thank you very much, Mr. Chairman, and you are to be commended for it is interesting as we have worked on the Subcommittee for a number of years, we have found that the vast amount of our work has focused on immigration, border security, and certainly as it should. Many are not aware that this is a Committee of first resort for those who are appealing and/or seeking claims against the United States of America. In fact, it is a Committee that I think has a very high responsibility, and that is to ensure to the American people that in spite of the bigness of the Government, the power of the Federal Government, that each individual person is special and important, that they feel if they have been injured by this Government, this Government has the obligation and duty and responsibility to be sensitive and responsible to addressing that grievance.

So I would like to repeat the topic of this hearing, the "Energy Employees Occupational Illness Compensation Program Act: Are We Fulfilling the Promise We Made to These Veterans of the Cold War When We Created the Program?"

I am very grateful that both the Chairman and myself are at least in sync on the idea that we should know more. So I congratu-

late you for this hearing.

Today's hearing will focus on Subtitle B of the Energy Employees Occupational Illness Compensation Act. Subtitle B covers three types of occupational illness associated with making nuclear weapons cancer where it can be shown that the cancer is at least as likely as not related to ionizing radiation exposure while employed at a nuclear weapons facility, the chronic beryllium disease or chronic silicosis disease as it is known. Energy Department Federal contractor and vendor employees who have contracted one of these illnesses or their survivors may be eligible for a lump sum of \$150,000 and prospective medical benefits. The act also provides for a \$50,000 supplemental payment to uranium miners, millers, or

their survivors who are eligible to receive \$100,000 under the Radiation Exposure Compensation Act and seems to be fair enough.

The radiation-related cancer claims at the Department of Health and Human Services through the National Institute for Occupational Safety and Health is required to estimate a worker's radiation dose if dose records are available. However, during the earlier years of the nuclear weapons programs, especially between the 1940's and 1970's, some workers were not monitored and the monitoring that was done sometimes were inadequate, I might add may have been lost in these years between this time and the time of their claim. Also, some records from this period were further destroyed.

The act provides a remedy for cases where it is not feasible to estimate radiation doses with sufficient accuracy and it is clear from job types that the worker's health may have been endangered by radiation exposures. Friends, it seems unlikely to me that anyone would voluntarily suggest that they have been exposed to radiation. Who would want to be subjected to that kind of danger and unnecessarily make a claim before the Federal Government? I can assure you from those who have had this experience and who have been harmed it is not a pretty picture. It is painful. It is a deadly

disease, and it alters your life drastically.

Under these provisions, workers or their unions may petition to be administratively designated as a special exposure cohort which establishes an unrebuttable presumption that certain cancers are work related. Members of a special exposure cohort are eligible for the 150,000 lump sum benefit if they have one of 22 radio-sensitive cancers and in general if they work at a covered facility for at least

1 year in a job that exposed them to radiation.

The HHS Secretary subject to review and recommendation from the Advisory Board on Radiation Worker Health makes a special exposure cohort designation. To date, the Secretary has denied two special exposure cohort petitions and approved six involving approximately 1,100 cases. The Administration recently declared its intention to reduce the number of special exposure cohorts in a memorandum referred to as an Office of Management and Budget pass-back. My friends, it saddens me that I can characterize that as saving a buck. The pass-back provides for establishing a White House-led interagency work group to develop options for administrative procedures that will contain the growth and the cost of benefits provided by the program. My other editorial comment is that is the highest level of bureaucracy-ese, meaning language, that confuses and of course seeks to eliminate or deny the program.

Options to be considered include requiring an administration clearance for all special exposure cohort designations, requiring an expedited review for outside experts, addressing any imbalance in the membership of the President's Advisory Board on Radiation and Worker Health, and imposing constraints on the Advisory

Board's audit contractor.

Let me join the Chairman and ask for the irregularities of this particular Advisory Board to be fixed immediately and that the fixing of the Board or the changing of the Board members not be for the purpose, as it has been perceived, of eliminating the benefits of so many. Might I suggest, as I listed the various new requirements, that all they represent is one bar after another for the innocent victims who offered and sacrificed their lives on behalf of their country. The Cold War was real. Ask anyone who lived in that period. Ask the children of the fifties who responded to the sirens that suggested they should go under their desks. Many today don't know of the bomb shelters that were built in houses throughout the forties and fifties.

People did it because their Government told them to do it. Now we find that the very workers who were willing to put themselves on the front lines to say I am a warrior of the Cold War, send me, allow me to serve my country, now are getting the back hand of America by its Government and being told that you'll have to jump

over the hoops in order be compensated.

Currently a special exposure cohort petition goes through an initial evaluation by NIOSH and its recommendation is then peer reviewed by the Advisory Board before it goes to the Secretary for a decision. These reviews are conducted in the open and on the record with an opportunity for input from experts and the petitioner. We need to be concerned about this system if it is broken or HHS is approving special exposure cohort petitions that should be denied. We will hear testimony on that issue today if that is the case, and, of course, certainly if there are fractures in the system, if it doesn't work or can be improved, we welcome the opportunity to do so, but personally I do not welcome the opportunity for camouflage and smoke and mirrors to deny innocent victims their right to their claims. Congress intended for these claims to be able to be compensated and they set out a very reasonable approach for those who are the victims of lost records or destroyed records or failed memory, but have the physical ailments and opportunity for affirmation of their ailments to be able to be compensated.

Five and a half years have passed since the Energy Employees Occupational Illness Compensation Act was enacted while I was here in the United States Congress, and the sick workers who were supposed to be served by this program, they are now dying. The Administration should be doing more to help these workers, not trying to make it more difficult for them to establish eligibility for compensation. It is too difficult already. This is not a time with the returning Iraqi veterans themselves suffering from heinous injuries, this is not a time to deny those who are willing to serve our country. This is not a time to deny their families, those families of those who are willing to serve their country. This is not a time to

save a buck on the patriotism of Americans.

These workers made a commitment to our country when the country needed them. Now it is our turn to help them in their time of need. I hope this hearing will generate not only the interest, but the information and solutions so that we can get back on track so that Americans will know when you offer yourself for service and say send me, Americans will stand up and applaud and be welcoming you home with the necessary response and compensation and nurturing for the injuries you suffered in the line of duty.

I yield back, Mr. Chairman.

Mr. HOSTETTLER. I thank the gentlelady.

The Chair now recognizes the gentleman from California for purposes of an opening statement.

Mr. Berman. Thank you very much, Mr. Chairman. I hadn't intended to give an opening statement, but unfortunately the timing of my own schedule conflicts and I'm not able to stay. I will have staff remaining to hear the witnesses; but I just want to say I was very pleased and I would say stunned by the openings that you and the Ranking Member gave and particularly, Mr. Chairman, sort of your reference to the historical development of this whole issue, the efforts to hide and conceal and the notion that right now you have this process that's called an effort to make it fair or balanced that is in reality focused on those workers where these historical events meant they were the least likely to know what they were being exposed to because there was no measurement.

So I think you made just a number—point after point, you were so on the case. The notion that this is a balance, it's a balance between justice and trying to save some bucks, a balance between exposure and trying to save some bucks, a balance between serious illnesses and life-threatening and in some cases life-taking illnesses and trying to save some bucks. This effort as revealed by the reports of this memo aren't about finding balance. It's about tying to bias the entire process in defiance of what congressional intent was

and I think defiance of reasonable compensation.

One hundred and fifty thousand wasn't an effort to try and measure the full extent of the pain and suffering of these people. It was a lump sum payment in lieu of that process to be done expeditiously for people for whom there was no measurements of exposure and they will have no other way to get compensated for their clearly employment-related illnesses, and I think both of you have called this exactly right. I support what you're doing, efforts to create new bureaucratic tiers for people to have to jump through in a context, by the way, where the process is already very slow. Large number of people who have filed claims haven't gotten them adjudicated yet, and as Ms. Jackson Lee pointed out, my guess is large numbers of people who are eligible aren't even aware that this program exists. That's where the efforts should be going, not finding ways to stack advisory committees and create new criteria to, "make it look better on a budget score sheet."

So I look forward to the reports of this hearing and the other hearings and both of your excellent efforts to try and hopefully keep this from being implemented.

Thank you very much.

Mr. HOSTETTLER. I thank the gentleman.

The Chair recognizes the other gentleman from California for purposes of an opening statement when ready.

[The Chairman confers with counsel.]

Mr. HOSTETTLER. At that time, we will be ready to hear the gentleman's opening statement. At this time, I will introduce the witnesses and—

[The Chairman further confers with counsel.]

Mr. HOSTETTLER. It seems at this point, he's ready for that opening statement, and the Chair recognizes the gentleman from California.

Mr. Gallegly. I appreciate the Chairman's recognition and allowing me to make an opening statement. I apologize for being a

little late. I've been on the Intelligence Committee in a briefing that kind of ran over.

On January 31st of this year, I wrote a letter to Secretary Chao expressing concern that a bare few Santa Susana field laboratory workers who had filed claims for the Energy Employees Occupational Illness Compensation Program had been compensated and asking the status of the other requests. I've not received a response.

So today I ask you, A, why is it that only 10 of 434 cases for workers who may be eligible for compensation under the Energy Employees Occupational Illness Compensation Program Act have received benefits? How many claims have been for workers, how many claims under EEOICPA by Santa Susana workers has the Department of Labor declined benefits on? C, many of Santa Susana workers sacrificed their health for the country. They are aging in population. When they can expect their final determina-

tion and payout on their applications for relief?

On its web site, the Department of Labor indicates that 31 claims have been referred to NIOSH and returned from NIOSH with dose reconstructions, yet when I look at the site profile at Santa Susana, the threshold studies, from what I understand, for the site have not been completed. The Department of Labor lists their status as under development. Can you explain how it is that 31 claims have been returned from NIOSH with dose reconstruction when the occupational environmental dose, the occupational internal dose, and the occupational external dose have not been completed?

Why is it that the Department of Labor requests less funding for settlement of these claims in FY 2007 than it did in FY 2006 when so many in my district still have seen no relief or help for their

medical bills whatever?

I yield back the balance of my time.

Mr. HOSTETTLER. I thank the gentleman from California.

At this time, I will introduce our panel—Mr. Shelby Hallmark is the Director for the Office of Workers Compensation Programs in the United States Department of Labor. Dr. John Howard is the Director of the National Institute for Occupational Safety and Health, or NIOSH. Dr. James Melius is the Administrator for the New York State Laborers Health and Safety Trust Fund and is a member of the Advisory Board on Radiation and Worker Health. Finally, Mr. Richard Miller is a Senior Policy Analyst with the Government Accountability Project.

Gentlemen, thank you for your presence here. As standard operating procedure for the Judiciary Committee, I will ask you now to stand raise your right hand, and take the eath

stand, raise your right hand, and take the oath.

[Witnesses sworn.]

Mr. HOSTETTLER. You may be seated. Let the record show that

the witnesses responded in the affirmative.

You will notice a set of lights that will help to aid us in the process of expediting the testimony process. You will have 5 minutes for your testimony. Without objection, your written statements will be made a part of the record. I'm going to ask you to stay as close to your 5 minutes as possible so that we can get to questions by the panel, and you will see a green light and then I believe it's an

amber light and then a red light when the 5 minutes is up. Thank you.

Mr. Hallmark.

TESTIMONY OF SHELBY HALLMARK, DIRECTOR, OFFICE OF WORKERS COMPENSATION PROGRAMS, U.S. DEPARTMENT OF LABOR

Mr. HALLMARK. Thank you, Mr. Chairman, for the chance to describe the Department of Labor's efforts regarding the program we call EEOICPA. I'm proud of what we and other agencies have done to build this program.

First I'd like to say my staff are committed to delivering these benefits promptly and accurately. We know that many energy workers have been harmed and many are deeply disillusioned by their Government's actions and by the long wait they've had to have their cases fairly heard. Our goal has been to make the Federal compensation program a reality that people can count on and quickly.

In 2001, we worked hard to bring the new Part B program on line. Secretary Elaine Chao presented the first check less than 10 months after enactment. Day one, we had a backlog of 30,000 cases and that backlog was under control within a year. To date, we've paid out \$1.4 billion under Part B. Our management of Part B has been credible to the served community. We have only three cases so far that have been appealed to court. A GAO review had no findings with respect to DOL's stewardship, and in October 2004, Congress chose to entrust the new Part E program to us as well.

gress chose to entrust the new Part E program to us as well.

Part E brought a new backlog of 25,000 cases that had been pending for years under the old Part D program with the Department of Energy. This time, the first check went out within less than 2 months and we paid out \$57 million under Part E before our regulations were even issued—on time—in May of 2005. To date, we've paid almost \$300 million under Part E, which is a good start but only a start, and to demonstrate even broader progress, we have committed to making initial decisions on at least three-quarters of all the old Part D cases by this September. We need to make this a real program.

We need to move faster on some aspects on computing benefits for living employees under this program. The pay-outs so far have been largely to survivors since that can be done quickly, but all aspects of the program are now fully operable and we're monitoring progress daily on wage loss and impairment payments for living workers. We will also use the feedback from our recent ombudsman's report to sharpen our processes.

The ombudsman's report also reported concerns regarding the dose reconstruction process. While we all agree this process has taken longer than we would like, it has been a massive undertaking and NIOSH has taken the job very seriously and is working very hard to expedite it.

We hear there are concerns with respect to the process of adding special exposure cohort classes, as you have spoken of, which conveys presumptive approval bypassing dose reconstruction for 22 listed cancers. As the lead agency for EEOICPA, we have long supported close coordination between all the departments which share its administration. We've tried to help NIOSH and the Advisory Board in their deliberations on SEC expansions especially in terms of the impact that new class designations have on the claims process. For example, designation of a class may extinguish the chance for benefits for some workers with non-listed cancers.

While HHS does the science of reconstructing radiation dose and deciding on new SEC classes, DOL must defend those findings in Federal Court. It's a key value for us as the adjudicator and the entity entrusted with explaining to the public the overall workings of EEOICPA that critical action such as extension of the SEC are based on fair understandable and consistent principles. Under no circumstances does DOL seek to cut benefits through our coordination efforts in this matter.

Determining the size and shape of an SEC class depends not only on scientific questions about radiation, but also on more mundane issues like placing workers in various locations within a facility. DOL has important information and insights with respect to those kinds of nonscientific issues. Also, clear definition of the boundaries of an SEC class is very important in individual case adjudication. DOL has sought input in the past designation process to ensure that we'll be able to fairly adjudicate those boundaries once a class is established. For example, the SEC class for the Oak Ridge Y-12 plant includes workers engaged in uranium enrichment operations or other radiological activities. Since the latter term has been hard to pin down, claims for various categories of work such as custodians, guards, construction workers, and so on could be judged either to be in or out of the class, which could cause adjudicatory problems and concerns for the claimants.

DOL has a fiduciary responsibility for EEOICPA to make sure that payments are in accord with the law as established by Congress, but our main focus is that the program is administered fairly, accurately, and consistently and that it will be understandable to claimants throughout the nuclear weapons complex now and for years to come. We've worked hard to achieve that result and we'll continue to so.

I'll be glad to answer questions when that time comes. [The prepared statement of Mr. Hallmark follows:]

PREPARED STATEMENT OF SHELBY HALLMARK

Mr. Chairman, and Members of the Committee, my name is Shelby Hallmark. I am the Director of the Office of Workers' Compensation Programs (OWCP), a component of the Employment Standards Administration (ESA), Department of Labor (DOL).

I am pleased to appear before the Subcommittee today to discuss the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). While we are proud of the progress DOL has made in implementing both Parts B and E of the Act, the EEOICPA has been and continues to be an interdepartmental activity, involving the closely coordinated efforts of the Departments of Energy (DOE), Health and Human Services (HHS), Department of Justice (DOJ), as well as Labor.

PROGRAM HISTORY

The EEOICPA was initially enacted on October 30, 2000. It established a federal payment program (Part B) under which DOE contractor employees and certain other employees and their eligible survivors are entitled to receive monetary compensation and medical benefits from the federal government for radiation-induced

cancer, beryllium disease or silicosis. Executive Order 13179 of December 7, 2000, assigned primary responsibility for Part B's administration to DOL to ensure that the program was up and running by July 31, 2001. We succeeded in issuing interim final regulations in May of that year and established a fully functioning program on schedule. Secretary of Labor Elaine Chao presented the first EEOICPA check on

August 9, 2001

Since then, DOL has received over 71,800 Part B claims covering 51,200 cases. (Each case relates to a single employee; more than one claim can be associated with a single case when multiple survivors are involved.) Our district office staff have a single case when multiple survivors are involved.) Our district office start have made recommended decisions or referred a case to NIOSH for dose reconstruction in over 95 percent of the cases received. There have been 47,877 Final Decisions with 19,280 approvals and 28,597 denials. DOL has issued in excess of \$1.3 billion in Part B compensation payments to over 17,600 claimants. Additionally, over \$88 million in medical benefits has been paid. The vast majority of denied claims are for conditions claimed that are non-covered conditions under Part B, largely due to confusion between Part B, which covers only three types of conditions, and the other segment of the statute, which covers all diseases caused by toxic exposures.

EEOICPA originally included a second assistance program, under Subpart D of the Act, that established a process under which DOE contractor employees and their eligible survivors could seek assistance from DOE in obtaining state workers' comeligible survivors could seek assistance from DOE in obtaining state workers' compensation benefits. Under this program, if a contractor employee's claim satisfied certain preliminary criteria, DOE was required to submit the employee's claim to a Physicians Panel, to determine whether the employee had contracted a covered illness as a result of exposure to a toxic substance at a DOE facility. If the Panel returned a positive finding that was accepted by the agency, DOE was authorized, to the extent permitted by law, to direct the DOE contractor not to contest the claim for state workers' compensation benefits.

In the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. 108–375 (October 28, 2004), Congress abolished Part D of EEOICPA. In its place, a new Part F. was created, and administration of the new program was

In its place, a new Part E was created, and administration of the new program was assigned to DOL. Part E establishes a new system of federal payments for DOE contractor employees and eligible survivors of such employees. Part E benefits were also extended to uranium miners, millers and ore transporters covered by section 5 of the Radiation Exposure Compensation Act. Congress also amended certain other provisions contained in EEOICPA that applied to Part B and specified that DOL prescribe interim final regulations implementing the amendments EEOICPA within 210 days of enactment.

When the amendment was passed in October 2004, there were more than 25,000 cases pending with the old Part D program, many for more than four years, thus creating an instant backlog for the new program. Accordingly, DOL identified certain types of claims that met specific, straightforward criteria contained in the amendment itself that could be adjudicated without detailed regulations. Within two months of enactment, DOL began providing compensation under the newly established Part E of the EEOICPA, using preliminary procedural guidance. Under the preliminary procedures, DOL issued over \$55 million to 447 recipients prior to the

issuance of regulations.

On May 26, 2005, DOL successfully met the congressionally mandated deadline to prescribe regulations and begin full implementation of the new Part E. The release of interim final rules (IFR), published in the Federal Register on June 8, 2005, provided guidance regarding DOL's administration of the Act and how the claims adjudication process will function. With the rule in effect, DOL can render decisions on all aspects of program. To further facilitate this process, DOL issued additional comprehensive procedural guidance in May 2005 and conducted training for all District Office field staff regarding the proper implementation of the new amendment. These procedures will be updated based upon the issuance of the Final Rule, and additional training will be conducted as needed.

DOL can and will make changes to the new regulations that are appropriate given public comment and its actual experience in implementing the Act when it issues final regulations. Because of DOL's experience in administering similar programs, and because of the close relationship of Part E of EEOICPA to the existing Part B,

DOL is confident that this process will again work well.

As noted, many claimants whose cases were transferred to DOL from DOE had been waiting for a decision for four years. To demonstrate our sense of urgency in addressing these claims, the Labor Department established a primary goal to issue 1,200 Part E payments by the end of FY 2005, less than a year following enactment of the program. That goal was exceeded. By September 30, 2005, 1,535 payments totaling over \$194 million in compensation benefits had been issued. The bulk of these compensation payments were made to surviving family members because the process for assessing impairment and wage loss to living workers was complex and took longer to establish under statutory and regulatory guidelines. Payments are now also being made to living employees, and DOL is committed to the swift, sure,

and accurate adjudication of these cases as quickly as possible.

Between the effective date of the enactment of the EEOICPA amendments on October 28, 2004, and February 21, 2006, DOL received the 25,000 plus occupational illness claims from the previous DOE program, as well as over 12,800 new Part E claims. We have made more than 7,200 Part E recommended decisions (the initial determination made in one of our four district offices), and more than 3,400 of those have gone through to final decision (the administrative judgment rendered by our Final Adjudication Branch). Compensation in excess of \$292 million has been issued to 2,319 recipients under the new Part E program. An additional 1,359 cases are in the pipeline for payment

in the pipeline for payment.

The DOL also initiated a series of Town Hall meetings to explain to affected workers or their survivors the benefits available, as well as explaining the IFR and other issues related to the implementation of Part E to affected workers or their survivors. Eighty-two meetings were held in cities that had the most claimants and potential claimants, such as Los Alamos, New Mexico; Oak Ridge, Tennessee; and

Hanford, Washington.

For greater efficiency and speed, OWCP is implementing the October 28, 2004, EEOICPA amendments, to the extent possible, by adjudicating all claims for benefits under Parts B and E of the EEOICPA as one EEOICPA claim. Where possible, decisions will be issued addressing both Part B and Part E simultaneously. However, partial decisions will be issued in cases where benefits under some provisions can be awarded but claims under other provisions require further development and documentation.

ADMINISTRATION OF EEOICPA

EEOICPA is administered by the Division of Energy Employees Occupational Illness Compensation (DEEOIC) in OWCP. Claim adjudication is accomplished through four EEOICPA District Offices located in the OWCP regional offices. These District offices are located in Jacksonville, FL; Cleveland, OH; Denver, CO; and Seattle, WA with jurisdiction based on the location of the employee's last employment. Headquarters, in Washington, DC, provides planning, budgeting, performance measures, accountability evaluations, policy, central medical bill processing, and administrative leadership. Additionally, final decisions are issued by the Final Adjudication Branch (FAB), which is independent from the District offices, through a National FAB office in Washington, DC, and four District FAB offices collocated with the District offices. DOL has hired over 180 additional personnel to administer both Parts B and E.

DEEOIC Resource Centers continue to assist employees and families filing claims. Assistance is provided through eleven strategically placed Resource Centers located in Oak Ridge, TN; North Augusta, SC; Paducah, KY; Portsmouth, OH; Denver, CO; Espanola, NM; Livermore, CA; Idaho Falls, ID; Richland, WA; Las Vegas, NV; and Amherst, NY. As a result of a successful cost-comparison competition under OMB Circular A–76, the resource centers, as part of the government's Most Efficient Organization (MEO), assumed additional responsibilities in employment verification and developing occupational histories for new Part E claims. Since August 2005, the resource centers fully completed 4,028 initial employment verification requests and 3,151 Occupational History Questionnaires.

EEOICPA PART B

For a worker or eligible survivor to qualify for benefits under Part B, the employee must have worked at a covered DOE, Atomic Weapons Employer, or beryllium vendor facility during a covered time period and developed one of the specified illnesses as a result of their exposure to radiation, beryllium or silica. Covered medical conditions include radiation-induced cancer, beryllium disease, or chronic silicosis (chronic silicosis is only covered for individuals who worked in nuclear test tunnels in Nevada and Alaska). Covered workers receive a one-time, lump-sum payment of \$150,000 as well as future medical treatment for the covered condition (medical services and evaluations only for beryllium sensitivity). Qualified survivors of deceased covered employees may also be eligible for the lump sum compensation amount of \$150,000. The EEOICPA also provides compensation in the amount of \$50,000 to individuals or their eligible survivors awarded benefits by the Department of Justice (DOJ) under Section 5 of the Radiation Exposure Compensation Act (RECA).

There are several different types of claims under Part B of the Act, which require different processing steps. Claims for the \$50,000 RECA supplement are the least complex, involving verification via the Department of Justice (DOJ) that a RECA award has been made, and documentation of the identity of the claimant (including survivor relationship issues). For claims involving beryllium disease, silicosis, or a "specified cancer" for workers at a Special Exposure Cohort (SEC) facility, the employment and illness documentation is evaluated in accordance with the criteria in the EEOICPA. The DOL district office will then issue a recommended decision to the claimant.

DOL can move directly to a decision on cases involving a "specified cancer" at an SEC facility because the Act provided a presumption that any of the twenty-two listed cancers incurred by an SEC worker was caused by radiation exposure at the SEC facility. In cases involving cancers other than the twenty-two specified cancers in the Act, the case will be referred to the National Institute for Occupational Safety and Health (NIOSH) for a dose reconstruction so that a determination can be made whether to award benefits based upon the probability that radiation caused the cancer. The dose is the relevant amount and character of radiation to which the individual was exposed related to his or her employment in the nuclear weapons com-

After NIOSH completes the dose reconstruction and calculates a dose estimate for the worker, DOL takes this estimate and applies the methodology also promulgated by the Department of Health and Human Services in its probability of causation regulation to determine if the statutory causality test is met. The standard is met if the cancer was "at least as likely as not" related to the covered employment, as indicated by a determination of at least a 50 percent probability. DOL's district office then issues a recommended decision on eligibility for EEOICPA benefits, which is subject to the same subsequent administrative procedures and appeal rights de-

scribed above with regard to other claims.

NIOSH recently designated several classes for inclusion in the Special Exposure Cohort. To date, these include the Uranium Division of Mallinckrodt Chemical Works at the Destrehan Street facility (St. Louis, MO) from 1942–1948 and from 1949-1957; AEC operations during the period from March 1949 through 1974 for the Iowa Army Ammunition Plant (IAAP); IAAP employees who worked as radiographers from May 1948 to March 1949 in support of AEC operations; employees involved in uranium enrichment operations or other radiological activities at the Y-12 Plant from March 1943 through December 1947; and certain employees at the Linde Ceramics Plant in Tonawanda, New York, 1942-1947. DEEOIC has issued special procedures for the proper handling of these claims and stands poised to develop and adjudicate claims arising out of these and any future new SEC designa-

The DEEOIC strives to achieve quality agency decisions and provide clear and effective communications to its customers and stakeholders. In its September 2004 report entitled "Energy Employees Compensation; Many Claims Have Been Processed, but Action Is Needed to Expedite Processing of Claims Requiring Radiation Exposure Estimates," the Government Accountability Office (GAO) evaluated "how. . .

sure Estimates," the Government Accountability Office (GAO) evaluated "how. . . Labor's procedures and practices ensure timely and consistent processing of claims not referred to NIOSH." Through January 2004, 83% of all claims not requiring NIOSH dose reconstruction were fully processed. GAO indicated it saw no need "to issue formal recommendations regarding DOL performance."

The Final Adjudication Branch (FAB) continues to perform well. To accommodate the anticipated Part E caseload, staff for the FAB has been doubled. In FY 2005 FAB issued 11,709 claim-level final decisions under Part B and 2,110 claim-level final decisions under Part E, significantly surpassing the operational plan goals. FAB conducted 656 hearings and responded to 897 requests from claimants for re-FAB conducted 656 hearings and responded to 897 requests from claimants for re-

view of the written record during the year.

EEOICPA PART E

The creation of Part E of EEOICPA established a new system of federal payments for DOE contractor employees and eligible survivors of such employees for illnesses determined to result from exposures to any toxic substances at a DOE facility. These benefits are also provided to uranium miners, millers, and ore transporters covered by Section 5 of the Radiation Exposure Compensation Act (RECA). Part E provides up to \$250,000 in compensation and medical benefits for accepted illnesses. Benefits are provided for any illness if it is established that it is at least as likely as not that exposure to a toxic substance was a significant factor in causing, contributing to, or aggravating an illness or death of the employee. Additionally, the Act provides that any determination to award benefits under Part B (including for RECA Section 5 claims), as well as any positive finding by DOE under Part D, is

an automatic acceptance of causation under Part E.

Part E compensation determinations involve components of impairment, wageloss, and survivor benefits. The maximum benefit is \$250,000 for all claims relating to any individual employee. Medical benefits do not count against the maximum compensation cap. Living employees are eligible for benefits based on impairment and years of qualifying wage-loss and survivors are eligible for survivor benefits that include additional benefits if there were also significant years of qualifying wage-loss associated with the accepted illness.

wage-loss associated with the accepted illness.

The statute defines survivors under Part E as a living spouse who was married to the employee for at least one year immediately prior to the death of the employee, and certain dependent children. If there is no living spouse, unlike in Part B, children are only eligible survivors if at the time of death of the employee they were under the age of 18 years old, under 23 years old and a full time student continuously since age 18, or any age if incapable of self support.

The Act provides a "basic" lump sum benefit of \$125,000 to eligible survivors where it is established that the employee was exposed to a toxic substance at a DOE facility; that it is at least as likely as not that the exposure caused, contributed to, or aggravated an illness; and, that the illness then caused, or contributed to the death of the employee. It also provides \$25,000 in additional benefits to eligible survivors of a deceased Part E employee, beyond the "basic" lump-sum payment in the amount of \$125,000, if the deceased employee had, up to his or her "normal retireamount of \$125,000, if the deceased employee had, up to his or her "normal retirement age" under the Social Security Act, at least ten aggregate calendar years of wage-loss of at least 50 percent of his "average annual wage." If an employee had at least twenty such years, the additional amount paid to an eligible survivor of such employee increases to \$50,000.

DEEOIC has contracted with a variety of health care professionals from a diverse background of medical disciplines to evaluate claims for causation and impairment. DEEOIC is assembling a network of physicians to review case files and will have physicians on-site at each of our four district offices to provide input to its claims professionals regarding complex medical issues. In addition, DEEOIC added a Medical Director to its National Office staff to assist with case file review and policy

determinations.

ADMINISTRATIVE CHALLENGES

The primary difficulty in implementing both parts of EEOICPA has been to get an effective claims processing system up and running in a very short period of time, so as to address large initial backlogs.

PART B

The statistics provided above indicate that we have been largely successful in addressing the Part B backlog, with the exception of those cases that require a dose reconstruction. More than 21,000 cases have been referred to NIOSH for dose reconstruction. struction since the program's inception, and about 11,600 dose reconstructions have been completed, leaving roughly 8,500 cases pending at NIOSH. This time-consuming process has been the source of significant concern, and NIOSH has taken numerous steps to speed up its production of completed reconstructions. During FY 2006, NIOSH has returned an average of 500 completed dose reconstructions per month, and they project resolving a large portion of the current inventory by the end of this fiscal year.

The creation of new SEC classes requires close coordination between DOL and NIOSH to determine which cases at the site in question have been affected by the new class and which continue to require dose reconstruction. Because each new SEC class designation has been unique in its rationale and in its impact on how (or if) dose reconstruction can be done for cancers that are not granted presumptive coverage, DOL and NIOSH have had to work out unique procedures for each class for determining how such cases will be processed. The return of large numbers of SEC cases also creates large unanticipated workload increases in DOL's district offices, and DEEOIC leadership has had to respond to those bulges in workload by shifting caseloads among the four district offices.

Once a class is added, DOL must also use the designated class definition to identify claims that meet the requirements for adjudication as an SEC claim. Recent additions to the SEC have proven to be problematic due to ambiguous or inconsistent class definitions. For example, the HHS designation document defined the Oak Ridge Y-12 class as employees who worked in uranium enrichment operations or "other radiological activities." It is not clear what functions or employee groups are covered by the latter term. Numerous claims from employees such as calutron building custodians, security workers, laborers, and others who could have been exposed in these facilities may not meet the definition as designated. Conversely, individuals who were likely not significantly exposed may be included in the SEC class due to the ambiguity of the class definition. DOL continues to coordinate with HHS/NIOSH to achieve the clearest and most accurate class definitions possible, so that claims decisions flowing from these determinations are understandable and fair.

PART E

While we are proud of our ability to get the new program up and running on time and within Congressional deadlines—and particularly of our ability to make a significant number of payments in the first year—Part E is more complex than the older program and has presented challenges in ensuring that all aspects are fully operational. In addition, efforts to ramp up case processing under the new Part E must be balanced with continued timely support of Part B claims processing, which has itself become more complicated with the declaration of several new SEC classes.

The start-up time for Part E was somewhat more protracted than we had hoped, especially with respect to the full implementation of procedures for handling wageloss and impairment rating determinations. These processes required the development of complex procedural guidance, engagement of medical consultants and retainers to carry out case evaluations, and extensive staff training. As a result, the great majority of payments made under Part E to date have gone to survivors, whose benefits are much simpler to compute.

Nevertheless, all the necessary components of the Part E program are now in place and, for the remainder of FY 2006, we anticipate a substantial increase in both the total number of cases being adjudicated and the numbers and types of payments being issued.

OFFICE OF THE OMBUDSMAN

The 2004 amendments also created an Office of the Ombudsman. In compliance with statutory requirements, on February 24, 2005, the Secretary appointed Donald Shalhoub to serve as the Ombudsman. The role of the Ombudsman is to conduct outreach to claimants and potential claimants; make recommendations to the Secretary of Labor on where to locate Resource Centers; submit an Annual Report to Congress by February 15, setting forth the number and types of complaints, grievances and requests for assistance received by the Ombudsman, and an assessment of the most common difficulties encountered by claimants and potential claimants under Part E. In making her selection, the Secretary picked an extremely qualified individual with long experience in addressing occupational safety and health issues and a commitment to assisting workers.

As you know, Mr. Shalhoub recently submitted his first Report to Congress. While his report naturally highlights the complaints and concerns some 600 claimants brought to his attention, we believe it is important to compare this number to the more than 45,000 individuals who have filed a Part E claim thus far. We believe the great majority of this community understands that DOL is working hard to respond to their needs, and recognizes that a new program of this kind will take some time to address everyone's claim, particularly since we inherited a backlog of 25,000 claims.

A significant percentage of the specific concerns raised by claimants relate to statutory restrictions (e.g., the exclusion of adult children from survivor benefits under Part E) which are beyond the purview of DOL. An additional group complains about the dose reconstruction process, which is being addressed by HHS/NIOSH. With respect to issues that do relate to DOL's administrative responsibilities, we take the concerns expressed in the Report seriously and will use them to improve our processes and especially our offices' communications with claimants.

In several areas, the issues raised indicate confusion about how existing policies and procedures actually work, or a lack of clarity of the program documentation we provide. To address these concerns and the Ombudsman's related recommendations, we will, among other actions, work with NIOSH and our own staff to ensure that the waiver and appeals processes involving dose reconstruction and the related Part B and Part E adjudications are more clearly explained; ensure that DEEOIC decisions and other documents make it clear whether they apply to Part B, Part E, or both; and issue general information materials explaining in more detail how wageloss and impairment rating decisions will be handled.

The Report discloses that the Ombudsman received 23 complaints that claims examiners do not always return phone calls. DOL is working hard to avoid such service lapses. We carefully track phone calls received from claimants and hold our employees accountable for meeting program standards for prompt response. In FY

2005, OWCP received 53,164 EEOICPA-related telephone calls, of which 37,060 were responded to at the time of the call. Of the remaining 16,104 which required a return call, over 96 percent were completed within 2 days. The program is striving to improve upon its customer service, and will seek to better those statistics in FY 2006.

The Report stated that 10 claimants believe that OWCP's District Offices do not share their sense of urgency because their claims have been reassigned to new claims examiners. We hope that the public will recognize that such reassignments have been necessary due to the addition of nearly 200 new employees during the past year and are part of our effort to expedite case processing across-the-board. We understand the concern and frustration of claimants who have been awaiting a decision for several years, we are committed to working as quickly as possible to resolve these cases, and we are keenly aware of the urgency for claimants who are ill, and in many cases, very elderly.

A number of claimants' comments stated that they believe the burden of presenting employment and exposure records rests solely on claimants. However, OWCP and NIOSH systematically gather employment and exposure information from DOE, the Former Worker Medical Screening programs, contractors who employed covered employees, the Social Security Administration, and many other sources. Thus, the vast majority of information used by NIOSH in creating a dose reconstruction is obtained from sources other than claimants. Similarly, most of the employment documentation used by OWCP in determining covered employment is obtained by OWCP from sources other than claimants, and we have created a database called "site exposure matrices" to assist claims examiners in determining the types of chemicals and toxic substances that existed at the major DOE facilities. These databases also help DEEOIC claims professionals assess relationships between potential exposures and a claimed illness. In addition, DEEOIC has added industrial hygienists and a toxicologist to its National Office staff to assist in exposure evaluation. It should be noted that no Part E claim was denied based on inadequate evidence of toxic exposure during 2005.

DOL PERFORMANCE GOALS AND OUTCOMES

The Labor Department is committed to the accomplishment of measurable outcomes and to holding ourselves accountable for achieving the fundamental goals of all the programs we administer. With respect to Part B of the EEOICPA, the DEEOIC established high performance standards focused on moving claims rapidly through the initial and secondary adjudication stages. Our Government Performance Results Act (GPRA) goals, even for the first full year (FY 2002), were challenging in light of the large number of first year claims and program start-up activities.

Our goal for initial processing was to make initial decisions in 75 percent of the cases within 120 days for cases from DOE facilities and from RECA claims, and within 180 days for Atomic Weapons Employer, beryllium vendor, and subcontractor cases (for which employment and other critical information is generally more difficult to obtain). Because we had received nearly 30,000 cases when our authority under Part B commenced on July 31, 2001, we knew in advance we would not meet those goals, which were conceptualized in terms of a normal, steady-state flow of incoming claims. However, establishing rigorous performance goals signaled to our own staff and to those potentially eligible for benefits that we were committed to efficiently processing claims. In fact, we took timely initial actions (either recommended decisions or referral to NIOSH for dose reconstruction) in about 48 percent of the cases during that first full year of operation (FY 2002), despite the backlog of cases from the previous year. The smaller number of final decisions completed in FY 2002 met our GPRA timeliness goals in 76 percent of cases.

During FY 2003, the DOL program was able to eliminate the initial backlog of

During FY 2003, the DOL program was able to eliminate the initial backlog of claims, leaving only a working inventory of about two to three months' incoming claims pending in our district offices. At the same time, and despite making decisions on many older cases as we cleared the backlog, the program was able to exceed its GPRA timeliness goals. Our district offices issued initial decisions within the target timeframe in 79 percent of all cases processed, in excess of the 75 percent goal. Our Final Adjudication Branch issued 77 percent of its final decisions within

the program standards, also in excess of a goal of 75 percent.

During FY 2004, we continued to improve on these results, exceeding our GPRA standards on all counts and driving down the average times to complete each phase of the different types of Part B claims. For example, the average time to complete an initial decision for cases from DOE facilities has been reduced from 98 to 73

days, and the average for cases from all other facilities and subcontractors is down from 123 to 99 days.

During implementation of Part E during FY 2005 our district offices continued to adjudicate Part B claims timely in 81 percent of the cases, exceeding the 80 percent goal. The Final Adjudication Branch issued 95 percent of its final decisions timely, well in excess of the 80 percent goal.

Accomplishment of these goals took the persistent, case-by-case effort of the entire staff, as well as the continuing support of our Solicitor's Office. Close and frequent coordination with HHS allowed us to move cases smoothly and efficiently to NIOSH when dose reconstruction is needed. In addition, DOL and DOE worked cooperatively to improve the employment verification process and reduce the average time for completion of DOE verifications from nearly 90 days at the beginning of FY 2003 to a current average of less than 45 days. These cooperative measures were instrumental in reducing Part B processing times.

The number of requests for administrative review has been relatively low, and only three Part B cases have been appealed in Federal district court, suggesting that the new program has reached a level of accuracy that builds credibility for its decisions.

With respect to Part E, as previously noted, DOL exceeded its FY 2005 GPRA goal for this Part by issuing more than 1,500 payments during the first 10 months following enactment. Cognizant of the long wait experienced by those who filed originally with the DOE Part D program, our GPRA goal for FY 2006 is to complete initial processing for at least 75% of the more than 25,000 cases transferred from DOE.

NÎOSH projected that by the end of FY 2006 most of the backlog of cases pending for dose reconstruction would be finalized and returned to DOL as well. Largely for these two reasons, we projected a major bulge (an increase of nearly \$1 billion) in EEOICPA payouts for FY 2006. We anticipate receiving a stable stream of new claims in FY 2006 and FY 2007 (approximately 10,000 under each Part); but, whereas many payments are expected to result in FY 2006 from the backlog clearance efforts both with respect to the old Part D claims and the cases pending at NIOSH, that volume was projected to decline in FY 2007, resulting in total payouts that will substantially exceed the FY 2005 experience, but will be much lower than FY 2006.

The estimated decrease in Part B benefits from FY 2006 to FY 2007 is not based on any projection of reductions or limitations in the number of additions to the Special Exposure Cohort. The budget impact of the Special Exposure Cohort process is not readily predictable because too many factors are unknown, e.g., which petitions will be successful, how many employees are involved, what new petitions will be forthcoming, etc. Since the compensation benefits are mandatory funding, if additions to the Special Exposure Cohort were greater than anticipated, benefits would still be paid regardless of the projections presented in the President's Budget.

In summary, I am pleased to report that all aspects of the EEOICPA, both Part B and E, are fully operational, and we anticipate accomplishing our challenging performance goals for both programs in FY 2006. We believe we have established a credible program and forged effective working relationships with our participating agencies—DOE, HHS and DOJ, as well as DOE contractors and labor unions. Between FY 2001 and FY 2006, DOL implemented two brand-new compensation programs with widely divergent benefit schemes. We promulgated new regulations, formalized procedures, hired and trained nearly 500 Federal employees nationwide, and administered benefit disbursement in accord with congressionally mandated criteria. We are confident that we will be able to rise to the challenge of resolving the remaining backlog of Part E cases, and, working with NIOSH, to similarly resolve the dose reconstruction backlog. Every member of the DEEOIC staff is keenly aware that many workers have been waiting many years for compensation and we are doing our best to serve them.

Thank you for the opportunity to describe our efforts in implementing EEOICPA. I would be pleased to answer any questions the Subcommittee may have.

Mr. HOSTETTLER. Thank you, Mr. Hallmark. Dr. Howard.

TESTIMONY OF JOHN HOWARD, M.D., M.P.H., DIRECTOR, NA-TIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, CENTERS FOR DISEASE CONTROL AND PREVEN-TION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. HOWARD. Thank you, Mr. Chairman, and Members of the Subcommittee. I'm pleased to appear before you today to talk about the HHS activities.

In 2002, HHS promulgated two regulations on the same day, one a dose reconstruction regulation and the other to assist the Department of Labor in determining probability of causation. In 2004, HHS promulgated a third regulation on the special exposure cohort

petition and petition evaluation processes.

NIOSH began developing a dose reconstruction program in the summer of 2001, establishing a robust scientific foundation as the basis for our program. We've hired two contractors to assist us with that activity. The first contract was awarded in 2003 to the Oak Ridge Associated Universities, and the second was awarded in 2005 to Battelle Science and Technology International. Of the 21,123 cases that we have received from the Department of Labor for dose reconstruction, we have returned to DOL as completed cases 13,813

or 65 percent of our program's caseload.

In addition to processing individual dose reconstructions, we've also been actively working on evaluating special exposure cohort petitions. Since HHS promulgated our role in 2004, we've received a total of 55 submissions for adding classes to the SEC. Of those, 26 did not qualify for evaluation, 14 are in the stage of being qualified, six have qualified as petitions and are being evaluated now, and nine were approved for addition to the SEC representing six classes of employees at four sites. Five of these six classes were initiated by petitions by former employees, survivors, or their representatives. One class, however, Linde Ceramics Plant, was added because NIOSH, on its own initiative, determined that data to estimate radiation doses with sufficient accuracy was not available for a specified time period.

To date, 20 submissions have been closed because they did not qualify. Some of these petitions were withdrawn by the applicants. Some lacked appropriate evidence despite substantial assistance from NIOSH, and some requested the addition of classes that were

already statutorily included in the congressional cohort.
Finally, the President charged HHS with administering a new Federal Advisory Committee, the Advisory Board on Radiation and Worker Health, to advise the Secretary of HHS. The Board is chaired by Dr. Paul Ziemer, an internationally-recognized health physicist, and consists of 12 distinguished members, one who is present here today, representing scientists, physicians, and representative workers, a membership which reflects the act's requirement that the Board include a balance of scientific medical and worker perspectives.

Since the Board first met in January 2002, Board members have met a total of 46 times in work groups, Subcommittees, or as the full Board. The Board made recommendation to the Secretary for the addition of all of the six SEC classes that have been added thus far. A technical support contractor was secured in 2003 to address the Board's request for assistance in better managing its workload. Many of the review comments of this contractor have been extremely constructive to us and to the Board and very useful in making sure that we have rigorous scientific peer review of our work.

Thank you, Mr. Chairman. I would be happy to answer any guestions you have.

[The prepared statement of Dr. Howard follows:]

PREPARED STATEMENT OF JOHN HOWARD

Mr. Chairman and Members of the Subcommittee, my name is John Howard and I am director of the National Institute for Occupational Safety and Health (NIOSH), part of the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS). I am joined today by Mr. Larry Elliott, Director of the NIOSH Office of Compensation Analysis and Support, and Dr. Lewis Wade, Senior Science Advisor at NIOSH. I am pleased to appear before you today to provide testimony on the status of HHS activities under the Energy Employees Occupational Illness Compensation Program Act of 2000 ("the Act").

I will describe and summarize the progress of the HHS responsibilities under the Act, delegated by the President under Executive Order 13179 issued on December 7, 2000.

- Develop scientific guidelines for determining whether a worker's cancer is related to the worker's occupational exposure to radiation ("probability of causation") and methods to estimate worker exposure to radiation ("dose reconstruction"),
- · Use the dose reconstruction regulation to develop estimates of radiation dose for workers who apply for compensation,
- Establish a process by which classes of workers can be considered for inclusion in the Special Exposure Cohort, and
- · Provide support for the Advisory Board on Radiation and Worker Health

REGULATIONS FOR DOSE RECONSTRUCTIONS AND CANCER CAUSATION

HHS was charged with promulgating two regulations. One regulation establishes methods for conducting radiation dose reconstructions for cancer claimants (42 C.F.R. pt. 82). Dose reconstruction is a science-based process for retrospectively estimating the amounts and types of radiation doses incurred by a person. This effort included substantial scientific work by NIOSH to develop specialized analytical methods and tools needed to estimate the occupational radiation doses of nuclear weapons workers

weapons workers. The second HHS-promulgated regulation establishes guidelines by which the Department of Labor (DOL) determines whether the cancer of an employee is "at least as likely as not' related to the radiation doses estimated for that employee through a dose reconstruction (42 C.F.R. pt. 81). This regulation is for determining the "probability of causation," which is the probability that a person's cancer was related to radiation from employment at the specified facility, required the further development of a scientific tool, the "Interactive RadioEpidemiological Program" (IREP). IREP is a computer program that uses "risk models" for associating radiation doses with risk information on different cancers. IREP estimates the probability of disease causation specific to each employee's unique history of exposures ability of disease causation specific to each employee's unique history of exposures to different types and quantities of radiation during the course of his or her employment. In the final development of this tool, NIOSH collaborated with the National Cancer Institute, which had created the initial paper version in the 1980s and was in the process of updating it in response to an extensive scientific review by the National Research Council.

In promulgating the two regulations, HHS invited and considered comments of the public and the Presidentially-appointed Advisory Board on Radiation and Work-er Health ("the Board"). The Board reviewed and advised HHS on both of these rules during the public comment and supported the final rules, which were finalized on May 2, 2002. The regulations are designed to provide efficiencies in dose reconstruction efforts for purposes of arriving at timely decisions on compensation. The regulations allow for new scientific findings and consensus to be integrated after proper scientific consideration.

An example of this recently occurred when NIOSH published a Federal Register Notice and provided an opportunity for the public to comment on a proposed change in the process for selection of target organs used in dose reconstructions for energy employees with lymphoma cancers. This change was in response to an evaluation by NIOSH of current scientific data on lymphoma, which revealed that the site of the radiation injury can differ from the site of the tumor or cancer origin documented in the medical files of a lymphoma cancer patient. On February 15, 2006, NIOSH finalized the new process (for selecting the dose reconstruction target organs for energy employees with lymphoma cancers). The new process selects the organ that would have received the highest radiation dose from among relevant, possibly irradiated organs, as determined through the dose reconstruction process, when the identity of the target organ is in question. This change is now being used to complete dose reconstructions for lymphoma cases and may result in DOL calculating a higher probability of causation determinations for select lymphoma cases. NIOSH is also reviewing the dose reconstructions for lymphoma cases that have already been completed and returned to DOL. If the new process will result in DOL calculating a higher

probability of causation that will result in approval of a denied case, a new dose

reconstruction will be provided to the claimant and to DOL.

DOSE RECONSTRUCTION PROGRAM

The second responsibility of HHS, delegated to NIOSH, is the development and administration of a dose reconstruction program to serve cancer claimants under the Act. This is the largest and most challenging responsibility assigned to HHS. The production scale and scientific complexity of the dose reconstruction program required by the Act are significant compared to other Federal compensation programs requiring dose reconstructions.

NIOSH began developing a dose reconstruction program in the summer of 2001. In accordance with its responsibilities to date, NIOSH established a broad scientific foundation, the cornerstones of which are the radiation dose reconstruction methods and cancer risk models for occupational radiation exposures. The scientific fields and disciplines needed for dose reconstructions include mathematics; health physics; bio-kinetic modeling; statistical treatment, analyses, and testing; exposure assessment; and nuclear engineering. The development and maintenance of the cancer risk models for this compensation program require epidemiology; statistical treatment, analyses, and testing; medical interpretation; and risk assessment modeling and communication.

To assist in conducting individual dose reconstructions, NIOSH develops different kinds of informational documents and updates them as necessary if more information is obtained.

Site Profile documents provide information on the radiation protection practices of a facility. The six sections of a Site Profile document are called Technical Basis Documents, and each address a specific topic, such as a site description, occupational medical dose, or occupational internal dose. Completion of individual dose reconstructions may require all, none, or only certain sections of a Site Profile document. As each Technical Basis Document is completed, it is used to complete dose reconstructions and assure consistency.

We also develop Technical Information Bulletins, which provide clarification on how a specific method can be used to complete a dose reconstruction, on how the information in a Technical Basis Document or Site Profile can be used to meet a specific need in the dose reconstruction process, or on how to provide specific technical information that supports or justifies the tables or information included in a Technical Basis Document or Site Profile.

NIOSH also developed and implemented procedures for performing dose reconstructions; developed a records and data management system; and initiated numerous records retrieval efforts. NIOSH established and coordinated efforts with DOL, the Department of Energy (DOE), and the Defense Threat Reduction Agency in the Department of Defense.

NIOSH has two contractors to assist with the development of site profile information and completion of dose reconstructions. The first contract was awarded on October 12, 2003, to Oak Ridge Associated Universities (ORAU). The contract involves personal interviews with the claimants, retrieval and validation of individual monitoring data, reconstruction of exposure conditions at various DOE and DOE contractor facilities (site profile development), and the completion of individual dose reconstructions. The second contract was awarded on October 12, 2005, to Battelle Science and Technology International (Battelle). The contract involves the reconstruction of exposure conditions at various Atomic Weapons Employer facilities and the completion of individual dose reconstructions.

Following are the status and accomplishments of the dose reconstruction program:

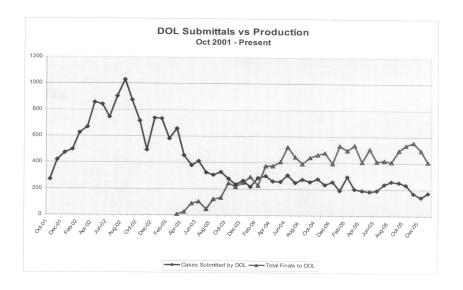
General Claim Information

- EEOICPA encompasses 362 covered sites. NIOSH has received claims from 195 of those sites, over 100 of which have five or fewer claims.
- Of the 362 covered sites, approximately 40 are DOE sites and represent the
 majority of claims; more than 300 sites are Atomic Weapons Employer sites
 (sites which processed or produced material that emitted radiation and was
 used in the production of atomic weapons, excluding uranium mining and
 milling).

Dose Reconstructions

- Cases sent to NIOSH by DOL for dose reconstruction: 21,092
- Cases returned to DOL: 13,742 (65% of total 21,092)

The chart below illustrates NIOSH progress in monthly caseloads:



Documents

- Developed 129 Technical Basis Documents, 40 Technical Information Bulletins
- Developed 63 implementation procedures (45 ORAU procedures and 18 OCAS procedures)

SPECIAL EXPOSURE COHORT

The next responsibilities of HHS are directly related to the dose reconstruction program: defining the requirements for adding classes of employees to the Special Exposure Cohort ("the Cohort") and developing a process for receiving, evaluating, and processing Cohort submissions received.

Under the Act, claims for members of the Cohort who have any of 22 specified

Under the Act, claims for members of the Cohort who have any of 22 specified cancers designated by the Act would not require dose reconstructions or a determination by DOL of probability of causation. Congress included in the Cohort certain employees of three DOE facilities, known as the gaseous diffusion plants, as well as employees of a nuclear weapons test site in Amchitka, Alaska. In addition, the President has authority, delegated to HHS, to designate additional classes of employees to be members of the Cohort, subject to Congressional review, if two tests are met:

- it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and
- (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.

On May 28, 2004, HHS promulgated a regulation to allow it to implement this authority—Procedures for Designating Classes of Employees as Members to the Special Exposure Cohort under EEOICPA (42 C.F.R. pt. 83). The guidelines used to evaluate the feasibility of reconstructing doses for a proposed Cohort class are established in this rule. It states that dose reconstructions can be performed with sufficient accuracy if: "NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose."

The regulation provides for petitions in two circumstances. One circumstance is when NIOSH has attempted to conduct a dose reconstruction for a cancer claimant and finds that the dose reconstruction cannot be completed because there is insufficient information to estimate the radiation doses of the claimant with sufficient accuracy. The second circumstance includes all other possibilities. For example, a petition may be submitted representing a class of employees whose members have yet to file claims under EEOICPA, or even have yet to be diagnosed with cancer.

to file claims under EEOICPA, or even have yet to be diagnosed with cancer.

Once the Cohort regulation was promulgated, NIOSH was able to begin considering petitions, working closely with petitioners to assist with their Cohort submissions in order to qualify the submission as a petition for evaluation. To qualify for evaluation, a submission must contain sufficient information to establish that the radiation exposures sustained by employees at a site were not monitored, either through personal or area monitoring; or that such records have been lost, falsified, or destroyed; or that there is no information regarding monitoring, source, source term, or process from the site. This information may be provided by documents, affidavits, reports from a health physicist or other individual with expertise, or a government report of a scientific or technical nature.

NIOSH uses a hierarchical approach to evaluate the types of information available to reconstruct doses. The primary data used for determining internal exposures are from personal monitoring data, such as urinalysis, fecal samples, and whole body counting results. If these are unavailable, the air monitoring data from breathing zone and area monitoring is used to estimate the potential internal exposure. If personal monitoring and area monitoring are unavailable, internal exposure estimates can be made from modeling potential exposures from the source term and process information. The source term is developed from the quantity of the radioactive material(s) involved or the exposure potential of the radiation generating device

The same hierarchy is used for determining the external exposures to the cancer site. Personal monitoring data from film badges or thermal luminescent detectors are the primary data used for determining external exposures to the cancer site. If there are no personal monitoring data, exposure rate surveys and source term modeling can be used to determine the potential external exposure. In addition to the occupational external exposures from facility operations, occupational medical exposures from routine X-ray examinations given to the energy employee as a condition of employment are also included in the external exposures. These exposures are estimated using technical information relative to the type of X-ray equipment used at a point-in-time at the facility. When all of the sources of data described above have been determined to be unsuitable for establishing maximum plausible radiation doses, it can be concluded that doses cannot be reconstructed with sufficient accuracy.

Once a submission has qualified for evaluation, NIOSH evaluates the petition based on the issues discussed above. A completed evaluation report is sent to both the petitioners and the Board. The Board reviews the petition and provides a recommendation to the Secretary of HHS on the feasibility of conducting dose reconstructions for members of the petitioning class. As required by the Act, the final step in the petitioning process is an opportunity for Congress to review certain designations by the Secretary of HHS. These decisions become effective in 30 days, unless Congress provides otherwise.

Current Cohort Information

• Six classes of employees at four sites have been added to the cohort. Three of these classes (Mallinckrodt Chemical Company—Destrehan Street; Iowa Army Ammunition Plant; and Y-12 Facility) were added due to petitions received from former employees, survivors, or their authorized representatives. One class, Linde Ceramics Plant, was added because NIOSH determined that data to estimate radiation doses with sufficient accuracy were not available for a specified time period.

- NIOSH is currently evaluating six submissions and will send completed evaluation reports to the petitioners and the Board. These submissions are Pacific Proving Grounds, Y-12 (Oak Ridge), Rocky Flats Plant, Oak Ridge Institute for Nuclear Studies, Ames Laboratory, and Chapman Valve.
- NIOSH notifies applicants of any requirements that are not met by the submission and assists the applicants with guidance through phone consultations and written communication in developing necessary information. Currently, NIOSH is providing such assistance to applicants involved with 11 submissions. It is not known which, if any, of these submissions will ultimately qualify for evaluation as a Cohort petition.
- To date, 20 submissions have failed to qualify for evaluation as Cohort petitions, and have been closed. Some submissions have been withdrawn by the applicants, and some submissions requested the addition of classes of employees to the Cohort that were already included in the statutory Cohort. Other submissions lacked appropriate evidence despite substantial assistance from NIOSH.
- On December 22, 2005, NIOSH published a notice in the Federal Register requesting public review and comment on proposed changes to the Cohort rule (42 C.F.R. pt. 83) to address changes to the Act authorized by the National Defense Authorization Act for Fiscal Year 2005 (codified as amended in scattered sections of 42 U.S.C.). Comments on the interim final Cohort ruled will be accepted until March 23, 2006.

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

Finally, the President charged HHS with administering a new Federal advisory committee, the Advisory Board on Radiation and Worker Health ("the Board"), to advise the Secretary of HHS. Members are invited to serve overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. HHS provides administrative services, funds, facilities, staff, and other necessary support services.

HHS nominated and the President appointed the initial member of the Board in 2001. The Board is chaired by Dr. Paul Ziemer, an internationally recognized health physicist, and consists of 12 members representing scientists, physicians, or representatives of nuclear weapons workers—a membership which reflects the Act's requirements that the Board include a balance of scientific, medical, and worker perspectives.

Board Accomplishments

- Since the first Board meeting in January 2002, Board members have met a total of 46 times in workgroups, subcommittees, as the full Board. The most recent meeting occurred this week.
- CDC secured a technical support contractor, Sanford Cohen & Associates (SC&A), on October 10, 2003 to address the Board's request for assistance in better managing its workload. SC&A is currently assisting the Board with their work on dose reconstruction reviews, site profile reviews, and the Cohort petitioning process.
- The Board has reviewed 60 dose reconstructions and 21 procedures of the NIOSH program. The Board's review of dose reconstruction procedures has been constructive. Many of the review comments raised by the Board's contractor, SC&A, have already been examined and changes for improvement have been made or are underway. Other comments are being addressed with feedback to the Board.
- The Board has made eight recommendations to the Secretary of HHS.

SUMMARY

In conclusion, NIOSH has made much progress in carrying out the responsibilities of HHS under EEOICPA and looks forward to continuing to improve its performance to assist workers who have cancer as a result of exposure to unique hazards in building the Nation's nuclear defense.

Thank you again for the opportunity to testify. I'm happy to answer any questions you may have.

Mr. Hostettler. Thank you, Dr. Howard. Dr. Melius.

TESTIMONY OF JAMES MELIUS, M.D., DRPH, ADMINISTRATOR, NEW YORK STATE LABORERS HEALTH AND SAFETY TRUST FUND, MEMBER OF THE ADVISORY BOARD ON RADIATION AND WORKER HEALTH

Dr. Melius. Thank you for inviting me to speak today. Although I will not be speaking on behalf of the Advisory Board, I will be speaking as a member of that Advisory Board and certainly can reflect the work of the Advisory Board that Dr. Howard described,

has done as part of this program.

In your opening statement and others, you pointed out the problem for the many people that worked at these site, the secrecy. They were not given complete information about what they worked with. I think that's very important to understand. These people, they did this work willingly. They understood the importance of this program for their country, but now that that has passed and now that there are compensation programs in place for them and one that is well-justified by their exposures as well as their sacrifices, I think it's very important that we maintain a fair program, a transparent, open program, that they feel that they are being treated fairly at this point in time. And one of the things that we've worked through the Advisory Board is to ensure that fairness and openness—that people see what the reasons are and that we have a sound and open process.

I am extremely concerned by some of the suggested changes. That we would lose that openness, that we would lose that perception of fairness, and therefore, lose the whole credibility of this pro-

gram.

As Dr. Howard has mentioned, the Advisory Board as established under the act are 12 members. We have distinct duties under the act that we need to carry out, and really in order to do them, in order to do really the volume of work required, we requested an outside contractor be hired to assist us. We went to hire that contractor through an open procurement process, a typical Government process, brought on Sanford, Cohen and Associates, and I would share with Dr. Howard that they have done an excellent job. They provide excellent and outstanding technical and scientific review and really what we would call in the scientific community peer review of the many technical documents, the many scientific issues that we need to deal with.

We also pay special attention to conflict of interest issues, both for everyone involved in it, the contractor that NIOSH has hired, but also for our own contractor (the Board's contractor), and the members of the Board, and we put our contractor through requirements that were much more stringent for some of the other groups that were involved in working on this program because we wanted to make sure that the claimants were reassured that they were receiving fair and unbiased review of their claims—that whoever was checking on them was not being tainted by past work or past associations or whatever, so take the extra step to make sure with that.

We've also used that contractor recently in reviewing the special exposure cohort petitions, and NIOSH, as Dr. Howard mentioned, produces a report. The Board then has to review this, again a lot of technical information that has to be dealt with in doing this, and it's taken time. We've paid a lot of attention to this area to make

sure that we are reaching correct recommendations that were then passed on to the Secretary of Health and Human Services, and our contractor again played a critical role in helping us to do that, again an open, transparent process. People petitioning for the special cohort, exposure cohort, are allowed to speak and to present their case and really to be part of all the proceedings that take place for this.

After we have gained some experience recently in doing this, especially particularly the initial eight special exposure cohort petitions that we were reviewing, we have sort of stepped back and we formed a small work group of the Advisory Board. I chaired that Board, and we developed a set of guidelines that we thought would improve the efficiency of the review process as well as provide a fair assessment and one that we could do in a way that would assure that from petition to petition that we were providing the same type of criteria for each petition. (We were treating everybody fair-

That report, I attached to my testimony. It's been made public. again, what can we do to improve the process, make it more efficient, but maintain the fairness and openness of this process.

Recently the Office of Management and Budget have suggested a number of changes to the program. You've listed those changes in your opening remarks. I think it's important to realize that we have a process in place that works. This is a process that was envisioned in the act. It's open. It provides sound technical peer review of these evaluations for special exposure cohort consideration. We don't need to make changes in it. We can improve it in some ways. The process really is good. It provides a balanced scientific and technical review, and I think to make the changes that have been suggested in the OMB document would simply destroy the credibility of this program. We can't have a secret review process underway.

Let me end my testimony there. I will be glad to answer questions at the appropriate time.

[The prepared statement of Dr. Melius follows:]

PREPARED STATEMENT OF JAMES MELIUS

Thank you for the opportunity to testify here today before the Subcommittee on Immigration. Border Security, and Claims regarding the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). Over my past twenty-years of work in occupational and environmental health, I have considerable experience evaluating occupational illness issues at Department of Energy nuclear weapons fa-cilities while working for the National Institute for Occupational Safety and Health and later as a member of various review and advisory committees including the Advisory Board on Radiation and Worker Health established under EEOICPA. I appreciate the Subcommittee's exercising its oversight with regard to this important program

I should note that I testify here today as a member of the Advisory Board on Radiation and Worker Health but do not speak on behalf of the Board. However, I can address the workings of the Board and its stated positions on various issues relevant to this hearing.

ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT

EEOCIPA was established to address the work-related cancers and other illnesses suffered by the thousands of men and women who helped build and maintain our nation's nuclear weapons starting during World War II and continuing into the present time. Especially during the early years of the program, these people worked under very difficult conditions. They worked under very tight deadlines using new manufacturing processes handling very dangerous materials, often with minimal protection from exposure to dangerous radioactive elements. They also worked under great secrecy, facing severe criminal penalties for any breach of secrecy. Often they were given very minimal information about the materials that they worked with and the potential health consequences of their exposures.

I want to emphasize that these people worked under these conditions willingly, knowing the critical importance of their work to our nation's security. However, many of these people and their families are now angry that this past secrecy and those difficult working conditions have not been acknowledged and have been used to deny their past claims for work-related illnesses. The credibility of the EEOICPA program to these people is very dependent on the fairness and transparency of the

program's procedures.

As a consequence of this work, these workers are at increased risk of developing cancer and other occupational illnesses. Because information on the exposures and the consequent health risks were hidden from these workers for so many years, Congress established the Energy Employees Occupational Illness Program in 2000 to provide some compensation to these workers and their survivors for their work-related health problems. In doing so, Congress recognized that attempting to provide fair and equitable compensation for people working at these facilities for the past 50 years or more was difficult and, in many cases, would not fully compensate these people or their families for their suffering and sacrifice for our country. The part of the Act under consideration at this hearing involves compensation for

The part of the Act under consideration at this hearing involves compensation for people with work-related cancer due to radiation exposures. The program as established in EEOICPA and implemented through the Department of Labor and the National Institute for Occupational Safety and Health (NIOSH) attempts to evaluate the past radiation exposures for the claimants at nuclear weapons facilities and then calculates the probability that their cancer was caused by exposures at the fa-

 $\operatorname{culity}(\mathbf{s}).$

NIOSH's major task under this part of EEOICPA is to obtain past monitoring records for the claimant along with other technical information on the facility(s) where they worked that would help to estimate the claimant's exposure. NIOSH then utilizes this information to estimate the cumulative radiation exposure for that individual. This is a complex task requiring review of many different sources of records and other information. A claimant may have had exposure to many different radioactive elements and have been exposed in many different manners. The monitoring records may extend back over 50 years and reflect time periods when monitoring methods were less precise than today. NIOSH has had to develop new procedures and correction factors to appropriately estimate these past exposures

dures and correction factors to appropriately estimate these past exposures. If a "reasonable" estimate of a claimant's exposure can be made, the probability that a claimant's cancer was due to this exposure is estimated. This procedure (established by the EEOICPA) utilizes a mathematical model developed by the National Cancer Institute and modified by NIOSH for use in this compensation program. The model is based on cancer studies of people exposed to radiation whose health status was traced for many years (mainly those exposed from the atomic weapon explosions in Japan during World War II). The procedure established under EEOICPA takes into account the risk that the claimant's particular cancer could be caused by their radiation exposures as well as the precision of that estimate (i.e., the possible error in the estimate due to the limitations of the health and exposure data). NIOSH then provides these data to the Department of Labor who performs the final calculations for the purposes of accepting or denying the cancer claim.

SPECIAL EXPOSURE COHORT

In establishing this program, Congress recognized that there would be circumstances where dose reconstruction would not be feasible due to the lack of adequate information on the claimant's exposure at the nuclear weapons facilities. Exposure records may not be available. The claimant may not have had their exposure to a particular radioactive material monitored during that time period. A method for measuring that particular exposure may not have been available at that time. Rather than requiring the claimant to somehow prove that they had sufficient exposures to warrant compensation (an almost impossible task given the length of time involved and the secrecy in place at the facilities), Congress established the Special Exposure Cohort.

The Special Exposure Cohort provides compensation for claimants with 22 specified cancers who worked at certain facilities for a specified length of time. Congress established four such groups in the legislation and gave the Department of Health and Human Services the power to add additional groups. Individuals or groups rep-

resenting claimants or potential claimants can petition NIOSH requesting that a specific group be added to the Special Exposure Cohort. If the petition is deemed valid by NIOSH, NIOSH then evaluates the merits of the petition and presents a report to the Advisory Board regarding the merits of adding the group to the Special Exposure Cohort. The Act provides that a new group may be added to the Special Exposure Cohort when the "it is not feasible to estimate the dose that they received with sufficient accuracy" and if their health was endangered as a result of their exposures. The Board then reviews the NIOSH evaluation report and makes an independent recommendation to the Secretary of HHS regarding the petition.

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

The Advisory Board on Radiation and Worker Health was established under EEOICPA to review the regulations establishing the methods to be used in the dose reconstruction effort and Special Exposure Cohort evaluations; to review the scientific validity and quality of the dose reconstruction effort; and to review the additional groups proposed for inclusion in the Special Exposure Cohort (described above). The Board is required to represent "a balance of scientific, medical, and worker perspectives".

The Board is appointed by the President. The Board has had up to thirteen members. One resigned due to a conflict of interest, and another died. Recently, two members were dismissed from the Board, and three new members were added. The current Board represents diverse view points including people who formerly worked for the Department of Energy or their nuclear facility contractors as well as union representatives from DOE nuclear facilities. This balance of diverse perspectives helps to ensure that the Board's deliberations are thorough and that different views on issues are discussed.

The Board meets approximately four or five times per year with most meetings lasting three days. Public meetings by conference call take place between meetings. In addition, work groups set up by the Board also meet by phone or in person between meetings. Most of these work group meetings are open to parties involved in the facility under consideration. Transcripts of these Work Group meetings are also made and posted on the NIOSH OCAS website.

Given the considerable workload required by the Act to review the dose reconstruction program, the Advisory Board has obtained the services of a technical contractor (Sanford Cohen and Associates) to assist in the technical review of dose reconstructions, related technical procedure documents, and the special cohort evaluation technical documents. This contractor was selected through a full and open government procurement process. The contractor provides a number of highly qualified technical specialists to assist the Board and has greatly facilitated the work of the Board

Working with the contractor, the Board has established a program for reviewing dose reconstructions for a sample of individual claims and the NIOSH procedures and developed technical documents that provide the basis for NIOSH's dose reconstruction program. The Board's contractor conducts its review under the direction of the Board and the contractor's technical review is presented to the Board for discussion before being finalized and transmitted to the Secretary of HHS. The procedures used by the contractor for its audit were established and approved by the Board. After the initial review of cases, procedures, and/or documents by the contractor, the Board has established a standard process to ensure that NIOSH has the opportunity to review and comment on the contractor's review before the Board finalizes our comments to the Secretary. The review covers a wide range of technical issues related to individual dose reconstruction to ensure that the dose reconstructions are being done in a scientifically sound and balanced manner.

The Board has paid special attention to issues of potential conflict of interest among all groups working on this program. Given the concern of the people who worked at these facilities about ensuring that the compensation program is handled in a fair and impartial manner, strong conflict of interest provisions are necessary to ensure the credibility of the program. In selecting a contractor for assisting the Board, specific conflict of interest requirements were included in the review and operation of this contract. Conflict of interest information for our contractor and for Board members are available to the public through the NIOSH website for this program.

THE ADVISORY BOARD AND SPECIAL EXPOSURE COHORT REVIEWS

The Advisory Board has reviewed approximately 8 new special exposure cohort groups (NIOSH has sometimes combined petitions or split proposed groups into different time periods). Seven have been approved, and one denied by the Board. Sev-

eral are pending including one that was reviewed at a recent Board meeting and then deferred pending the receipt of further information from NIOSH (Pacific Prov-

All of these petitions have involved the early years of nuclear weapons production when monitoring data were sparse. In some cases, NIOSH's recommendation has been followed, while in others the Board's recommendation has differed from that of NIOSH. In some cases, the discussion of the petition has stretched over several Board meetings. In nearly, all cases the Board's vote on our recommendation has been close to unanimous despite the diversity of viewpoints on the Board.

The Board has worked with NIOSH to establish a sound and thorough independent technical and scientific review of the NIOSH evaluation of the special exposure cohort petition. I believe that this is what is envisioned under EEOICPA. The Board's contractor has done substantial work to review relevant scientific and technical documents and data, and there has been a thorough discussion of the scientific issues at the meetings. The petitioners have had good access to the review process

and a fair opportunity to provide their input.

Recently, the Board has worked with NIOSH to improve the process. Late last year, the Board has worked with NOSH to improve the process. Late last year, the Board established a working group of four Board members that I chaired to review our procedures for evaluating Special Exposure Cohort petitions and evaluations. The Working Group held a meeting in November 2005 with NIOSH staff participating to develop draft guidelines for our review. Draft guidelines were development of the process. Late last year, the Board members that I chaired to review our procedures and evaluations. oped, and this document was reviewed by other Board members and by NIOSH and made available to the public for review and comment. After some revisions based made available to the public for review and comment. After some revisions based on comments from Board members, the draft guidelines were discussed at our January Board meeting. The Board voted to adopt the guidelines with the understanding that they could be modified at a later time based on additional comments received from outside parties. I have attached a copy of the guidelines with my testimony. These guidelines provide a framework for the Board's review of Special Exposure Cohort petitions and NIOSH's evaluation of those petitions. The guidelines provide general criteria for evaluating information that might be used for dose reconstruction to determine whether are not that information provides a basis for adequate

tion to determine whether or not that information provides a basis for adequate dose reconstruction (i.e., "feasible to estimate the dose that they received with sufficient accuracy"). The Board believes that the guidelines will help to make the Special Exposure Cohort process more efficient, more timely, and provide a fair process for all groups seeking that status. The Advisory Board has also established a specific role for our contractor to assist in the review of Special Exposure Cohort ac-

My understanding is that the Department of Labor and the Office of Management and Budget have suggested some actions to address a perception that the current Special Exposure Cohort process is not working adequately. On the contrary, I believe that the current procedures provide what was called for in the EEOICPA legislation. First, the process is open to the public and to input from the public. Failure to ensure this level of transparency would severely damage the credibility of the program. Secondly, the process provides for sound scientific and technical review of any SEC recommendation by an independent advisory board with the assistance of a contractor with relevant scientific and technical expertise. This review process is similar to the scientific peer review programs in place for other government programs that are based on scientific and technical information. Thirdly, the recent changes to the process in accordance with the working group report should help to facilitate a more timely review process and, at the same, time one that ensures consistency and fairness in SEC recommendations.

In summary, I believe that the Advisory Board with the assistance of our technical contractor is providing sound and fair independent reviews of groups proposed for inclusion in the Special Exposure Cohort as required by the EEOICPA legislation. I would be glad to answer any questions that you may have.

Mr. HOSTETTLER. Thank you, Dr. Melius.

Mr. Miller.

TESTIMONY OF RICHARD D. MILLER, SENIOR POLICY ANALYST, GOVERNMENT ACCOUNTABILITY PROJECT

Mr. MILLER. Thank you, Mr. Chairman.

My name is Richard Miller. I'm a Senior Policy Analyst for the Government Accountability Project. Among its functions, GAP oversees agencies implementing the Energy Employees Compensation Program and serves as an information hub for claimants, Congress, and the media. I have been privileged to work on the bipartisan effort that led to the enactment of this landmark legislation in 2000, which included testifying before this Subcommittee in September of 2000. We appreciate the opportunity to testify again before the Subcommittee and commend the Chairman of the Subcommittee for using the Committee's jurisdiction to conduct oversight hearings.

Congressional investigations an numerous oversight reports have documented that radiation dose records of the Department of Energy and its vendors were, as you have stated earlier, nonexistent, incomplete, or unreliable. My written statement lists three examples in Nevada, Iowa, and Kentucky, but there are many more. In cases where there is inadequate monitoring, Congress wanted to ensure that nuclear weapons workers with cancer would not face an insurmountable burden of proof when they filed a claim. Congress put in place a relief valve that when it is not feasible to estimate dose with sufficient accuracy and there is a reasonable likelihood that the class of workers may have been endangered from radiation exposure. They have a remedy, and that is to be designated as a member of the special exposure cohort.

There is a four-step process for evaluating these special exposure cohorts —with built-in checks and balances to ensure that all viewpoints are heard and that each SEC designation is scientifically credible. The Secretary of HHS, as you have heard, makes the final decision after receiving a recommendation from the Advisory Board.

While there are six special exposure cohorts that have been approved to date, HHS has denied two and disqualified nearly 20 at its earliest stages of review, and the inference in the OMB passback document that these are being handed out like candy simply is not supported by the record. We have seen in particular well-merited approvals at Mallinckrodt in St. Louis, at the Iowa Army Ammunition Plant in Burlington, Iowa, at Linde in Tonowanda, New York, and for the Y-12 Calutron workers in Oak Ridge, Tennessee.

Today my testimony will primarily focus on the pass-back memo which outlines five options to reduce the number of SECs approved by the Secretary of HHS in order to, quote, contain the growth in benefit costs. OMB has proposed four actions in a document which, I note, was not included in the President's budget request. That came to light independently and separately, which if adopted constitute a direct attack on the checks and balances set forth in the law: One, by requiring the Secretary to secure through the Administration or White House-led task force before making any approvals; by addressing this so-called, "imbalance," in the Advisory Board; by adding yet another outside review on top of the Advisory Board's review; and by imposing unspecified constraints, quote-unquote, on the Advisory Board's audit contractor.

These administrative changes if implemented in whole or in part will undermine the credibility of benefit determinations. By requiring Administration clearance, the OMB memo implies a lack of trust in the Secretary of HHS's decisions. Administration clearance—and I want to be very clear on this point. Administration clearance is not merely an innocent call for improved communica-

tions as we have heard from OMB and other witnesses here today. This is not about drawing sharper boundaries about SECs in order to more precisely adjudicate claims. It is a plan for preempting the legal authority and the professional judgment of the Secretary and the Advisory Board. The term "imbalance" and "constraints" that are discussed in this OMB memo must be defined. Frankly, the memo committed the error of candor by using those words.

It appears that the OMB considers the advice provided by the President's Advisory Board and even perhaps its audit contractor as not trustworthy and that absent Administration intervention, unwarranted benefits are going to be paid out through special exposure cohorts, and yet, as we have heard, the Advisory Board is required by law to have a balance of medical, scientific, and worker perspectives and as well there has to be a balance proscribed under the Federal Advisory Committee Act.

It's with that in mind that we note that two members of the Advisory Board were removed without cause in January of 2006, and three members were appointed, including two with potential conflicts of interest. That too is troubling.

Given the OMB's goal of reducing special group cohort approvals as a way to cut benefit costs, the call to address any imbalances in the Advisory Board looks like a prescription to add new Board members with a philosophical tilt against special cohorts. Indeed, the Office of Management and Budget memo commends the Employment Standards Administration within the Labor Department for bringing concerns about SEC benefits costs to the attention of OMB. DOL's fingerprints on this OMB memo has regrettably stained its reputation as a dispassionate claims adjudicator.

The Energy Employee Compensation Act was an apology for putting defense nuclear workers in harm's way and not adequately protecting them, and in turn these workers expect that the Government will honor its commitment to provide fair compensation decisions. Yet this OMB memo suggests that they, the Administration, are intent on dishonoring this commitment. It rubs salt in the wounds of these patriotic Cold War workers to hear that the goal is to constrain benefit costs.

There are six new special exposure cohort petitions currently under evaluation, and this pass-back memo hangs ominously over these and future SEC evaluations. If HHS is directed to deny SECs as a way to reduce benefits costs, even though there are inadequate records to make a fair compensation decision, then these workers and their families have every reason to be cynical.

In conclusion, unless the OMB's options outlined in this passback memo are disavowed at the highest levels of the Administration, these Cold War veterans can justifiably question whether each SEC denial is a product of OMB budget-cutting and political meddling rather than a scientifically-credible decision. It is imperative that we restore the program's credibility.

I thank you for your time.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF RICHARD D. MILLER

GOVERNMENT ACCOUNTABILITY PROJECT

NATIONAL OFFICE
1612 K STREET, NW SUITE #1100 • WASHINGTON, D.C. 20006
202.408.0034 • <u>www.whistleblower.org</u>

TESTIMONY OF RICHARD D. MILLER SENIOR POLICY ANALYST GOVERNMENT ACCOUNTABILITY PROJECT

BEFORE THE

COMMITTEE ON JUDICIARY SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY AND CLAIMS U.S. HOUSE OF REPRESENTATIVES

"THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT – ARE WE FULFILLING THE PROMISE WE MADE TO THESE VETERANS OF THE COLD WAR WHEN WE CREATED THE PROGRAM?"

MARCH 1, 2006

SUMMARY OF TESTIMONY OF RICHARD MILLER, GOVERNMENT ACCOUNTABILITY PROJECT

An OMB "Passback" memo to the Department of Labor ("DOL") outlines options for administrative procedures to reduce the number of Special Exposure Cohorts ("SEC") approved by the Secretary of Health and Human Services ("HHS") as a way to contain the growth in benefit costs under the Energy Employees Occupational Illness Program Act ("EEOICPA"). The OMB memo implies that the HHS's decision making process is out of control, that the President's Advisory Board on Radiation and Worker Health ("the Advisory Board") and its audit contractor are not trustworthy, and that, absent Administration intervention, unwarranted benefits will be paid out for radiation related cancers.

In providing for Special Exposure Cohorts as part of EEOICPA, Congress found that the radiation dose records of the Department of Energy ("DOE") and its vendors were of questionable reliability, and were concerned that the absence of exposure monitoring would leave nuclear weapons workers with cancer facing an insurmountable burden of proof. EEOICPA provides claimants with a relief valve where it is not feasible to estimate the radiation dose to workers with sufficient accuracy: HHS may designate additional members of the SEC after receiving a recommendation by the Advisory Board. Members of the SEC receive an automatic presumption that their cancer is work related if they have 1 of 22 "radio sensitive" cancers and were employed in a job with potential radiation exposure for 1 year—without having to secure a radiation dose reconstruction through the National Institute for Occupational Safety and Health ("NIOSH"). Subtitle B provides a \$150,000 lump sum benefit plus medical benefits.

Congress mandated a 4-step SEC evaluation process with checks and balances to ensure that all viewpoints are heard and that each SEC designation is scientifically credible. OMB has proposed 4 actions which, if adopted, constitute a direct attack on the checks and balances set forth in law by (1) by requiring the HHS Secretary to secure permission of the Administration or a White House led task force before making any SEC designations; (2) by loading the Advisory Board with members who will oppose SECs in the name of addressing "imbalance"; (3) by adding another review on top of the Advisory Board for each SEC decision; and (4) by imposing unspecified "constraints" on the Advisory Board's audit contractor. The result: budget cutters and political advisors will dictate SEC decisions, in place of a transparent scientific process.

Atomic workers served their nation's defense by building and testing nuclear weapons, while putting their health in jeopardy. Most would do it over again without hesitation, if called upon to do so. They expect, in turn, that the Government will honor its commitment to provide fair compensation decisions if they were made ill from their work in nuclear weapons facilities. However, this Passback memo suggests that OMB is intent on dishonoring this commitment. The DOL's fingerprints on OMB's plan stains their reputation as an impartial arbiter of claims.

Unless the OMB's plans are disavowed at the highest levels, the credibility of the Energy Employees Compensation program is in jeopardy. Nuclear workers can and will justifiably question whether each and every denial is a product of interference driven by OMB budget cutters—rather than a scientifically credible decision—unless OMB/DOL's posture is reversed.

INTRODUCTION

I am Richard Miller, a Senior Policy Analyst with the Government Accountability Project ("GAP"), a non profit organization based in Washington, D.C. Although GAP's work is primarily focused on supporting whistleblowers, our programs include the oversight of the agencies implementing EEOICPA. GAP serves as an information hub for claimants, Congress, unions and the media. GAP assisted with the EEOICPA reform amendments in 2004 which were included in the FY 05 Defense Authorization Act (P.L.108-375). Prior to GAP, I was a staff representative for DOE atomic weapons employees, and worked on the bi-partisan effort to enact EEOICPA¹ as part of the FY 01 Defense Authorization Act (P.L.106-398).

We appreciate the opportunity to testify today before the Subcommittee, and commend the Judiciary Committee for using its jurisdiction to conduct oversight hearings on EEOICPA.

The effort to secure compensation for workers made ill from employment in nuclear weapons facilities has been underway for over 40 years. Since the late 1940s, senior Atomic Energy Commission officials recognized that "cancer is a specific industrial hazard of the atomic energy business." Beginning in the late 1950s, Congress held a series of hearings on establishing a federal compensation scheme for nuclear weapons workers. This effort has been driven by the inability of state workers' compensation programs to adequately deal with occupational illnesses (as opposed to injuries), and the difficulty in overcoming the unlimited resources spent by the Energy Department to defeat such claims—without regard to merit.

UNMONITORED RADIATION EXPOSURES ARE THE REASON FOR SPECIAL EXPOSURE COHORTS

Numerous government and scientific reports document that the DOE failed to properly monitor workers at its nuclear weapons facilities, and that many of its records are unreliable-

¹ See: Testimony of Richard Miller before the Senate HELP Committee, Subcommittee on Employment, Safety & Training, May 15, 2000; the House Judiciary Committee, Subcommittee on Immigration & Claims (http://www.house.gov/judiciary/mill0921.htm) on September 21, 2000; and the Senate Energy Committee, November 21, 2003 (S. Hrg. Report 108-334, http://www.access.gpo.gov/congress/senate/senate/Seh108.html) ² Letter from E.W. Goodpasture, Vice Chair, Advisory Committee on Biology and Medicine, to Gordon Dean, Chairman AEC, December 1, 1951. Also see: Early Health Problems of the US Nuclear Weapons Industry and Their Implications for Today, Senate Committee on Government Affairs, S.Prt.101-63, December, 1989.

especially between the 1940s and the 1970s. Major deficiencies in monitoring programs persisted into the early 1990s at a number of DOE sites. Three examples follow:

• Nevada Test Site--Workers at the Nevada test site in the 1950s and 1960s were laid off or removed from the higher paying jobs in "forward areas" if they exceeded their quarterly dose limit of 3 rem. Supervisors were responsible for keeping track of the dose limits. Monitors placed radiation dose badges between 2 inch thick lead bricks when workers approached their quarterly limits. Workers at the Hardtack II blast were told "don't get overexposed; we don't have anyone to replace you."

NIOSH's site profile for the Nevada Test Site excludes exposures during the period of atmospheric weapons testing prior to 1963, and excludes exposures to workers at 10 underground tests which blew out or vented radiation during the period between 1958-1986. There are no beta monitoring records prior to 1975.

• Iowa Army Ammunition Plant--Prior to 1968, fewer than 3 percent of the workers were monitored for external radiation exposure at the Iowa Army Ammunition Plant (IAAP) where they assembled and disassembled over 20 types of nuclear weapons. There are no internal radiation monitoring records throughout the 26 year history of this plant.

HHS approved a Special Exposure Cohort for the IAAP nuclear weapons workers, after receiving a unanimous Advisory Board recommendation (11-0). The audit contractor and board members reviewed classified weapons design records to ascertain the feasibility of reconstructing radiation dose at the IAAP and concluded it could not be done.

Paducah Gaseous Diffusion Plant-Uranium enrichment plant workers inhaled extremely radiotoxic dusts containing plutonium-239 and neptunium-237 from recycled uranium at the Paducah, Kentucky site, but were not adequately protected or monitored for nearly 40 years. A 1960 Atomic Energy Commission (AEC) memo explains why:

There are possibly 300 people at Paducah who should be checked out, but they [Union Carbide] hesitate to proceed to intensive studies because of the union's use of this as an excuse for hazard pay.

I also pointed out to Dr. Ward the need to get post mortem samples on any of these potentially contaminated men for correlation of tissue content

³ William J. Brady, Principal Health Physicist, Nevada Test Site (1952-1991), Review of the NIOSH Site Profile for the Nevada Test Site, December 13, 2005, SCA-TR-TASK 1-0006

March 11, 1960, C.L. Dunham, Director of the Division of Biology and Medicine, Atomic Energy Commission

with urine output, but I am afraid the policy at this plant is to be wary of the unions and any adverse public relations.

Paducah's management did not monitor workers (dead or alive) for neptunium and plutonium intakes until 1992—three years after the plant stopped processing recycled uranium. A DOE-sponsored exposure assessment in 2000 found that maximally exposed workers could have received a committed dose between 599-2,238 rem to the bone.⁵ Whole body annual dose limits are 5 rem per year. EEOICPA designated Paducah plant workers who were employed between 1952-1992 for at least one year as members of the SEC--due to the lack of monitoring,

SPECIAL EXPOSURE COHORT: WHAT HAPPENS IF THERE IS NOT ENOUGH DATA TO RECONSTRUCT DOSE ?

EEOICPA directs NIOSH to establish procedures to "reconstruct" the radiation dose where records are missing or workers were unmonitored. However, in cases where "reasonable" doses cannot be estimated, claimants face an insurmountable burden of proof in establishing a may, subject to a recommendation by the Advisory Board, administratively designate classes of workers at a covered facility as members of the Special Exposure Cohort, without need for further legislation, if:

- (1) it is not feasible to estimate dose with sufficient accuracy the radiation dose that the class received; and
- (2) there is a reasonable likelihood that such radiation dose may have endangered the health of the members of the class.

Members of the SEC receive \$150,000 lump sum plus prospective medical costs for 22 listed cancers⁶. NIOSH estimates the 22 cancers cover 60% of the cases filed in this program.

⁵ U.S. Department of Energy, Office of Environment, Safety and Health, Exposure Assessment Project at

the Paducah Gaseous Diffusion Plant, December 2000, p. 77

The 22 listed cancers are: lung, bone, kidney, leukemia (other than chronic lymphocytic leukemia), multiple myeloma, lymphomas (except Hodgkin's disease), thyroid, male or female breast, esophagus, stomach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary or liver.

In 2000, EEOICPA legislatively designated 4 classes of workers as members of the Special Exposure Cohort: Enrichment plant workers at Portsmouth, Ohio; Paducah, Kentucky; Oak Ridge K-25 plant in Oak Ridge, TN; and workers employed at the Amchitka Island Test Site in Alaska during underground weapons tests. EEOICPA's Special Exposure Cohort provisions are modeled, in part, on those provided to uranium miners⁷, uranium millers/ore transporters⁸, and civilian atomic weapons test site personnel⁹ under the Radiation Exposure Compensation Act (42 USC 2201 note), as well as military personnel under the Atomic Veterans program (38 C.F.R. § 3.309(d))¹⁰. Although the compensation levels vary between programs, the common theme amongst these programs for radiation exposed workers is that claimants who meet the employment tests can be compensated without providing further proof that the cancer was caused by radiation exposure.

Executive Order 13179 issued on December 8, 2000 directed the Secretary of HHS to promulgate regulations for establishing membership in the SEC, and to consider and issue determinations on petitions by classes of employees to be treated as members of the SEC.

FOUR STEP ADMINISTRATIVE REVIEW PROCESS FOR EVALUATING SECS

There is a four step administrative review process for evaluating SEC Petitions:

⁷ A presumption is provided to uranium miners employed in uranium mines located in Colorado, New Mexico, Arizona, Wyoming, South Dakota, Washington, Utah, Idaho, North Dakota, Oregon, and Texas at any time during the period beginning on January 1, 1942, and ending on December 31, 1971, and who were exposed to 40 or more working level months (WLMs) of radiation while employed in a uranium mine, or worked for at least one year in a uranium mine during the relevant time period, and contracted primary lung cancer or certain nonmalignant respiratory diseases.

⁸ A presumption is provided to uranium millers or ore transporters located in Colorado, New Mexico, Arizona, Wyoming, South Dakota, Washington, Utah, Idaho, North Dakota, Oregon, and Texas at any time during the period beginning on January 1, 1942, and ending on December 31, 1971, who worked in a uranium mill or transported uranium (or uranium-vanadium ores) for at least one year during the relevant time period and contracted primary lung cancer, certain nonmalignant respiratory diseases, renal cancer, and other chronic renal disease including nephritis and kidney tubal tissue injury.

⁹ A presumption is provided to individuals who participated onsite in a test involving the atmospheric detonation of a nuclear device within the official boundaries of the Nevada, Pacific, Trinity, or South Atlantic Test Sites and, after the onsite participation, the claimant contracted one of 21 specified cancers.
¹⁰ The following atomic veterans are covered: internment as a prisoner of war (POW) in Japan; post-war occupation

¹⁰ The following atomic veterans are covered: internment as a prisoner of war (POW) in Japan; post-war occupation of Hiroshima or Nagasaki; participation in atmospheric nuclear weapons testing (such as the Nevada Test Site or the Pacific Proving Grounds); participation in underground nuclear weapons testing at Amchitka Island, Alaska; or assignment to a gascous diffusion plant at Padueah, Kentucky; Portsmouth, Ohio; or K-25 at Oak Ridge, Tennessee.

- (1) NIOSH first "qualifies" SEC petitions to make sure they are complete, and then evaluates such petitions within 180 days, after which it issues a recommendation to the petitioners and the Advisory Board;
- (2) the Advisory Board conducts an independent review and votes on a recommendation to the HHS Secretary. Subject to Advisory Board direction, the audit contractor assesses technical issues:
- (3) the Secretary issues a final agency decision within 30 days of receipt of the Advisory Board's recommendation and transmits it to Congress; and
- (4) Congress has 30 days to veto a SEC designation or allow it to go into effect.

As of February 26, 2006, this process was followed with 8 petitions. It has resulted in the approval of 6 SECs at 4 sites. HHS has denied 2 petitions and disqualified nearly 20 at the earliest stages of review. The SEC approvals to date are:

- Mallinckrodt Chemical Works, St. Louis, Missouri (1942-1948 and 1949-1957)
- > Iowa Army Ammunition Plant, Burlington, Iowa (1948-1949 and 1949-1974)
- Linde Ceramics, Tonowanda, New York (1942-1947)
- ➤ Y-12 Calutron Workers, Oak Ridge, Tennessee (1943-1947)

These four facilities listed above performed work during the earliest years of the nuclear weapons production operations. In these 6 cases, the HHS determined that there was no formal health physics program, and where the radiation monitoring did exist, it was too limited to complete a credible radiation dose estimate. About 1,125 cases are covered which involve the compensation of the 22 listed cancers, according to recent NIOSH statistics.

There are 5 SEC petitions which have been "qualified" and are undergoing evaluation.

Two have exceeded the 180 day deadline for submission to the Advisory Board (Rocky Flats and Y-12). Four of these SEC Petitions are on the Agenda for the April 2006 Advisory Board:.

- Rocky Flats Plant, Denver, Colorado
- Y-12 Plant steamfitters and pipefitters from 1949-1957, Oak Ridge, Tennessee
- Ames Laboratories, Ames, Iowa
- Pacific Proving Grounds, Marshall Islands
- · Chapman Valve, Springfield, Massachusetts

The following nine petitions are in the early stages of review and have not yet been "qualified" for evaluation:

- o NUMEC, Apollo, Pennsylvania (1957-86)
- Fernald Site, Harrison, Ohio (1951-89)
- o Monsanto Research, Dayton, Ohio (1943-46
- o Nuclear Metals, Concord, Massachusetts (1981-1991)
- o Blockson Chemical, Joliet, Illinois (1952-62)
- Oak Ridge Institute for Nuclear Studies, Oak Ridge, Tennessee (1950-1956)
- Hanford, Washington, DuPont employees 1943 to September 1, 1946
- o Los Alamos Lab, Los Alamos, New Mexico (1943 to 1975)
- Y-12 Nurses, Oak Ridge Tennessee (1956 to 1957 and 1962 to 1964)

OMB'S "PASSBACK" DETAILS WHITE-HOUSE LED INTERAGENCY GROUP TO REVIEW ADMINISTRATIVE OPTIONS TO REDUCE SICK WORKER BENEFIT COSTS

The Office of Management and Budget (OMB) "Passback" to the DOL states:

- Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Part B. ESA¹¹ is to be commended for identifying the potential for a large expansion of EEOICPA Part B benefits through the designation of Special Exposure Cohorts (SEC). The Administration will convene a White House-led interagency work group including HHS and Energy to develop options for administrative procedures to contain growth in the cost of benefits provided by the program. Discussions are not limited to, but will involve, the following five options.
 - 1. Require Administration clearance of SEC determination[s];
 - Address any imbalance in membership of President's Advisory Board on Radiation and Worker Health;
 - Require an expedited review by outside experts of SEC recommendations by NIOSH;
 - Require NIOSH to apply "conflict of interest" rules and constraints to the Advisory Board's contractor; and
 - Require that NIOSH demonstrate that its site profiles and other dose reconstruction guidance are balance[d].

ANALYSIS OF THE OMB OPTIONS AND RECOMMENDATIONS

1. "Require Administration clearance of SEC determination|s|."

In order to "contain growth in the cost of benefits," OMB's "Passback" memo proposes to have Administration officials clear all decisions by the HHS Secretary regarding SEC petitions. If adopted, the requirement for "Administration clearance" would apparently override

¹¹ ESA is the Employment Standards Administration within the DOL. The Office of Workers' Compensation Programs (OWCP) which administers EEOICPA is part of ESA.

the scientific findings of the HHS Secretary, NIOSH, the Advisory Board and its contracted health physicists, and pre-empt the 4-step review process outlined in EEOICPA. By having OMB (or an interagency group which they convene) override the scientific review process and the legal requirements set forth in EEOCIPA and HHS regulations (42 CFR Part 83), it would appears to render the Advisory Board's work largely ceremonial and will undermine the credibility of the program

To date, each SEC petition has gone through a rigorous, public scientific assessment of a facility's radiation monitoring practices and production hazards to determine if "it is not feasible to estimate dose with sufficient accuracy." In addition to reviewing the NIOSH Special Cohort Evaluation Reports, the Advisory Board has tasked their audit contractor, S. Cohen and Associates (SC&A), to assist in the technical analysis. SC&A's health physicists interview site experts, review historical records, and analyze the technical approaches used by NIOSH, and then present their independent assessments to NIOSH, the Board and the public. Congress also relies upon these assessments for guidance in judging the scientific issues.

OMB's desire to contain the growth in the cost of benefits curiously overlooks the questionable growth of administrative costs. NIOSH's dose reconstruction contractor has seen its costs grow from \$74 million to at least \$200 million over five years.

DOL's FY 07 Budget Request projects a drop in Subtitle B benefits from \$460 million in FY 2006 to \$277 million. DOL has not explained whether this accounts for implementation of the options outlined in the OMB "Passback" memo, or whether this merely reflects a falloff in claims activity as NIOSH works down its backlog of dose reconstruction cases, or whether it reflects both.¹²

Conclusion: New SEC petitions could be denied or reduced in scope if the White

 $^{^{12}}$ The savings from eliminating new SEC might save upwards of \$100 million, but this amounts to less than 6/1000ths of a percent of annual entitlement spending 3/100ths of a percent of the deficit.

House/OMB dictates decisions on SECs to the HHS Secretary. The price for political meddling is that SEC denials will lack credibility and will be presumed to be decided by the White House based on budget grounds rather than scientific grounds. Budget-driven SEC decisions should not override or circumvent the scientific review process. The costs that have run out of control are those for the dose reconstruction contractor, not SECs.

2. "Address any imbalance in membership of President's Advisory Board on Radiation and Worker Health."

The term "imbalance" must be defined. Given the OMB's goal of reducing the approval of Special Cohorts, this option appears to be designed to load the Advisory Board with new members who would have a philosophical tilt in favor of DOE's radiation dosimetry programs and against SECs. This mindset defeats the very purpose of an independent Advisory Board which is to instill credibility in the scientific evaluation process—and not serve as a rubber stamp for anyone.

The General Accounting Office recommended that the Defense Department establish an Advisory Board for the Atomic Veterans program because there was strong criticisms by veterans groups about the validity of the dose estimates and the conflicts of interest by the agency and contractors performing the dose reconstructions. GAO found¹³:

Veterans and veterans' service organizations have expressed concern over the completeness of data used by DOD and the methodology it uses to estimate doses, particularly doses from inhaled or ingested radioactive particles. Some are also skeptical about DOD's ability to be unbiased in the dose reconstruction process, since DOD was responsible for the atmospheric testing that exposed the veterans to radiation.

To prevent conflicts of interest, EEOICPA precluded DOE or its staff from performing dose reconstructions. However, after NIOSH was assigned this task, it contracted with a major DOE prime contractor, Oak Ridge Associated Universities (ORAU), to perform the dose reconstructions. ORAU staffed up with DOE contractor staff, thereby circumventing the

¹³ Veterans Benefits: Independent Review Could Improve the Credibility of Radiation Exposure Estimates, Report to the Committee on Veterans Affairs, January 2000, GAO/HEHS-00-32, pp. 8

statutory prohibition intended to prevent this conflict of interest. These conflicts have raised significant doubts about the credibility of the science being used for dose reconstruction. To date, NIOSH's conflict of interest policy has been largely ineffectual, and NIOSH staff has allowed ORAU to evade key restrictions. The presence of such glaring conflicts of interest increases the necessity of having an independent Advisory Board to serve as a check and balance.

The GAO assessment of the Atomic Veterans Program identified a need for peer review:

The Institute of Medicine has been critical of the program's lack of quality control, including the lack of a peer review process. The National Research Council has also suggested that dose reconstruction be reviewed, or subjected to peer review, by outside independent scientists. It has reported that such review could result in greater public confidence in dose reconstruction.

The drafters of EEOICPA heeded the GAO's advice, and established an Advisory Board to conduct a peer review through "an independent review process." It is tasked to: (1) make recommendations on Special Exposure Cohorts, (2) audit the quality of dose reconstructions, and (3) assess NIOSH procedures.

EEOICPA requires the Advisory Board to have a balance of medical, scientific and worker perspectives, and authorizes staff support for the Board activities. The Advisory Board is appointed by the President and operates under the Federal Advisory Committee Act. It has 12 members at present. It meets at least quarterly and has 8-12 subcommittee or working group meetings per year. To date there have been 35 full Board meetings

After the White House added several workers to meet the statutory requirements in late 2001, the Board enjoyed a genuine "balance" in terms of perspectives—with a 6-6 split. However, this balance required Board members to reach a consensus and no perspective dominated.

In January 2006, the White House removed two members without cause (Dr. Anderson of Wisconsin and Mr. Espinosa of New Mexico), and appointed three new members (Mr. Poston of

Texas, Dr. Lockey of Ohio and Mr. Clawson of Idaho). Since these new members have not participated in Board deliberations up to this point, it is premature to judge the impacts of these changes. However, two of these new members may have conflicts of interest. One individual has had two of his children working for a subcontractor to NIOSH; and another Board member serves as a DOE-appointed expert serving as a defense expert in evaluating workers' compensation claims.

There has been an ongoing effort to impair the independence and effectiveness of the Advisory Board even prior to the OMB/DOL recommendation:

- In 2004-5 NIOSH program staff worked to weaken the independence of the Advisory Board and its audit activity. NIOSH staff blocked the Board from using its audit contractor for SEC Reviews. Staff said that the auditor was engaging in "scope creep."
- NIOSH Program staff urged the White House Presidential Personnel Office to replace Dr. Anderson and Mr. Espinosa, even though, from my perspective, they were contributing effectively to the work of the Board¹⁴.
- In December 2004, DOL declared that there was a \$3 million ceiling for the 5-year audit
 process, even though Congress had not set a cap. As the dose reconstruction program
 grew and NIOSH's projected costs tripled, it became evident that the audit effort would
 be larger than originally anticipated.

Although EEOICPA does not specify term limits for Advisory Board members, HHS-established 3 year terms. The term for 4 of the 12 Advisory Board members expired in August 2005; however, they continue to serve at the pleasure of the President. Based on the Passback memo, it appears that OMB and DOL would like to replace some of these Board members as a way to reduce approvals of Special Exposure Cohorts.

Conclusion: The OMB plans to address "any imbalance" in the Advisory Board appears to be code language to load the Advisory Board with new members who will oppose new SEC's and reduce benefit costs. A genuinely balanced and independent Board—coupled with an audit contractor which is not threatened with constraints—is essential to counter this program's built-

This is based on attending 32 of the 34 Advisory Board meetings that were open to the public.

in conflicts of interest. Should the OMB move forward with the option to further stack this Board, the program's scientific credibility will be crippled. As a result of the three recent Board appointments, it is likely that Board has taken on more decidedly pro-DOE bias. This will make it all the more difficult for the Advisory Board to hold accountable those former DOE contractor staffers who are conflicted.

3. "Require an expedited review by outside experts of SEC recommendations by NIOSH."

There is already an outside "peer review" of SEC Petitions. But OMB seems to want another one which circumvents the Advisory Board. Under the current process, NIOSH must justify to the Advisory Board why it cannot reconstruct dose, if it recommends approval of an SEC. Likewise, it must prove to the Advisory Board that it can reconstruct dose for a representative sample of cases, if it recommends the denial of a SEC Petition. The Advisory Board's review of SEC Petitions involves the following elements:

- NIOSH "site profiles" are critically evaluated to look at data adequacy. The Board asks
 "is there enough data to reconstruct a reasonable radiation dose estimate?"
- The Advisory Board has developed formal criteria. They evaluate whether "co-worker"
 data is a reliable surrogate when individual dose records are missing. Site experts are
 frequently consulted on working conditions to test NIOSH's assumptions against the real
 world. The audit contractor has assisted with these technical assessments.
- Example: Mallinckrodt never measured worker exposure to three extremely radiotoxic
 substances. The audit contractor demonstrated that these unmonitored isotopes dominated
 the radiation risk for certain organs. NIOSH contended that it could estimate dose for
 these unmonitored exposures in theory, but the Board wanted more than conjecture. To
 evaluate this, the Board secured 4 audit reports, held 3 dedicated Board meetings,
 exchanged data in working groups, and demanded NIOSH provided "proof of process."
- SEC petitioners are invited to address the Advisory Board and participate in working group meetings and conference calls.
- The Advisory Board and NIOSH carry out their reviews in open meetings which are transcribed. Phone calls between the audit contractor and NIOSH are memorialized in detailed written summaries. Congress is able to monitor this process. This transparency increases credibility.

<u>Conclusion:</u> DOL has never voiced a technical concern about an SEC Petition at an Advisory Board meeting, yet OMB proposes a duplicative review process to second guess HHS and the Advisory Board. Absent an open and deliberative evaluation process, the DOL's review

will lack scientific credibility. EEOICPA provides the HHS Secretary with 30 days from receipt of the Advisory Board's recommendation to render a decision. As a practical matter, it is unlikely that an "expedited review" could evaluate complex issues in 30 days.

Unless the goal is to circumvent the Advisory Board's peer review process, or counter their recommendations, why have a second review?

4. "Require NIOSH to apply "conflict of interest" rules and constraints to the Advisory Board's contractor."

OMB/DOL needs to declare what it perceives to be audit contractor's conflicts of interest and what it means by the term "constraints" on the contractor.

When the audit contract was being developed, the Advisory Board imposed conflict of interest requirements far more stringent that those required under federal law because the integrity of the technical advice provided to the Advisory Board had to be beyond reproach. Indeed, these restrictions are far greater than those imposed on NIOSH, Oak Ridge Associated Universities ("ORAU"), or members of the Advisory Board. The Advisory Board is fortunate to have been able to find a "white hat" firm which brings the needed technical competence while having complete independence from the DOE and its contractors.

SC&A submitted a conflict of interest plan to the Advisory Board on August 24, 2004 which restricts any SC&A Team members who was previously involved in health physics programs at a DOE site from having any involvement in auditing at that site. This plan also prohibits SCA Team members from having any involvement, if they served as an expert witness for DOE in cases involving radiation related claims. Further, SC&A cannot bid on work with NIOSH, DOE, or their contractors while they are serving as the audit contractor.

Some SC&A staff have well-publicized positions on the weaknesses in DOE's radiation dosimetry programs, and their skepticism is well founded. SC&A reports have exposed weaknesses in NIOSH site profiles and dose reconstructions. Their approach in auditing is well-

balanced: they have found cases where radiation dose is underestimated and other cases where radiation dose is overestimated. To resolve technical differences, the Advisory Board oversees a 6-step "comment resolution" process between NIOSH staff and SC&A staff. In some cases, NIOSH has revised its technical approaches in response to the audit findings, and in other cases SC&A has withdrawn findings after receiving more information. A standardized set of procedures drives this peer review process.

The conflicts of interest which have significantly tainted this compensation program are rooted in ORAU—not SC&A. As noted above, ORAU has a 5-year contract with NIOSH for dose reconstruction and SEC evaluations. ORAU hired current and former DOE contractor and federal staff who managed health physics programs at the DOE sites where they are now tasked to write key documents used on compensation decisions. Listed below are five examples of conflicts of interest involving DOE contractor staff performing site profiles for ORAU:

- Hanford, Washington--Jack Fix and Don Bihl, who work for Battelle and managed Hanford's health physics programs for many years, were hired to write the Hanford Site Profiles (and revisions) for NIOSH. Battelle is still under contract to DOE to run the radiation dosimetry programs at Hanford.
- Idaho Labs, Idaho-- Norm Rohrig and Bryce Rich both managed the INEEL radiation protection programs, and prepared the NIOSH site profile at INEEL. Bryce Rich's disclosure indicates that served as a defense expert on radiation related worker claims.
- Pantex, Texas--Jerome Martin is leading the team writing the NIOSH/ORAU Pantex site profile. He previously managed the Pantex site health physics program.
- Paducah, Kentucky--Carol Berger wrote an internal radiation dose report for Martin Marrietta at Paducah in 1992. Then she was hired to write the "bulk of" NIOSH's internal radiation dose site profile at Paducah (internal dose), where she simply cut-and-pasted her previous assessment, which had been found several years ago to incorrectly minimize exposure to transuranics such as neptunium-237 and plutonium-239.
- Rocky Flats, Colorado—Roger Falk was a radiation monitoring manager at the DOE Rocky Flats plants from 1996 to 1998, and is now employed by ORAU as a "Principal Author" of the NIOSH site profile at Rocky Flats. He is assisting NIOSH/ORAU efforts in evaluating a Special Cohort Petition from the Rocky Flats workforce. While these individuals have important site knowledge which NIOSH and ORAU should

tap, the job of writing key decision documents means individuals with conflicts of interest are presumably assessing the validity of their previous work for application in a NIOSH site profile. Defects in scientific assessments have been directly traced to these conflicts of interest. Some individuals were expert witnesses on workers' radiation claims; they should not be writing key documents for a site where they had previously served as an expert. We note that the Director of NIOSH is now aware of these conflicts and is reworking the conflict of interest policy. However, we are puzzled how OMB/DOL could have overlooked these well-advertised conflicts of interest is puzzling, if rooting out conflicts of interest was a genuine concern.

It appears that OMB/DOL's goal is to hobble the effectiveness of the Advisory Board's audit contractor. The DOL's FY 07 budget request specifically removes the line item for the Advisory Board's audit contractor. NIOSH and the Advisory Board receive their funds for this program though DOL, instead of direct allocations from the Treasury. This pass-through budgeting process allows DOL to impact the work of NIOSH and the audit contractor. In response to DOL's threat to cut off funding for the audit contractor, the FY 06 Labor/HHS Appropriations Act allocated \$4.5 million for the Advisory Board and its audit contractor.

In late 2004, certain NIOSH Program Staff took actions which threatened the audit contractor's independence. We are pleased that NIOSH Director Howard eliminated "triple-hatting" where the senior manager overseeing the dose reconstruction program, Larry Elliott, was also serving as both the Designated Federal Official to the Advisory Board (which is overseeing his program) and overseeing the audit contractor's budget. Given the purported concern about conflict of interest, it is troubling that OMB overlooked this conflict of interest.

¹⁵ The FY 06 Labor, IIIIS Appropriations Act states: "[n]ot later than 30 days after enactment, in addition to other sums transferred by the Secretary of Labor to the National Institute for Occupational Safety and Health ("NIOSH") for the administration of the Energy Employees Occupational Illness Compensation Program ("EEOICPA"), the Secretary of Labor shall transfer \$4,500,000 to NIOSH from the funds appropriated to the Energy Employees Occupational Illness Compensation Fund (42 U.S.C. 7384e), for use by or in support of the Advisory Board on Radiation and Worker Health ("the Board") to carry out its statutory responsibilities under EEOICPA (42 U.S.C. 7384n-q), including obtaining audits, technical assistance and other support from the Board's audit contractor with regard to radiation dose estimation and reconstruction efforts, site profiles, procedures, and review of Special Exposure Cohort petitions and evaluation reports.

<u>Conclusion:</u> Given the stringent "conflict of interest" requirements already imposed on SC&A under their contract, the OMB's proposal appears to be without basis. OMB needs to declare why it is recommending the imposition of "constraints," in addition to SC&A's existing conflict of interest requirements, and how this will improve the quality of the audit.

SUMMARY

Atomic workers served their nation's defense by building and testing nuclear weapons, while putting their health in jeopardy from exposure to radiation, beryllium and other toxic substances. Claims for radiation related cancers depend on credible and complete radiation records. Where workers went unmonitored, and it is not feasible to estimate radiation dose with sufficient accuracy, Congress provided that workers may petition to be members of the Special Exposure Cohort and receive an automatic presumption their cancer was work related.

The OMB has recently outlined a set of options for administrative actions intended to cut SEC approvals as a way "contain growth in the cost of benefits." If implemented, these will eviscerate the statutory checks-and- balances designed to ensure fair decisions, and undermine the credibility of benefit determinations.

A heartfelt bipartisan effort led to the enactment of EEOICPA as a way to help these patriotic Cold War Veterans. If the Government now decides to "stack the deck" by dictating to HHS that they must deny SECs as a way to reduce benefit costs—even though there are inadequate records to make a fair compensation decisions—then the workers and their families have every reason to be cynical.

Unless the OMB's options outlined in the "Passback" memo are disavowed at the highest levels of the Administration, nuclear workers can justifiably question whether each and every denial is a product of political interference—rather than a scientifically credible decision. It is imperative that we restore the program's credibility.

Mr. HOSTETTLER. Thank you, Mr. Miller.

At this time, we will move to questions from the Subcommittee. First of all, Mr. Hallmark, I'd like to ask you about the issue of balance. Do you believe that the Advisory Board is unbalanced? According to the OMB memo, there is a desire for there to be balance on the Advisory Board, and what type of balance would be required to assist in what the OMB seems to say should be the mission of containing costs for the program?

Mr. HALLMARK. Well, Mr. Chairman, as I said, cost containment is not part of any strategy or involvement that the Department of Labor has had in this process. I would say, however, that the Board is a balanced FACA committee in the sense that it's representing different groups involved in the activity; however, from our perspective, we have seen indications, especially in terms of the presentations of the Board's contractor, of a not complete adherence to the instructions given by Congress to the Board, that is, that the Congress gave the Board the responsibility to evaluate the "scientific validity and quality" of dose reconstruction activities.

It appears from our hearing and reading of the activities of the Board and the contractor that the criterion has been shifted to be one of "can dose reconstructions become more overestimated than they started out to be." To back up a little bit, the statute rightly and NIOSH I think correctly makes every effort to give the benefit of the doubt to the worker and to provide where estimation ranges are open, to provide as much overestimation as is appropriate to make sure that the individual is getting a fair shake and that obstacles are removed. That's the baseline.

The discussion that has occurred in the Board and especially from the contractor has been almost exclusively focused on whether or not further examples or further additions of overestimation can be added to that process. There has been almost no discussion about whether any of the dose reconstructions under review are, in fact, overestimates beyond plausibility that yield an outcome that is not what was intended by Congress.

That's the balance issue that I would say needs to be addressed

with respect to the Board.

Mr. HOSTETTLER. I appreciate the fact that you point out that cost containment was not something that the law called for and that DOL does not recognize that, but it's my understanding that the pass-back memo actually commends a DOL employee for potentially large expansion of the benefits due to special exposure cohorts. Who at the Department at Labor would have suggested the impetus for the OMB pass-back memo regarding the expansion of benefits and the cost containment? Because either the Department of Labor was not thinking about that issue or they were asked by OMB, but somehow OMB took what DOL gave them and created a discussion memo talking about containing costs.

Who at DOL gave that input to OMB?

Mr. HALLMARK. Well, I am the face of DOL with regard to this program with respect to the interfaces with NIOSH, the Department of Energy, OMB, and others. So if there's a party who is involved in those kind of discussions, and as I said, the Department of Labor believes close coordination and discussion is appropriate in this multi-department entity and we have pursued that. It

wouldn't be appropriate for me to discuss the internal discussions about budget, which are always outside of the general discussion, but that's part of my role.

Mr. HOSTETTLER. All right. Thank you.

Dr. Howard, what do you make of the five options that are listed in the OMB document? OMD's suggestion that, first of all, the SEC, special exposure cohort, designation should be okayed by the Administration as opposed to the Secretary of HHS would tend to inform us that somebody at OMB or the Administration does not trust the Secretary to make this determination. I don't want to put words in your mouth, but that's kind of what it looks like at its surface.

Is there some reason for us to believe that?

Dr. Howard. I don't think so, Mr. Chairman. We're very proud of our Secretary, Secretary Michael Leavitt, and he does an excellent job with understanding our program and receiving our information that comes to us through this process that we start out with the petitioner, our evaluation, the Board presentation, the Board deliberation, their contractor's review, their vote, and finally

it goes through me to the Secretary.

I think it's fair to say that in terms of the balances issue, one could say that balance, like beauty, is sometimes in the eye of the beholder, and we try very hard at NIOSH as the primary source to receive nominations that eventually work their way through our department to the White House that makes the final decision about individuals. That's an open process. We invite anyone who has a nominee that fits in to these three categories that are statutorily based—the medical, scientific, and worker perspectives—invite them to give us those names and to vet them and bring them through the process.

So we think, as Dr. Melius mentioned, even to the point of nomination of members to the Board, we want to be as transparent as

possible.

Despite having those folks in those capacities, when you get on Board, as we all are, we're biased in various ways, and I think Mr. Miller referred to conflict of interest issues. We're trying to have the state-of-the-art conflict of interest for us, for our contractors, for the Board members. So we hope that despite whatever biases members bring to the Board, that they work hard on these very difficult scientific issues, and for the last 4 years that I've been in this program, I really have to applaud each of them for doing that. They spend countless hours going through extremely technical material, and I think they are personally very assiduously aware of their own biases and controlling that and looking at the science.

So I would say that we're trying very hard to achieve balance in

every way possible.

Mr. HÖSTETTLER. Have you been informed, has NIOSH or the department been informed, in general of this notion of a two-track ap-

proval of SEC designation?

Dr. Howard. Well, we are aware of that language. I would just say from the transactional process point of view, we have some very stringent statutory time lines that we honor, we try to honor in every way possible. We're not perfect in that, but we certainly try very hard. I don't see how there is room time-wise for any other

kind of review, even if such a review was thought to be in the best interest of the Government. It's a very tight process. So I don't see how it's practicable.

Mr. HOSTETTLER. Thank you. I agree, Dr. Howard.

Then one more question. My clock hasn't been up, and so we will

officially designate my time as 5 minutes.

Dr. Melius, you referred to the OMB document as creating changes in the program, and do you believe that the document actually creates substantive changes in the program if the document is enforced, executed, if the provisions of the document are enforced?

Dr. Melius. It certainly would, because it would change the whole process of the program, would make large parts of the process closed because it would be done within the Administration, not as part of an open review process, and as well as—you know, again, it's hard to tell what's meant by balance of the Board, but one would then also change the Board. So the whole workings of the program be changed, but particularly the lack of transparency to the process for what I see to be very little gain. I mean, we have I think a strong peer review. We continue to work to make it stronger, a scientific review. As I said, we have an excellent contractor as well as Board members, and I think it's important to clarify our contractor doesn't tell us what to do. We tell the contractor what to do.

The reviews that they do are under our direction. The reports that are submitted to the Secretary and the final recommendations are made by the Board members, not by our contractor. We asked our contractor to look at issues such as the benefit of the doubt or claimant favorability. That was one of the criteria they are supposed to look at in doing the reviews. So we have in essence tried to have a full and open review process, and I think the proposed changes would just change that so drastically. As I said in my testimony, I think it would very seriously undermine the whole credibility of the program, which is critical.

Mr. HOSTETTLER. Thank you, Dr. Melius.

The Chair recognizes the gentlelady from the Texas, Ms. Jackson, for questions.

Ms. JACKSON LEE. Thank you again, Mr. Chairman, and again

I offer my appreciation.

Let me say to the witnesses that I found your testimony to a one very instructive. Forgive me if I have to leave after this first line of questioning inasmuch as another Committee will be having a classified briefing in a few minutes, and so I will have to depart. I know that we'll have a follow-up meeting and hearing where other officials will provide information as well.

Let me ask, Mr. Hallmark, is the Department of Labor attempt-

ing to cut the benefits of these potential victims?

Mr. HALLMARK. No, we are not. As I said in my comments earlier, Ms. Jackson Lee, the department's interest is to make sure that the program is, in fact, fair and consistent. The benefits that we pay are mandatory entitlement benefits. They are adjudicated case by case, and the Treasury fills our funding to make sure that the moneys are there to pay whatever cases we approve.

We're not in business of trying to change the outcome in that respect, nor do we have particular views of a particular class being included or not included as an SEC.

Ms. Jackson Lee. In the course of attempting to, and I put this in quotes, fix the Advisory Board or fix the problem, did OMB engage the Department of Labor in your assessment of the program or your assessment of their potential changes? Did you have discussions with OMB?

Mr. Hallmark. As I said earlier, the discussions within the realm of putting together the President's budget are not open to the public, obviously, but we do talk about costs and streams of benefits and projections and so on as a normal discussion that goes on back and forth between Federal agencies and OMB each year.

Ms. JACKSON LEE. Well, would you have made recommendations

for this program to be cut?

Mr. HALLMARK. No. Are you referring, perhaps, to the projections in the 2007 budget?

Ms. Jackson Lee. I am and the fact that the program is perceived as being costly and that some of the procedural changes that OMB may be offering go more to saving money than to the substance of the program. So in the course of having to report on your budget, would DOL have inadvertently recommended that this program be cut?

Mr. HALLMARK. No, not at all.

Ms. Jackson Lee. Inadvertently or advertently.

Mr. Hallmark. No. I don't think that happened at all. The issue is with respect to projected budget outlays that are in the President's 2007 budget. These are estimates that we make based on our experience with the program to date and our understanding of the flow of cases through the pipeline. There is a reduction between 2007 and 2006 because we estimated a large increase in 2006, over \$1.5 billion being paid out this year with a reduction back to a more normal level in 2007. That had nothing to do with any assumption of changes to the program or policy implications at all. It was strictly based on our best understanding of how cases would be adjudicated in that time period.

Ms. Jackson Lee. So there was no advocacy on your part to

eliminate and/or downsize the program?

Mr. HALLMARK. Not at all, no. As I said, we want to see this program work as it was intended by Congress to work, and that's been our goal right from the beginning.

Ms. JACKSON LEE. Thank you.

Dr. Melius, thank you for your presentation. You are a Board member at this point. What is your tenure, sir? When were you appointed?

Dr. Melius. I was appointed as part of the original Board. So I think we started meeting in 2002.

Ms. JACKSON LEE. And do you have a sense of when your term ends?

Dr. Melius. My term is actually up, I believe. There have been delays in—we're continuing to serve. There are delays in the process, and we will see what happens. I don't know what will happen.

Ms. Jackson Lee. And the Board is comprised of how many members?

Dr. MELIUS. Currently, 12 members, and with the three additional members, I believe that brings us up to 13.

Ms. Jackson Lee. And are they all filled at this point?

Dr. Melius. They are all filled. We have three new Board members that have—as I mentioned before, two of the Board members were dismissed that had served really since the beginning, essentially, and then three new Board members were added. Those Board members will officially start serving at our next meeting, I believe, in April.

Ms. Jackson Lee. Obviously you may not be able to speak to the new Board members, but the distinguished members who served, were they competent and concerned about the program to your un-

derstanding or maybe what you saw of their work?

Dr. Melius. Yes. They've all spent a lot of hours, a lot of time devoted to this program. They represent—it's a diverse group. We represent a range of backgrounds, a range of views on a number of issues. We have struggled and had disagreements on certain issues, and we have worked very hard to try to reach consensus. I think most of our votes on issues, such as SEC recommendations, have been not unanimous, but close to unanimous. We work hard to reach agreement, to reach a complete understanding of the issues and so forth. We all have different backgrounds. I think that's helpful to the process.

Ms. Jackson Lee. You have offered some very important testi-

mony.

Mr. Chairman, I hope that we take note of Dr. Melius, who I understand is an M.D. and a Ph.D. and seems to be competent to me, and we should track whether or not after he leaves this room today he gets a very open-ended letter thanking him for his service. I will be outraged and I would like us to be collectively outraged, and I would like to insist upon his ability to continue his work. The fact that he has extended himself to come to this hearing should be noted.

Dr. Melius, you mentioned secrecy, and obviously that's not what we went intend to do with the Advisory Board, but on the other hand seeks to ensure fairness. The outside contractor was to add to that fairness and transparency. So, in essence, what could we possibly be fixing with the new options that seem to now being recommended? And let me share them with you: requiring the Administration clearance for all special exposure cohort designations, requiring an expedited review to outside experts, addressing any imbalance in membership of the President's Advisory Board on Radiation Worker Health, and imposing constraints on the Advisory Board's audit contractor.

What help does that give the decision-making and the ability for

petitions or claimants to be heard?

Dr. Melius. As I said in my testimony, I think we have a good sound process in place. The changes proposed, I do not think will add significantly to that. As Dr. Howard has pointed out, the only thing that some of those changes would add would be more time, and we already have a significant problem with this program, people waiting many years for their claims to be reviewed and adjudicated. We don't need to add that to the special exposure cohort process.

So I can see no significant benefit to the proposed changes and I can see losses in terms of time and timeliness and losses in terms of credibility by not maintaining an open and transparent process.

Ms. JACKSON LEE. In the work that you do, is your work paper-

work, or do you actually get to see the claimants?

Dr. Melius. Our Advisory Board holds meetings. Dr. Howard was warning me. We actually have to be careful not to interact too much on specific claims.

Ms. Jackson Lee. I understand.

Dr. Melius. Because of legal issues that are beyond me, but they are real. However, we do hold all of our Advisory Board meetings, nearly all of them at sites that are near the Department of Energy sites. We have public meetings usually in the evening so it's more convenient for people. So we hear from many of the claimants and their families in that general session.

Ms. Jackson Lee. And that's where I'm going. In the course of hearing from individuals, can you say that you have heard some very powerful stories, some very devastating stories, that most of what you've heard would err on the side of overwhelming as opposed to frivolous?

Dr. Melius. Oh, absolutely. These are not frivolous claims. These are people with cancer. Often we've had people come before our Board who are literally dying of cancer and are obviously frustrated by the delays in adjudicating their claims. We also have survivor family members with some very heart-wrenching stories about what their father did in working at the facility and with their frustration at not being able to have some of that information understood or not understanding why it takes so long for their claims to be adjudicated, but these are all people that, again, who worked so hard and sacrificed so much for our country.

I've spent 20 years working around these sites with doing studies and meeting with people, and people are all so dedicated and work so hard and again are just so frustrated by the secrecy, the denial, the initial denial that there was any problem, very happy that Congress recognized that something needed to be done, that they deserved compensation with this program, and some continued frustration with the fact that it takes time, that it's such a complicated and difficult program, and I think we need to keep that in mind as we work on this program and certainly in anything we do to try the fix this program.

Ms. Jackson Lee. I'd like to thank you very much.

If the Chairman would indulge me just to pose a question to Mr. Miller since he was so intimately involved in the constructing of this process, Mr. Miller, you mostly likely have been engaged in, I guess, partly the writing or the necessity of this legislation. One, do you have any knowledge of whether there's any whistle-blower protection for the Board or advisory members? Would that be a worthy addition? Do you know of the number of former representatives of unions that may be on the Board? And then, lastly, would you just comment for me your view as to whether or not the layering that seems to be offered by OMB is more stifling and stymieing the work of the Advisory Board or does it help the claimant in terms of making his or her case?

Mr. MILLER. Let me answer your questions, if I may, in reverse order.

First, I'd just like to point out that the OMB pass-back memo is, in fact, part of the deliberative process that Mr. Hallmark was talking about and was not made public, and had it not been made public, we would not know that this was the real hidden hand influencing who is on the Board, what happened to the audit contractor, and that the White House was second-guessing these decisions. So I'm very pleased, at least, that you held this hearing to air this out.

I think the problems are fairly straightforward. If the Government is going to stack the deck by dictating to HHS that they must deny special cohorts as a way to save money, then the credibility of the program crumbles. Period. It's not a science-driven process. It's a budget-driven process, and what Mr. Hallmark said here, frankly, is that the Department of Labor is very concerned about this becoming a budget-driven process, and while they may profess that it is not, his fingerprints or that of his colleagues are all over this document.

So I'm concerned that we have a process where scientifically-credible decisions are going to be subordinated to White House demands for budget cost constraints, and I think at the end OMB may have already started to play their hand in this process, as we've seen with the recent Board changes.

Secondly, with respect to the question of whistle-blower status for Board members, you point out that perhaps Dr. Melius took some courage to appear here today since his tenure is up, as is it for three other members and that the question of, "balance" as implied at least in this memo is that they need a balance of people who are going to put their elbow on the scale to deny benefits. The balance that I would hope the Board would have would be a six to six balance, which we have had over the previous three or 4 years, and in a genuinely balanced situation—and I have been to 32 of 34 open Board meetings—what we witness is a debate going on amongst the various perspectives and viewpoints and expertise that actually forces consensus decisions. If one side dominates over the other, you rubber stamp decisions or you allow people's biases to run amuck. It is my concern that the two Board members that were dismissed without cause and replaced with three new members may, in fact, affect that balance going forward.

Whether Advisory Board members need whistle-blower protection is a good question. I think everyone deserves and should have whistle-blower protection, particularly those who come to Congress and express their views and concerns. I believe there's a bill called the Paul Revere Act which specifically addresses that point.

Having said that, I would hope that you all would continue your vigilance with respect to what happens to the Board members as we go forward, and I very much appreciate it. Chills went up my spine when I noted that you picked up on the risk and exposure that these Board members have.

Thank you.

Ms. Jackson Lee. Thank you very much, Mr. Chairman.

Might I just say that as I depart, I know there are other questions, that with all of our work that we have to do with the raging

debate on immigration, I can't imagine that this is no less important, and I hope we'll follow this through to very end.

And I yield back. Thank you.

Mr. HOSTETTLER. Thank you. The Chair recognizes the gentleman from California for questions.

Mr. GALLEGLY. I thank for the Chairman for yielding, and I won't take my full 5 minutes because I know the witnesses probably wouldn't appreciate an hour and 20 minutes of my questions.

In any event, I'd just like to preface my remarks. I'm sure some of you are aware that I have represented the folks in the 21st, the 23rd, and the 24th Congressional District over the past 20 years which takes in the Santa Susana site, better known by many as Rockadine. In fact, my home has been within just a few miles of that site for the last 40 years.

I'd like to pose a question to both or either or Dr. Howard or Mr. Hallmark going back to my opening statement. In fact, I made reference to the fact that this site study or side profile or the threshold studies had not been completed yet. Some of these claims, the 31 specifically had been returned from NIOSH with instructions, and I do understand. The two questions I have, number one, is it is my understanding that as of two o'clock this afternoon, the study was reported out on the web site after we had sent many letters and made many phone calls, and I found it interesting that it was posted at two o'clock this afternoon, yet it was dated February 22nd. Now, I know it takes a long time to get through that little wire, and I'm not really totally computer literate, but it seems like even the mail service is faster than that.

So in any event, maybe you can explain that little detail, but more importantly than that is the issue of how you can explain 31 claims being sent back with instructions before you had a study to refer to. Either Mr. Hallmark or Dr. Howard.

Dr. Howard. I guess I'm being volunteered to start, and I may have to get back to you on the record on the details of this, sir, but as I understand it, in terms of the claims that we had at NIOSH that were pulled, the issue was over the eligibility of the claimants. My understanding is that the site is quite large. Portion of it are covered. Portions of it are not covered. And it was not a data access problem. I've been told that the site contact that we have for data is excellent and quite capable and is giving us any data that we require to do individual dose reconstructions.

That's my understanding right now, the information that I have with regard to this. Which portions of the site is covered, where the cases that we have, the employees that we have, which part of the site did they work at in terms of being eligible or not eligible, those are the issues that I think NIOSH was dealing with, and since those are not issues that we determine, those are more eligibility issues between DOE and DOL. That's my understanding.

Mr. GALLEGLY. For the record then, just so I understand, the 31 claims that had been returned, the threshold studies or the site profile would have been irrelevant for those specific 31 cases.

Dr. HOWARD. I don't think we got to the science issues in those cases. We were still at the eligibility issues.

Mr. HALLMARK. John, if I can interrupt, I think it is possible and does happen often that even if the site profiles have not all been

completed at a given site, there are some cases which on their face can be addressed without that further documentation. In other words, the case may be clearly compensable or clearly not compensable.

Mr. GALLEGLY. Can you say specifically for the record that was the case in these 31 cases?

Mr. Hallmark. I cannot say that for the record today.

Mr. Gallegly. I would appreciate, Mr. Chairman, if we could make the request that the Committee direct DOL to get us a formal response on that, because I think it's a very legitimate question.

Mr. HALLMARK. It's a very legitimate question.

Mr. Gallegly. And it's hard for me as a layperson to comprehend how you can make a final determination on something as important as this without the information necessary to make the adjudication, and so from a layman's standpoint, I ask that question, but that's one of the purposes of us being up here, to ask those type of questions.

Mr. Hallmark, I know that my friend from Houston, Ms. Jackson Lee, made a reference to the funding and the differential between

'06 and '07.

Mr. Hallmark. Yes.

Mr. Gallegly. And yet I'm still having a little problem with that, and maybe you can help me, because of the 434 cases that I'm aware of, only 10 have actually received any form of compensation through EEOICPA. I guess that's the way some pronounce it. In any event, you know what I mean.

Mr. HALLMARK. Yes.

Mr. GALLEGLY. If only 10 of 434 have received compensation, it's hard for me to understand why the budget is being cut in the future, through the next year from the present year, when you have basically maybe 5 percent, if that, and 95 percent that haven't been adjudicated.

Mr. HALLMARK. First of all, you weren't in the room when I addressed the question earlier, I believe. The issue here with regard to the budget is we make projections of what we think the outlays

are going to be.

Mr. Gallegly. Pardon me, but I was in the room and I did hear you say that, and I did make reference to Ms. Jackson Lee's question was, but my question was I still wasn't clear because there wasn't the analogy of 10 of 434, and that's why I'd like to have that part addressed.

Mr. HALLMARK. The projections for the large increase in the pipeline were for 2006, that a very large number of cases would be cleared out of the pipeline both under Part B, because my good friend Dr. Howard's staff would be clearing a lot of the cases that are currently in their jurisdiction and would come to us and then we would be able to pay them at the Department of Labor. With respect to the new Part E, a large number of the cases which we inherited from the Department of Energy would be moving through our adjudication process and reaching fruition in 2006.

So we projected that compared to a \$600 million pay-out in '05, we would have a \$1.5 billion paid out in '06, then falling back to, I believe, around \$800 million in '07. That appears to be a reduc-

tion in the '07 context, but it's really just the projections as best we make them about how cases were going to come to fruition. Now, obviously, if they don't, if fewer cases get adjudicated in '06, then that 1.5 number will turn out to be too high and more cases will probably end up falling into the 2007, and whatever money is required to make these payments will be provided by the Treasury.

Mr. Gallegly. Would it be safe for me then to say that my question is answered with great optimism on the part of the department, that the real answer to the question is we should be excited about the fact that it is going to be less next year than this year because it's your projection of those 434 cases, the overwhelming majority of them will be resolved this year even though only a pittance has been resolved in the past?

Mr. Hallmark. Well, first of all, the 400 is a small percentage

of the total value volume we're talking about.

Mr. Gallegly. I understand that, but I would think that Santa Susana should be represented pretty much as well as the other sites, and, believe me, I'm as concerned about the other sites as I am this. I'm just more intimately involved in this with the sheer numbers, and I would think that that percentage would bear pretty

much a fair relationship across the country.

Mr. Hallmark. Well, I would actually have to take issue with that notion in the case of Santa Susana, because as Dr. Howard alluded, there was a fairly substantial delay in coming to closure on what the actual dimensions of coverage are at that site under this program. This had to do with the designation that was originally produced by the Department of Energy with respect to which parts of the Santa Susana/E-Tech Rocketdyne facility were, in fact, to be covered, and there was a lengthy period of trying to come to closure on that. A relatively narrow original designation has now been broadened to cover a much larger area. That decision was reached in September of 2005, but as a result of the interplay that went on before that, these cases, the cases that you're particularly concerned about, and I understand why that is, were not moving forward on the same track as at many other sites.

So, in fact, while we will do our best, and I'm sure Dr. Howard's staff will do their best, to move them forward, now that those issues have been put behind us. They are behind the curve vis-a-

vis a number of other facilities.

Mr. Gallegly. Well, to say that I haven't been aware of what's gone on for the past 20 years there would be an understatement or an overstatement, however you want to refer to it, but I don't think there's been a meeting in the last at least 19 years where my staffers or myself, where someone hasn't been present; and prior to that, I happened to be Mayor of the city for 7 years of Simi Valley. So for 27 years, I have been very well connected with the problems of what we refer to as "on the hill".

I hope that now that we've got some of these roadblocks or diversions behind us that there will be an extra effort to clear these files, because folks, these people are dying. There are people that are dying, and the clock means more to them than it does to maybe some other Federal projects that we might have out there, if it was a bridge or a highway or whatever, because these folks are living with a very short clock, and I would just appeal to you from a humanitarian standpoint to try to do the right thing. I've got a lot of folks that are directly physically affected by this, and I make that appeal to you.

With that, Mr. Chairman, I yield back.

Mr. Hostettler. I thank the gentleman. I'm going to have a few more questions, not many, but I would like to elaborate on the budgetary implications of the OMB memo vis-a-vis the actual budget, and to quote from the OMB memo, quote, ESA, the Employment Standards Administration is to be commended for identifying the potential for large expansion of EEOICPA Part B benefits with the designation of special exposure cohorts, or SEC, unquote. Now, as far as the budget is concerned, if there is a large expansion of Part B benefits without the creation of a new regime or significant changes to the program, I would think that the budget would reflect a, "large expansion or increase in expenditures on the part of the EEOICPA Part B benefits."

But as I look at the actual budget appendix on page 733, the estimated expenditures for 2006 are \$460 million and the budget estimation for 2007 is \$277 million, a significant reduction in Part B benefits to be paid out, and we're discussing this memo in depth, at length. So if there hasn't been significant changes and the Department of Labor is suggesting to OMB that there's going to be to a large expansion of benefits, how are we—once again, without substantial changes to the program, how are we projecting signifi-

cant reductions in the expenditure of Part B benefits?

Mr. HALLMARK. Mr. Chairman, the estimates for both Part B and Part E are based on our actuarial projections, primarily based on the experience to date with some input of information about known incoming changes in the process through the pipeline, as I've mentioned earlier. In the case of Part B as in the case of Part E, we projected an increase in '06. In the case of Part B, that was because we anticipated a larger number of cases coming back from NIOSH than in the past, and the anticipation was that that was then going to taper off in 2007. That's the reason for the number going somewhat down in 2007.

We did not try to make the projections contingent upon the outcome of the SEC class determination process as that is in a sense unpredictable in terms of which classes might be acted upon at which timeframe. So those kinds of forecasts are not included in

the projections that are in the President's budget.

Mr. Hostettler. But these are mandatory expenditures. I guess my question is which one is right. Is the memo right? Because if they're mandatory expenditures, there would have to be the provision, if there was—if they're mandatory expenditures and they are being projected to be a large expansion in mandatory expenditures, I guess my question is, once again, which one is right? Is the budget right or is the identification of large expansion of Part B benefits right?

Mr. Hallmark. Well, if there were a large number of broad SEC classes created, that would change the budget projections that we

Mr. Hostettler. Actually, that would change the actual outlays.

Mr. Hallmark. The projections are what they are, but it would change the outlays, and that would cause a differential vis-a-vis

what we've projected.

Mr. HOSTETTLER. Right. And I guess what my question is, is that OMB creates the budget, that helps in the budget process, is being informed by DOL that there's going be a large expansion of benefits just as they would be from HHS with regard to a large expansion of prescription drug benefits for seniors through Part D. They would reflect that in their budget authority requested. Now, if instead of a third of seniors signing up for prescription drugs, twothirds of seniors signed up, then the outlays would far outpace the B.A., that was projected, but if everyone recognized that probably two-thirds of seniors were going to sign up the B.A. request, the budget authority request, would reflect that. They would be consistent. I guess that's my question. I appreciate the response. It's just a little confusing.

If I can go on to Mr. Miller. Let me ask you about the audit contractor's work. Is it your understanding, your experience, that the audit contractor's work product is satisfactory and useful to the

process?

Mr. MILLER. Thank you, Mr. Chairman. The audit contractor's process is governed by the series of procedures that the Advisory Board had to put in place first, and so they work within a set of very standardized sets of questions. If they review a site profile, they look at data adequacy, compliance with regulations. Yes, they do look at questions of claimant favorability, because that's written into virtually every single NIOSH guidance document, and so to that extent, Mr. Hallmark is right. Where Mr. Hallmark, though, perhaps may be overstating the case is that this audit contractor has produced audits that I have reviewed, redacted, that show overestimates and they flag it when NIOSH or its dose reconstruction staff have overestimated cases. They have recently identified cases that were referenced at the most recent Advisory Board meeting where the improper procedures were used and it may have led to significant overestimates which may have actually even led to inappropriate compensation, although we don't know that because that has yet to be revealed; but the very fact that they put up a red flag and call it as they see no matter what is I think what you want to count on in a peer review process.

The characterization I think that Mr. Hallmark made was both unfair and unsupported by the record. From a claimant's perspective, there is something very important about having this audit contractor. They do not bring to the table a set of baggage from having been at the Department of Energy creating and running those dosimetry programs, and they take a wire brush over the assumptions that NIOSH and its dose reconstruction contractor which is a major DOE contractor—and they bring, they dig right into the assumptions and the roots and the adequacy of the data

and the validity of what's being looked at.

They ask the questions which, frankly, claimants lack the expertise to even dig into. And in the end, claimants if their claim is denied, don't have ability to say you're misestimating my dose unless it's something really obvious and glaring, and they're counting on the Advisory Board and a truly independent audit contractor to give credibility to the process that the problems are caught whole-sale, that the procedures that are found get fixed across the Board. Claimants aren't bringing individual claims and saying I want to appeal to the Advisory Board. They're not allowed to do that, but the generic problems that have to get rooted out can't get rooted out there, particularly, as Dr. Howard was saying, they're very focused, I think recently, on conflict of interest. But as our testimony points out, many of the people writing the core guidance documents for this dose reconstruction program managed the health physics programs at DOE sites. They have significant professional conflicts of interest, and we have documented that this has tainted the quality of science coming out of this program, and the only way to effectively get at the taint and the quality of the science in this program is for there to be an effective check and balance. Without that, we all have to walk away, throw up our hands, and say it lacks credibility.

And so for the OMB document and Mr. Hallmark to try to knock the knees out from underneath this check and balance, this peer review process, it is really quite troubling, because at the end of the day, if he prevails and the OMB prevails in this process, I'm not sure claimants are going to have much confidence at all that they have anybody who is really looking at it, looking at all these assumptions under a microscope and scrubbing them.

Mr. HALLMARK. Mr. Chairman, if I could respond.

Mr. Hostettler. Yes, Mr. Hallmark.

Mr. HALLMARK. I'm sorry to interrupt, but since I've been taken issue with, I'd like to just respond a moment.

I think it's fair to say that the SC&A folks have a clear statement of conflict of interest with respect to having responsibilities or having prior experience in dealing with DOE contractors as support for DOE contractors or working for DOE contractors. They do not, however, come to table with no baggage since many of the analysts for SC&A, in fact SC&A itself, have served as retainers for individuals who are suing either the Department of Energy or the United States Government or similar entities. So they're on the other side of the table.

So Mr. Miller's view of balance in this respect is different than mine. I believe that conflict of interest requirements should apply on both sides of the house and that we should look to see whether individuals who are making judgments about a particular site have had involvement at that site on the DOE side or on the other side.

Mr. HOSTETTLER. I appreciate that. I think we received testimony from Dr. Melius that there was stringent conflict of interest provisions from the audit contractor that even exceeded those of the dose reconstruction contractor.

Is that not accurate, Dr. Melius? Is that what I heard?

Dr. Melius. Correct.

Mr. HALLMARK. I believe that the stringency is on the issue of making sure that the SC&A individuals have had no dealings whatever as support for DOE. I'm looking at the SC&A disclosure documents that are on their web site now, and the question that is answered is have they served as an expert witness in litigation defending workers' compensation or other radiation claims, and the answer is no. The answer, I think would be, yes, however, if the

question were posed have you served as an expert witness in litigation for the plaintiff's side, and in my view, that kind of involvement is also a potential conflict of interest and has not been addressed, at least in the documents that SC&A has on its web site.

Mr. MILLER. Mr. Chairman, if I could respond.

Mr. HOSTETTLER. If I could just ask a question, and the question, I guess, is why isn't that question asked?

Mr. HALLMARK. The issue of plaintiff status?

Mr. Hostettler. Yes.

Mr. HALLMARK. I assume because the answer would be yes, and that would raise the question of whether there was, in fact, a conflict of interest that should bar at least the participation of those individuals at particular sites where they have a current interest.

Mr. Hostettler. I guess my question is isn't that the purpose of an audit contractor—to actually give a reason for the claimant community to believe that the process is transparent. I mean, if I were going to choose one, and I think actually Dr. Howard pointed out the very true fact of human nature that we're all going to come to the table with some perspective, some bent, and that's totally understandable. As a person who is a budget hawk, potentially sometimes to a fault, I would come to a lot of these issues looking at the dollar figures. This does not happen to be one of those and is far from it, but so we all come to the table with a certain perspective.

So as an audit contractor, I would think we would want someone that if they had a bent, then they would have a bent toward the claimant community. I think we would recognize that. But the individual that is actually the entity that is actually doing the science, is the dose reconstruction contractor, and would be the one that we would want to have as little conflicts of interest because science, being somewhat familiar with it as I am, is not an issue of interest. It is an issue of science, and so we would want that standard, and then we would want this other entity that would be more like I said, because as Mr. Miller pointed out, the claimant community, by and large lay people, they want somebody that's looking into this situation, that's asking all the right questions, that are meddling, however you want to put it, and are keeping us all honest, including Congress, about this process.

So you have a very good point, Mr. Hallmark. I understand that, and I would presume that the audit contractor would be bent that way, because, in fact, the Federal Government harmed these people knowingly, and so I would want somebody in the process that would be looking over our shoulder, because if we did it once, we might be predisposed to doing it again, collectively, all of us. All of us, not any one particular entity, not any one Administration, Congress, nobody, no one person.

So anyway, the point is very well taken.

Mr. Hallmark. If I could extend my remark for a moment, I think I want to repeat that NIOSH came into this process following congressional guidance to ensure that dose reconstruction was done on a basis that leaned over backwards to be favorable to the claimant, and I think they've done that from the very start of this program.

I think the point that I'm trying to make with regard to the issue of balance is that if the Board's review of what NIOSH does only looks at one-half of the equation, could they lean further over. Then it raises the question about is there a point about which plausibility is lost? And if no one is really looking at plausibility, then there is no check and balance in the system. The system is going to be focused entirely on moving the bar to the side of further exag-

geration or further overestimation.

This is a non-adversarial program. So there is no party that has standing within the EEOICPA program to say, no, we object; that claim is too far; that's gone beyond plausibility. There is no employer interest, or the Department of Energy has no standing in this program to appeal or to argue. So if the Board and its contractor look only at one side of the equation, then the entire program will move that way, because I would also submit that science is in this case part of a discussion, and the science is open a range of possibilities, and NIOSH is reasonably guided by what their Board tells them, and I think the outcome of that can be other than balanced and objective in the long run if, in fact, there is only one equation, only one criterion being applied.

I think that's the substance of what we're trying to say.

Mr. HOSTETTLER. Sure. I appreciate it.

Dr. Melius, yes.

Dr. Melius. I'll try to do this very briefly. Two points: One is the Board had long discussions on the conflict of interest issue and how to achieve a correct balance and this issue of which side people had appeared on in various situations, and we actually reached the same conclusion that you just stated—that we needed to pay special attention to the issue of people that had worked for the Department of Energy facilities giving the past history of what went on. The other issue was subordinate to that, not totally ignored, but it was subordinate to that.

Secondly, to Mr. Hallmark's last statement, I would just reiterate that the Board does look at both sides of this, of these issues, that we're trying to reach a fair and balanced view of this. I shouldn't use the word "balance" probably anymore here, or imbalanced or whatever, but we want to come up with a fair assessment, and we have instructed our audit contractor to look at a range of issues, some of which would lead to overestimates, some which might lead to underestimates, and then we try to reach our conclusions based on what is the right balance dealing with that.

I think it's important to note that much of the recent deliberation of the Board has involved special exposure cohorts where there large numbers of records are missing and going back in time, and without going into technical details, they are difficult to do. So NIOSH is often trying to make the best it can do if it is going to be able to do dose reconstruction based on very little data. So there really is a fundamental question. If you're only using a very small amount of data, is that fair to the claimant to do it in that way.

So we may have looked a little bit more on the side of, well, how do you extrapolate from little data to a lot of data. You don't want to punish the person for there not being records of their exposures. So maybe much of the discussion has been more on that side, but overall, as Mr. Miller has pointed out, if you want to look through

the reviews that the contractor has done on individual cases, there's a mix. Some cases overestimate. Sometimes underestimations of the exposures or whatever is being specifically looked at, and then we need to step back and say, Well, what's the right way of doing a fair overall estimate of that person's dose.

So we ask the contractor to look at all sides and then report back

o us. Mr. Hostettler. Thank you, Dr. Melius.

And Mr. Miller.

Mr. MILLER. Mr. Chairman, thank you. I would just like to draw your attention to page 14 of our testimony where we cite five separate examples where the NIOSH through its contractor, Oak Ridge Associated Universities, has hired individuals who managed the health physics programs and in some cases served as expert witnesses defending workers' radiation compensation claims. For example, at the Idaho laboratories in Idaho, there is an individual who wrote the guidance document, the threshold document that Mr. Gallegly was talking about, that was used for evaluating compensation claims, and so in numerous, numerous cases defending

compensation claims for radiation-related illness.

If Mr. Hallmark wanted to apply his conflict of interest criteria to Oak Ridge Associated Universities, you would have an exodus out the door of health physicists and a paucity of individuals to work on those cases. So the question then becomes checks and balances, and it goes back to that earlier point. If the pool of health physicists out there is relatively shallow, which it is, and many of them come directly out of the revolving door of managing the health physics programs and at the same time bring their own perspectives and biases, including having testified on the record as an expert witness in defending these claims at these sites, and are writing the guidance documents, they themselves are caught between what they've said on the public record and what they're obligated to do for NIOSH, and the question is who technically is out there that's going to ask the pointed questions in a technically astute manner.

If I can just give you one example, in the case of Paducah, Kentucky, NIOSH hired an individual who wrote an internal dose assessment report for Martin Marrieta who ran that plant. She cut and pasted her own previous work directly into the NIOSH site profile which had been found previously to incorrectly minimize exposures to the very isotopes of concern, and then NIOSH went through going through four tiers of review, rubber stamped it, sent

it out the door, and adjudicated cases accordingly.

Now, fortunately in this instance, Senator McConnell picked up on this and has asked NIOSH to review this again and they have agreed to do so, but I would only use this as an example of someone who brought her own bias to the table, cut and pasted her work in. It was incorrect to start with. It had been criticized in the open literature, and who is going to be out there that's going to be astute enough to catch that if you are relying on the same individuals in the system to serve as your audit contractor? You need a set of fresh eyes that aren't wedded to that system. That's what Sanford, Cohen brings.

Mr. Hostettler. Thank you.

Thank you, gentlemen. We are concluded. I want to thank you for your testimony and your appearance here today. This is a very difficult issue, and I commend you for the work that you're doing to resolve these differences.

Our next hearing on this issue will be held next week on Thursday. We will continue in this. Your contributions have been extraordinary to the record on this. Congress had intentions when we originally passed the law to right this wrong that was done by the Federal Government so many years ago to these people. Once again, I want to thank you for your participation and the work.

The Subcommittee being completed, we are adjourned.

[Whereupon, at 6:01 p.m., the Subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

PREPARED STATEMENT OF THE HONORABLE SHEILA JACKSON LEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS, AND RANKING MEMBER, SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY, AND CLAIMS

Today's hearing will focus on Subtitle B of the Energy Employees Occupational Illness Compensation Act. Subtitle B covers 3 types of occupational illness associated with making nuclear weapons, "cancer," where it can be shown that the cancer is at least as likely as not related to ionizing radiation exposure while employed at a nuclear weapons facility; "chronic beryllium disease," and "chronic silicosis."

Energy Department federal, contractor, and vendor employees who have con-

tracted one of these illnesses, or their survivors, may be eligible for a lump sum of \$150,000 and prospective medical benefits. The Act also provides for a \$50,000 supplemental payment to uranium miners/millers, or their survivors, who were eligible to receive \$100,000 under the Radiation Exposure Compensation Act.

For radiation related cancer claims, the Department of Health and Human Services (HHS), through the National Institute for Occupational Safety and Health (NIOSH), is required to estimate a worker's radiation dose if dose records are avail-

able. However, during the earlier years of the nuclear weapons programs, especially between the 1940s and the 1970s, some workers were not monitored and the monitoring that was done sometimes was inadequate. Also, some records from this period

were lost or destroyed.

The Act provides a remedy for cases where it is not feasible to estimate radiation doses with sufficient accuracy, and it is clear from job types that the workers' health may have been endangered by radiation exposure. Under these provisions, workers (or their unions) may petition to be administratively designated as a "Special Exposure Cohort," which establishes an unrebuttable presumption that certain cancers are work related. Members of a Special Exposure Cohort are eligible for the \$150,000 lump sum benefit if they have one of 22 radiosensitive cancers and, in general, if they have worked at a covered facility for at least one year in a job that exposed them to radiation

The HHS Secretary, subject to a review and recommendation from the Advisory Board on Radiation and Worker Health, makes the "Special Exposure Cohort" designations. To date, the Secretary has denied 2 Special Exposure Cohort petitions

and approved 6 involving approximately 1,100 cases.

The Administration recently declared its intention to reduce the number of Special Exposure Cohorts in a memorandum referred to as an, "Office of Management and Budget (OMB) passback." The passback provides for establishing a White House-led interagency work group "to develop options for administrative procedures that will contain the growth in the cost of benefits provided by the program."

Options to be considered include requiring an administration clearance for all Special Exposure Cohort designations; requiring an expedited review by outside experts; addressing any imbalance in membership of the President's Advisory Board on Radiation and Worker Health; and imposing constraints on the Advisory Board's audit contractor.

Currently, a Special Exposure Cohort petition goes through an initial evaluation by NIOSH, and its recommendation is then peer reviewed by the Advisory Board before it goes to the Secretary for a decision. These reviews are conducted in the open and on the record with an opportunity for input from experts and the peti-

We need to be concerned about this system if it is broken or HHS is approving Special Exposure Cohort petitions that should be denied. We will hear testimony on that issue today.

Five-and-a-half years have passed since the Energy Employees Occupational Illness Compensation Act was enacted, and the sick workers who were supposed to be served by its programs are dying. The Administration should be doing more to help these workers, not trying to make it more difficult for them to establish eligibility for compensation. It is too difficult already.

These workers made a commitment to our country when the country needed them.

Now, it is our turn to help them in their time of need.

PREPARED STATEMENT OF JOHN MAURO, Ph.D., CHP, PROJECT MANAGER, S. COHEN & ASSOCIATES (SC&A, INC.)

Chairman Hostettler, Ranking Member Jackson-Lee, and Members of the Subcommittee, thank you for the opportunity to submit testimony regarding the role my firm, S. Cohen & Associates (SC&A, Inc.), plays in supporting the critical independent advisory function of the Advisory Board on Radiation and Worker Health (the Board) under the Energy Employees Occupational Illness Compensation Program Act (the Act or EEOICPA).

First, I would like to provide an overview of who we are, our role, and how we have approached our technical work for the Board over the past two years. This will be followed by a more detailed description of our contractual requirements and accomplishments. I will conclude by briefly offering our perspective on the value of the

technical inquiries that we have made.

SC&A is a small business providing professional services in the radiation sciences. The majority of our work over the past 25 years has been for government clients, including the Environmental Protection Agency, Nuclear Regulatory Commission, Centers for Disease Control and Prevention, and Defense Nuclear Facilities Safety Board. Our reputation has been built on our technical expertise and on the ethical standards that we have brought to our work on sensitive public issues, such as nuclear waste management, contaminated site cleanup, and the health risks of radiation. While this past experience is deep and diverse, it does not include radiation protection support for the Department of Energy or its operating contractors.

SC&A CONTRACT ROLES AND RESPONSIBILITIES

On October 14, 2003, a three-year, task order contract (200–2004–03805) was executed between the Centers for Disease Control and Prevention (CDC) and SC&A. Under this contract, SC&A's role is to provide technical assistance to the Board in fulfilling its mandate under EEOICPA, which has amongst its charges the task of reviewing a reasonable sample of dose reconstructions for scientific validity and quality, assessing the methods and procedures for dose reconstruction, reviewing Special Exposure Cohort (SEC) petitions, and advising the Secretary of Health and Human Services (HHS) in these matters.

All tasks under this contract are performed in accordance with Federal acquisition regulations and protocols mandated by the Federal Advisory Committee Act (FACA). In summary, the Board, in open session, identifies tasks that they would like SC&A to perform, and that are within SC&A's contractual statement of work. The NIOSH Designated Federal Official, who currently also serves as the NIOSH Project Officer for this contract, and the NIOSH Contracting Officer participate in this process. Once the Board agrees on the scope of a given task order, the Board, in cooperation with the NIOSH Project Officer and Contracting Officer, issues a Task Order Request for Proposal (TORP). In response to the TORP, SC&A prepares a proposal of work, which includes the task order scope of work, a budget, schedule, technical approach, and assigned personnel. The Board and the NIOSH Contracting Officer review SC&A's proposal, provide any comments or additional direction to SC&A, and SC&A submits a revised proposal, as required. During open session, the Board approves the proposal of work, and work begins.

proves the proposal of work, and work begins.

Before work on a task order can begin, SC&A is required to submit a quality assurance plan and a conflict of interest plan to implement controls over documents as needed in order to meet the requirements of the Privacy Act, and to prepare written technical procedures that must be reviewed and approved by the Board in open session. The procedures that SC&A has prepared to date flow directly from the Act and the regulations that implement the Act, namely 42 CFR Part 82, which deals with dose reconstructions, and 42 CFR Part 83, which deals with SEC petitions. Hence, everything we do is designed to assess the degree to which NIOSH work products under the Act meet the letter and intent of the Act and its implementing

regulations.

To date, SC&A has been authorized by the Board to perform a number of task orders (six in total, at a projected cost of \$6.5 million through September 31, 2006;

i.e., about \$2 million per year), which can be conveniently grouped into four categories of services, as follows:

- 1. Review of the procedures, guidelines, and other "tools" being used by NIOSH to perform dose reconstructions: To date, SC&A has either reviewed or is in the process of reviewing a total of about 60 NIOSH and NIOSH contractor procedures, and approximately 30 workbooks. Workbooks are computer programs that help NIOSH dose reconstructors perform their work in accordance with the dose reconstruction procedures.
- 2. Review of site profiles: To date, SC&A has either reviewed or is in the process of reviewing 15 site profiles pertaining to specific Department of Energy (DOE) or Atomic Weapons Employee (AWE) facilities. Site profiles are technical documents that provide background information and technical direction to dose reconstructors on how to go about reconstructing doses for particular facilities.
- 3. Review of adjudicated dose reconstructions: To date, SC&A has reviewed or is in the process of reviewing 80 dose reconstructions performed by NIOSH. The dose reconstructions performed by NIOSH are being used by the Department of Labor in support of compensation decision-making under the Act.
- 4. Technical support to the Board in matters related to Special Exposure Cohort petitions: To date, SC&A has been requested by the Board to perform the following SEC-related tasks: (1) prepare a report that presents a review of the procedures developed by NIOSH for use in evaluating SEC petitions, (2) prepare procedures to be used by SC&A and the Board for reviewing SEC petitions and/or SEC evaluations prepared by NIOSH, (3) review the Ames Laboratory SEC petition, and (4) perform focused reviews of Board-selected issues related to the Y-12 and Rocky Flats SEC petitions. We have also provided technical support to the Board on the Mallinckrodt and Iowa Army Ammunition Plant SEC petitions by evaluating the relevance of certain issues raised in the site-profile review process for determining the feasibility of dose reconstruction under the SEC regulation (42 CFR Part 83).

All of our work products are either delivered to designated Board members as preliminary draft reports, which are works in progress and are not distributed to the public, or are delivered to the full Board as draft reports that are immediately made available to the public. The draft reports contain SC&A findings resulting from our reviews of NIOSH procedures, guidelines, workbooks, site profiles, dose reconstructions, and SEC evaluation reports. The delivery of these reports triggers an issues-resolution process under the direction of a Board-designated working group. A working group consists of a chairperson, about three other Board members, representatives of NIOSH, and representatives of SC&A. The mandate of the working group is to discuss the technical details of SC&A findings with an aim toward resolution of the issues. Working group meetings often involve participation by interested members of the public, and the meetings are transcribed and are a part of a public record.

The implementation of the working group concept has become increasingly more productive and efficient as experience has been gained and the process streamlined. SC&A's analyses have often been pivotal in the Board's findings on the NIOSH dose reconstruction program, including instances where over-conservatism in technical approach could lead to significant overestimates of radiation doses, and those where the NIOSH procedures being reviewed were not resolving uncertainties in favor of the claimant in a manner laid out in the regulation (42 CFR Part 82). SC&A has recognized the pragmatic approach that is incumbent upon NIOSH in balancing science with delivering defensible dose-reconstruction determinations. While SC&A takes this perspective into account in its reviews, we see our function as ensuring that the work done in dose reconstruction and SEC petition evaluation conforms to the standards of sound science and resolution of uncertainties that exist in favor of the claimant, as required by the regulations. We believe the results achieved to date speak for themselves and will be enumerated in more detail later in this statement.

At full Board meetings, in open session, the Chairman of the working group reports progress on the issues-resolution process to the Board. If it appears that the working group has gone as far as it can in resolving issues, the Board holds an issues-resolution session, where each issue is discussed in open session, and the issue is closed out to the extent possible. Closeout of an issue involves a statement by the Board that either (1) SC&A withdraws its findings based on additional information provided by NIOSH, (2) NIOSH concurs with SC&A's findings and has taken action or plans to implement an action that resolves the issue to the satisfaction of the Board and its contractor, or (3) the issue remains unresolved to varying de-

grees, and there is no further action necessary by SC&A to participate in the resolution process for that issue.

The important point to be made here is that all activities by the Board and its contractor are fully transparent and traceable back to the Act and its implementing regulations.

SC&A EVALUATIONS HAVE BEEN VALUE-ADDED

To date (i.e., since the beginning of the project on October 14, 2003), SC&A has delivered 32 reports to NIOSH and the Board at a cost of \$3.7 million. While the detailed analyses contained in, and hence the length of, the reports is one indication of the amount of work that has gone into them, we have tried to review for this hearing some of the more important accomplishments in programmatic terms. The 10 most important of these, culled from a larger list, are described as follows:

- 1. SC&A's reviews of NIOSH and ORAUT dose reconstruction procedures and dose reconstructions identified a substantial number of technical errors and have entailed programmatic corrections, procedural changes, and re-reviews of adjudicated cases. For example, seventy-five percent of dose conversion factors (DCFs) used to convert the readout on a personnel dosimeter to the dose to the organ of concern were in error and are being corrected. SC&A also identified an error in the methods used to reconstruct the doses to lymph modes. NIOSH has acknowledged this oversight, revised its procedures, and is currently planning to review about 1,000 previously adjudicated cases.
- 2. Our review of several site profiles revealed incomplete radionuclide lists or inadequate consideration of radionuclide concentrations, leading to serious underestimation of doses or to incorrect conclusions about the feasibility of dose reconstruction or both. For instance, for the Mallinckrodt Chemical Works (MCW) facility, the site profile coverage of several radionuclides—thorium-230, protactinium-231, and actinium-227—was deficient. SC&A's assessment showed that in many cases these radionuclides would be the largest contributors to radiation dose. SC&A's analysis showed that the methods proposed by NIOSH in the site profile would have led to significant underestimates of radiation dose to many MCW workers. Similarly, at Y-12, Savannah River Site, and other sites, SC&A has identified radionuclides that were omitted from consideration or inadequately considered. For instance, SC&A's reviews showed that inadequate evaluation of trace radionuclides in recycled uranium, including plutonium and neptunium, would also lead to significant underestimates of dose.
- 3. The methods adopted by NIOSH to reconstruct the doses for early workers at the Iowa Army Ammunition Plant (IAAP) were found by SC&A to be so overly conservative (i.e., result in excessively high dose estimates) that they would have resulted in inequities in compensation for post-1963 workers who did the same work as workers in 1950s and early-1960s. The latter would have been compensated due, in part, to an effort to protect classified data, but the former would have been denied compensation for the same cancers and the same work.
- 4. SC&A's review of several site profiles revealed that NIOSH often has not paid adequate attention to the problem of data integrity (i.e., can we trust the completeness, representativeness, and accuracy of the data?). SC&A's work has uncovered data integrity problems at Rocky Flats and the Nevada Test Site. Those issues are currently undergoing investigation by NIOSH.
- 5. SC&A's review and analysis of several of the site profiles has shown that many of the concerns of claimants, site experts, and members of the public had technical merit and had not been given adequate consideration. Examples include incidents such as cobbling of uranium rods at Bethlehem Steel, high-fired plutonium oxides at Rocky Flats, and trace radionuclides, such as protactinium-231 and actinium-227 at Mallinckrodt. More recently, the identification of a data integrity problem in part of the external dose record at the Nevada Test Site has revealed a critical issue for NIOSH review, which had not been identified in its site profile for that site.
- 6. SC&A's review of the Bethlehem Steel site profile identified numerous deficiencies in the methods used for performing dose reconstruction. This has resulted in significant changes to the Bethlehem Steel site profile and the direction being given by NIOSH to the dose reconstructors. The degree to which these changes may affect adjudicated claims is under review by NIOSH.

- 7. SC&A's review of the application of NIOSH's dose reconstruction procedures revealed that in some cases these procedures were inappropriately applied and resulted in large overestimates of the reconstructed doses for some workers. Specifically, NIOSH developed certain procedures, such as ORAUT-OTIB-0004, for the express purpose of maximizing doses for cases that were clearly non-compensable. This strategy of deliberately overestimating doses for non-compensable cases is appropriate as a means to expedite the dose reconstruction process and is in accordance with the provisions of 42 CFR Part 82. However, SC&A identified cases where these procedures were misapplied, resulting in potential inequities in compensation.
- 8. SC&A's reviews of site profiles and dose reconstructions revealed the use of inappropriate technical assumptions that result in scientifically implausible intakes of radionuclides. In many instances, NIOSH employed standardized simplifying assumptions in performing dose reconstructions as a means to expedite the dose reconstruction process. However, in many instances, these assumptions were inappropriate to the exposure setting experienced by the worker. One example is the application of a set of default radionuclides that apply to specific classes of facilities (such as nuclear reactors), but not to others (such as at non-reactor facilities). This results in dose reconstructions that are without scientific basis.
- 9. SC&A's review of NIOSH's procedures for performing claimant interviews indicates that there are inequities in the interview process for survivor claimants. Specifically, it is often not possible for survivor claimants to answer the questions posed in an interview, resulting in a degree of frustration on the part of the claimants. SC&A has suggested procedures for remedying these inequities. The Board working group, SC&A, and NIOSH are currently discussing this issue.
- 10. SC&A's review of site profiles (and complex-wide procedures) revealed that the guidance contained therein is at times without technical basis, often confusing, and has resulted in erroneous dose reconstructions. For example, SC&A identified recurring problems regarding neutron dosimetry and protocols for assigning neutron doses. One facility that is affected by these issues is Hanford. Also, NIOSH's procedures are often confusing and contradictory, resulting in numerous errors in dose reconstructions, especially in the assignment of uncertainty in the reconstructed doses. NIOSH is remedying this situation by revising its procedures and preparing computerized workbooks that help to avoid these problems.

The preceding illustrative findings are not presented to emphasize fault with NIOSH's program—the scale and scope of the agency's dose reconstruction mandate under EEOICPA is particularly daunting and technically complex. It is to underscore the integral role that SC&A has already played in support of the Board to bring important issues and deficiencies to the attention of NIOSH, so that suitable actions can be taken.

SC&A ASSURES INDEPENDENCE AND EXPERTISE OF ITS WORKFORCE

The worth and integrity of SC&A's technical work derives directly from our corporate ethic and the people that staff this project. As with our other contracts, SC&A has assigned only the most qualified professionals to this contract. These include specialists in internal and external radiation dosimetry, environmental and medical radiological programs, and nuclear facility operations and safety. We have strived for a diversity of expertise and experience, because we believe that gives us the capability to add true value to the highly technical assessments that NIOSH performs, and facilitates professional discourse on issues of science and technical judgment. We have also looked for individuals who have a proven talent for analyzing complex technical issues that require inquisitiveness and a probing mind to uncover errors and discrepancies. Finally, while we rigorously and openly apply internal conflict-of-interest requirements to preclude individual conflicts of interest, we have also been open to a diversity of backgrounds, including former DOE federal auditors, non-profit interests, and industry consultants, with the common denominator being professionals who do not have conflicts of interest, who are experts on the subject, and who are experienced in performing independent technical inquiries.

Before closing, it is important to emphasize that the very nature of the support services SC&A provides to the government requires the highest level of oversight of conflict-of-interest issues. This is especially true for the services we are providing to the Board under this contract. SC&A's conflict-of-interest plan was submitted in final form in October 2004, and was approved by the Board. Fundamental provisions

of the plan include that no individual can work on this project if (1) they currently work for NIOSH or (2) if they have ever defended the government against workers compensation claims. In addition, no SC&A team member that has worked in the past at a Federal facility can serve in a lead capacity on any task issued under this contract dealing with that facility. These and other conflict-of-interest requirements are enforced by SC&A's COI Plan Administrator, and each member of the project team is required to submit a conflict-of-interest disclosure statement that is maintained current and published on SC&A's web site (http://www.scainc.com/niosh—disclosures.html).

CONCLUSION

In closing, we believe the audit role that SC&A has provided in support of the Board for the EEOICPA program has proven effective and is becoming more influential and efficient as experience is gained by all parties. We believe our success to date results from our efforts to build program value by focusing on high priority findings, balancing scientific soundness with the practical constraints of a compensation program, and identifying instances of over-conservatism as well as deficiencies requiring more claimant favorability. We appreciate the imperative of avoiding conflicts of interest amongst our staff and organization, and have a very rigorous conflict-of-interest program in place. Moreover, we believe that the diversity of our team and its dedication to scientific rigor have resulted in the objective and careful analyses mandated by the charge of the Board. We also believe that the careful consideration that SC&A has given to claimant, site expert, and public comments has led to better science, fairer procedures for dose reconstruction, and higher confidence of the public in the program.

As various SC&A reviews progress, we are addressing a number of issues that are common to many future DOE and AWE sites, thereby providing a generic means to achieve closure at multiple sites with an anticipated net savings in time and costs. Increasing efficiencies being realized due to experience gained by all parties—particularly more recently with SEC evaluations—are likewise leading to efficiencies that should translate into cost savings.

We appreciate the opportunity to submit this testimony and to be a part of this important national program to compensate civilian veterans of the Cold War.

RESPONSES OF SHELBY HALLMARK, DIRECTOR, OFFICE OF WORKERS COMPENSATION PROGRAMS, U.S. DEPARTMENT OF LABOR, TO POST-HEARING QUESTIONS FROM THE HONORABLE JOHN N. HOSTETTLER

U.S. Department of Labor

Employment Standards Administration Office of Workers' Compensation Programs Washington, D.C. 20210

JUN 2 8 2006

File Number:

Honorable John H. Hostettler Chairman, Subcommittee on Immigration, Border Security, and Claims House Committee on the Judiciary 2138 Rayburn House Office Building Washington, DC 20515-6216

Dear Chairman Hostettler:

This is in response to your letter dated May 25, 2006, transmitting follow-up questions regarding my testimony before your Subcommittee on March 1 of this year concerning the Energy Employees Occupational Illness Compensation Program Act (EEOICPA)

- Please provide actual administrative outlays related to the Energy Employees
 Occupational Illness Compensation Program Act (EEOICPA) for the
 Department of Labor (BOL) and for the National Institute for Occupational
 Safety and Health (NIOSH) since the date of enactment through the end of
 FY2005, plus expected costs for FY06.
- 1. EFOICPA administrative obligations (in millions) have been as follows:

Agency	FY 2001-2005	FY 2006 (projected)
DOL Part B	\$188	\$51
HHS/NIOSH*	\$166*	\$60:
DOL Part E	\$35*	\$60

*Reflect full amounts transferred to HHS (and recorded as obligations in the EEOICPA administrative expenses account). HHS obligated \$161 million in FY2001-2005, and expects to obligate \$x million in FY 2006.

** FY 2005 only

- 2. You raised technical concerns in your testimony about the precise boundaries of Special Exposure Cohorts (SECs). You cited a Y-12 SEC as an example. Has DOL brought these concerns to the Advisory Board on Radiation and Worker Health (ABRWH) and discussed them on the record to define the actual boundaries around this particular SEC in order to address any ambiguity? If not, why not? Is this not an appropriate forum to improve communications regarding issues regarding SEC definitions?
- DOL has brought this issue to the attention of the Advisory Board on a number of occasions. Once an SEC class is designated, DOL must adjudicate relevant claims in accordance with the designation, regardless of the implementation problems that may



result from imprecise class definitions. From the initial Board deliberations on SEC petitions, DOL has stressed the need for HHS/NIOSH and the Board to be as precise as possible in their definition of proposed classes as well as the rationale to ensure uniformity in application and DOL's ability to adjudicate claims in a fair and uniform manner.

- Is the DOL concerned about the costs related to future SEC designations?
 Please explain why.
- 3. DOL has a fiduciary responsibility for EEOICPA, and must ensure that benefits are paid in accordance with the statute. However, as indicated in my testimony, our main concern with respect to SEC class additions relates to the uniform application of the criteria for designation of additional SEC classes and the impact such designations have on potentially deserving claimants. DOL believes that the fairest way to identify deserving claimants is through the dose reconstruction process, and that—consistent with the law—SEC classes should be approved only when reconstruction is not possible. Approximately one-third of the cases for which benefits have been approved through the dose reconstruction process involve only non-specified cancers. Many of these deserving claimants would have their claims for benefits extinguished (or their chances of approval reduced nearly to zero) if they are included in a newly designated SEC class, because SEC status grants presumptive eligibility only to class members who have one of the specified cancers. While HHS is responsible for reviewing SEC petitions and declaring any new classes, DOL must ultimately adjudicate claims involving such classes, and must defend decisions under the program in court.
- 4. Currently there is a 4 step evaluation process for reviewing SECs that was set up under EEOICPA. The Office of Management and Budget (OMB) Passback memo encourages yet another review, as well as requiring Administration clearance. Is it the view of DOL that the participants in this process are not applying appropriate due diligence? If so, which specific participants are not applying appropriate due diligence?
- 4. As a multi-agency program, EEOICPA relies on the work of a number of agencies, all of which exercise due diligence in performing their respective roles. These individual agency responsibilities must be well coordinated to provide for fair and uniform adjudication of claims and compensation to deserving claimants. As the Office of Management and Budget has stated, however, the Administration does not intend to change the process governing whether to add new SEC classes.
- 5. What is the basis for the DOL/Administration's concern about "imbalances" in the Advisory Board composition? Is the option of changing the Advisory Board's composition rooted in a desire to find individuals who will disfavor SEC designations?

- 5. It would not be appropriate to comment on internal deliberations involved in the development of the President's Budget. DOL has no view about the creation of additional SEC classes, other than that the process should be consistent with statutory requirements. Our interest is in ensuring that selection criteria to designate SECs are uniformly applied, new SECs are unambiguously defined, and all potential claimants are treated fairly.
- 6. Does DOL find the judgement of past or current ABRWH members untrustworthy in rendering decisions that the President appointed them to do? Please identify those members and why they are not trustworthy in rendering decisions. Which Advisory Board members would DOL like to see removed to address DOL's concerns about "imbalance"?
- 6. HHS, not DOL, is responsible for overseeing and supporting the President's Advisory Board; the President is responsible for the appointment of Advisory Board members. We have not attempted to advise either HHS or the President regarding the service of current or former members of the Board; we did observe that several members of the Board have continued to serve after their designated term expired. It is our observation that the Board's members have worked very hard since its inception, and that they have conducted themselves in a professional, serious, and public-spirited manner throughout.
- 7. Which, if any, of the five options in the OMB passback memo is the White House interagency working group mentioned in the passback memo planning to formally or informally implement? Please list the items, and the particular plans for implementation.
- 7. It would not be appropriate to comment on internal deliberations involved in the development of the President's Budget. However, I believe the Administration has made clear that there is no White House-led, EEOICPA-related interagency workgroup, and that it is not pursuing any of the options outlined in the memo you cite.
- 8. Are there plans not listed in the OMB passback memo that the interagency working group is going to implement?
- As I stated in the previous response, there is no White House-led, EEOICPA-related interagency work group.
- Are you the primary author of the 5 options outlined in the OMB passback memo? If not, please advise who is.
- It would not be appropriate to comment on internal deliberations involved in the development of the President's Budget.

- 10. What part of the SEC evaluation process is not working properly that would cause the Administration or DOL to seek Administration clearance of each SEC designation?
- 10. The Administration is not seeking to "clear" SEC determinations made by HHS. As spelled out in my testimony and reiterated in the foregoing responses, however, DOL believes that close coordination between the various agencies involved in administering EEOICPA is critical; in the absence of close coordination, there is potential for complications and delays in adjudicating cases and paying benefits.
- 11. Is it the opinion of the DOL that Secretary of Health and Human Services (HHS) has not given adequate due diligence to his review of any of the SEC's approved to date?
- 11. DOL believes that all the agencies involved in administering EEOICPA are exercising due diligence in carrying out their roles. Based on our experience in adjudicating and litigating claims, DOL believes that the definition of some of the new SEC classes could have been more carefully drawn so as to avoid potential adjudicatory difficulties. As noted in my testimony, this is one of several reasons why DOL seeks to increase coordination between the agencies to produce the best possible program decisions. We believe there has been confusion on this point, and DOL's position has been mischaracterized as opposition to the creation of new SECs. Our concern about adequately defining SEC classes is not the same as opposing the creation of additional SECs consistent with statutory criteria.
 - 12. What are DOL's views about adjudicating non-SEC cancers when there is insufficient data to reconstruct occupational internal and external dose with sufficient accuracy? To the best of our knowledge, no claims have been approved for compensation based exclusively on x-ray dose. In those cases when occupational internal and external dose cannot be reconstructed, why shouldn't claimants be told there is not adequate data to reconstruct their dose, they have a non-SEC cancer, and therefore their claim is automatically denied?
 - 12. DOL has worked to coordinate closely with HHS/NIOSH on newly designated SEC classes with respect to the handling of cases involving cancers which are not among the 22 specified radiogenic cancers. For each class, the rationale for the class has particular implications for the handling of these non-specified cancer cases. Where no exposure data are available, or where the data has been declared unusable, claimants with non-specified cancers may have no eligibility for a dose reconstruction, and hence no avenue for eligibility under Part B of EEOICPA. In some classes (e.g., the early years at the Y-12 Site) HHS/NIOSH has determined that it can reconstruct only the radiation dose these workers with non-specified cancers received as a result of mandatory periodic medical x-rays. HHS/NIOSH has determined that such radiation is measurable and must be included in the overall dose of covered workers where such x-rays were a condition of employment and hence work-related, and that a partial dose reconstruction can be prepared based on this

residual information. We have been advised by NIOSH that there are a few possible cancer situations where medical x-ray exposure alone might be sufficient to qualify the claimant for a 50% or higher Probability of Causation (PoC), presumably because x-ray machinery used in the 40's and 50's was crude and emitted large amounts of radiation compared to modern equipment. Although the vast majority of non-specified cancers will not be found eligible based on medical x-rays only, there seems no real alternative to NIOSH conducting a partial dose reconstruction with the data that is available.

- 13. What are DOL's views about adjudicating non-SEC cancers when there is adequate external penetrating radiation dose information, but not adequate internal dose information? Should skin cancers be adjudicated in these cases?
- 13. As noted in the response to question 12, DOL works closely with HHS/NIOSH to determine how non-specified cancer cases will be handled for each newly designated SEC class. In SEC classes such as the later years at Mallinekrodt, HHS/NIOSH has declared that it cannot estimate internal dose, but uscable external dosimetry data exists for many workers. Again, NIOSH can conduct a partial dose reconstruction using the available external information only (or external dose plus medical x-ray dose if appropriate), and in some few cases even the partial reconstruction may be sufficient to reach the 50% PoC level. This outcome does not appear to be inconsistent with the statute and governing regulations.
- 14. How much is included in the DOL's FY 07 budget estimate for administrative costs for the Advisory Board on Radiation and Worker Health and its audit contractor?
- 14. The FY 2007 President's Budget for EEOICPA includes \$52.3 million for HHS/NIOSH activities. HHS/NIOSH advises us that, of this total, \$2.5 million is projected to be used for the SC&A contract used to support the Board's review of NIOSH activities, and another \$340,000 is estimated to be used for the expenses of the Board itself. HHS also advises us that they expect some of the FY 2006 earmark for the Board's activities to be carried over for use in FY 2007.
- 15. What is the definition of "balance" as referred to in the OMB document in your opinion? Do you think there is a problem with the audit contractor employees because of conflicts of interest or bias? If so, how do you see that as negatively affecting the claims process?
- 15. It would not be appropriate to comment on internal deliberations involved in the development of the President's Budget. However, as I testified on March 1, in my view, the process whereby the SC&A contract staff have critiqued NIOSH's dose reconstruction, site profiles, and SEC petition evaluations appears to have exceeded the statutory mandate to the Board, which is to evaluate the scientific validity and accuracy of NIOSH's work. SC&A representations before the Board have instead focused almost exclusively on whether or not the assumptions utilized by NIOSH in a

given context could have been even more "claimant favorable" – that is, whether there might be assumptions or statistical techniques that would even further overestimate the dose to which a worker or group of workers were exposed. This has meant that the contractor (and consequently the Board) has spent little time focusing on whether NIOSH's assumptions are plausible, realistic, valid, and sufficiently accurate for compensation determinations, and almost all their time considering whether there might be some possibility that the exposure could have been even greater than estimated.

The issue of the contractor's potential conflict of interest was also addressed in my testimony on March I. Since that time, SC&A's specific conflict of interest with respect to the Pacific Proving Ground and the Nevada Test Site has been noted by the Advisory Board, and I believe SC&A has been recused from involvement at those sites. I understand that individual employees of SC&A may also have potential conflicts at various sites, either due to former employment with DOE, or due to involvement with individuals and groups engaged in suing DOE or the U.S. Government. Individuals who are currently employed as advisors to polantiffs in such suits would have a vested interest in magnifying exposures and the potential for health endangerment at those sites. Such conflicts of interest need not distort the findings of this program if they are fully reported both with respect to previous work for DOE or DOE contractors and employment with plaintiff groups, if appropriate recusal actions are taken, and if the Board and the support contractor apply the statutory criteria ("scientifically valid and accurate") in evaluating NIOSH's

- 16. Do the individuals involved in processing these claims at DOL feel these claims should be treated the same as FECA (Federal Employees Compensation Act) and Longshore Harbor Workers Act? If so, why?
- 16. Claims adjudication staff within OWCP's Division of Energy Employees Occupational Illness Compensation are trained to process and decide EEOICPA cases according to the governing statute, published DOL and HHS rules, and policies and procedures promulgated by DEEOIC. Each program within OWCP, including the FECA and Longshore programs you inquire about, has its own statutory, regulatory, procedural and case law framework, and the various programs' staff are focused on carrying out the requirements of their own program. White EEOICPA has benefited from the pool of experienced claims talent that OWCP could draw upon from its other programs, the adjudicatory process for EEOICPA is unique and sui generis, and our staff treats it that way.
- 17. Do you feel there is imbalance in NIOSH's procedures on site profiles and dose reconstructions? If so, why?
- 17. HHS/MOSH has from the beginning, and in line with the intent of the statute, made every effort to make its dose reconstructions and related documents distinctly claimant favorable. It was originally estimated that only 1-2 percent of dose

reconstruction cases would result in a finding of 50% Probability of Causation and hence approval for benefits. To date, NIOSH dose reconstructions are running at an overall 28% approval rate, and that rate has been steadily climbing. For dose reconstruction cases decided since December 29, 2005, the approval rate has been 38%. These statistics are not troublesome, provided that Congress is aware that they result from policy determinations made by HHS/NIOSH in administering the dose reconstruction methodology.

- 18. Senate appropriators felt compelled to specifically earmark funds to be transferred from your agency to NIOSH for the sole use of the Board in its audit function. Was the Board facing signals from BOL that funds would not be provided beyond an initial allocation to conduct their independent review? Your agency specifically requests the removal of that earmark in the FY 07 year's budget request-why? What is your position on the amount of funding being provided for this function? What is your position on the dose reconstruction contractors funding demands? Do you believe the NIOSH contractor cost increases are more justified than cost increases for the audit contractor? If so, why?
- 18. Since the inception of the program, funding for the entire HHS/NIOSH activity associated with EEOICPA has been appropriated to the Department of Labor and then transferred to HHS. While DOL serves as a conduit, we do not exercise oversight over HHS's implementation of its budget; within the Executive Branch, that oversight is the responsibility of HHS and OMB. We are not knowledgeable about the Senate's reasoning for establishing a specific earmark for Advisory Board funding in FY 2006 appropriations language for this program; however, it is our understanding that HHS has always devoted a portion of its overall budget to support of the Board and the support contractor. The FY 2007 President's Budget proposes to remove the earmark for FY 2007 because appropriate funding for the Board can be provided from the overall requested HHS budget for EEOICPA without the need for a specific set-aside.

As indicated, DOL is not responsible for overseeing HHS's allocation of resources for EEOICPA, nor for its management of its contractors. Our interest is in seeing that the dose reconstruction process and related site profile and SEC petition processes are carried out in a scientifically valid, accurate, and consistent way, and that HHS/NIOSH processes and returns cases for adjudication by DOL as rapidly as possible. HHS/NIOSH must assess the proper mix between funding for the actual production of dose reconstructions and the documents needed to support them, as well as for SEC petition processing, vs. funding for review and evaluation of that work

19. Individuals, government employees and contractor employees in key roles within this program, have expressed open hostility towards this program and/or the claimant population in public on more than one occasion. Are you aware of this? If not, what do you think are appropriate actions by DOL and NIOSH with regard to these individuals? How do you remedy the effect these actions have on the public perception of your agencies? integrity with regard to the program?

- 19. I am not aware of the expressions of "open hostility towards this program" to which you refer. The DOL staff engaged in this program are dedicated to successfully carrying out the mission of EEOICPA, and I believe they are not only delivering the services the statute intended, but doing so in an overwhelmingly positive, customeroriented manner. The HHS/NIOSH staff and contractors with whom I have been associated are likewise serious, professional, and dedicated to the delivery of this program's services to covered workers and their survivors.
- 20. Please indicate whether each of the 31 cases at the Santa Susana site (Rockadine) discussed at the March 1, 2006, hearing were clearly compensable or non-compensable without the need for a completed site profile as reference and the basis for each of the 31 decisions.
- 20. The 3! cases that had been decided via dose reconstruction at the Santa Susma (Rocketdyne) site at the time of the March 1, 2006, hearing were done using dose reconstruction techniques that do not require a completed site profile. Not all sites have completed site profiles, but two categories of dose reconstructions can be carried out even in the absence of those guidance documents. These include cases that are clearly not compensable for which NIOSH procedures call for the use of overestimation techniques, as well as those for which available case-specific information is sufficient to produce a dose reconstruction that results in payment of compensation. NIOSH has now completed the site profile for this facility.

I hope this information is helpful. Please feel free to contact me at (202) 693-0031 if you have questions about these responses.

sincercly,

Shelby Hallmark

Director

RESPONSES OF JOHN HOWARD, M.D., M.P.H., DIRECTOR, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, TO POST-HEARING QUESTIONS FROM THE HONORABLE JOHN N. HOSTETTLER

1. What are the cumulative Oak Ridge Associated Universities (ORAU) contract costs through March 1, 2006?

\$126,003,422.88

- 2. Please break out how much National Institute for Occupational Safety and Health (NIOSH) and ORAU each spent for the site profiles, site profile reviews, site profile revisions, Special Exposure Cohort (SEC) evaluations, supplements to SEC evaluations and documents produced through the Advisory Board on Radiation and Worker Health (Advisory Board) interactions/supplemental reports as of this date for each of the following sites: (e.g., a cost for each site):
 - 1) Mallinckrodt Chemical 1942-1957
 - 2) Iowa Army Ammunition Plant 1949-1974
 - 3) Rocky Flats
 - 4) Y-12 1942-1957
 - 5) Linde (Tonowanda)

Currently, NIOSH and ORAU do not have an internal cost tracking system that breaks out the cost of activities by site. However, ORAU does track costs by individual tasks within the contract. From the start of the ORAU contract (September 2002) through March 2006, the cumulative cost for site profile development is \$28.7 million and for activities associated with SEC evaluations is \$2.9 million.

3. Please describe the 4-step process for evaluating an SEC petition. Is this process adequate, or do you believe the additional review called for in the Office of Management and Budget (OMB) passback memo is necessary to ensure adequate rigor in reviewing SEC petitions?

The procedures for designating classes of employees as members of the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) are set forth at 42 C.F.R. pt. 83. These procedures describe the information that may serve as the basis for a petition, and require that the petitioner be provided reasonable time and assistance in developing relevant information in support of the petition. The rule provides for administrative review of decisions concerning petitions, and outlines the roles of NIOSH; the Advisory Board on Radiation and Worker Health (ABRWH or "Advisory Board"); the Secretary of HHS ("the Secretary"); and Congress in determining whether the statutory requirements for adding classes of employees to the SEC have been met. We believe these processes conform to the requirements in EEOICPA.

4. Please describe the SEC petitions that were approved to date. Were these approvals well-justified on the scientific criteria set forth in the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) Section 3626 (42 USC 7274q)?

As of June 6, 2006, the following classes of employees have been added to the SEC or are pending action by the Secretary:

Facility	Class definition	Date of final effect		
Mallinckrodt Chemical	All employees who worked at	May 12, 2005 (1942-1948)		
Company Destrehan Street Plant St. Louis, Missouri	least 250 days during the period from 1942 through 1957	November 13, 2005 (1949- 1957)		
Iowa Army Ammunition Plant Burlington, Iowa	All employees who worked at least 250 days on Line 1 during the period from March 1949 through 1974;	June 19, 2005 (1949-1974)		
	radiographers who worked in support of Line 1 operations from May 1948 through March 1949	September 24, 2005 (radiographers)		
Y-12 facility Oak Ridge, Tennessee	All employees who worked at least 250 days in uranium enrichment operations or other radiological activities during the period from March 1943 through December 1947	September 24, 2005		
Linde Ceramics Plant Tonawanda, New York	All employees who worked at least 250 days during the period from October 1, 1942 through October 31, 1947	January 7, 2006		
Pacific Proving Ground Marshall Islands	All employees who worked at least 250 days during the period 1946 through 1962	June 26, 2006		
Nevada Test Site Mercury, Nevada	All employees who worked at least 250 days during the period from January 27, 1951 through December 31, 1962	June 26, 2006		

For each of the petitions representing these classes of employees, NIOSH found that the petitioners had provided sufficient information to qualify the petition for evaluation, the Advisory Board (after considering, among other things, the materials and recommendations made by NIOSH) recommended that the Secretary add these classes of employees to the SEC, and the Secretary accepted the Advisory Board's recommendations and determined that the statutory scientific requirements for the addition of the class of employees to the SEC had been met.

5. Have the three new members of the Advisory Board been evaluated for conflicts of interest? Please provide copies of their conflict of interest disclosure statements, waiver letters and financial disclosures.

Copies of interest disclosure statements, waiver letters and financial disclosures currently on file for these three Board members are attached.

6. Do you support continuing the independent peer review process that has been established by the Advisory Board? Has this improved the credibility of the program?

NIOSH fully supports independent reviews of the scientific basis of the dose reconstructions developed in support of compensation decisions made under EEOICPA. Under the provisions of the EEOICPA, the Advisory Board has been tasked to advise the President (and, by delegation, the Secretary) on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program. From the beginning, NIOSH has supported the independent review process by providing the administrative and financial support necessary for the Advisory Board to carry out this role. Within the guidelines of the Government procurement process, NIOSH assisted the Advisory Board in engaging the services of a technical support contractor. NIOSH continues to support the Advisory Board's independent review process and actively participates with the Advisory Board and their support contractor in the joint resolution of issues that have been raised.

Except for those few meetings that do not involve scientific decision making, NIOSH has adopted the policy that all Advisory Board working group meetings are open to the public and that transcripts are posted on our website. We strongly believe that the open scientific discussions conducted during the review process have enhanced the credibility of the program.

7. What is the average cost of a dose reconstruction?

In March 2004, NIOSH estimated the average cost of a dose reconstruction was \$6900. We are currently updating this estimate.

8. Has ORAU met NIOSH's overall goals for performing dose reconstructions under its 5-year contract in terms of cost, quality of science, and management of conflicts of interest?

ORAU has met NIOSH's overall goals in these areas.

Although costs are considerably higher than the original award, this is due to the incomplete understanding of the effort required at the time of award. NIOSH recognized that many things that were unknown at the time of the award would affect the overall effort required, so a cost-plus-award fee contract mechanism was selected. The added cost is due to the amount of effort that has turned out to be necessary.

NIOSH considers the quality of science in ORAU's products to be very good. ORAU's work is subject to rigorous review by NIOSH, the Advisory Board on Radiation and Worker Health, and the Advisory Board's contractor. The process of review, comment, and resolution is an important part of the scientific process.

At the time of contract award, NIOSH did not specify criteria for management of conflict of interest, which includes management of perceived conflicts. Rather, it required ORAU to submit its own conflict of interest policy for individuals who performed dose reconstructions. NIOSH's direction to ORAU with respect to conflict of interest has evolved over the life of the contract, and ORAU has adjusted its practices accordingly. NIOSH is implementing a conflict of interest policy that will apply uniformly to all contractors on the project.

NIOSH actively manages ORAU's contract to ensure good performance. In accordance with ORAU's contract, NIOSH evaluates ORAU's performance for award fee purposes every six months. The evaluation criteria change for each period as the priorities of the program change, and assessment reports evaluate ORAU's progress against those criteria. Those assessments have been provided in the past and are being provided at the present in response to document requests. They provide a summary of NIOSH evaluation of ORAU performance. A change in ORAU project key personnel late in 2005 has been followed by noted improvement in NIOSH's evaluation of performance.

9. When NIOSH awarded the 5-year contract to ORAU for approximately \$70 million, did NIOSH Program staff expect the cost would increase to \$200 million? If not, when did that become apparent?

When NIOSH awarded the 5-year contract to ORAU, there was no similar program to inform it about the amount of effort involved. Because so much was unknown about the amount of effort that would be required, a cost-reimbursable contract mechanism, specifically a cost-plus-award-fee contract, was used. NIOSH expected that the cost could easily increase above \$70 million, but was not in a position to predict the expected increase with any degree of precision.

Examples of unknowns that would influence the effort require were the nature and completeness of Department of Energy records, research required to complete scientifically valid dose reconstructions, the extent of the scientific review process, and the complexity of the Special Exposure Cohort process. The Special Exposure Cohort rule was not published until 2004, well after the contract was awarded. The increased cost is due to the complexity of the work that is required, not due to a cost overrun or change in the scope of the contract.

Within a few months of contract award it became clear that a contract of \$70 million over 5 years would not come close to producing the amount of progress needed in light of the large amount of work facing the program. By December of 2004 it appeared that the total cost for the 5 year contract would be about \$200 million.

10. The Labor HHS Appropriations Act (P.L. 109-149) requires a report from NIOSH within 180 days evaluating whether any additional radiosensitive cancers should be added to the list of compensable cancers used for SECs. Will this report

be sent to Congress on schedule? Will NIOSH solicit comments from experts in radiation epidemiology before submitting this report?

A draft of this report has been prepared and has undergone internal NIOSH review, with reviewers including those with expertise in radiation epidemiology. The draft report is currently in internal comment resolution. Upon completion of internal comment resolution, the revised report will be submitted to external subject matter experts for their review. NIOSH believes in the value of external subject matter expert reviews of our scientific products, and has therefore solicited the services of five external expert reviewers, all of whom have expertise in radiation epidemiology. The report will be provided to Congress as soon as possible, following resolution of comments from all external and internal reviews.

11. What is the status of the NIOSH report to Congress on residual radiation and residual beryllium required by P.L. 108-375?

NIOSH has received draft evaluations of the sites covered in the relevant provision of the Defense Authorization Act of 2005. These draft evaluations are being reviewed and incorporated into the final report. The report is on schedule to be delivered to Congress on time.

12. What level of funding is needed in FY 2007 for the Advisory Board and its audit contractor?

Advisory Board Cost Projections by Fiscal Year			Advisory Board Obligations by Fiscal Year				
Fiscal Year	ABRWH Support Costs	Audit Contractor Costs	Total Projected Costs	Fiscal Year	ABRWH Support Costs	Audit Contractor Costs	Total Actual Obligations
FY 2002	\$170,000	\$0	\$170,000	FY 2002	\$130,552	\$0	\$130,552
FY 2003	\$595,000	\$300,000	\$895,000	FY 2003	\$246,871	80	\$246,871
FY 2004	\$330,000	\$750,000	\$1,080,000	FY 2004	\$294,385	\$1,084,951	\$1,379,336
FY 2005	\$330,000	\$850,000	\$1,180,000	FY 2005	\$286,189	\$3,240,318	\$3,526,507
FY 2006	\$290,000	\$850,000	\$4,500,000	FY 2006**	\$232,619	\$2,119,297	\$2,351,916
FY 2007	\$450,000	\$4,050,000	\$4,500,000	FY 2007			
FY 2008	\$450,000	\$4,050,000	\$4,500,000	FY 2008			1

NOTE: Advisory Board Support costs include: PS&B and travel for Advisory Board Members. Rental space for meetings, meeting transcriptionist, supplies, etc

^{**} In FY 06, there was an earmark of \$4.5M for support to the Advisory Board. Obligations for FY 06 are YTD as of June 6, 2006. NIOSH projects the Advisory Board expending an additional \$111,000, for a total obligation of \$2.5M in FY 06. The remaining \$2M will be carried over to FY 07.

13. What do you see as the definition of "balance" as referred to in the OMB passback document? What type of "balance" would be required to assist in the OMB mission to contain costs associated with SEC approvals?

NIOSH strives to establish a scientific basis for its responsibilities under EEOICPA. Rigorous independent review of the scientific elements underlying dose reconstruction and evaluation of SEC petitions is one way to ensure that these products are balanced.

14. Do you believe NIOSH procedures or the Advisory Board and their decisions have been "unbalanced"?

NIOSH procedures and the Advisory Board's advice and recommendations have not been unbalanced. The two items are a system of "checks and balances" that in my estimation, appear to be working as intended. As you know, Federal Advisory Committee Act (FACA) advisory committees have played an important role in shaping programs and policies of the Federal government. The Advisory Board is a balance of perspectives based on its membership of professional scientists, physicians, and workers that has provided advice and recommendations to the Secretary and NIOSH on the development of guidelines; the scientific validity and quality of dose reconstruction efforts; and on whether there is a class of employees who were exposed to radiation but for whom it is not feasible to estimate their radiation dose and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of the class.

15. Do you think there is a problem with the audit contractor employees because of conflicts of interest or bias? If so, how do you see that as negatively affecting the claims process?

NIOSH believes that it is important to bring all perspectives to the table in the independent review process. As long as conflict of interest is dealt with in an open and consistent manner, we do not see this negatively influencing the claims process. This includes full disclosure of potential conflicts by all parties engaged in the conduct and preparation of review documents.

16. Why do you think OMB chose the five options in the Passback as primary ways to contain costs?

I have no insight into the reasons OMB chose the five options.

17. The conflict of interest policies accepted by NIOSH for the audit contractor and the dose reconstruction contractor differ in substance. The dose reconstruction contractor's policy appears less stringent. Do you feel that conflicts of interest and bias on the part of contractors processing claims are as detrimental to the program's integrity as they would be on the part of the audit contractor? If so, why aren't they held to the same standard?

NIOSH acknowledges that different contractors have adopted different conflict of interest policies. NIOSH believes that all contractors should be held to the same high standards when it comes to conflict of interest. Consequently NIOSH is implementing a conflict of interest policy that will apply to all contractors on the project.

18. One employee of NIOSH's contractor, Mr. Falk, served as a site dosimetrist and radiation dosimetry manager at the Rocky Flats plutonium foundry from 1966 to 1998. He is listed as a subject expert and site expert for the Rocky Flats site profile, and he also did the Rocky Flats neutron dose re-assessment project for ORAU. IN preparing these assessments, Mr. Falk is reviewing his previous work as a dosimetry manager. While his expertise should be used, isn't Mr. Falk's involvement as a site expert and a subject expert at Rocky Flats a conflict of interest? If not, why not? Additionally, Mr. Falk is also participating in the preparation of the SEC Evaluation Report for Rocky Flats? Is this a conflict of interest? If not, why not?

Dr. Roger Falk is listed as the subject expert for ORAUT-TKBS-011-5, the Technical Basis Document for the Rocky Flats Plant - Occupational Internal Dose. In this capacity, Dr. Falk authored this section of the Rocky Flats Technical Basis Document (TBD) in 2004. As part of the approval process for this document and as evidenced by the signatures appearing on the first page of this TBD, Dr. Falk's work was reviewed by the ORAU TBD Team Leader (Dr. Robert Meyer), the ORAU Task 3 Manager (Judson Kenoyer), with concurrence by the ORAU Project Director (Dr. Richard Toohey), and NIOSH approval by the NIOSH OCAS Health Science Administrator (Dr. James W. Neton). None of these individuals has a conflict of interest at the Rocky Flats site. As part of the established NIOSH approval process for TBDs, the document has also undergone independent reviews by NIOSH health physicists prior to Dr. Neton's signature. The Advisory Board's audit contractor, Sanford, Cohen and Associates (SC&A) has also reviewed this document. By virtue of Dr. Falk's employment at the Rocky Flats site, he could have a real or perceived conflict of interest. However it is not accurate to state that "Mr. Falk is reviewing his previous work as dosimetry manager". Rather Dr. Falk provided his site-specific expertise, which then underwent extensive independent review by non-conflicted individuals on the ORAU Team, NIOSH, the ABRWH audit contractor, and the ABRWH itself. As posited in the text of the question, "his expertise should be used". NIOSH believes that by clearly identifying the authorship of the TBDs used and by subjecting TBDs to rigorous independent reviews and conflict of interest standards, we are utilizing the expertise of individuals with historic knowledge appropriately.

This explanation similarly pertains to Dr. Falk's involvement in the SEC Evaluation Report (ER) for Rocky Flats. The SEC process itself implicitly necessitates the involvement of individuals and parties with real or perceived conflicts of interest, including site experts consulted by NIOSH and SC&A. Dr. Falk's employment at Rocky Flats and his potential future membership in a SEC class designated at the site could constitute real or perceived conflicts of interest. Dr. Falk is listed as one of five Site Experts for this document, and his contributions are clearly identified in the text of the report. The ER Document Owner is Karin Jessen of the ORAU Team, and a peer review

was completed by Dr. Brant Ulsh of NIOSH, an additional review was completed by Dr. Jim Neton of NIOSH, and the document was approved by Larry Elliott of NIOSH. None of these individuals have conflicts of interest at the Rocky Flats Site. The ER is currently being independently reviewed by SC&A and the ABRWH Working Group and has been presented to the ABRWH at large for their review. Again, NIOSH believes that by clearly identifying the contributions of potentially conflicted individuals to the ER and by subjecting ERs to rigorous independent reviews and conflict of interest standards, we are utilizing the expertise of individuals with historic knowledge appropriately.

19. Committee staff attended the recent Advisory Board meetings in Oak Ridge, Tennessee and Denver, Colorado. Public comment discussions were quite disturbing. Claimants gave glaring testimony about the quality of work being done by NIOSH's dose reconstruction contractor. Examples of people receiving denials for the wrong cancer, denials because the evaluation applied standards for the wrong job category or work area even after claimants provided the correct information repeatedly, and NIOSH claims interviewers arguing with claimants about these basic pieces of claimant-known information because the computer screen in from to them had the incorrect information. After 4 years, why are these kinds of mistakes and this kind of attitude tolerated? The contractor's costs have nearly tripled. Why has there been so little attention paid to this large increase in contractor costs and, as audits have disclosed in several instances, the scientifically incomplete work product that is being repeatedly provided by this contractor? What actions have been taken to address this waste of taxpayer funds? Why do you think there is no focus on this cost issues by OMB in their document?

As you know, claims are filed through the Department of Labor (DOL). At that point it is DOL's responsibility to determine and verify the energy employee's covered employment (location and time period) and health condition (cancer). Cases are then referred to NIOSH for dose reconstruction. NIOSH must use the information verified by DOL for the dose reconstruction. Twice a year NIOSH sends claimants a Dose Reconstruction Activity Report. The report includes the current status of their claim and other miscellaneous information. One of the items included in the report is a summary of the employment and cancer information for their claim. Claimants are encouraged to review the information for accuracy and contact DOL if any of the information in incorrect. Claimants are also informed to contact DOL if any new information is to be added to the case file. Under EEOICPA, NIOSH does not have the authority to add additional employment, change employment dates, add new cancer information, or change listed cancers on a case. Changes of that nature must come to us from DOL. Whenever a discrepancy is found in the data, the claimant is encouraged/informed to contact DOL. We also follow-up with DOL on these issues to see if the claimant has contacted DOL. Unfortunately, there are many instances in which it is not noticed by the claimant that the information in the case file is incorrect or that there is additional employment or cancer information to be added to the case until the dose reconstruction has been drafted or completed. Both NIOSH and contractor staffs are aware that all new and corrected information on a case must come from DOL.

Contractor cost issues are addressed in the responses to questions 8 and 9.

20. Individuals, both Government employees and contractor employees, in key roles within EEOICPA, have expressed open hostility towards this program and/or the claimant population in public. Are you aware of this? If not, what do you think NIOSH should do to address these actions? How do you remedy the effect they have on the public perception of your agencies' integrity with regard to the program?

I am personally not aware of such actions, and would find them unacceptable. NIOSH and contractor staff are encouraged to adhere to a high level of professional conduct. I will follow up on any specific examples of such actions of which I am made aware.

21. The FY 2005 Defense Authorization Act conference report stated that: "Conferees are concerned that the administrative process for designating additional special exposure cohorts (SEC) is too slow and should be accelerated... new timelines have been included. Within 180 days of receipt of a petition for designation as members of a SEC, the Director of NIOSH must submit to the Advisory Board a recommendation on that petition, including all supporting documentation. During the 180-day period when NIOSH is preparing the petition for review by the Advisory Board, NIOSH should identify all deficiencies in the petition within the first 30 days." NIOSH has issued an Interim Final Rule that states that the 180-day time frame does not start until NIOSH has identified any petition deficiencies and completed qualification, whereas the law requires all qualification and evaluation of the SEC take place within 180 days. Moreover, NIOSH's rule sets no time limits on qualifying the petition. Thus, the intent of placing 180-day time limit in the law is evaded. What can be done to bring this rule into conformance with Congressional direction?

HHS did not evade the 180-day deadline. The statute requires that within 180 days of receiving an SEC petition that NIOSH submit a recommendation on that petition to the Advisory Board on Radiation and Worker Health, making it reasonable to assume that a petition should be defined by the requirements specified for a petition at that time in 42 C.F.R. pt. 83. NIOSH had worked and continues to work with petitioners to assist them in addressing the requirements for a petition. Petitioners frequently require a substantial amount of time to contact NIOSH, to clarify information that had been submitted, to identify unmet requirements, to obtain advice on addressing such requirements, and to address such requirements. Thus, the interim final rule was designed to incorporate the 180-day deadline for NIOSH to conduct its evaluation without impinging upon the work between the petitioners and NIOSH to prepare a qualified petition.

It is the intent of NIOSH to continue to provide for the needs of petitioners in the petition preparation process to the extent possible, within the constraints of the statutory requirements.

RESPONSES OF JAMES MELIUS, M.D., DRPH, ADMINISTRATOR, NEW YORK STATE LABORERS HEALTH AND SAFETY TRUST FUND, MEMBER OF THE ADVISORY BOARD ON RADIATION AND WORKER HEALTH, TO POST-HEARING QUESTIONS FROM THE HONORABLE JOHN N. HOSTETTLER

New York State Laborars'
Health & Sofiety Trust Fund
18 Careston Massis Business of
Albors, New York 122
12, 130, AM 214 - 800, 777, 7711
For. 518 AVR 1621



June 29, 2006

The Honorable John N. Hostettler, Chairman Subcommittee on Immigration, Border Security, and Claims
Congress of the United States
House of Representatives
2138 Rayburn House Office Building
Washington, DC 20515-6216

Dear Chairman Hostettler:

This letter is in response to your letter of June 16, 2006, regarding my testimony at the March 1, 2006 hearing of the Subcommittee on Immigration, Border Security, and Claims on "The Energy Employees Occupational Illness Compensation Program Act — Are We Fulfilling the Promise We Made to these Veterans of the Cold War When We Created the Program?" I have addressed each of your questions below:

 Do you believe that the Board's audit contractor, Sanford Cohen and Associates (SC&A), provides technically sound analysis?

I believe that SC&A provides excellent technical analysis for the Board. SC&A has employed an excellent group of technical specialists to assist with this project and have provided prompt scientifically rigorous review of NIOSH dose reconstructions, site profiles, and SEC evaluations. NIOSH has not yet established its own rigorous scientific review system for this program (this is partially due to the need to address the large backlog of cases, etc.). Therefore, the SC&A review often uncovers a substantial number of technical issues in their reviews that need to be addressed by NIOSH and their contractors. The SC&A reviews, and the subsequent effort to resolve these issues (done under the direction of the Board), have resulted in a significant improvement in the technical foundation of the dose reconstructions and SEC evaluations and, therefore, has improved the fairness of the compensation program for the claimants

An affiliate of the Jabaers' Marie land Union of Nesta America, ARCIDO 2. Do you agree with the Department of Labor's (DOL) criticisms that the audit contractor has adopted a posture that demands that NIOSH make implausibly high radiation dose estimates?

This criticism made by DOL at the subcommittee hearing is not based on any sound analysis of the audit process. The lack of exposure monitoring data for many workers who worked at DOE facilities was recognized by Congress when passing this law (including the Special Exposure Cohort provision). As I stated at the hearing, we should not punish the claimant because his/her exposure neorords are not available for dose reconstruction by assuming that they had no or little exposure. We must estimate that exposure in a manner that is fair to the claimants. In SC&A's reviews, the "claimant favorableness" of the assumptions that NIOSH uses in estimating the exposure in question are just one of the factors that the Board has requested that SC&A evaluate. Other factors, including the bechnical basis for the estimate, are also evaluated. In my experience, SC&A's reviews have been balanced. In some instances, they may point out that the procedure used by NIOSH is not as claimant-favorable as the situation warrants while in many other instances, they have pointed out that the assumptions or procedures being used are too claimant-favorable because they do not have a sound technical basis.

Does timeliness in performing dose reconstructions play into the Board's assessment of whether it is feasible to reconstruct dose, or is it limited to technical limitations;

To a limited extent, the Board has considered timeliness in performing dose reconstructions in our review of feasibility. Our recently adopted procedures for the review of SEC evaluations provide for the consideration of timeliness but without explicit criteria. The fact that NIOSH is still developing site profiles for some sites and still establishing dose reconstruction procedures limits the Board's ability to establish firm benchmarks for timeliness for dose reconstruction. On the other hand, some claimants have waited for over four years for their claims to be processed, and this is clearly not fair or just. I would note that the Board has very little information on the outstanding claims and unless a site is part of an SEC petition review, a specific group of backlogged claims would not be brought to the Board's attention unless NIOSH requested the Board's advice on some issue relative to these cases.

4. Given the past history of NIOSH program interference with the independence of the Board, do you have any recommendations on how to better structure the Advisory Board to ensure independence?

I believe that the independence of the Board is critical to the credibility of the compensation program. While appointment of an Executive Secretary from outside the internal NIOSH OCAS program has greatly improved the situation, there are still many potential issues that could compromise the independence of

3

the Board. The OMB document discussed at the Subcommittee hearing raised possible ways to interfere with the Board's independence. A statutory change to change the Board to an independent commission would be one method of improving the independence of the Board. Working within the present structure, I believe that appropriating an independent budget for the Board (including its contractor) would help to ensure our independence. In addition, providing one or two technical staff people assigned full time to the Board would also help by allowing the Board to conduct its work without being dependent on NIOSH OCAS staff.

5. Should the Advisory Board have contracting authority?

While contracting authority would be helpful in ensuring that the Board had independent control over its contractor(s), I am not sure that it necessary. It would also require the Board to become familiar with federal contracting procedures and requirements and could take time away from more important Board issues. However, the assignment of technical staff to the Board would assist the Board in overseeing the contract, even if the NIOSH/CDC contracting staff continued to handle the administrative aspects of the contract(s).

8. Has the Board received signals from the DOL regarding the availability of funds necessary to conduct their independent review? Where has that resistance come from and what have been the arguments? Do you feel that there is any justification for concern about the expense of the audit contractor review?

DOL representatives (Shelby Hallmark and Pete Turcic) have raised concerns about the potential expense of the audit contract at public meetings of the Board. At the time that they mentioned these concerns, I do not recall that they raised any specific technical or performance concerns about the contractor. Rather, they pointed out that DOL "controlled" the budget for the Board's work and that resources were limited. Resources for the contractor needed to be balanced with other program needs. However, Mr. Hallmark's testimony at the subcommittee hearing certainly implies that their concerns were not just fiscal but related to their disagreements with the technical advice being offered by the contractor. As I stated at the subcommittee hearing, I believe that the Board has exercised appropriate oversight of the work and expenses of the contractor. The Board has discussed the reasons why the initial cost estimates for the work being done by its contractor were lower than the actual costs and that the higher costs were justified given the technical complexity of the program. The Board has not approved some proposals from SC&A because the Board believed that the proposed costs were too high. This is a normal part of the oversight involved in contract management. However, the overall effort by SC&A has been appropriate and the costs well justified.

7. As a Board member, what is your opinion of the quality of the work product coming out of NIOSH/ORAU for the Board's initial review? Does this explain why the scope of the audit has increased?

NIOSH and its contractor had a large and very complex task to establish the technical basis for the dose reconstruction program. They had to establish procedures for estimating exposures at a large number of diverse DOE sites with many different exposures, some occurring over 50 years ago. They were not able to use "standard" methods but rather had to adopt procedures often developed for circumstances where modern monitoring techniques were being used. The need for procedure development, the complexity of the exposures at the DOE facilities, and the limited monitoring data (especially in the early years) made the initial establishment of the dose reconstruction program for all sites very difficult. As might be expected, NIOSH devoted most resources to the development of procedures, site profiles, etc. and addressing the backlog of cases but, in my opinion, did not develop an adequate independent technical peer review program. For the most part, NIOSH also used the same contractor to develop and then apply the procedures for dose reconstruction. While this approach may have been more efficient, it limited the technical independence of those involved in reviewing the procedures, etc. (i.e., everybody worked for the same organization) that having multiple contractors could have encouraged. This need to try to quickly address the large backlog of cases and the use of a single contractor for procedure development and application limited the adequacy of the technical review of the procedures was done by the Board's contractor and, not surprisingly, our contractor found many technical issues requiring further review in a number of the documents that they reviewed. This, in turn, greatly increased the scope of the work done under these audits.

 Do you feel there is imbalance in NIOSH's procedures on site profiles and dose reconstructions?

While I believe that NIOSH has attempted to develop a belanced approach for developing site profiles and dose reconstructions, I believe that the pressures to address the large backlog of cases in the program has resulted in a selective imbalance in the information used in the dose reconstructions. In the initial rush to develop site profiles, NIOSH relied on readily available documents about exposure monitoring at the sites and, in many cases, relied on information provided by people who operated those exposure monitoring programs on behalf of DOE contractors (the latter is the subject of ongoing concerns about inadequate conflict of interest provisions in the program). NIOSH did not have an adequate program for obtaining information from worker representatives and experienced site personnel who could provide information on problems with those monitoring programs (e.g., poor record keeping, gaps in coverage, etc.) Therefore, the site profiles did not capture or document these problems. Thus, when NIOSH or their contractors used the site profiles for dose reconstructions

RESPONSES OF RICHARD D. MILLER, SENIOR POLICY ANALYST, GOVERNMENT ACCOUNTABILITY PROJECT, TO POST-HEARING QUESTIONS FROM THE HONORABLE JOHN N. HOSTETTLER

Response of Richard Miller, Senior Policy Analyst, Government Accountability Project to the questions for the record for the House Committee on the Judiciary, Subcommittee on Immigration, Border Security & Claims

Has NIOSH been effective in managing ORAU's conflict of interest? Have these
conflicts of interest impacted the credibility of ORAU's work? Please provide
examples.

Many of the persons working on this compensation program, whether as federal or contractor employees, had been involved in managing radiation protection programs for the Department of Energy (DOE) or its contractors and must now render judgments on their previous work, or that of their colleagues or employers. As ORAU concedes, the critical consideration is not whether potential conflicts of interest (COI) exist—they do—but whether there is a plan to identify and avoid them. Driven by production imperatives, NIOSH and ORAU have failed to police numerous conflicts of interest and were slow to plug loopholes when they were identified. For example, when the Advisory Board on Radiation and Worker Health (ABRWH) repeatedly requested that NIOSH expand ORAU's conflict of interest policy to go beyond dose reconstructions and include the development of "site profiles," it took over a year to amend the policy to add in the words "site profile". Site profiles are documents which outline key assumptions used in radiation dose estimates for purposes of compensation. When ORAU's COI policy was finally amended to cover site profiles, NIOSH and ORAU intentionally built in ambiguities which allowed these conflicts to persist.

ORAU's contract now prohibits individuals from preparing site profiles at sites where the individual had been previously employed performing dose assessments for DOE or its contractor. The ORAU contract also requires that it compile a data base and submit it to NIOSH outlining all potential conflicts of interest for each individual by site (including whether subcontractors are "reviewing reports, assessments, surveys, documents, and records that they organizationally or individually have been responsible for authoring, developing or submitted to DOE or its contractors"). The same policy requires disclosure of individual conflicts of interest on a web site, and bars individuals from preparing site profiles, dose reconstructions or special cohort reviews if the individuals had "voluntarily served as expert witnesses on behalf DOE or a DOE contractor in defense of radiation claims or suits."

A month after the ORAU contact was awarded in September 2002, Larry Elliott, the Director of NIOSH's Office of Compensation and Analysis Support (OCAS) announced to the ABRWH that he would commence an audit of conflict of interest compliance within 9 months. It appeared NIOSH was going to be serious in managing the conflict of interest policy. However, no such audit was ever conducted. Rather, Mr. Elliott pivoted on NIOSH's assurances that conflict of interest would be policed, and requested that the ABRWH consent to waive conflict of interest with respect to the development of certain site profiles. When the ABRWH rejected this request, NIOSH turned a blind eye to ORAU's breach of its contractual requirement to abide by its conflict of interest policy. For example:

- ORAU hired Carol Berger as a subcontractor to prepare the Paducah, Kentucky facility internal radiation dose technical basis document, even though Ms. Berger had prepared transuranic exposure estimates (neptunium-237 and plutonium-239) for the DOE's contractor at Paducah in 1988. Ms. Berger's 1988 radiological assessment was criticized for underestimating worker exposures in 2000 as part of a DOE-sponsored radiation exposure assessment. Her previous work underestimated potential exposures 5-10 fold. However, when drafting the NIOSH site profile document in 2004, Ms. Berger ignored that earlier critique and simply cut and pasted tables from her 1988 radiation exposure report directly into the NIOSH site profile. Despite 4 layers of review, ORAU and NIOSH failed to identify the fact that she overlooked published critiques of her previous work and that her conflicts of interest impacted the quality of the work she submitted to NIOSH. This is a case where tainted science is traceable to an individual's conflict of interest.
- After 7 months of public and Congressional inquiries, NIOSH-OCAS issued a Contract Oversight Team report which conceded that Ms. Berger's work underestimated potential exposure, but NIOSH staff could not find a breach of any aspect of the ORAU conflict of interest policy. Had the ORAU policy been implemented, the Berger conflict would have been flagged, and Ms. Berger's involvement would have been barred. When the Oversight Team report was brought to the attention of NIOSH Director John Howard, he initiated changes to preclude this kind of conflict from recurring. However, no systematic COI audit has been undertaken by NIOSH.
- NIOSH and ORAU allowed the former DOE Rocky Flats radiation protection
 manager, Roger Falk, to craft major portions of site profiles and a Special Exposure
 Cohort Evaluation Report in violation of its conflict of interest policy. Roger Falk
 also served as an expert witness in defense of workers' compensation claims at Rocky
 Flats, in further breach of the conflict of interest policy.
- ORAU retained Battelle Pacific Northwest Labs as a subcontractor to research and
 prepare the site profile for the Hanford facility and the Pacific Northwest Lab, even
 though Battelle Pacific Northwest Labs has a contract with the DOE to manage the
 radiation dosimetry programs at these two sites. This appears to be at odds with the
 ORAU policy which prohibits contractor elements from participating in research on
 site profiles "for those DOE sites or activities where it is the prime contractor, team
 member to a prime contractor, program manager or subcontractor managing
 dosimetry programs...."
- ORAU hired staff to prepare its site profile at the Idaho National Labs and the Pantex facility who had managed the respective site's health physics programs or had served as expert witnesses defending DOE or its contractors, in apparent breach of contract.

To our knowledge, NIOSH has not taken any action to enforce its conflict of interest policy in the aforementioned cases, even though conflicts have been brought to NIOSH's attention by a

number of entities, including worker representatives at the respective sites. Until NIOSH treats violations of the COI policy as a breach of contract, and disallows costs for products and services delivered to the government in violation of its conflict of interest policy, the absence of consequences provides precious little incentive for meaningful compliance.

2. Do claimants have confidence in the work of the audit contractor?

To date, Sanford Cohen and Associates (SC&A) has supported the ABRWH's technical assessments of dose reconstructions, site profiles, technical procedures and special exposure cohort reviews with integrity. SC&A's contract imposes a high bar with respect to conflict of interest, and with one exception (work for the Defense Threat Reduction Agency), has assiduously avoided any potential conflicts. SC&A's questioning attitude, its expertise, and willingness to listen to workers employed in nuclear facilities has led most claimant groups to have confidence in their work. However, SC&A's work scope is driven by the ABRWH, and should the ABRWH or NIOSH limit the depth of their reviews, confidence would be impaired. Likewise, the loss of balance in the composition of the ABRWH puts at risk the credibility of the audit process.

To date, SC&A has uncovered missing production processes in site profiles, and raised concerns about data reliability which were overlooked by NIOSH/ORAU. For example, questions on data reliability were identified by SC&A in their audit of the site profiles for the Nevada Test Site after interviewing the former rad safe manager for this site. SC&A questioned the feasibility of reconstructing radiation dose to cyclotron workers at the Oak Ridge Y-12 facility, when NIOSH had initially asserted otherwise in their SEC Evaluation Report. SC&A raised technical issues regarding the Bethlehem Steel site profile which has driven major revisions. SC&A's technical assessment of classified information regarding the feasibility of estimating dose from nuclear weapons pits led the ABRWH to conclude dose could not be reconstructed at the Iowa Army Ammunition site. Without SC&A's support of the ABRWH, it would be far less effective.

The Department of Labor (DOL) claims that the audit contractor is biased in favor of the claimants and they only focus on underestimation of dose. SC&A has flagged questionable overestimates almost as often as they found errors that lead to underestimates. DOL's meddling with the audit process by promoting a change in the balance of the ABRWH, or seeking to cut off funding for the Board's work, taint its reputation as an impartial claims adjudicator.

3. Does NIOSH provide adequate assistance to petitioners in filing SEC Petitions?

Claimants face a variety of hurdles in filing SEC petitions: (1) qualifying a Special Exposure Cohort (SEC) petition that meets the minimum informational requirements under the SEC Rule 42 CFR 83.13; (2) producing evidence that it is not feasible to reconstructing dose with sufficient accuracy, since this involves proving a negative.

Except for NIOSH-initiated additions to the Special Exposure Cohort under 42 CFR Part 83.14, NIOSH has used a legalistic approach to disqualify SEC Petitions. In working with petitioners at Chapman Valve, NUMEC and Los Alamos Labs, NIOSH has sent letters which

contain threats to dismiss SEC petitions simply because petitioners unwittingly checked the wrong box, or an affidavit was not notarized. Trivial matters like this could be resolved with a phone call.

NIOSH announced on June 7, 2006 that it is assigning a staffer to assist petitioners; however, the autonomy of this individual to assist petitioners is untested. For example, will the SEC staffer have the autonomy to develop facts necessary to develop a winning SEC petition, or will they be constrained to echo the wishes of OCAS management? Some NIOSH/ORAU management have expressed open hostility towards SECs, because they believe that SECs lead to overcompensation, and/or that with enough time and money they can develop generic models which extrapolate radiation dose estimates from other atomic weapons facilities or time periods. Once NIOSH decides that it will fight an SEC petition, it hires ORAU staff (some of whom have conflicts of interest) to develop strategies and conduct research to defeat SEC petitions. In the technical exchanges which take place with the Advisory Board, petitioners are outmatched. For this reason, NIOSH should provide technical assistance to petitioners through a non profit organization or university which is not conflicted. While we are pleased that NIOSH has designated a staffer to handle the mechanics of filing a petition, this person lacks the requisite independence to provide technical assistance with developing the rationale for a petition.

Even when claimants succeed with getting their petition "qualified" for evaluation, NIOSH has frequently violated the 180-day time limit to deliver an SEC Evaluation Report to the ABRWH. In the case of the Rocky Flats SEC Petition, NIOSH took 440 days from the date of receipt to the date they submitted its report the ABRWH. NIOSH failed to meet the 180-day deadline for the Chapman Valve facility (which was due on May 8, 2006 and is still pending) and was overdue on the Evaluation Report for the Oak Ridge Y-12 facility (for 1948-1957). There are no legal consequences for NIOSH failing to comply with the time limits in the law.

4. What specific actions would you recommend to protect the independence of the SEC review process in light of the OMB Passback memo?

The independence of the SEC process is endangered on several fronts: Labor Department and OMB interference with SEC designations; White House efforts to alter the balance of the Advisory Board; and White House/OMB/DOL efforts to impose constraints of audit contractor. In addition, delays will result from adding reviews by entities outside of the ABRWH and its audit contractor.

Recommendations:

- Congress should amend EEOICPA and have Congress make directed appointments to the Advisory Board on Radiation and Worker Health, with an equal number appointed by the majority and minority leaders in the House and Senate.
- 2) Congress should require that all communications on SECs involving HHS, OMB, DOL or other agencies be conducted in the open before the Advisory Board. If DOL or OMB objects to a recommended decision, they should put it on the record in the full light of day for the

- Board to evaluate. Further, not more than 21 days should elapse between an Advisory Board recommendation, and the transmittal of such recommendation to the Secretary of HHS.
- Congress should amend EEOICPA to designate that the Secretary of HHS (or the Director of NIOSH) should make all decisions on SECs, instead of assigning such responsibilities to the President.
- 4) The Advisory Board should have its own line item in the President's budget request, and the ABRWH should be authorized to establish the terms and conditions for its audit contract staff, define the scope of work, and recommend the budget necessary to carry out its work.
- 5) The Advisory Board should be designated, by statute, as the exclusive body to undertake reviews and make recommendations on SECs to the HHS Secretary. Further, the Advisory Board's recommendations should be adopted by the Secretary of HHS, unless the Secretary makes a finding that there is compelling evidence that would override the recommendation of the Board.
- 6) The statute should be clarified to mandate that transparency is a requirement of the program. Should classified information be used by NIOSH/DOL to deny a claim or SEC petition, then claimants or petitioners should be given technical assistance to appeal their case using independent experts with appropriate security clearances.
- HHS should receive funds for administrative costs for this program directly from Congress, instead of having the funds flow through DOL first

5. What are your views on the NIOSH Interim Final Rule with respect to Special Exposure Cohorts?

(a) Section 3166 of the FY 05 Defense Authorization Act (P.L. 108-375) states:

"DEADLINES—(1) Not later than 180 days after the date on which the President receives a petition for designation as members of the Special Exposure Cohort, the Director of the National Institute for Occupational Safety and Health shall submit to the Advisory Board on Radiation and Worker Health a recommendation on that petition, including all supporting documentation."

NIOSH/CDC issued an interim final rule (IFR) on December 22, 2005 which interprets the above cited passage to mean that the 180-day clock starts running after NIOSH reviews and initially "qualifies" the SEC petition, rather than 180 days from the receipt of the petition. NIOSH/CDC misread the law and the accompanying Conference Report which requires that SEC recommendations be submitted to the Advisory Board within 180 days from receipt of an SEC petition—not from the date the petition is "qualified". The Conference Report (H. Rep. 108-767) states that "During the 180-day period when NIOSH is preparing the petition for review by the Advisory Board, NIOSH should identify all deficiencies in the petition within the first 30 days." This language makes clear that NIOSH must complete the petition "qualification"

and the subsequent technical "evaluation" within a 180-day time frame. NIOSH/CDC never reconciled the conflict between the IFR and the plain language of the Conference Report.

NIOSH needs to amend the rule to require the 180- day clock to commence upon the agency's receipt of the SEC petition. As part of the IFR, NIOSH relabels SEC petitions as mere "submissions" until the petition has been "qualified." NIOSH should desist from linguistically redefining the term "petition" to be a mere "submission" as a way to squeeze out additional time for the SEC review. The concept of a "submission" as distinct from a "petition" is not in the law and NIOSH should not be re-legislating through the rulemaking process.

Moreover, even if the 180-day clock could start at the point that a petition was "qualified," the IFR sets no time limits on how long it will take to "qualify" a petition. The Preamble says it can take "months," but qualifying a petition is, if NIOSH were to work efficiently, a simple matter of helping petitioners complete a form. Some qualifying SEC petitions have justifications as short as 1 sentence. It is remarkable that 5+ years after enactment of EEOICPA, when more than adequate time has elapsed for NIOSH to secure records, that NIOSH is trying to wriggle out of the 180-day deadline to process SEC petitions.

(b) The IFR unfairly reduces the time to only 7 days for a petitioner to file an appeal regarding the disqualification of an SEC petition.

Seven days is far too short of a time period to prepare an appeal. We strongly urge HHS to re-establish a 30-day time period for petitioners to file an appeal from the receipt of a letter disqualifying a petition, and should an appeal be granted, then NIOSH can extend the deadlines beyond 180 days. In the Advisory Board Conference call on March 15, 2006, OCAS Director Larry Elliott suggested that 7 days was not a hardship for petitioners, because all that is required is a letter notifying NIOSH that a petitioner desires an appeal. That is not what the IFR states. 42 CFR 83.11(c) requires that petitioners must "specify why the proposed findings should be reversed based on the petition requirements and on the information that the petitioners had already submitted." This requires a full exposition of issues, not a mere notification. The IFR should be clarified to make clear that a petitioner may refile a new petition, without prejudice, if new information materializes at a later date.

(c) The Rule should define the legal significance of the HHS Review Panel.

§83.18 of the IFR provides for an administrative review of a "final" Secretarial decision to deny a SEC petition through a 3-person HHS Review Panel. However, the HHS Review Panel findings and their recommendations are not binding on the Secretary. Their findings are purely advisory. The Rule should clarify whether a petitioner's exhaustion of remedies occurs upon issuance of a final Secretarial determination, or whether an appeal to this Review Panel is necessary prior to a petitioner seeking judicial review. The HHS Review Panel appears to have no legal weight, inasmuch as the Secretary can freely ignore the HHS Review Panel findings.

6. Should Congress have a role in making appointments to the Advisory Board?

Presently, the President makes appointments to the Advisory Board. EEOICPA requires

that the Board have a balance of medical, scientific and worker perspectives. Further, the Federal Advisory Committee Act requires the Board to have a balance in perspectives. Today, the Board's composition does <u>not</u> meet the statutory tests. The White House removed two members in January 2006 without any apparent cause. At present the Board has only two worker representatives out of 11 members. To be in balance, two additional worker representatives should be added, which will result in workers having 4 of 13 slots. In January, the Administration appointed new members, two of whom have significant conflicts of interest—one has children working for the dose reconstruction contractor, and another served as an expert witness for the Department of Energy involving claims filed by sick workers.

Despite the statutory requirement for independence, DOL, NIOSH and OMB have all been tempted to alter the balance of the Advisory Board membership to suit their agendas. For example, NIOSH program staff sought to influence the composition of the Advisory Board and limit the scope of the audit contractor's work -- an inherent conflict of roles since the Board and it audit contractor audit NIOSH's program. The OMB Passback recommends changing the composition of the Advisory Board as a way to reduce benefit costs. DOL has disdained the work of the Advisory Board, sought to reduce or cut off its funding, and urged that NIOSH bring the Board back under control.

To ensure the Board is balanced and abides by Congressional intent, EEOICPA should be amended to provide for Congress to make directed appointments. As noted above, an equal number should be made by the majority and minority leaders in the House and Senate.

7. Do you think the audit contractor has the confidence of the claimant community? As you know, the Committee observed claimant input at the Oak Ridge Board meeting. Is the negative sentiment unique or commonplace in the claimant community? What is the opinion generally of the dose reconstruction contractor?

As noted in question 2 above, the audit contractor has earned the trust of claimants due to their rigor, care and willingness to listen to workers.

Claimants lack confidence in the quality of the work product generated by NIOSH and DOL because NIOSH and its contractor, ORAU, appear to uncritically accept as valid the historical radiation dosimetry records at DOE and AWE facilities. Many exposures went unmonitored, but NIOSH presumes almost universally that the dose records are valid. NIOSH started out managing this program with a different philosophy, and did not presume regularity in the radiation dose records; however, at some point they ceased to critically question the completeness or validity of the data. NIOSH only appears to be willing to take a hard look when the Advisory Board and its audit contractor review a Special Exposure Cohort petition and NIOSH is required to defend the validity of data and the availability of records. Unfortunately, this is a very time consuming process, and far too few facilities are subject to this kind of critical review

When dosimetry information is not available, NIOSH frequently assumes that the worker did not need to be monitored and they assign a complex wide dose for non-production workers. NIOSH frequently fails to interview co-workers to validate work history that cannot be

documented. Claimants are often aware of production history which were not captured in site profiles or applied to dose reconstructions. For example, the initial site profile at Rocky Flats failed to adequately reflect the extent of worker exposure to high fired oxides of plutonium, and denied claims for lung cancer for workers employed in buildings where there had been releases of these highly insoluble forms of plutonium. Once the site profile came under review by the Advisory Board and its audit contractor, and a Special Cohort petition was in play, did NIOSH bother to correct its errors.

The NIOSH radiation dose reconstruction reports which are provided to claimants are incomprehensible, even to health physicists, and despite repeated requests, NIOSH has not modified its reports to make them intelligible. As such, few bother to file appeals. NIOSH construes the small number of appeals as an indicator that claimants are happy with the process. The low rate of appeals is a function of claimant bafflement. To address this, the Ombudsman's office needs to be expanded to assist claimants with their appeals under Subtitle B. DOL sought to weaken the authority of the Ombudsman as part of the House-Senate conference to the FY 05 Defense Authorization Act. That decision to water down the responsibilities of the Ombudsman needs to be revisited.

The dose reconstruction contractor's work is tainted by conflict of interest at far too many locations, and when workers raise concerns with NIOSH or ORAU they are either ignored or trivialized. Health physicists who managed radiation dosimetry programs at a given site are tasked with the responsibility for developing site profiles using the reports and data they generated in a previous career. Their work is tainted by conflict of interest, and neither ORAU nor NIOSH have indicated any willingness to enforce compliance with the Conflict of Interest policy. ORAU has served as one of DOE's technical experts for fighting radiation related claims. One member of the ORAU team, Dade Moeller, advertised itself as an expert for hire to help fight radiation related claims. Claimants are alarmed to see ORAU's costs skyrocket from \$70 million to \$200 million for dose reconstruction. Absent a balanced Advisory Board and a credible support contractor, there is no mechanism to critically assess the validity of ORAU and NIOSH's work

8. Even when there is monitoring data available from a facility, can that data be relied upon to be accurate. If so, why? If not, why not? Is this true complex wide, or is there a range of validity in record keeping. If there is a range, what is it?

The validity of records varies from facility to facility, but in general the quality and validity of dose records prior to 1970 is questionable. Even in the 1980s and early 1990s, fundamental defects were identified by DOE's Tiger Teams. These Tiger Team reports spotted systemic weaknesses, but they are rarely used by NIOSH in assessing the validity of the dose records they are using for compensation claims. A summary of the Tiger Team findings is attached. In the mid-1990s, the Mound facility's radiation protection program was so deficient that the corporate radiation protection manager for EG&G recommended a suspension of all radiological work until systems were put in place. For example, bio-assay samples were allowed to sit in a refrigerator for 3 years unanalyzed.

At some sites, certain very radio toxic isotopes were never monitored (such as actinium-227 at Linde and Mallinckrodt), or such monitoring only began in the 1990s (such as transuranics at the enrichment plants in Portsmouth, OH, Paducah, KY and Oak Ridge K-25). At one nuclear weapons assembly plant there were no internal radiation dose monitoring records for its entire history (1948 and 1975), either because the records are missing or the monitoring was never done.

Some sites used "cohort" sampling techniques, which sampled a small percentage of those employed in each job (guard, assembly worker, engineer, etc), rather than targeting the most exposed. The presence of limited cohort sampling impairs the ability to develop a credible co-worker model.

The electronic databases used by ORAU/NIOSH have not been validated against the raw records, and unless the source records are recovered, there is no way to know if the electronic record has been censored or massaged. Censoring involves the removal high dose readings.

In some cases, radiation dose badges were left in buckets, lockers outside radiation areas, or placed between lead bricks so that workers did not exceed their maximum levels in order to avoid the risk of being laid off from their jobs (this is called "bucket dose"). Radiation dose records have been altered at some sites to minimize liability concerns.

9. Do you think possible inaccuracies are allowed for in dose reconstructions? How about the audit contractor review?

NIOSH compensates for uncertainty by using claimant favorable assumptions (e.g., material solubility, exposure geometry, etc.). But large errors can be and are introduced in dose reconstruction because NIOSH tends to oversimplify work history and frequently excludes worker exposures from accidents and incidents. In some cases they borrow data from other covered facilities, even though the law requires them to use data from the site where workers were employed. Survivors' capacity to provide detailed work history is limited, because they do not have first hand knowledge. In addition, NIOSH's quality control does not include "blind" dose reconstructions where the same case is given to several dose reconstructors to see if they come back with a comparable result. This is a programmatic weakness. The audit contractor was tasked to do blind reviews, but to date none have been assigned by the Advisory Board. Since only 2-½ % of dose reconstructions are audited by the audit contractor, inaccuracies will slip through, but the selection process for audits is designed to cover as many facilities and time periods as possible.

10. The Government Accountability Project has expressed views on the new conflict of interest policy for ORAU. Could you please briefly explain your concerns.

The GAP presented a critique of NIOSH's June 7th draft conflict of interest policy at its June 14, 2006 Advisory Board meeting, which included the following points:

 Omits the specific restrictions on organizational conflict of interest that have been in place for the past 4 years.

- Does not require public disclosure of corporate conflicts of interest.
- Does not bar individuals who managed radiation protection programs (e.g., so
 called "site experts") from guiding the development of SEC petition reviews and
 writing portions of site profiles, even though they are conflicted. No mechanism
 to ensure that COI restrictions are not evaded by having a titular author claim
 ownership for a document that was written by others.
- Fails to designate an individual responsible for policing and enforcing violations
 of the conflict of interest policy for both NIOSH and ORAU staff.
- Fails to adopt EEOICPA's statutory prohibition restricting DOE employees from developing site profiles or other dose reconstruction guidance.
- Fails to clarify whether conflict of interest restrictions under U.S. Code Title 18 (Conflict of Interest) takes precedence over the new COI policy.
- Applies ORAU's weaker COI policy to the Advisory Board's audit contractor.
 The audit contractor should be held to a higher standard.

Attachment: Summary of DOE's Tiger Team findings

LETTER FROM SANFORD COHEN, PRESIDENT, S. COHEN ASSOCIATES, INC.



March 6, 2006

Ms. Cindy Blackston Counsel U.S. House of Representatives Committee on the Judiciary 2138 Rayburn House Office Building Washington, D.C. 20515

Dear Ms. Blackston:

I attended the recent oversight hearing on March 1, 2006 relating to the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). Allegations were made at that hearing that my company, SC&A, Inc., has a conflict of interest with respect to the support that we are providing to the Advisory Board on Radiation and Worker Health, based on the mistaken notion that SC&A has received retainers from claimants. The purpose of this letter is to clarify the record. SC&A has never performed work on behalf of workers claiming benefits under the EEOICPA.

I appreciate having the opportunity to correct the record.

Sincerely

Sanford Cohen President SC&A, Inc.

6868 OLD DOMINION DRIVE * SUITE 301 * McLean, Virginia * 22101 * 703.893.6600 * Fax 703.821.8236

 \bigcirc