AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

EXAMINING MISCONDUCT AND INTIMIDATION OF SCIENTISTS BY SENIOR DOE OFFICIALS

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT &
SUBCOMMITTEE ON ENERGY

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

September 21, 2016

Serial No. 114–94

Printed for the use of the Committee on Science, Space, and Technology

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

U.S. GOVERNMENT PUBLISHING OFFICE
22–563PDF WASHINGTON : 2017

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HON. LAMAR S. SMITH, Texas, *Chair*

FRANK D. LUCAS, Oklahoma
F. JAMES SENSENBRENNER, JR., Wisconsin
DANA ROHRABACHER, California
RANDY NEUGEBAUER, Texas
MICHAEL T. MCCAUL, Texas
MO BROOKS, Alabama
RANDY HULTGREN, Illinois
BILL POSEY, Florida
THOMAS MASSIE, Kentucky
JIM BRIDENSTINE, Oklahoma
RANDY K. WEBER, Texas
JOHN R. MOOLENAAR, Michigan
STEVE KNIGHT, California
BRIAN BABIN, Texas
BRUCE WESTERMAN, Arkansas
BARBARA COMSTOCK, Virginia
GARY PALMER, Alabama
BARRY LOUDERMILK, Georgia
RALPH LEE ABRAHAM, Louisiana
DARIN LAHOOD, Illinois
WARREN DAVIDSON, Ohio
EDDIE BERNICE JOHNSON, Texas
ZOE LOFGREN, California
DANIEL LIPINSKI, Illinois
DONNA F. EDWARDS, Maryland
SUZANNE BONAMICI, Oregon
ERIC SWALWELL, California
ALAN GRAYSON, Florida
AMI BERA, California
ELIZABETH H. ESTY, Connecticut
MARC A. VEASEY, Texas
KATHERINE M. CLARK, Massachusetts
DON S. BEYER, JR., Virginia
ED PERLMUTTER, Colorado
PAUL TONKO, New York
MARK TAKANO, California
BILL FOSTER, Illinois

SUBCOMMITTEE ON OVERSIGHT

HON. BARRY LOUDERMILK, Georgia, *Chair*

F. JAMES SENSENBRENNER, JR., Wisconsin
BILL POSEY, Florida
THOMAS MASSIE, Kentucky
DARIN LAHOOD, Illinois
WARREN DAVIDSON, Ohio
LAMAR S. SMITH, Texas
DON BEYER, Virginia
ALAN GRAYSON, Florida
ZOE LOFGREN, California
EDDIE BERNICE JOHNSON, Texas

SUBCOMMITTEE ON ENERGY

HON. RANDY K. WEBER, Texas, *Chair*

DANA ROHRABACHER, California
RANDY NEUGEBAUER, Texas
MO BROOKS, Alabama
RANDY HULTGREN, Illinois
THOMAS MASSIE, Kentucky
STEPHAN KNIGHT, California
BARBARA COMSTOCK, Virginia
BARRY LOUDERMILK, Georgia
LAMAR S. SMITH, Texas
ALAN GRAYSON, Florida
ERIC SWALWELL, California
MARC A. VEASEY, Texas
DANIEL LIPINSKI, Illinois
KATHERINE M. CLARK, Massachusetts
ED PERLMUTTER, Colorado
EDDIE BERNICE JOHNSON, Texas

CONTENTS

September 21, 2016

EXAMINING MISCONDUCT AND INTIMIDATION OF SCIENTISTS BY SENIOR DOE OFFICIALS

WEDNESDAY, SEPTEMBER 21, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND
SUBCOMMITTEE ON ENERGY,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittees met, pursuant to call, at 10:08 a.m., in Room 2318, Rayburn House Office Building, Hon. Barry Loudermilk [Chairman of the Subcommittee on Oversight] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6371
www.science.house.gov

Subcommittees on Energy and Oversight

Examining Misconduct and Intimidation of Scientists by Senior DOE Officials

Wednesday, September 21, 2016
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witnesses

Dr. Sharlene Weatherwax, Associate Director, Biological & Environmental Research, U.S. Department of Energy

Dr. Noelle Metting, Radiation Biologist, U.S. Department of Energy

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HEARING CHARTER

Wednesday, September 21, 2016

TO: Members, Subcommittee on Oversight and Energy

FROM: Majority Staff, Committee on Science, Space, and Technology

SUBJECT: Joint Subcommittee hearing "Examining Misconduct and Intimidation of Scientists by Senior DOE Officials"

The Subcommittees on Oversight and Energy will hold a joint hearing titled *"Examining Misconduct and Intimidation of Scientists by Senior DOE Officials"* on Wednesday, September 21, 2016, at 10:00 a.m. in Room 2318 of Rayburn House Office Building.

Hearing Purpose:

This hearing will examine actions by Senior U.S. Department of Energy officials to intimidate scientists and withhold information from the Committee on Science, Space, and Technology during the legislative process.

Witness List

- **Dr. Sharlene Weatherwax**, Associate Director, Biological and Environmental Research, U.S. Department of Energy
- **Dr. Noelle Metting**, Radiation Biologist, U.S. Department of Energy

Staff Contact

For questions related to the hearing, please contact Aaron Weston of the majority staff at (202) 225-6917.

Chairman LOUDERMILK. The Subcommittee on Oversight and Energy will come to order.

Without objection, the Chair is authorized to declare a recess of the subcommittee at any time.

Welcome to today's hearing entitled "Examining Misconduct and Intimidation of Scientists by Senior DOE Officials." I now recognize myself for five minutes for an opening statement.

Good morning, and welcome to today's Oversight and Energy Subcommittee hearing examining the intimidation of scientists at the Department of Energy.

Congressional oversight and authority to access information is a constitutional authority granted to Congress. Without open dialogue with the federal agencies, Congress cannot gather the information needed to effectively legislate. Today, we will examine a clear case of this committee's request for information directly related to the legislative process and the executive branch's actions to block Congressional access to federally funded research.

Unfortunately, what we will learn at today's hearing is not an isolated incident. It fits a pattern of intentional misinformation from the Obama Administration officials, ranging from FDIC to NIST to EPA, and now the Department of Energy. While today's hearing is disturbing in many ways, I am most concerned with this incident because it appears that unelected DOE officials sought retribution against a DOE scientist simply for respecting the constitutional authority of Congress in order to advance political priorities.

The Committee on Science, Space, and Technology is the authorizing committee for scientific research and development. In order to fully inform the legislative process, committee staff must be able to engage in open discussions with federal researchers to fully understand the scope and value of existing programs. In fact, this open dialogue is protected in each annual appropriations act we pass in the House.

Federal law prohibits department and agency officials from stifling communications with Congress and penalizes those who seek to silence federal employees by prohibiting the payment of their salaries by the U.S. Treasury. I would request unanimous consent that this provision of law be included in the record.

[The appears in Appendix I]

Chairman LOUDERMILK. Transparency from executive agencies is necessary to ensure Congress' ability to carry out our oversight and legislative responsibilities effectively. In this case, communications with DOE are central to the Committee's oversight of accountable use of taxpayer funds in scientific research. Sadly, it appears that politics has disrupted this important dialogue between Congress and the Department of Energy, and derailed important scientific research in the process.

When DOE decided it wanted to redirect funds to support President Obama's Climate Action Plan, the Department sacrificed the Low Dose Radiation Research Program to achieve this goal. This program is the federal government's only program to investigate whether the types of radiation received by Americans every day are dangerous. This research is vital to understanding radiation doses to patients undergoing CT scans or PET scans, or the hazards of radiation to workers in the nuclear industry.

The Low Dose Program is also crucial to understanding the effects of a dirty bomb or nuclear accident on potential victims, so it is a key research program to protecting our homeland. This is clearly science in the national interest.

But when this committee took steps to specifically authorize this important research, DOE pushed back. When Dr. Noelle Metting, the DOE scientist in charge of this program, provided honest input on the merits of the Low Dose Program, she was subsequently fired by DOE senior management, all for the "crime" of working to conduct what is clearly important research and explaining that research to Congressional staff.

I want to make absolutely clear that Congress is not directing the technical experts on how to specifically carry out research. Instead, Congress decides the broad priorities and policy goals, and makes sure that taxpayer funds are spent responsibly on research with the greatest potential, while DOE carries out research at Congressional direction. It is disappointing that DOE's senior management would attempt to usurp this process and silence a federal researcher to advance political goals in violation of appropriations laws.

This Administration's bullying and intimidation must stop. I hope at today's hearing we will get to the bottom of the intimidation, deception, and misinformation conducted by the DOE officials for political priorities.

[The prepared statement of Chairman Loudermilk follows:]

COMMITTEE ON
SCIENCE, SPACE, & TECHNOLOGY
Lamar Smith, Chairman

For Immediate Release
September 21, 2016

Media Contact: Kristina Baum
(202) 225-6371

Statement of Oversight Subcommittee Chairman Barry Loudermilk (R-Ga.)
Examining Misconduct and Intimidation of Scientists by Senior DOE Officials

Chairman Loudermilk: Good morning and welcome to today's Oversight and Energy Subcommittee hearing examining the intimidation of scientists at the Department of Energy.

Congressional oversight and authority to access information is a constitutional authority granted to Congress. Without open dialogue with the federal agencies, Congress cannot gather the information needed to effectively legislate. Today, we will examine a clear case of this Committee's request for information directly related to the legislative process, and the Executive branch's actions to block Congressional access to federally funded research.

Unfortunately, what we will learn at today's hearing is not an isolated incident.

It fits a pattern of intentional misinformation from Obama Administration officials, ranging from FDIC to NIST to EPA – and now the Department of Energy (DOE). While today's hearing is disturbing in many ways, I am most concerned with this incident because it appears that unelected DOE officials sought retribution against a DOE scientist simply for respecting the Constitutional authority of Congress in order to advance political priorities.

The Committee on Science, Space, and Technology is the authorizing committee for scientific research and development. In order to fully inform the legislative process, Committee staff must be able to engage in open discussions with federal researchers to fully understand the scope and value of existing programs. In fact, this open dialogue is protected in each annual appropriations act we pass in the House.

Federal law prohibits department and agency officials from stifling communications with Congress and penalizes those who seek to silence federal employees by prohibiting the payment of their salaries by the U.S. Treasury. I would request unanimous consent that this provision of law be included in the record.

Transparency from executive agencies is necessary to ensure Congress' ability to carry out our oversight and legislative responsibilities effectively. In this case, communications with DOE are central to the Committee's oversight of the accountable use of taxpayer funds in scientific research. Sadly, it appears that politics

has disrupted this important dialogue between Congress and the Department of Energy, and derailed important scientific research in the process.

When DOE decided it wanted to redirect funds to support President Obama's Climate Action Plan, the Department sacrificed the Low Dose Radiation Research program to achieve this goal.

This program is the federal government's only program to investigate whether the types of radiation received by Americans every day are dangerous. This research is vital to understanding radiation doses to patients undergoing CT scans or PET scans, or the hazards of radiation to workers in the nuclear industry.

The Low Dose program is also crucial to understanding the effects of a dirty bomb or nuclear accident on potential victims, so is a key research program to protecting our homeland. This is clearly science in the national interest.
But when this Committee took steps to specifically authorize this important research, DOE pushed back. When Dr. Noel Metting, the DOE scientist in charge of this program, provided honest input on the merits of the Low Dose program, she was subsequently fired by DOE senior management. All for the "crime" of working to conduct what is clearly important research, and explaining that research to Congressional staff.

I want to make absolutely clear that Congress is not directing the technical experts how to specifically carry out research. Instead, Congress decides the broad priorities and policy goals, and makes sure that taxpayer funds are spent responsibly on research with the greatest potential, while DOE carries out research at Congressional direction. It is disappointing that DOE's senior management would attempt to usurp this process, and silence a federal researcher to advance political goals – in violation of appropriations law.

This Administration's bullying and intimidation must stop. I hope that at today's hearing we will get to the bottom of the intimidation, deception and misinformation conducted by DOE officials for political priorities.

###

Chairman LOUDERMILK. I now recognize the Ranking Member, the gentleman from Virginia, for an opening statement.

Mr. BEYER. Thank you, Mr. Chairman, very much. And later on, I'm sure we'll have a chance to distinguish between political priorities and scientific priorities because they are different.

I want to thank the Chairmen Loudermilk and Weber for today's hearing and thank you, Doctors, for testifying.

In February this year, the Science Committee began investigating the Department of Energy's attempt to stop funding the Low Dose Radiation Research Program and the related personnel action that resulted in the removal of longtime Program Manager Dr. Noelle Metting.

As a businessman, as a former Ambassador, as someone who's been involved in transition of federal agencies and for presidential elections, I think I know what good and bad management looks like. I also represent many federal employees, and they often call my office when they see evidence of mismanagement or are treated poorly or unfairly themselves.

From everything I know, it seems to me that in this instance the Department of Energy was a bit overzealous in the removal of Dr. Metting and badly mishandled this case. This all stems from a briefing October of 2014 requested by a majority staff member, and I'd like to note that the Democratic committee staff members were not present, nor were they invited to the meetings so we can't attest firsthand to what actually happened. We can only rely on the accounts given during the formal transcribed interviews with only two of the four DOE officials that were present.

On that note, I'm disappointed that yet another investigation by the committee's majority appears incomplete. To my knowledge, the committee's majority never formally interviewed Dr. Metting or the other DOE staff member who was present during the October incident. And, in addition, Dr. Weatherwax, who is also testifying today, was not even present for the meeting or post-meeting discussion that resulted in the removal of Dr. Metting. So good luck today, Dr. Weatherwax.

While I don't believe that Dr. Metting's actions at the briefing should be characterized as that of a whistleblower, I do strongly support the right of federal employees to petition their government and speak openly about their work without fear of retaliation. As a federal employee, Dr. Metting should have felt unbridled in her answers to and interactions with Congressional staff.

I certainly know as a sometime boss and manager I always want to hear all sides of an issue, yes and no, to make good decisions. I would strongly recommend that the Department take a closer look at how they handle situations like the one we're talking about today.

On that point, the scientific integrity policy that the Department released in 2012 could certainly use a second look or potentially an update. The policy leaves gray areas that can create confusion and misunderstanding, and relative to other executive agency branches, DOE's scientific integrity policy is not nearly as robust. Agencies like the Department of Interior, NASA, NOAA have led the way in this effort. And given the quality and the quantity of scientific re-

search at DOE, I'd really expect more from DOE leadership on this front.

I also look forward to learning more about the future of low dose radiation research today. I'd urge the Department to be more clear with Congress about their intentions and rationale for changes in research priorities to make sure they're based on science and not, as our Chair suggested, on politics.

There's been a general lack of communication from DOE on these particular research activities involving low dose radiation research. I hope we can avoid similar occurrences in the future. The clearer the communication early on, the better off.

Before I conclude, I'd also like to add that I find this halfhearted investigation especially ironic, given that the committee's majority is engaged in clear intimidation of government scientists that are conducting client change research at NOAA, including a issuing a subpoena to NOAA Administrator and former astronaut Dr. Kathryn Sullivan for emails of the scientists all because the majority disagreed with the results of a twice peer-reviewed scientific study.

And I'd point out that I don't believe the majority has ever produced a shred of evidence that would have justified the subpoena, although they made numerous unsubstantiated allegations of scientific misconduct by NOAA scientists.

I think if we're going to talk about chilling effects on scientists, we need to look across the complete board.

I think we can all agree that all scientists—government, academia, private sector—should be free of undue influence, be it politics or profit. Our policy decisions should be guided by our research by our world-class scientists. When they speak loudly in unison, we should listen. I don't think that's always been the case in this Congress or on this committee.

Lastly, this incident highlights the necessity of basic due process requirements, appeals, and federal employee protections, as well as the right of federal employees to have the right to union representation. If my friends on the majority are sincere about their concern for federal employees, and I hope they are, I'd encourage them to keep this hearing in mind next time Congress considers legislation intended to erode due process and collective bargaining rights for federal employees.

My dad spent a year in Eniwetok 1956, '57, as provost marshal when they were testing nuclear weapons, so I'm very interested in what the impact of low-dose radiation is because he's only 92–1/2 right now.

So, Mr. Chairman, I yield back.

[The prepared statement of Mr. Beyer follows:]

OPENING STATEMENT
Ranking Member Don Beyer (D-VA)
of the Subcommittee on Oversight

House Committee on Science, Space, and Technology
Subcommittees on Oversight and Energy
"Examining Misconduct and Intimidation of Scientists by Senior DOE Officials"
September 21, 2016

Thank you Chairmen Loudermilk and Weber for holding today's hearing and thank you to the witnesses for testifying.

In February of this year, the Science Committee began investigating the Department of Energy's intent to stop funding the Low Dose Radiation Research Program and the related personnel action that resulted in the removal of the long-time Program Manager, Dr. Noelle Metting.

As a businessman, former Ambassador, and someone who has been involved in the transition of federal agencies after Presidential elections, I know what good and bad management looks like. I also represent many federal employees and they often call my office when they see evidence of mismanagement or are treated poorly or unfairly themselves.

From everything I know, it seems to me that in this instance the Department of Energy was a bit over-zealous in the removal of Dr. Metting and badly mishandled this case.

This all stems from a briefing in October 2014 requested by a Majority staff member. I would like to note that Democratic Committee staff members were not present nor were they invited to the meeting, so we cannot attest first-hand as to what occurred during the briefing in question. We can only rely on the accounts given during the formal transcribed interviews from two of the four DOE officials that *were* present.

On that note, I am disappointed that yet another investigation by the Committee's Majority appears incomplete. To my knowledge, the Committee's Majority never formally interviewed Dr. Metting or the other DOE staff member present during the October incident. Moreover, Dr. Weatherwax, who is also testifying today, was not even present for the meeting or post-meeting discussion that resulted in the removal of Dr. Metting.

While I do not believe Dr. Metting's actions at the briefing should be characterized as those of a whistleblower, I do strongly support the right of Federal employees to petition their government and speak openly about their work without fear of retaliation. As a Federal employee, Dr. Metting should have felt unbridled in her answers to and interactions with Congressional staff.

I would strongly recommend that the Department take a closer look at how they handle situations like the one before us today. On that point, the scientific integrity policy that the Department released in 2012 could certainly use a second look and potentially an update. The policy leaves gray areas that create confusion and misunderstanding. Relative to other Executive Branch agencies, DOE's scientific integrity policy is not nearly as robust. Agencies like the Department

of Interior, NASA, and NOAA have led the way in this effort. Given the quality and quantity of innovative scientific research at the Department, I would expect more leadership from DOE on this front.

I also look forward to learning more about the future of the Low Dose Radiation Research Program today. I would urge the Department to be more clear with Congress about their intentions and rationale for changes in research priorities going forward. There has been a general lack of communication from DOE on these particular research activities involving low dose radiation research. I hope we can avoid similar occurrences in the future. The clearer the communication from the start the faster we can work together to settle our differences.

Before I conclude I would like to add that I find this half-hearted investigation especially ironic given that the Committee's Majority has engaged in clear intimidation of government scientists that are conducting climate change research at NOAA, including issuing a subpoena to NOAA Administrator and former astronaut Dr. Kathryn Sullivan for the emails of scientists all because the Majority disagreed with the results of a twice peer-reviewed scientific study. I would point out that I do not believe the Majority has ever produced a shred of evidence that would have justified that subpoena, although they made numerous unsubstantiated allegations of scientific misconduct by NOAA's scientists.

I think we can all agree that all scientists, whether in government, academia, or the private sector should be free of undue influence, be it politics or profit. Our policy decisions should be guided by our research and our world-leading scientists. When they speak loudly and in unison, we should listen. Unfortunately, I don't think that is always the case in Congress or on this Committee, but we'll save that conversation for another day.

Lastly, this incident highlights the necessity of basic due process requirements, appeals, and federal employee protections, as well as the right of federal employees to have the right to union representation. If my colleagues in the Majority are sincere about their concern for federal employees, I would encourage them to keep this hearing in mind next time Congress considers legislation intended to erode due process and collective bargaining rights for federal employees.

Thank you Mr. Chairman. I yield back.

Chairman LOUDERMILK. Thank you, Mr. Beyer. And for the record, I agree with you. It is very important that we have the true testimony from the others that were in that meeting. And for the record, this committee did invite Dr. Julie Carruthers and Dr. Todd Anderson, who were present during the briefing October 16, 2014, but the Department of Energy chose not to provide those witnesses for today's hearing.

At this point I'd like to recognize the Chairman of the Subcommittee on Energy, Mr. Weber, for his opening statement.

Mr. WEBER. Thank you, Mr. Chairman. I appreciate it.

And good morning. As Chairman of the Subcommittee on Energy, I have spent this Congress focusing on basic research that can benefit our nation by enabling technology breakthroughs.

Throughout its history, the Department of Energy (DOE) has conducted research in support of nuclear energy and nuclear weapons complex. It has also explored the impact of radiation so that our nation's researchers, industry, and military can safely handle nuclear material—I bet you're all about that, Dr. Metting—also maintain the nation's nuclear weapons program, and dispose of that same nuclear waste. In my opinion not only good energy policy but good national security policy that the Chairman alluded to. This use-inspired basic research leads to scientific discoveries and long-term benefits for the energy industry and for our national defense.

Today, we will examine the Department's decision to terminate the Low Dose Radiation Research Program, and may I add the only federal program currently conducting research in this area.

This program does three things. It provides research that can inform authorities setting nuclear safety standards for the public. Low dose research can also provide, number two, new data to enable federal emergency response agencies to more accurately set evacuation zones from radiological incidents. And number three, it provides research to enable practicing physicians to decide when and how to use diagnostics to detect cancer in patients. The research conducted in the Low Dose Program can also facilitate, I guess a fourth thing, medical research efforts to even combat cancer. Other than that, the research is really not useful.

I'm being facetious obviously. When DOE chose to close down the Low Dose Program, this committee began to examine this research program. Why was that? Committee staff contacted DOE specifically to hear from technical experts about the broad impact of this basic research program and the potential value this research could yield for domestic energy, medical discovery, and national security to put it in a nutshell. And as this committee took steps to authorize the Low Dose Program through the legislative process, we relied on these open conversations with DOE researchers to draft legislation that would prioritize this important research and responsibly invest American tax dollars.

These kinds of frank discussions between researchers and Congressional staff are absolutely vital in this legislative process. Members of Congress must be able to trust that the information they receive from DOE is nonpartisan and, quite frankly, is delivered without political bias. Congress must get access to these facts. We have to make good policy. There's no way around that.

Unfortunately, the Department violated Congressional trust by attempting to censor information provided to committee staff. And what's worse, a DOE scientist was punished for speaking to Congress. That is simply unacceptable.

Congress must be able to expect a high standard of accountability and honesty from federal agencies to effectively legislate and fulfill our constitutional duty to the public. When scientists get fired for speaking honestly about their work, it is clear that politics are negatively impacting the work of Congress and stifling public dialogue, not to mention stifling research in those key areas that I alluded to.

I want to thank our witnesses for testifying today, particularly Dr. Metting for being willing to share her unfortunate experience with the committee. I hope that by exposing DOE's misconduct in this case, we can prevent this kind of inappropriate action in the future and preserve scientific integrity and transparency at the Department. American taxpayers deserve nothing less.

Mr. Chairman, I yield back.

[The prepared statement of Mr. Weber follows:]

COMMITTEE ON
SCIENCE, SPACE, & TECHNOLOGY
Lamar Smith, Chairman

For Immediate Release
September 21, 2016

Media Contact: Kristina Baum
(202) 225-6371

Statement of Energy Subcommittee Chairman Randy Weber (R-Texas)
Examining Misconduct and Intimidation of Scientists by Senior DOE Officials

Chairman Weber: Good morning. As Chairman of the Subcommittee on Energy, I have spent this Congress focusing on basic research that can benefit our nation by enabling technology breakthroughs. Throughout its history, the Department of Energy (DOE) has conducted research in support of our nuclear energy and nuclear weapons complex, exploring the impact of radiation so our nation's researchers, industry, and military can safely handle nuclear material, maintain the nation's nuclear weapons program, and dispose of nuclear waste.

This use-inspired, basic research leads to scientific discoveries and long-term benefits for the energy industry and our national defense. Today, we will examine the Department's decision to terminate the Low Dose Radiation Research program, the only federal program currently conducting research in this area.

This program provides research that can inform authorities setting nuclear safety standards for the public. Low dose radiation research can also provide new data to enable federal emergency response agencies to more accurately set evacuation zones from radiological incidents, or provide research to enable practicing physicians to decide when and how to use diagnostics to detect cancer in patients. The research conducted in the Low Dose program can also facilitate medical research efforts to combat cancer.

When DOE chose to close down the Low Dose program, this committee began to examine this research program.

Committee staff contacted DOE specifically to hear from technical experts about the broad impact of this basic research program, and the potential value this research could yield for domestic energy, medical discovery, and national security.

And as this committee took steps to authorize the Low Dose program through the legislative process, we relied on these open conversations with DOE researchers to draft legislation that would prioritize this important research and responsibly invest American tax dollars.

These kinds of frank discussions between researchers and Congressional staff are absolutely vital in the legislative process. Members of Congress must be able to trust

that the information they receive from DOE is non-partisan and is delivered without political bias. Congress must get access to the facts.

The Department violated Congressional trust by attempting to censor information provided to committee staff.

And what's worse, a DOE scientist was punished for speaking to Congress. That is simply unacceptable.

Congress must be able to expect a high standard of accountability and honesty from federal agencies to effectively legislate. When scientists get fired for speaking honestly about their work, it is clear that politics are negatively impacting the work of Congress and stifling public dialogue.

I want to thank our witnesses for testifying today, particularly Dr. Metting for being willing to share her unfortunate experience with the committee. I hope that by exposing DOE's misconduct in this case, we can prevent this kind of inappropriate action in the future and preserve scientific integrity and transparency at the Department.

###

Chairman LOUDERMILK. I thank the gentleman from Texas.

And now, I'd like to introduce our witnesses. Our first witness today is Dr. Sharlene Weatherwax, Associate Director for Biological Environmental Research at the U.S. Department of Energy. She has previously served in a number of different positions within the DOE, including as the Division Director and Program Manager for the Biological System Science Division of the Office of Biological and Environmental Research, and Program Manager in the Office of Basic Energy Sciences.

Dr. Weatherwax received her bachelor of science in biochemistry from the University of California at Los Angeles and her Ph.D. in biochemistry from the University of California at Berkeley.

Our final witness today is Dr. Noelle Metting, Radiation Biologist at the U.S. Department of Energy's Office of Environment, Health, Safety, and Security within the Office of Public Radiation Protection. Dr. Metting previously worked in the DOE's Office of Science, Office of Biological and Environmental Research where she managed the DOE's Low Dose Radiation Program. In addition, she worked for 20 years as a laboratory research scientist at Pacific Northwest National Laboratory.

Dr. Metting received her master's degree in radiological sciences from the University of Washington and her doctor of science in cancer biology from Harvard.

I now recognize Dr. Weatherwax for five minutes present her testimony.

TESTIMONY OF DR. SHARLENE WEATHERWAX,
ASSOCIATE DIRECTOR,
BIOLOGICAL AND ENVIRONMENTAL RESEARCH,
U.S. DEPARTMENT OF ENERGY

Dr. WEATHERWAX. Mr. Chairman, Ranking Members, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the Department of Energy's Low Dose Radiation Research Program and the decision to end the program in fiscal year 2016.

My name is Dr. Sharlene Weatherwax, and I'm the Associate Director for Science and Biological and Environmental Research, or BER, in DOE's Office of Science. I have earned my Ph.D. in biochemistry from the University of California at Berkeley, and I have research expertise in microbial enzymology and plant molecular biology.

I joined the Department of Energy in 2001 as a career federal employee and—first as a Program Manager for the Office of Basic Energy Sciences and then in BER. I rose to the Senior Executive Service position of Biological System Science Division Director in 2008 and became the Associate Director for BER in 2011. I am responsible for strategic program planning, budget formulation and execution, and coordination with other DOE program offices and other federal agencies.

BER supports fundamental research in scientific user facilities to support DOE's energy, environment, and basic research missions, drawing upon the scientific expertise of researchers at academic and industrial institutions and the DOE national labs.

The BER Biological Systems Science Division supports a diverse portfolio of fundamental research and technology development, serving as the basis for the competent redesign of microbes and plants for sustainable biofuel production, improved carbon storage, and controlled biological transformation of materials such as nutrient and contaminants in the environment.

There is a very competitive environment for funding within BER with exciting new scientific opportunities due to the rapidly changing nature of biological science. Since completion of the human genome sequence in 2003, the genome sequencing and analysis tools at the DOE's Joint Genome Institute have enabled BER's Genomic Science Program to be at the forefront of developing the scientific basis for translating genetic parts list for plants and microorganisms into scientific knowledge about biological system functions.

This research is exemplified in the Bioenergy Research Centers, which were started 2007. The centers continue to produce the innovative science needed to foster production of fuels and chemicals from renewable biomass and are working to translate these basic science results to practical outcomes for industry and society.

BER is also at the forefront of deciphering the underlying principles of genomic expression in order to design new biological functions. With continued understanding of the genomic potential of plants and microbes comes the ability to manipulate and design new pathways into plants and microbes work. Biosystem design concepts are at the heart of the ongoing biotechnology revolution and key to maintaining international leadership.

In addition to these major efforts in bioenergy-related research, BER has managed a basic research program in low-dose radiation research since 1998. Over the past 18 years, the program has provided new type technological advances and fundamental scientific understanding of the mechanisms cells use to sense, repair, and adapt the impacts of low-dose radiation. Research investigations have included a number of critical biological phenomena induced by low-dose exposure, including adaptive response, bystander effects, genomic instability, and genetic susceptibility.

The program was not intended to address regulatory policy but rather to advance the fundamental science of radiation impacts on biological processes. To date there are no studies that have been able to establish with sufficient certainty a threshold level of radiation below which the risk for cancer is zero despite decades of research in this area. Any changes to the current protection standards would require strong and compelling evidence that a higher amount of radiation exposure is safe.

The low-dose—the DOE Low Dose Radiation Research Program is ending in fiscal year 2016 as BER's biology portfolio continues to shift more towards bioenergy, biodesign, and environmental microbiology research missions. Funding levels have been steadily decreasing since 2012 with $1 million appropriated to complete the program in fiscal year 2016.

The total amount of appropriated funding that the DOE Office of Science has devoted to the Low Dose Research from its inception is over a quarter of $1 billion, and the program outcomes and data are available to the community and other interested agencies through peer-reviewed scientific publications.

Biology is rapidly transforming to a more quantitative and predictive science, and the BER biology portfolio continues to extend its genome science efforts to plants and microbes to develop the fundamental scientific understanding needed for solutions to energy challenges of the future.

Thank you for inviting me to speak about the Low Dose Radiation Research Program. I look forward to answering the committee's questions.

[The prepared statement of Dr. Weatherwax follows:]

Testimony of Associate Director Sharlene Weatherwax
Office of Biological and Environmental Research
Office of Science
U.S. Department of Energy
Before the Committee on Science, Space, and Technology
U.S. House of Representatives
September 21, 2016

Mr. Chairmen, Ranking Members, and Members of the Subcommittees, thank you for the opportunity to appear before you today to discuss the Department of Energy's (DOE) Low Dose Radiation Research Program and the decision to end the program in FY 2016.

My name is Dr. Sharlene Weatherwax, and I am the Associate Director for Science in Biological and Environmental Research (BER), in the Department of Energy's Office of Science. My formal education and PhD are in biochemistry, and I have been with the Department for over 15 years, first in the office of Basic Energy Sciences and then in BER. The Low Dose Radiation Research Program is one portfolio element within BER's Biological Systems Science Division.

The Biological Systems Science Division supports a diverse portfolio of fundamental research and technology development to achieve a predictive systems-level understanding of complex biological systems to advance DOE missions in energy and the environment. By integrating genome science with advanced computational and experimental approaches, the Division seeks to gain a predictive understanding of living systems, from microbes and microbial communities to plants and other whole organisms. This foundational knowledge serves as the basis for the confident redesign of microbes and plants for sustainable biofuel production, improved carbon storage, and controlled biological transformation of materials such as nutrients and contaminants in the environment.

BER strategic science directions are guided by input from the research community, scientific workshops, the National Science and Technology Council, the National Academy of Sciences and the Office of Biological and Environmental Research Advisory Committee (BERAC). There is a very competitive environment for funding within BER, with exciting new scientific opportunities identified in workshop reports, DOE's Quadrennial Technology Report, and other sources. One reason for BER's competitive portfolio is the rapidly changing nature of BER science. BER has been instrumental in accelerating the development of DNA sequencing technology over the past 20+ years, culminating in the completion of the human genome sequence in 2003. This scientific and technological triumph of the human genome project, conducted in partnership with the National Institutes of Health, has sparked a revolution in biotechnology that continues to this day with a modest $4 billion Federal investment yielding an enormous economic impact estimated (in 2011) at $796B[1].

[1] http://www.battelle.org/docs/default-document-library/economic_impact_of_the_human_genome_project.pdf

Over the last 15 years, DOE has transformed its genome science toward DOE-mission relevant efforts in energy and the environment. The DOE Joint Genome Institute (JGI) is a direct descendent of sequencing projects initially funded to sequence the human genome. Building upon genome sequencing production at the JGI, providing the genetic "parts lists" for plants and microorganisms, BER's genomic science program has been at the forefront of developing the fundamental knowledge needed to efficiently convert plant biomass into fuels and chemicals as replacements for those currently derived from petroleum. BER basic research is developing the scientific basis for producing the fuels and chemicals needed for a modern society from more sustainable, renewable biomass resources. For example, BER supports basic research to develop new bioenergy crops and improved biofuel production processes[2]. This research is exemplified in the Bioenergy Research Centers (BRCs)[3], started in 2007. The BRCs, now in their ninth year of operation, continue to produce the science needed to foster production of fuels and chemicals from renewable biomass by: 1) developing dedicated bioenergy crops across a range of plant species (ex. grasses, trees); 2) improving methods to breakdown biomass into its component parts (cellulose, hemicellulose, lignin); 3) genetically modifying microorganisms for efficient conversion of cellulosic sugars and/or lignin to fuels and chemicals; 4) developing the integrative knowledge needed to sustainably support a biofuels industry, and; 5) working with industry to translate basic science results to commercial practice. To date (Aug. 2016) the BRCs have produced 2314 peer-reviewed manuscripts that have been cited over 70,000 times and 1098 intellectual property disclosures, applications, or patents.

Additionally, BER science continues to be at the forefront of deciphering the underlying principles of genome expression in order to design new biological functions. With continued understanding of the genomic potential of plants and microbes comes the ability to manipulate and design new pathways into plants and microbes for beneficial purposes. Biosystem design concepts are at the heart of the ongoing biotechnology revolution and key to maintaining international leadership in a very competitive biotechnology field.

More recent integrative science within BER combines efforts across the portfolio to develop a deeper understanding of sustainable practices for bioenergy production. BER's efforts in plant and microbial systems biology is being combined with environmental process understanding to develop new sustainability research approaches for bioenergy production. Better understanding of complex plant-soil-microbe interactions that drive sustainable bioenergy crop production will

---

[2] Lignocellulosic Biomass for Advanced Biofuels and Bioproducts workshop report: http://science.energy.gov/~/media/ber/pdf/workshop%20reports/Lignocellulosic_Biomass_for_Advanced_Biofuels_and_Bioproducts.pdf

[3] 2014 Bioenergy Research Centers report available online: http://genomicscience.energy.gov/centers/BRCs2014HR.pdf

enable reliable predictions of bioenergy crop yield under differing environmental conditions and/or geographic regions, important for sustaining a bioenergy industry.

In addition to these major efforts in bioenergy-related research, BER has also managed a basic research program in Low Dose Radiation Research since 1998. At that time there was ample evidence from atomic bomb survivor studies to clearly indicate a statistically significant linear response between observed human health effects (cancer) and radiation at relatively high doses but no statistically significant data available at the low doses (less than 100mSv) more commonly experienced by most people. The low dose program was developed to specifically address what if any effects low doses of radiation could have on human health below 100mSv[4].

Over the past 18 years the program has provided new technological advances and fundamental scientific understanding of the mechanisms cells use to sense, repair and adapt to the impacts of low dose radiation. Research investigations have included a number of critical biological phenomena induced by low dose exposure including adaptive responses, bystander effects, genomic instability, and genetic susceptibility. The program has supported the development of systems genetic strategies, including the role of epigenetics in integrated gene function and response of biological systems to environmental conditions, with a goal of translating molecular-scale effects of low dose radiation to whole model organisms. The program outcomes and data are available to the community and other interested agencies through peer-reviewed scientific publications.

The program more recently has also supported epidemiological research such as the "Million Worker Study" being conducted by the National Council on Radiation Protection and Measurements. The health effects of low dose radiation are subtle and very difficult to experimentally discern. Very large sample sizes are needed to lend sufficient statistical power to the analysis of the experimental observations. This large epidemiological study is evaluating data collected and available from over a million radiation workers; funding is provided not only by DOE, but also by the Nuclear Regulatory Commission, Environmental Protection Agency, and National Aeronautics and Space Administration. Analysis of the results could provide the necessary statistical power to draw conclusions and make recommendations on the health effects of low dose radiation. This study focusing on analysis of former radiation workers and veterans complements research from the Division of Cancer Epidemiology and Genetics of the National Cancer Institute (NCI), one of the National Institutes of Health (NIH). The Division's Radiation Epidemiology Branch specifically focuses on identifying, understanding, and quantifying the risk of cancer in populations exposed to medical, occupational, or environmental radiation, and to advance our understanding of radiation carcinogenesis. The total amount of funding that the

[4]Millisievert. The sievert is the SI unit for dose of ionizing radiation on the human body. The average person receives about 3.1 mSv per year from natural radiation. http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html

DOE Office of Science has devoted to the Low Dose Research Program from its inception is over a quarter of a billion dollars.

The program was not intended to address regulatory policy but rather to advance the fundamental science of radiation impacts on biological processes. The Environmental Protection Agency and the Nuclear Regulatory Commission (NRC) bear the responsibility for establishing generally applicable and legally enforceable standards for the protection of human health and the environment from radioactive materials. EPA standards set protective limits on the radioactivity in soil, water and air that comes from human use of radioactive elements. The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety and promote the common defense and security. The NRC sets dose limits for both members of the public and workers in the nuclear industry.

Current radiation protection standards are based on the presumption that any exposure to radiation presents some risk of cancer to the exposed individual. That is, the relationship between cancer risk and radiation exposure is linear and there is no threshold level of radiation below which there is not some risk of cancer. Any changes to the current protection standards would require strong and compelling evidence that a higher amount of radiation is safe.

The "EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population" book describes EPA's methodology for estimating cancer risks from radiation exposure based on the National Research Council's 2006 report "Biological Effects of Ionizing Radiation (BEIR VII)," as well as on other updated science. The book calculates cancer risk estimates separately by age at exposure, sex and potentially affected organ. Its risk estimate methodology reflects the scientific consensus of the BEIR VII committee and presents the scientific basis for the estimates. The book takes into account recommendations made by EPA's Science Advisory Board (SAB), which completed its review in January 2010.

The SAB relied on advice from its Radiation Advisory Committee panel of non-EPA scientists chosen for their objectivity, integrity and expertise in radiation science and protection; additionally, the book has undergone an extensive peer review process, which included opportunities for the public and stakeholders to provide comment (https://www.epa.gov/radiation/blue-book-epa-radiogenic-cancer-risk-models-and-projections-us-population#tab-1). EPA risk assessment regarding other cancer-causing exposures also follows the linear no-threshold (LNT) methodology in the absence of mode-of-action and/or biological data to the contrary as a public-health-protective measure[5].

[5] https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

To date, there are no studies that have been able to establish with sufficient certainty a threshold level of radiation below which a risk of cancer is zero, despite decades of research in this area. In the absence of sufficient data to the contrary, the LNT model continues to be the accepted, albeit conservative, standard on which current radiation worker protection standards are based. Current National and International bodies (National Council on Radiation Protection and Measurements, NCRP; International Commission on Radiological Protection, (ICRP)) continue to recommend the use of the LNT.

The DOE Low Dose Radiation Research program is ending in FY 2016 with a substantial record of fundamental research that has been disseminated in the primary research literature. Despite the program's many research accomplishments, there are no definitive research results sufficient to revise the linear no-threshold model for cancer caused by low dose radiation exposure, and BER's Biological System science portfolio continues to shift more towards bioenergy, biodesign, and environmental microbiology missions. Funding levels for the Low Dose Radiation Research program have been steadily decreasing since 2012, with $1M appropriated to complete the program in FY 2016.

In June 2015, the Secretary of Energy's Advisory Board (SEAB) was asked by the Secretary to provide a perspective on whether DOE should continue low dose radiation research. SEAB provided a response letter to the Secretary indicating that a small focused program should be maintained and asked that the Office of Science be charged with commissioning a small group of experts to propose a modest multi-year research program in low level radiation exposure. SEAB also acknowledged that "[DOE] should not assume that the results of such a research program would be conclusive[6]."

The Biological and Environmental Research Advisory Committee, our standing advisory committee in BER, was charged[7] in October 2015 to follow-up on SEAB's response. The subcommittee of discipline experts will address the SEAB recommendations and issue a letter report in October 2016.

The Office of the Associate Under Secretary for Environment, Health, Safety and Security continues to conduct and support health studies and other research activities to determine if DOE workers and people living in communities near DOE sites are adversely affected by exposures to hazardous materials from DOE operations; by enabling appropriate responses to disease outbreaks and radiation accidents; and to address critical research needs for important occupational exposures. These efforts also include international health studies and activities providing new knowledge and information about the human response to ionizing radiation and other industrial exposures encountered in the workplace or within nearby communities; and as a result of nuclear weapons testing, use and accidents. These activities are mandated by Congress or required by international agreement and include studies of human health, environmental

[6] http://energy.gov/seab/downloads/letter-low-level-radiation-research
[7] http://science.energy.gov/~/media/ber/berac/pdf/Reports/LD_Program_Charge_Letter.pdf

impacts, and provision of medical services in several countries including a long term study (since 1947) of Japanese atomic bomb survivors, believed to have the longest history of any ongoing international research program.

BER basic research programs continue to lead exciting and revolutionary changes in biological research for DOE and the Nation. Biology, as a science, is rapidly transforming to a more quantitative and predictive science thanks in large part to BER's pioneering efforts within the human genome project. BER continues to extend its genome science efforts to plants and microorganisms to develop the fundamental scientific understanding needed for solutions to energy challenges of the future.

Thank you for this opportunity to testify, and I look forward to answering any questions you may have.

Dr. Sharlene C. Weatherwax, Ph.D.
Associate Director of Science
for Biological and Environmental Research
U.S. Department of Energy

Dr. Weatherwax is the Associate Director of Science in Biological and Environmental Research (BER) within the Department of Energy's Office of Science, the principal federal funding agency of the Nation's research programs in high-energy physics, nuclear physics, fusion energy sciences, materials and chemical sciences biological and environmental sciences, and computing sciences. She has previously served in a number of different positions within the DOE, including as the Division Director and program manager for the Biological Systems Science Division of the Office of Biological and Environmental Research, and program manager in the Office of Basic Energy Sciences. In 2005, Dr. Weatherwax co-organized a joint workshop with DOE's Office of Energy Efficiency and Renewable Energy, resulting in the DOE bioenergy roadmap from fundamental to applied research entitled "Breaking the Biological Barriers to Cellulosic Ethanol." This led to the competitive, merit-reviewed establishment of three Office of Science Bioenergy Research Centers (BRCs) to provide critical science and technology solutions for our energy needs. Dr. Weatherwax has managed the three BRCs, multidisciplinary partnerships between national laboratories, academic and industrial research institutions. She has participated in a number of interagency activities and is a co-chair of the NSTC Subcommittee on Life Sciences.

Dr. Weatherwax received her B.S. in Biochemistry from the University of California at Los Angeles and her Ph.D. in Biochemistry from the University of California at Berkeley. Her independent research includes the study of light- and hormone-regulated plant gene expression. She is a member of the American Society of Plant Biologists and the American Society for Microbiology.

With an annual budget of more than $600 million, the Office of Biological and Environmental Research is the nation's leading supporter of fundamental research and facilities for energy, climate, and the environment. The Biological and Environment Research (BER) program mission is to understand complex biological, climatic, and environmental systems across spatial and temporal scales ranging from sub-micron to global, from individual molecules to ecosystems, and from nanoseconds to millennia. This is accomplished by exploring the frontiers of genome-enabled biology; discovering the physical, chemical, and biological drivers of climate change; and seeking the geochemical, hydrological, and biological determinants of environmental sustainability and stewardship.

As Head of the Office of Biological and Environmental Research, Dr. Weatherwax serves as one of the Associate Directors of the Office of Science. She is responsible for strategic program planning, budget formulation and execution, program integration with other Office of Science activities and with the DOE technology offices, and interagency integration.

Chairman LOUDERMILK. I now recognize Dr. Metting for five minutes.

TESTIMONY OF DR. NOELLE METTING,
RADIATION BIOLOGIST,
U.S. DEPARTMENT OF ENERGY

Dr. METTING. Good morning, Mr. Chairman, Ranking Members, and other Members of the Subcommittees on Energy and Oversight. Thank you for this opportunity to testify at the hearing this morning.

I'm a scientist, a radiation biologist currently working for the Department of Energy Office of Environment, Health, Safety, and Security. I'm actually on detail from DOE's Office of Science and BER where from the year 2000 until December of 2014 I had, among other duties, been tasked with managing DOE's Low Dose Radiation Research Program.

Over the previous 20 years, I was a laboratory research scientist, an experimentalist working in Pacific West—Northwest National Lab. I have a master's of science from the University of Washington and a doctor of science from Harvard University.

In my remarks today I will share my personal experience of being fired by DOE and suffering long months of unemployment that occurred as a direct outcome of my participation in a briefing for Congressional staff.

In a nutshell, the circumstances surrounding this intimidation and retaliation are these: Congressional staffers requested an overview of the Low Dose Program so my immediate supervisor, Dr. Todd Anderson, asked me to prepare a PowerPoint presentation. It was duly reviewed, amended, and finalized.

In a pre-briefing meeting attended by myself and Drs. Anderson, Carruthers, and Huerta, it was decided that for the Congressional staff briefing I would present my slides and handouts and respond only to the scientific questions, while Drs. Anderson and Carruthers would handle the budget and policy issues.

During the Congressional briefing the following day on October 16, I presented the agreed-upon material and answered accurately the many scientific missions directed to me by House staff member Dr. Aaron Weston and Senate fellow Dr. Ron Faibish. The staffers were very knowledgeable in the science, their questions thorough and comprehensive, showing real interest in the subject. In fact, this deep knowledge was unexpected by all of us.

After the briefing ended and the Hill staff had left, Dr. Carruthers accused me of advocating and lobbying for the program and of being too enthusiastic about research results. I was shocked. During the briefing, I had answered all the questions based on my knowledge as a scientific subject matter expert, all the questions based on—with no intention of lobbying for the program itself. My only motivation was to fully and truthfully inform Congress about the state of DOE's Low Dose program research.

Drs. Carruthers and Anderson repeatedly accused me of lobbying. Confronted with this unwarranted and unjustified onslaught, I reminded them that they had already—that they already knew I disagreed with their plan to end support of the program. I also mentioned my concern as to how SC management had han-

dled a specific Congressional directive to designate an extra $16 million to the fiscal year 2012 budget for Fukushima-related low-dose research.

Thus began an unjust and painful saga of unrelenting intimidation. In just over one uncomfortable month—week after the briefing—one uncomfortable week Dr. Anderson removed me as Manager of the Low Dose Program and detailed me to unclassified duties. My management obviously did not want me answering any more questions, scientific or—the questions about the Low Dose Program.

A month later on December 4, 2014, a notice of proposed removal was issued, charging me with insubordinate defiance of authority and inappropriate workplace communication. I was put immediately on administrative leave, subsequently denied access to the contents of my former office. There followed a very long period of stressful activity at my home, alone during the usual workweek, cut off from my peers, trying to build a defense to the charges, guided by my NTEU representative.

In early January, I filed a disclosure and complaint with the Office of Special Counsel regarding the $16 million budget directive, also sending information to DOE's Inspector General. Five months later, a final decision of removal was issued by the deciding official Dr. Steven Binkley and effective May 16 of 2015.

I'm sorry I'm going over. Shall I continue?

On the next business day, Dr. Sharlene Weatherwax, Associate Director of BER, was seen rolling a dumpster to my old office, and thus began or perhaps continued the removal of the contents, including irreplaceable hardcopy notes, files, and documents and some of my personal possessions. You may now appreciate that intimidation and retaliation in this case is somewhat self-evident.

It's revealing that after an appeal to the Merit Systems Protection Board and just before the appeal hearing started, DOE reached settlement with me. I'm currently employed but feel there's continuing intimidation of scientists.

To this day I've not been granted the right to inspect remaining materials from my old office or to retrieve missing personal items.

I suggest it's unacceptable that scientists are put under pressure to espouse views that are not their own and that federal scientists are persecuted for presenting accurate information, professional opinion to those charged with providing funds for this research.

Now, in my written testimony I have a lot of information, timeline, and information about the Low Dose Program.

Thank you for inviting me to share this experience.

[The prepared statement of Dr. Metting follows:]

TESTIMONY OF
Noelle F. Metting, Sc.D.

BEFORE THE
HOUSE COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY'S
ENERGY SUBCOMMITTEE & OVERSIGHT SUBCOMMITTEE

HEARING ON
Examining Misconduct and Intimidation of Scientists by Senior DOE Officials

September 21, 2016

Good morning Mr. Chairmen, Ranking Members, and other Members of the Subcommittees on Energy and Oversight. Thank you for the opportunity to testify at this hearing.

I am a scientist, a Radiation Biologist, currently working for the Department of Energy Office of Environment, Health, Safety and Security within their Office of Public Radiation Protection (DOE/EHSS/AU-22). I am actually on detail from DOE's Office of Science, Office of Biological and Environmental Research (DOE/SC/BER), where, from the year 2001 until December of 2014, I had, among other duties, been tasked with managing DOE's Low Dose Radiation Research Program. For the previous 20 years, I had been a laboratory research scientist working at Pacific Northwest National Lab. I have a Master of Science from the University of Washington, and a Doctor of Science from Harvard University. In my remarks today I will share my personal experience of being fired by DOE, and suffering long months of unemployment, that occurred as a direct outcome of my participation in a briefing for Congressional Staff.

In a nutshell, the circumstances surrounding this intimidation and retaliation are these: Congressional staffers requested an overview of the Low Dose Program, so my immediate supervisor, Dr. Todd Anderson, asked me to prepare a PowerPoint presentation which was duly reviewed, amended, and finalized. In a pre-briefing meeting attended by myself and Drs. Anderson, Carruthers, and Huerta, it was decided that for the Congressional Staff briefing I would present my slides and handouts, and respond only to scientific questions, while Drs. Anderson and Carruthers would handle the budget and policy issues.

During the Congressional briefing the following day, Oct. 16, I presented the agreed upon material and answered accurately the many scientific questions directed to me by House Energy Subcommittee staff member and Council Mr. Aaron Weston and Senate Fellow, Dr. Ron Faibish. The staffers were very knowledgeable in the science, their questions thorough and comprehensive, showing real interest in the subjects. This deep knowledge was unexpected.

After the briefing ended and the Hill staff had left, Dr. Carruthers accused me of advocating and lobbying for the Program and of being too enthusiastic about the research results. I was shocked. During the briefing, I had answered all the questions based on my knowledge as a scientific subject-matter expert, with no intention of lobbying for the Program itself. My only motivation was to fully and truthfully inform Congress about the state of DOE's Low Dose Program research. Drs. Carruthers and Anderson repeatedly accused me of lobbying. Confronted with this unwarranted and unjustified onslaught, I reminded them that they already knew I disagreed with their plan to end support of this research field. I also mentioned my concerns as to how SC/BER management had handled a specific Congressional directive to designate an extra $16 million to the FY2012 budget for Fukushima-related low dose research.

Thus began an unjust and painful saga of unrelenting intimidation. In just over one uncomfortable week after the briefing, Dr. Anderson removed me as Manager of the Low Dose Program and detailed me to unclassified duties. My management obviously did not want me answering any more questions about the Low Dose Program. A month later, on Dec. 4, 2014, a Notice of Proposed Removal was issued, charging me with "Insubordinate Defiance of Authority" and "Inappropriate Workplace Communication". I was put immediately on administrative leave and subsequently denied access to the contents of my former office. There followed a very long period of stressful activity at my home, alone during the usual work week, cut off from my peers, trying to build a defense to the charges and guided by my NTEU union representative.

In early January I filed a Disclosure and a Complaint with the Office of Special Council regarding the $16 million dollar budget directive, also sending information to DOE's Inspector General.

Five months later, a final decision of Removal was issued by the Deciding Official, Dr. Steven Binkley, and effective May 16, 2015. On the next business day, Dr. Sharlene Weatherwax, Associate Director for BER, rolled a dumpster to my old office and thus began, or perhaps continued, the removal of the contents, including irreplaceable hardcopy notes, files and documents, and some of my personal possessions.

The Subcommittee may now appreciate that intimidation and retaliation in this case is self-evident.

It is revealing that after I appealed to the Merit Systems Protection Board, and just before the Appeal Hearing started, DOE reached a settlement with me. I am currently employed, but feel there is continuing intimidation. To this day I have not been granted the right to inspect the remaining materials from my old office or to retrieve missing personal possessions.

I suggest it is unacceptable that scientists are put under pressure to espouse views that are not their own, and that federal scientists are persecuted for presenting accurate information and professional opinion to those charged with providing funds for the research, Congress.

In my Written Testimony I have appended a detailed Time Line and a Statement of Facts and Issues prepared originally for my Appeal to the Merit Systems Protection Board. I also include narrative

from the Office of Special Council (OSC) Whistleblower Disclosure and the OSC Complaint of Possible Prohibited Personnel Practice forms that were filed in January of 2015, the decision letter from the OSC Disclosure Unit, and some background on DOE's Low Dose Radiation Research Program.

Thank you again for inviting me to share my experience.

Time Line -- Congressional Staff Briefing of 16 Oct 2014

2014

01 Oct 2014– Received email from Aaron Weston asking for overview and question period regarding Low Dose Program. Forwarded note immediately to my manager, Dr. Todd Anderson.

15 Oct 2014– Pre-briefing meeting, Germantown Building; Drs. Anderson, Julie Carruthers, and me in Todd's office with Dr. Marcos Huerta on telephone

16 Oct 2014 – Briefing in Forrestal Building with Hill staffers Aaron Weston and Ron Faibish

16 Oct 2014 – Post-briefing meeting with Todd, Julie, Marcos, and me

27 Oct 2014 – Todd's office for scheduled performance appraisal; I signed electronically on 29th

29 Oct 2014 –Detail to Other Duties within BER (memo dated October 29, 2014)

04 Dec 2014 – Notice of Proposed Removal (same day as Christmas party!)

04 Dec 2014 – Notice of Administrative Leave

December 2014 until May 2015 – Represented by NTEU for defense (Barry Clark)

2015

~30 January 2015 – **Sent forms to Office of Special Counsel (OSC)**; Disclosure Unit (form OSC-12, disclosure of possible wrongdoing in handling of designated $16M) and Complaint Unit (form OSC-11, complaint of possible retaliation for disclosing suspicion of mishandling of $16M at post-briefing)

13 May 2015 – Letter of Decision from Dr. Steve Binkley (Deciding Official), removal from position effective beginning May 16 (Saturday)

18 May 2015 – Sharlene was seen rolling dumpster down hall to my old office—filling dumpster..! Email to Barry Clark to ask for help

20-21 May 2015 -- Barry sent strong email protesting the ransacking of office; seemed to have halted the activity

22 May 2015 – OSC Disclosures Unit informed me by letter that information provided on Form OSC-12 **is not sufficient** to determine with "substantial likelihood" that wrongdoing was committed.

May-June 2015 – Unexpectedly received some of my possessions from office; several boxes delivered to my home on different days

9 June 2015 – Retained the firm of Alan Lescht and Associates for appeal to Merit Systems Protection Board **(MSPB)**

12 June 2015 – Appeal filed with MSPB

6 Oct 2015 – Received first draft of settlement offer from DOE

Oct/Nov 2015 – No agreement was reached, my lawyer determined we should proceed to MSPB Hearing

12 Nov 2015– MSPB Hearing date. Just before the hearing started, settlement was reached, eventually signed, then approved by MSPB

14 Dec 2015 – Reported to work again, DOE Office of Environment, Health, Safety and Security, Forrestal Building

15 Dec 2015 – Called BER to ask about remaining office contents, was invited to come in and look for possessions. When I arrived, I was told that AD Dr. Weatherwax was on vacation and had left word that I could NOT look at office contents until she had spoken to me personally on her return. I passed by old office, and it was completely empty.

21 Dec 2015 – My new supervisor, Edward Regnier, Director of AU-22 informed me that Dr. Weatherwax said she would not allow me to see remaining office materials; did not want to speak with me or to visit her in Germantown Building – too disruptive.

MSPB Prehearing Statement – Narrative Summary

Taken from APPELLANT'S CORRECTED PREHEARING STATEMENT

Dated: November 4, 2015

UNITED STATES OF AMERICA
MERIT SYSTEMS PROTECTION BOARD
WASHINGTON REGIONAL OFFICE

NOELLE METTING, Appellant,
v.
DEPARTMENT OF ENERGY, Agency

I. STATEMENT OF FACTS AND ISSUES

A. Facts

Appellant was previously employed by the U.S. Department of Energy (the "Agency") as a Senior Radiation Biologist, EJ-0401-04, with the Office of Science ("SC"). Appellant has been a radiation biologist since 1981, and she worked for the federal government for more than 13 years. Throughout her career, she has had no history of discipline or performance issues. As a federal employee, she always received at least fully successful ratings on her performance evaluations.

During her employment with the Agency, Appellant served as the Program Manager of the Low Dose Radiation Research Program ("LDRRP"). Her first-line supervisor was Dr. Todd Anderson, Director, Biological Systems Science Division, SC. On October 1, 2014, Appellant received an email from Aaron Weston, a Congressional staffer. Mr. Weston asked if Appellant would meet with him and Dr. Ron Faibish, Fellow, Senate Energy and National Resources Committee, to discuss the LDRRP. Pursuant to the Agency's policies and procedures, Appellant did not reply directly to the email and forwarded it to Dr. Anderson.

Dr. Anderson sent it to his supervisor, Sharlene Weatherwax, and to the Agency's Congressional Affairs Office. Dr. Anderson asked Appellant to develop a PowerPoint presentation to provide a high-level overview of the LDRRP to Mr. Weston and Dr. Faibish. Appellant sent her draft presentation to Dr. Anderson and Dr. Julie Carruthers for review and implemented all changes they requested.

On October 15, 2014, Appellant met with Dr. Anderson and Dr. Carruthers, and Dr. Marcos Huerta via teleconference, to prepare for the briefing. At that meeting, Dr. Anderson and Dr. Carruthers told Appellant that she would share handouts with the briefing participants, present her slides, and answer scientific questions. It was understood that Dr. Anderson and Dr. Carruthers would handle questions about the budget and policy.

Dr. Anderson, Dr. Carruthers, Dr. Huerta, and Appellant presented the briefing to Mr. Weston and Dr. Faibish the following day, October 16, 2014. Appellant handed out the approved materials and began presenting her slides. Almost immediately, Mr. Weston and Mr. Faibish began asking Appellant complicated questions about the effects of low dose radiation (e.g., adaptive response, radiation-induced

cancer, hormesis, low dose-rate epidemiology). They wanted to know what results were obtained from the research Congress funded.

Before Appellant answered questions, she looked pointedly at Dr. Anderson and Dr. Carruthers to give them an opportunity to interject, but they did not. As Dr. Anderson and Dr. Carruthers had instructed her on October 15, 2014, Appellant answered the questions about scientific and research-related issues, and deferred all questions about the budget to Dr. Anderson. On two occasions, Dr. Carruthers asked Appellant to continue with her slides, and she did.

However, the Congressional staffers continued to ask Appellant questions about the details of the research. When asked to elaborate about the adaptive response research, Appellant mentioned a newly published paper on research conducted in 2014, which she had recently received from Program Investigator Zhi-Min Yuan. One of the staffers asked Appellant to confirm that the research discussed in the paper was conducted in 2014; he sounded surprised that the LDRRP still had ongoing research. Appellant had a copy of the paper in her briefcase because she had been reading it earlier, and she gave the paper to Dr. Faibish. Mr. Weston also asked for a copy of the paper, and it was agreed that Appellant would send a copy to Mr. Weston via Janine Benner.

One of the staffers asked Appellant if she believed 100 mSv was a reasonable level to define as a "low dose." Appellant truthfully responded that she believed 150 mSv might be more appropriate, but that the LDRRP defined "low dose" as 100 mSv. When questioned about animal research, Appellant answered that new results showed the critical need to study whole biological systems (the "systems biology" approach) in order to see subtle biological effects, such as radio-adaptive responses in normal tissues.

In response to a question about how the Million US Worker Epidemiological Study (the "Million Worker Study") was relevant to the LDRRP, Appellant confirmed that the Million Worker Study was relevant to the very low radiation doses that had been experienced after the Fukushima nuclear accident in the wake of the recent Japanese earthquake and tsunami. Either Mr. Weston of Dr. Faibish asked Appellant about the progress of the Million Worker Study and when it would be completed. Appellant answered that the completion date was uncertain because the project was not fully funded.

The staffers discussed H.R. 5544 with Drs. Anderson and Carruthers. One of the staffers turned to Appellant and asked whether, in her scientific opinion, a National Academies report on low dose research would be appropriate at that time. Appellant said that, in her opinion, it would be appropriate.

After the briefing ended, Dr. Carruthers confronted Appellant and accused her of advocating for LDRRP and being too positive about the research results. Appellant was shocked and asked why no one had interrupted to redirect the conversation as they saw fit. The discussion became heated. Dr. Carruthers told Appellant had made a big mistake by communicating her enthusiasm for the LDRRP to Congressional staffers, and she and Dr. Anderson accused Appellant of lobbying and refusing to follow their instructions. Appellant felt attacked and cornered. She was clearly upset and said that she disagreed with the Agency's plan to end the LDRRP, which Dr. Carruthers and Dr. Anderson already

knew. Appellant also questioned them about how SC management handled a specific Congressional directive to designate an extra $16 million to the LDRRP budget for FY2012.

Appellant did not inappropriately communicate enthusiasm, lobby, or refuse to follow instructions. Rather, she truthfully answered the questions posed by Mr. Weston and Dr. Faibish because she felt obligated to provide honest answers to Congress. Based on Dr. Carruthers' and Dr. Anderson's criticism and accusations, it is clear that they expected Appellant to either misrepresent the LDRRP results or withhold information from Congress.

Appellant never refused to "subordinate herself to the SC management position" or said that she would "take every opportunity to undermine SC management decisions." She never did anything to oppose SC management for the remainder of her employment with the Agency.

On or about October (29) 2014, Dr. Anderson removed Appellant as Program Manager for LDRRP and detailed her to a position with unclassified duties. On December 4, 2014, Dr. Anderson issued a Notice of Proposed Removal (the "Proposal"), proposing to terminate Appellant for one charge of "Insubordinate Defiance of Authority" and one charge of "Inappropriate Workplace Communication."

Appellant, by her National Treasury Employees Union ("NTEU") representative Barry Clark, submitted a written response to Deciding Official Dr. Steven Binkley, Associate Director, Advanced Scientific Computing Research, SC, on or about December 17, 2014. Appellant, via Mr. Clark, provided an oral reply on February 3, 2015. In her written and oral replies, Appellant asserted that the Agency had proposed her removal in retaliation for her whistleblowing activity. Appellant alleged that the charges could not be sustained, that the penalty was unreasonably harsh pursuant to the factors set forth in Douglas v. Veterans Administration, 5 M.S.P.B. 313 (1981), and that she was being retaliated against for whistleblowing. Specifically, Appellant made protected disclosures when she refused to misrepresent and withhold information about the LDRRP from Congressional staffers during the briefing on October 16, 2014. Appellant alleged that she also made protected disclosures on October 16, 2014, when she questioned SC management's handling of a Congressional directive to increase funding for the LDRRP in FY2012.

On May 13, 2015, Dr. Binkley issued a Letter of Decision (the "Decision"), in which he stated that he had decided to sustain both charges and remove Appellant from the federal service effective May 16, 2015. Dr. Binkley incorrectly found that the preponderance of the evidence showed that Appellant had engaged in the alleged misconduct. He also failed to properly consider the Douglas factors and imposed an unreasonable penalty of removal. Appellant filed the instant appeal with the Board on June 12, 2015.

B. Issues

1. Whether the Agency proved by preponderant evidence that Appellant engaged in "Insubordinate Defiance of Authority" on October 16, 2014, as specifically stated in the Proposal;

2. Whether the Agency proved by preponderant evidence that Appellant engaged in "Inappropriate Workplace Communication" on October 16, 2014, as specifically stated in the Proposal;

3. Whether removal was a reasonable penalty for the charged misconduct; and

4. Whether Appellant's removal was a product of retaliation for whistleblowing.

II. AFFIRMATIVE DEFENSE OF RETALIATION FOR WHISTLEBLOWING

...etc...not included here

Dated: November 4, 2015

NARRATIVE FROM THE OFFICE OF SPECIAL COUNCIL FORMS

After the briefing I voiced my doubts concerning a $16 M funding decision made by SC/BER management in FY2012.

I believed I was fired because after the briefing Drs. Carruthers and Anderson confronted me, accusing me of lobbying. During the ensuing heated discussion, I revealed my discomfort with the handling of some extra funding that had been directed by Congress to be used for low dose research having relevance to the recent Fukushima nuclear disaster. The Notice of Proposed Removal refers to my remarks in rather exaggerated language: *"... You also disparaged BER management of the LDRRP and insulted BER Associate Director Dr. Sharlene Weatherwax....regarding the funding of the million man project...."*

Here I provide the following account of suspicions, taken from the disclosure of possible wrongdoing that I filed with the OSC (form OSC-12) late in January of 2015:

> I believe and disclose that The Department of Energy's Office of Science (SC) management, and particularly the Office of Biological and Environmental Research (BER) failed to follow the express direction of the 112th Congress as regards the use of funds specifically designated to be spent on Fukushima-related radiobiology research. As the long-time Program Manager for DOE's Low Dose Radiation Research Program, funded within BER's Radiological Sciences/Radiobiology Subprogram/Activity, I have direct personal knowledge of the events and records involved.
>
> On March 11, 2011, a devastating earthquake and tsunami hit Japan, resulting in huge loss of life from the tsunami flooding, and a subsequent nuclear disaster at the Fukushima Daiichi power plant. In one of many efforts by the United States Government to respond to the public's concern over the uncertainties of this ongoing health risk, legislation was initiated to fund new research relating to low dose human exposure to radiation. The budget for FY 2012 had been delayed in a continuing resolution, but was resolved in Conference between the House and the Senate. CONFERENCE REPORT 112-331 (Military Construction and Veterans Affairs and Related Agencies Appropriations Act, 2012) was the vehicle for making appropriations for most federal government operations for the remainder of FY2012. It includes the following paragraph on page 854 for DOE/SC/BER:
>
> > ***"Within available funds, $16,000,000 is provided for radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public, and to conduct studies of health impacts at and around the Fukushima Daiichi nuclear plant." (Conference Report 112-331)***
>
> As Program Manager for the Radiobiology Activity in BER (the Low Dose Radiation Research Program), I was told there would be substantial additional funds available for new DOE research in this activity. In discussions with BER Associate Director Dr. Sharlene Weatherwax, she told me that she would not support actual research in Japan. I then suggested that we use the $16M to support the major cost of a large US-based epidemiology study that had successfully proven itself as a pilot project: The Million U.S. Worker Study. The Study looks at the health of over a

million radiation workers from the beginning of the nuclear age (including ~365,000 former DOE workers) who had received very low doses in the range of those expected from Fukushima. Dr. Weatherwax approved this idea, the full project proposal was successfully reviewed, and the appropriate paperwork was obtained, including the official signature of Dr. William Brinkman, then our Director (SC-1) for Office of Science. This signature was necessary because the budget for the five-year project was over a $10 M administrative limit, and thus needed the SC-1 approval. Coordination of the effort for approvals between Dr. Brinkman (SC-1), Dr. Dehmer (SC-2) and BER was handled by Dr. Julie Carruthers (working for SC-2) and Dr. Steven Binkley (then working directly for Dr. Brinkman). Ms. Joanne Corcoran within BER coordinated the research budget under direction of BER AD Dr. Weatherwax. Ms. Corcoran is still in BER and can verify this information. At the last possible moment, Dr. Weatherwax informed me that she had decided against committing to fund the Million US Worker Study for the entire period, due to budget concerns, and that DOE/BER had less than $1 M to spend on the Study for that year. She implied that we would pick up the funding in the out years, but did not allow me to write the revised Selection Statement to say as much.

I maintained hope that the special funding would be carved out in the next fiscal year, as Dr. Weatherwax had implied. However, the outcome was that the specified $16 M was never fully allocated for its intended purpose. I now believe it was wrongly redefined to cover the already-funded ongoing research projects of the Low Dose Program for FY2012. I finally realized this when I looked up the FY 2013 Congressional Budget Request from DOE (February 2012). The detailed budget justification for BER (page 143) stated in part:

> ***"...Funding is completed in FY 2012 for studies of DNA damage and repair in response to low dose radiation of specific gene targets in single cell culture models and for studies informing the exposure risks at the Fukushima Daiichi nuclear plant...."***

This statement is simply not the truth -- the critical study that was to better inform the scientific community and the public on the exposure risks at the Fukushima Daiichi nuclear plant had only just barely begun to be funded. The DOE/SC/BER management seems to have brazenly ignored the clear wishes of Congress (laid out in Conference Report 112-331), and then actually lied about completing the work in the FY 2013 Congressional Budget Request. Rather than accept that Congress might want to decide how best to spend our scarce research budget, they purposefully misinterpreted the words in Conference Report 112-331, in order to fund research of their own choosing.

I trust there is a rule against such conduct, and that it can be applied in this egregious instance of wrongdoing. It is very disillusioning to know that at least some of our federal management cannot be trusted to carry out the letter and the spirit of the expressed wishes of Congress.

Please note that it was very hard for me to believe at first that this incident really happened, but my resolve to report it became sufficiently strong when I realized that my knowledge of the incident was perceived to be a possible threat by my managers, such that I am now being unreasonably targeted for removal. I am concurrently submitting a form OSC-11 Complaint of

Possible Prohibited Personnel Activity, based on a previous informal disclosure to my management of the information now contained in this Whistleblower Disclosure.

(NOTE: The full text of Conference Report 112-331 is at http://www.gpo.gov/fdsys/pkg/CRPT-112hrpt331/pdf/CRPT-112hrpt331.pdf. The Conference Report pertained to H.R. 2055, the Consolidated Appropriations Act, 2012 (Enrolled Bill [Final as Passed Both House and Senate]); which became Public Law 112-74 on 12/23/2011. The full text of the FY 2013 Congressional Budget Request (Feb 2012) is at http://energy.gov/cfo/reports/budget-justification-supporting-documents.

The following is taken from the complaint of retaliation that I also filed with the OSC (form OSC-11) in January of 2015:

"On 12/04/2014 I was served with a Notice of Proposed Removal in connection with an event that warrants no such extreme action. I believe the proposed extreme action is retaliation due to a perceived threat to my management that I would submit a disclosure of wrongdoing, after I had privately told SC management of my suspicions about a possible misuse of funds in FY2012-FY2013.

At a post-briefing meeting on 10/16/2014 in the presence of my SC/BER Division Director Todd Anderson, Office of Science (SC), advisor for SC-2 (Patricia Dehmer) Julie Carruthers, and DOE special advisor for SC-1 (P Dehmer, Acting) Marcos Huerta, I voiced my concerns on how BER Associate Director Sharlene Weatherwax had managed funds meant to be spent on new research related to Fukushima in FY2012-13. As Program Manager for the program involved with this research, I knew that less than $1M of the $16 M designated by Congress was finally allocated by Dr. Weatherwax for the purpose. I told them that I suspected my management had not represented the matter truthfully in subsequent communications with higher management and with Congress. On 12/04/2014 I received a Notice of Proposed Removal in connection with the briefing itself that I believe is completely unwarranted. I believe the proposed firing is preemptive retaliation for my comments and their perception that I would submit a disclosure of wrongdoing. NOTE: I am submitting OSC-12 Disclosure of Wrongdoing concurrently with this retaliation disclosure.

I believe it is retaliation because the charges made in the Notice of Proposed Removal are gross exaggeration, misstatement, and deliberate misinterpretation of the events of, and surrounding, the briefing of Hill staffers that took place 10/16/2014. I am in the process of rebutting the outrageous allegations with the help of Union (NTEU) representation, but have filed no formal grievances concerning their allegations or acts of retaliation. Witness statements provided to me are not to be trusted, because with the possible exception of Dr. Huerta, the witnesses and their bosses are all implicated in the FY2012-13 wrongdoing. Other persons at the briefing did not provide, or were not asked to provide statements, only those who would naturally have an interest in the FY2012 wrongdoing.

As a final indication and evidence of retaliation, I frankly find it highly suspicious that Dr. Steven Binkley was chosen to be the Deciding Official for my Notice of Proposed Removal, as he is also implicated in my disclosure of wrongdoing, having been (I believe) the closest advisor of our then SC-1 in FY2012-13, Dr. William Brinkman. Dr. Binkley could easily have been a critical party in the funding decisions leading to the wrongdoing.

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

112TH CONGRESS
1st Session

HOUSE OF REPRESENTATIVES

REPORT
112–331

MILITARY CONSTRUCTION AND VETERANS AFFAIRS AND RELATED AGENCIES APPROPRIATIONS ACT, 2012

CONFERENCE REPORT

TO ACCOMPANY

H.R. 2055

DECEMBER 15, 2011.—Ordered to be printed

In order to increase transparency and accountability across all Science activities, the Department is directed, not later than September 1, 2012, to create a performance ranking of all ongoing multi-year research projects across the six major Science research programs, including those at universities, national laboratories, Energy Frontier Research Centers, Energy Innovation Hubs and other recipients, by comparing current performance with original project goals. The report shall include an inventory of the number and dollar amount of awards that have been terminated in fiscal years 2011 and 2012 before their multi-year awards have concluded.

The conferees direct the Department to provide to the House and Senate Committees on Appropriations, not later than February 10, 2012, a budget scenario for fiscal years 2013 and 2014 with the Office of Science funded at the fiscal year 2012 level, highlighting funding levels for each major program and project, including activities, such as ITER, with *scheduled changes in funding* requirements.

Advanced Scientific Computing Research.—The conferees provide $442,000,000 for Advanced Scientific Computing Research. The conferees support the exascale initiative, but note that future funding for the initiative is contingent upon delivery of the joint exascale plan, as directed. The conferees provide the budget request for the Leadership Computing Facilities and for High Performance Production Computing, in support of continuing petascale upgrades at the three facilities.

Basic Energy Sciences.—The conference agreement provides $1,694,000,000 for Basic Energy Sciences. The conference agreement includes $24,300,000 to continue the Fuels from Sunlight Energy Innovation Hub, and $20,000,000 to establish the Batteries and Energy Storage Energy Innovation Hub. The conference agreement includes up to $100,000,000 for the existing Energy Frontier Research Centers; $10,000,000 for predictive modeling of internal combustion engines; $8,520,000 for the Experimental Program to Stimulate Competitive Research; and no funding for gas hydrates research within the Office of Science.

The conference agreement includes $97,000,000 to fund each major item of equipment at the level provided in the budget request. Funding provided for the Linac Coherent Light Source II at SLAC is for the exploration and design of the two-tunnel option.

Biological and Environmental Research.—The conference agreement provides $611,823,000 for Biological and Environmental Research. Within available funds, the conference agreement includes $12,000,000 to continue nuclear medicine research with human application. The conferees direct the Department to report to the House and Senate Committees on Appropriations, not later than June 1, 2012, on the Administration's strategy to continue funding this research through more appropriate federal agencies with health-focused missions.

Within available funds, $16,000,000 is provided for radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public, and to conduct studies of health impacts at and around the Fukushima Daiichi nuclear plant.

DOE/CF-0074
Volume 4

Department of Energy
FY 2013 Congressional Budget Request

Science
Advanced Research Projects Agency-Energy

Biological and Environmental Research
Funding Profile by Subprogram and Activity

(Dollars in Thousands)

	FY 2011 Current	FY 2012 Enacted	FY 2013 Request
Biological Systems Science			
Genomic Science			
Foundational Genomics Research	39,260	63,111	67,292
Genomics Analysis and Validation	10,000	10,000	10,000
Metabolic Synthesis and Conversion	39,912	19,462	19,462
Computational Biosciences	12,683	16,395	16,395
Bioenergy Research Centers	75,000	75,000	75,000
Total, Genomic Science	176,855	183,968	188,149
Radiological Sciences			
Radiochemistry and Imaging Instrumentation	17,540	19,410	17,540
Radiobiology	23,926	15,528	10,620
Total, Radiological Sciences	41,466	34,938	28,160
Ethical, Legal, and Societal Issues	1,000	0	0
Medical Applications	4,000	0	0
Biological Systems Facilities and Infrastructure			
Structural Biology Infrastructure	15,765	14,895	14,895
Joint Genome Institute	68,932	68,500	69,187
Total, Biological Systems Facilities and Infrastructure	84,697	83,395	84,082
SBIR/STTR	0	9,184	9,382
Total, Biological Systems Science	*308,018*	*311,485*	*309,773*
Climate and Environmental Sciences			
Atmospheric System Research	27,822	26,392	26,392
Environmental System Science			
Terrestrial Ecosystem Science	28,727	40,274	51,957
Terrestrial Carbon Sequestration Research	2,966	0	0
Subsurface Biogeochemical Research	48,838	27,380	27,380
Total, Environmental System Science	*80,531*	*67,654*	79,337

The approaches employed include genome sequencing, proteomics, metabolomics, structural biology, high-resolution imaging and characterization, and integration of information into predictive computational models of biological systems that can be tested and validated.

The subprogram supports operation of a scientific user facility, the DOE Joint Genome Institute (JGI), and use of structural biology facilities through the development of instrumentation at DOE's national user facilities. Support is also provided for research at the interface of the biological and physical sciences, and in radiochemistry and instrumentation to develop new methods for real-time, high-resolution imaging of dynamic biological processes.

Explanation of Funding Changes

(Dollars in Thousands)

	FY 2012 Enacted	FY 2013 Request	FY 2013 vs. FY 2012
Genomic Science	183,968	188,149	+4,181
Genomic Science research remains a priority activity, with Foundational Genomics Research increasing for the development of synthetic biology tools and biodesign technologies for plant and microbial systems relevant to bioenergy production, carbon and nutrient cycling, and environmental change. Targeted research in Metabolic Synthesis and Conversion on cellulosic ethanol and biohydrogen decreases, as the DOE Bioenergy Research Centers continue to conduct research on advanced renewable biofuels. Computational Biosciences continues to enable the Systems Biology Knowledgebase tools and integrative analysis of plant and microbial functional genomics experimental datasets.			
Radiological Sciences	34,938	28,160	-6,778
Radionuclide imaging research for real-time visualization of dynamic biological processes in energy and environmentally-relevant contexts continues, while concluding training activities to transfer synthetic and instrumentation knowledge to the nuclear medicine research community. Research is specifically prioritized to enable mechanism-based models that incorporate both radiobiology and epidemiology, reducing activities in cell-to-cell communication, cell aging and senescence, and cell microenvironment. Funding for research informing the exposure outcomes of the Fukushima Daiichi nuclear reactor is completed in FY 2012.			
Biological Systems Facilities and Infrastructure	83,395	84,082	+687
Funding continues to support large-scale, complex genome sequencing and analysis at the Joint Genome Institute, with increasing emphasis on understanding comparative or community-scale plant and microbial genomics. Support continues for the development of instrumentation at SC's synchrotron light sources, neutron sources, and next-generation user facilities for analyzing biological structure-function relationships.			
SBIR/STTR	9,184	9,382	+198
SBIR/STTR funding levels are a set percent of overall research funding.			
Total, Biological Systems Science	311,485	309,773	-1,712

Radiological Sciences

Overview

Radiological Sciences supports radionuclide synthesis and imaging research for real-time visualization of dynamic biological processes in energy and environmentally relevant contexts. The activity has significantly transitioned from its historical focus on nuclear medicine research and applications for health to focus on real-time, whole organism understanding of metabolic and signaling pathways in plants and nonmedical microbes. Radionuclide imaging continues to be a singular tool for studying living organisms in a manner that is quantitative, three dimensional, temporally dynamic, and non-perturbative of the natural biochemical processes. The instrumentation research focuses on improved metabolic imaging in the living systems, including plants and microbial-communities, relevant to biofuels production and bioremediation of interest to DOE. The activity also supports fundamental research on integrated gene function and response of biological organisms to low dose radiation exposure, through systems genetics analysis in model systems and epidemiological studies. This activity contributes a scientific foundation for informed decisions regarding remediation of contaminated DOE sites and for determining acceptable levels of human health protection, for both cleanup workers and the public, in the most cost-effective manner.

Funding and Activity Schedule

Fiscal Year	Activity	Funding ($000)
FY 2011 Current	Research supported the development and use of innovative radiotracer chemistry and complementary radionuclide imaging instrumentation technologies for quantitative *in vivo* measurement of radiotracer concentration and site-specific chemical reactions. Research was initiated to examine epidemiological models for low dose radiation exposure.	41,466
FY 2012 Enacted	Core research activities in radiotracer synthetic chemistry and complementary imaging instrumentation continues; additional activity includes nuclear medicine research with human application as directed by Congress (in the FY 2012 Energy and Water Development Appropriations conference report [H. Rpt. 112-331]), and a report will be prepared for a strategy to continue this research through more appropriate federal agencies with health-focused missions. Research is completed for integrated training in radiotracer synthetic methodology and *in vivo* imaging and detection relevant to nuclear medicine applications. Funds support a limited number of systems genetic studies of integrated gene function and response to the environment, drawing on prior studies of specific gene targets and individual cellular response and focusing only at the tissue or whole organism level. H. Rpt. 112-331 directs continuation of research to help determine health risks from exposures to low levels of ionizing radiation, as well as studies of health impacts at and around the Fukushima Daiichi nuclear plant.	34,938
FY 2013 Request	Funding continues for core research activities in radiotracer synthetic chemistry for real-time visualization of dynamic biological processes in the energy and environmentally-relevant contexts. Funding is completed in FY 2012 for studies of DNA damage and repair in response to low dose radiation of specific gene targets in single cell culture models and for studies informing the exposure risks at the Fukushima Daiichi nuclear plant. Research will be completed for the development of a limited number of systems genetic reference mouse populations. Priority research begins to address integration of mechanism-based models that incorporate both radiobiology and epidemiology.	28,160

(Dollars in Thousands)

	FY 2011 Current	FY 2012 Enacted	FY 2013 Request
Radiochemistry and Imaging Instrumentation	17,540	19,410	17,540
Radiobiology	23,926	15,528	10,620
Total, Radiological Sciences	41,466	34,938	28,160

Ethical, Legal, and Societal Issues

Overview

The activity addresses ethical, legal, and societal impacts for application of genomic research results in bioenergy, synthetic biology, and nanotechnology. Beginning in FY 2012, research related to the societal benefits and implications of DOE mission areas will be addressed within relevant Genomic Science programmatic activities. Beginning in FY 2013, 5% of funding for synthetic biology and biodesign activities in Foundational Genomics Research will be directed toward this research.

Funding and Activity Schedule

Fiscal Year	Activity	Funding ($000)
FY 2011 Current	Funds supported the completion of individual studies on the societal impacts of synthetic biology and bioenergy.	1,000
FY 2012–2013	Activity is completed.	0

Medical Applications

Overview

This activity supports the design, fabrication, integration, and testing of a 240+ microelectrode visual prosthesis device (the artificial retina). DOE's role in this effort was completed in FY 2011.

Funding and Activity Schedule

Fiscal Year	Activity	Funding ($000)
FY 2011 Current	BER research on the development of the components of an artificial retina was completed in FY 2010. In FY 2011, research was completed on the 240+ electrode artificial retina device integration and final testing and refinement of the assembled device for readiness to transition to pre-clinical testing.	4,000
FY 2012–2013	Activity is completed.	0

U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505
202-254-3600

May 22, 2015

Dr. Noelle F. Metting
13033 Middlebrook Road
Germantown, MD 20874

Re: OSC File No. DI-15-1807

Dear Dr. Metting:

The U.S. Office of Special Counsel (OSC) has completed its review of the information you referred to the Disclosure Unit. You alleged violations of laws, rules, or regulations; gross mismanagement; and an abuse of authority by employees of the U.S. Department of Energy (DOE), Office of Science, Office of Biological Research (BER) in the District of Columbia.

OSC is authorized by law to determine whether a disclosure should be referred to the involved agency for investigation or review, and a report. OSC may refer allegations of violations of law, rule, or regulation; gross mismanagement; a gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety. Disclosures referred for investigation and a report by the agency must include information sufficient for OSC to determine whether there is a substantial likelihood of wrongdoing. If a substantial likelihood determination cannot be made, OSC will determine whether there is sufficient information to exercise its discretion to refer the allegations. OSC does not have the authority to investigate disclosures and therefore, does not conduct its own investigations.

In determining whether there is a substantial likelihood that wrongdoing has occurred, OSC considers a number of factors, including the sufficiency and specificity of the information provided and whether the whistleblower has reliable knowledge of the information, such as first-hand knowledge or documentation. Information based on assumptions or speculation does not provide OSC with a sufficient basis to refer allegations to the head of an agency for investigation. Further, we do not have the authority to investigate disclosures, interview subjects or experts, or conduct audits of records through the disclosure process. Rather, our review of a disclosure is based solely on the information the whistleblower provides to OSC.

You alleged that BER improperly used funding appropriated by Congress for "radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public, and to conduct studies of health impacts at and around the Fukushima Daiichi nuclear plant." Specifically, you stated that BER instead used the funds to fund an ongoing study of DNA damage and repair in response to low dose radiation. You also alleged that BER misrepresented their actions by stating that the designated funds would be used for "studies informing exposure risks at the Fukushima Daiichi nuclear plant."

After review and consideration of the information you provided, we have determined that we are unable to refer your allegations to the Secretary of Energy for investigation. Based on the language of the appropriation, Congress granted the agency some amount of discretion with regard to what research to use the funding for. It appears that the ongoing research project on DNA damage in response to low dose radiation falls within the types of work permitted to be funded by the appropriation used because the study involves health impacts from exposure to low levels of radiation. Furthermore, it does not appear that BER misrepresented what the funding would be used for by stating that the research being conducted was "informing the exposure risks at the Fukushima Daiichi nuclear plant" because DNA damage is a potential exposure risk of low levels of ionizing radiation. Accordingly, the information you provided is not sufficient to determine with a substantial likelihood that BER employees engaged in an abuse of authority, gross mismanagement, or violated a law, rule, or regulation. Therefore, we will not take further action regarding these allegations.

Should you wish to pursue these matters further, outside of OSC, you may contact the DOE Office of Inspector General (OIG) as follows: *mail* –1000 Independence Avenue, SW, Mail Stop 5D-031, Washington, DC 20585; *e-mail* – ighotline@hq.doe.gov; *phone* – (800) 541-1625. More information about DOE OIG can be found on their website at www.energy.gov/ig/office-inspector-general.

Finally, you alleged that BER officials have taken personnel actions against you in retaliation for disclosing the alleged wrongdoing described above. Whistleblower retaliation is an allegation of a prohibited personnel practice and is reviewed by OSC's Complaints Examining Unit (CEU). I understand that you filed a prohibited personnel practices complaint that is currently pending review with CEU examiner James Booker. *See* OSC File. No. MA-15-1770. If you have any questions regarding your prohibited personnel practice complaint, please contact Mr. Booker at (202) 254-3675 or jbooker@osc.gov. Because the Disclosure Unit does not review allegations of prohibited personnel practices, we will take no further action regarding those allegations.

Based on the above, we have closed our file on this matter. If you have any questions or comments, please contact me at (202) 254-3678.

Sincerely,

Treyer Mason-Gale
Attorney, Disclosure Unit

KPG:TMG/sss

INFORMATION ON DOE LOW DOSE RADIATION RESEARCH PROGRAM

Briefly, two points should be made about DOE's Low Dose Program:

- **There was, and still is, a critical societal need to study the biological effects of low dose radiation exposure to humans**

  What is low dose research? Who needs the research, and why? Here is a concise description of DOE's Low Dose Program that can be found on DOE's current Program webpage:

  http://science.energy.gov/ber/research/bssd/low-dose-radiation/

  Biological Systems Science Division (BSSD)

  ## Radiobiology: Low Dose Radiation Research

  The Low Dose Radiation Research Program supports competitive peer-reviewed research aimed at informing the development of future national radiation risk policy for the public and the workplace. The Program supports the Department of Energy's missions in energy and environment and contributes to understanding of radiation-related health impacts at and around the Fukushima Daiichi nuclear plant.

  ### Program Description

  The Low Dose Program is unique within the U.S. government in supporting experimental radiation biology research that studies the effects of very low dose exposures. Since its beginning in 1999, the focus of research has been to study cellular and molecular responses to doses of X- or gamma- radiation that are at or near current workplace exposure limits; in general, for total radiation doses that are less than 100 millisievert (10 rem). Currently about 40% of Program funds support research projects at academic institutions and the remaining 60% support program-project research at three DOE National Laboratories, LBNL, ORNL, and PNNL. An Investigators' Workshop is held yearly, and focused topical workshops are held as needed.

  ### Program Funding Opportunity Announcements

  Announcements are posted on the DOE Office of Science Grants and Contracts Website and at grants.gov. Information about preparing and submitting applications, as well as the DOE Office of Science merit review process, is available at the DOE Office of Science Grants and Contracts Website.

  For current announcements visit BER Funding Opportunities.

  Currently funded research studies focus on radio-adaptive responses, systems genetics of inter-individual variation, low dose and/or low dose-rate effects on: a) proteomic responses, b) the immune system, c) epigenetic regulation, and d) molecular and cellular hallmarks of aging. Several of the experimental projects include important mathematical/risk modeling components. The Low Dose Program is also supporting, through intra- and inter-agency efforts, a mortality study of the early U.S. workers of the nuclear age. The "Million U.S. Worker Study" builds on the investments made and foundations laid by researchers and government agencies over the past

30-40 years. These efforts had established early worker cohorts that can now provide answers to questions on the lifetime human health risks associated with low-level radiation exposures.

Why the Program's Research is Important

The Program supports the Department of Energy's missions in energy and environment. It also contributes to understanding of radiation-related health impacts in and around a facility such as the Fukushima Daiichi nuclear plant. Program research is providing high-value scientific data for input in determining health risks from exposures to low levels of radiation. Performing measurements at low doses is critically relevant because radiation exposures associated with human activity are almost always very low dose and/or low dose-rate exposures. Human exposures are mainly from medical diagnostic tests, but exposures might also occur during waste cleanup, environmental isolation of materials associated with nuclear weapons and nuclear power production, catastrophic natural events, or possibly terrorism incidents. A strong scientific underpinning for our risk regulation is critical to adequately and appropriately protect people while making the most effective use of our national resources.

Data Sharing Policy

Low Dose Program investigators are expected to effectively communicate research results through publication in peer-reviewed journals, and when possible to provide data in a format amenable to deposition in widely held databases. Investigators are also encouraged to communicate with the wider community of concerned persons, so that current thinking and public debate incorporate sound science.

Program Accomplishments

Research from DOE's Low Dose Program re-examines existing paradigms and provides the results that support the development of new, biological paradigms. One example that challenges an old assumption is the finding that exposure to a low vs. high dose of radiation results in both qualitatively as well as quantitatively different cellular and molecular responses, thus demonstrating non-linear response with respect to dose. Another is the finding that in addition to high-dose biological damage that may lead to cancer, very low dose radiation exposure may participate in beneficial biological outcomes by stimulation of our natural tissue surveillance mechanisms. These processes are shaped by physical exposure parameters that include dose, dose-rate and dose-distribution. The research has underscored the importance of the Low Dose Program's effort to study intact-tissue biological response to a stressor such as radiation exposure, rather than studying only the initial events within an individual cell. Low Dose investigators were responsible in 2006 for initiation of a highly valued series of International Systems Radiation Biology workshops. Finally, the Low Dose Program has taken a leading role on the world stage in arguing for the critical need for greater communication and coordination between the fields of radiation biology and epidemiology.

As of March 2012, the Program has produced 737 peer-reviewed publications. Please visit the Program website for a list of publications and additional discussion of research findings and future directions.

Last modified: 3/5/2016 8:04:51 PM"

I note that in checking out the link now provided for the Program website (see above), only the internet archive site "***Wayback Machine***" is accessed.

- **DOE's Low Dose Radiation Research Program is widely recognized for successfully addressing critical research questions related to biological effects of low dose radiation exposure.**

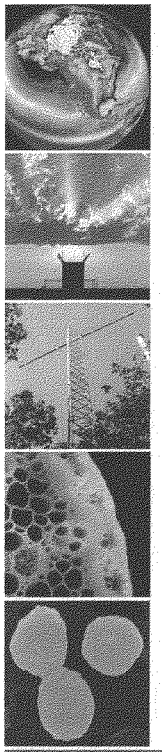
  a. **Formal reviews of the Low Dose Program**: The DOE/BER Advisory Committee (BERAC) "Committee of Visitors" (COV) reviews (http://science.energy.gov/ber/berac/ber-cov/) as well as other BERAC reviews, gave consistently excellent scores and comments to the Low Dose Program. COV reports for 2005, 2008, 2011, and 2014 include this Program. As an example, the 2014 COV report says in part:

  > ***"Low Dose Radiation***. *The Low Dose Program currently focuses on the effects of low dose radiation from the molecular and cellular level to the organismic level with in vivo (murine and porcine) models of low dose radiation effects seen as a significant and unique strength of the program. The research investigates both the targets of transformation (epithelial cells) and the stroma that impact tumor growth. Program productivity has been high with over 700 peer-reviewed publications in its 15-year history. The relative contribution of the SFAs versus University-centered research was not determined by this COV.*
  > *The Low Dose Program is unique in addressing issues central to potential health effects from environmental, occupational, and accidental as well as low-dose medical exposures to ionizing radiation that are a significant and continued concerned of the US public. Past research has led to changes in how the risk of radiation and the mechanisms of radiation carcinogenesis are perceived. Most studies of radiation risk have focused on cancer incidence following relatively high doses to the survivors of the A-bombs in Japan in 1945, as well as other populations exposed to acute high doses of radiation. Much less is known about the risks at low doses of <0.1 Gy (10 cGy or 10 mSv), which are frequently encountered as the result of occupational, medical or environmental exposure. Thus, the acquisition of solid scientific evidence regarding the effects of low dose exposure is vital to guiding public policy including exposure limits and radiation remediation standards. Despite the vital importance of the information generated by this program the budget has been reduced from $21.7M to $6.2M in the time span covered by this review (2011-2013). The allocation has been evenly divided between National Lab SFAs and the remaining University research groups. Unfortunately, the absence of new low dose SFA solicitations in this review period will compromise the future of this important program."*

  b. **As the premier low dose radiation research program in the world,** DOE's Low Dose Program led the field and has become the model on which other countries based their low dose program research portfolios. As Program Manager, I had amassed years of correspondence and meeting notes recording the many interactions that I, the Chief Scientist

for the Program, and the Principle Investigators had undertaken for the purpose of coordinating with colleagues in the European Union, Japan, India, and China. (Unfortunately, as the contents of my office were discarded without my having an opportunity to inspect and save important records such as these, copies were not readily found.)

c. **Through the years, both formal and informal letters praising** the quality and importance of the Low Dose Program have been sent to the Office of Science from upper management in the DOE Offices of Nuclear Energy (DOE/NE; Dr. Peter Lyons), Environmental Management (DOE/EM; Dr. Ines Triay), and Environment, Health, Safety and Security (DOE/EHSS; Mr. Andrew Wallo). Praise was also received by colleagues in several other federal agencies who managed radiation research portfolios that did not overlap into the low dose region. (Unfortunately, as the contents of my office were discarded without my having an opportunity to inspect and save important records such as these, copies were not readily found.)



DOE's Low Dose Radiation Research Program

Overview and Update

NF Metting, Sc.D., Program Manager

16 October 2014

U.S. DEPARTMENT OF ENERGY | Office of Science | Office of Biological and Environmental Research

U.S. DEPARTMENT OF ENERGY
Office of Science

The Low Dose Radiation Research Program supports competitive peer-reviewed research aimed at informing the development of future national radiation risk policy for the public and the workplace.

U.S. DEPARTMENT OF ENERGY
Office of Science

DOE's Low Dose Program:

Is the only program within the U.S. government focusing on low dose biological research

- **DOE** focuses on worker and public safety from very low dose x- and gamma-ray exposures encountered in energy production and environmental cleanup

In contrast:

- **NASA** focuses on astronaut safety from high energy particulate radiation exposures encountered in space flight
- **NIH** (NCI, NIEHS, NIAID) mostly research focused on moderate to higher dose clinically-relevant exposures (200 rads and higher)
- **DOD/AFRRI** focuses research on higher dose exposures, relevant to preserving the health and performance of U.S. military personnel and protecting the public

Who is (or should be) interested in Low Dose Program research?

U.S. DEPARTMENT OF ENERGY
Office of Science

- **Department of Energy**
  - Office of Nuclear Energy (**NE**; nuclear power sustainability)
  - Office of Environment, Health, Safety, and Security (**AU**-20,10; setting implementation standards for DOE workers and public)
  - Office of Environmental Management (**EM**; clean up levels; high cost)
  - National Nuclear Security Administration (**NNSA**; emergency response)
  - General Council (**GC**-70; NEPA documentation)

- **Environmental Protection Agency**
  - Setting of general regulatory standards
- **Nuclear Regulatory Commission**
  - Setting of regulatory standards for nuclear power industry
- **Departments of Labor; Transportation; NASA**
  - Worker safety
- **Department of Homeland Security**
  - Emergency response
- **Department of Defense**
  - Military action, emergency response

- **General public** (fear levels: Fukushima, Chernobyl, TMI, …)

DOE's Low Dose Program:

U.S. DEPARTMENT OF ENERGY
Office of Science

Supports basic research to decrease the uncertainties and shrink the confidence intervals around the central estimate of risk

- DOE uses risk probability as a basis for radiation protection, but it is not used directly to define radiation protection standards
- Regulatory standards are generally defined as a function of dose, or the directly measurable quantities of exposure, activity, or concentration
- Regulatory levels are consistent with US-NRC and EPA, and with recommendations from NCRP, ICRP
- The risk uncertainty rises drastically in the low dose regime (where we regulate)

Regulation at the upper confidence limit of risk is the current policy decision

Outline

U.S. DEPARTMENT OF ENERGY
Office of Science

- **History:** *Research to develop a better scientific basis for understanding exposures and risks to humans*
- **Biology:** old assumptions, new paradigms
- **The Low Dose Program today**
- **Million U.S. Worker Study**

U.S. DEPARTMENT OF ENERGY
Office of Science

The Low Dose Program was initiated in 1999 with a workshop:

Bridging Radiation Policy and Science
An international meeting of experts
Airlie House Conference Center
1 – 5 December 1999

"The lowest dose at which a statistically significant radiation risk has been shown is ~ 100 mSv (10 rem) of x-rays."

Other Programs are now supported:

- **MELODI** (**M***ultidisciplinary* **E***uropean* **Lo***w* **D***ose* **I***nitiative*)
  - DoReMi, OPERA, RadEpiBio
- **Japan**
- **Other** (China, Korea, India,…)

The Low Dose Program:

U.S. DEPARTMENT OF ENERGY
Office of Science

- **Provide mechanistic data for the development of a scientific basis for radiation standards in the low dose region**
- **Possible in 1999 because of**
  - **Extensive biological advances associated with**
    - sequencing of the genome
    - the development of gene expression arrays
    - the expansion of information on cell-cell and cell matrix communication
  - **Technologies such as single cell irradiators**
    - (The first research program to emphasize whole tissue responses using these advances)

Historic Animal Studies

U.S. DEPARTMENT OF ENERGY
Office of Science

- Historic mega-mouse and -dog studies were conducted from1970s – '90s (49,000 mice, 17,000 beagle dogs)

- Historic (and newer) studies have shown
  - A pronounced dose-rate effect for cancer
  - Strong low dose "sparing" effect
  - Data and tissue archives

- Animal studies help determine if cellular and molecular observations influence disease outcome
- Animal data still provide a link between cell and molecular mechanisms and human epidemiological data for risk assessment.

U.S. DEPARTMENT OF ENERGY
Office of Science

In 1999, five research needs were identified:

- **Understanding biological responses to low dose radiation exposures**
- **Low dose radiation versus endogenous oxidative damage**
- **Thresholds for low dose radiation**
- **Genetic factors affecting individual susceptibility**
- **Communication of research results**

The real challenge: to do research at 10 rads or less

Fourteen years later – 2014

U.S. DEPARTMENT OF ENERGY
Office of Science

Radiation physics (energy deposition) *dictates a linear induction of initial events as a function of dose*

Radiation biology *shows us that the subsequent biological response is much more complex*

- ***DNA repair***
- ***Cell apoptotic death***
- ***Cell/tissue growth and replacement***
- ***Immune system surveillance***
- ★ ***Metabolic shift after low (but not high) dose exposure is protective — very new…***

U.S. DEPARTMENT OF ENERGY
Office of Science

Fourteen years later – 2014

Program Research Results

- Biological systems detect and respond to very low doses of radiation
- Cells not directly exposed can show a biological response to the low dose radiation exposure of neighboring cells
- Cell-cell and cell-matrix communication are critical in the total response to radiation, resulting in whole tissue or organism responses as compared to individual cell responses
- Qualitatively different molecular-level responses result after low doses of radiation vs. high doses of radiation
- Many cellular and tissue-level responses demonstrate non-linear responses with respect to radiation dose
- In addition to radiation-induced DNA damage, other processes are induced by low dose radiation that participate in either increasing or deterring carcinogenesis

Fourteen years later – 2014

Old Assumptions		*New Paradigms*
Qualitatively similar radiation effects occur at high and low dose exposures	→	Qualitatively different processes are induced by high vs. low doses/dose-rates
All radiation effects contribute to the process of carcinogenesis	→	Many radiation effects do not contribute to the process of carcinogenesis
DNA damage is the only mechanism responsible for increasing cancer risk	→	In addition to DNA damage, cancer risk is highly dependent on the cell microenvironment
↓		
These assumptions have been prevalent since World War II		We now know much more about biology and radiobiology

The Low Dose Program in 2012 (1)

U.S. DEPARTMENT OF ENERGY
Office of Science

- **12th year of Program**
- **Joint funding of research with NASA's Space Radiation Research Program**
  - Cellular and molecular responses in normal tissues
  - After high LET radiation exposures
  - At fluences approximating the space environment (high single-cell doses but low tissue doses)
- **Re-analysis of Radiobiology Tissue Archive data at Northwestern University**
  - The Woloschak laboratory hosts several radiobiology archives containing data and tissues from radiobiology very large (mouse, dog) studies conducted in the second half of the 20th century
- **Research to enable mechanism-based models that incorporate both radiobiology and epidemiology**

The Low Dose Program in 2012 (2)

U.S. DEPARTMENT OF ENERGY
Office of Science

- **Currently funded projects:**
  - **University-based**
    - Three 5-yr Program Projects in 5th year
    - 21 radiobiology projects in 3rd (last) year or no-cost extensions–
      - 7 of these are joint NASA-DOE projects
    - **Million U.S. Worker Study**
  - **National Lab SFAs: LBNL, PNNL**
- **Communication links with the public; science to inform public debate**
  - Website
  - Workshops
  - Dose ranges charts
- **>700 peer-reviewed publications** *(www.lowdose.doe.gov)*
- **New public awareness:**
  - **Medical diagnostic doses (CT scans)**
  - **Fukushima – evacuation/relocation**

The Low Dose Program in 2014

U.S. DEPARTMENT OF ENERGY
Office of Science

- **Currently funded projects:**
  - **University-based**
    - Two 5-yr Program Projects in no-cost extension
    - 9 radiobiology projects in last-year or no-cost extensions–
      - 3 of these are joint NASA-DOE projects
    - **Million U.S. Worker Study (DOE support ending;** supplemented by NASA, NRC, and EPA interagency transfers; needs ~$5 M/y, 4 yrs)
  - **National Lab SFAs: LBNL, PNNL (less than $ 1M/yr)**
- **Communication links with the public; science to inform public debate**
  - Website (no longer fully funded, but still accessed by public)
  - Workshops (last one in 2010) http://lowdose.energy.gov/workshops.aspx
  - Dose ranges charts (still requested; ~28,000 given out to date)

Program Coordination: Intra- and Inter-agency

U.S. DEPARTMENT OF ENERGY
Office of Science

- **Coordination with DOE/HS:** DOE's Office of Health, Safety and Security—regular meetings with colleagues in HS-13 (Office of Domestic and International Health Studies) [now is AU-10, AU-20]
- **Coordination with NASA:** Joint support of research grants with NASA Space Radiation Health Program; regular meetings, reviews
- **Coordination with AFRRI:** meetings, reviews
- **RABRAT** –quarterly meetings with agency colleagues interested in radiobiology and emergency response to radiological events (NCI, NIAID, AFRRI, EPA, DOD, DHS, FDA, CDC, DOE)
- **ISCORS:** Interagency Steering Committee on Radiation Standards, regularly attend meetings as BER observer
- **Coordination with Europe:** MELODI and DoReMi; representatives attend each other's meetings; peer reviewers
- **Coordination with Japan:** representatives attend our Workshops, visit, peer review

Program Evolution /Planning

1999

- Endogenous oxidative damage
- DNA damage and repair
- Adaptive responses
- Bystander effects
- Genetic susceptibility
- Genomic instability
- Risk Communication

Current

- Endogenous oxidative damage
- DNA damage and repair
- Adaptive responses
- Bystander effects
- Genetic susceptibility
- Genomic instability
- Epigenetics (2006)
- Aging endpoints/ homeostasis (2008)
- Tissue-emergent carcinogenesis
- Low dose epidemiology
- Risk Communication (website, Dose Ranges chart)

2010+

- Adaptive responses
- Genetic susceptibility
- Epigenetics
- Tissue-emergent carcinogenesis*
- U.S. workers epidemiology
- Risk Communication (website, Dose Ranges chart)

* Includes endogenous oxidative damage, genomic instability, aging, homeostasis, and metabolic studies

Low Dose Epidemiology: The Million U.S. Worker Study

- **Discussed informally at the Workshop: Low Dose Epidemiology—What Can it Tell Us?** ***December 10-11, 2008***
- ***Considered in Office of Science call for ARRA*** *(Recovery Act)*
- **Application via the 2010 Office of Science open call -- "Pilot Study of One Million American Workers and Veterans Exposed to Radiation"** *funded in FY2010*
- **"Epidemiologic Study of One Million U.S. Radiation Workers and Veterans";** *funded in FY2012 along with interagency support from NRC, NASA, and EPA*
- **The Study populations** include early DOE and Manhattan Project workers, atomic veterans who participated in nuclear weapons testing in the 1940s and 1950s, nuclear utility workers, medical workers and others involved in the development of radiation technologies, as well as nuclear navy personnel.

The Million U.S. Worker Study - attributes

- **STUDY IS LARGE:** The study is 10 times larger than the study of Japanese Atomic Bomb Survivors There are no other studies in the world which are as large, with good estimates of dose, with long term follow-up.
- **MANY HIGH-DOSE EXPOSED WORKERS**: There are more high-dose workers in this study than among the Japanese A-bomb survivors, but the workers received their dose gradually over time and not all at once.
- **UNCERTAINTIES WILL BE CONSIDERED**: The research is designed to address the issues of uncertainties in dose estimates during the study.
- **BUILDS ON HUGE PAST EXPENDITURE BY US GOVERNMENT**: The study builds upon a tremendous amount of research, over 50 years, and few components are *de novo*. The total cost paid so far is in the hundreds of millions of dollars.
- **INTER-AGENCY SUPPORT**: The Study is a national effort, with DOD, US-NRC, NCI, and DOE already contributing to the overall vision and funding support. NRC, NASA, and EPA are providing inter-agency funding to the DOE grant.
- **WILL CONSIDER BIOLOGICAL AND EPIDEMIOLOGICAL DATA**: Finally and importantly, the grantees intend to consider the latest radiation biology in applying biologically-sound models to help estimate risks in the low dose region.

BIOGRAPHY

Dr. Noelle F Metting is a Radiation Biologist, currently working for the Department of Energy Office of Environment, Health, Safety and Security within the Office of Public Radiation Protection (DOE/EHSS/AU-22). Formerly, she worked in DOE's Office of Science, Office of Biological and Environmental Research (DOE/SC/BER), where, from the year 2001 until December of 2014, she managed DOE's Low Dose Radiation Research Program. For the previous 20 years, she worked at Pacific Northwest National Laboratory as a laboratory research scientist. Dr. Metting earned a Master of Science in Radiological Sciences from the University of Washington, and a Doctor of Science in Cancer Biology from Harvard University, with a doctoral dissertation entitled *Studies of Radiation-Induced Mutagenesis and Cell Cycle Perturbation.*

Chairman LOUDERMILK. And thank you, Dr. Metting. I now recognize myself for five minutes for questions.

Dr. Metting, I appreciate your testimony. In your testimony, as well as your written testimony, I believe you stated that when you were confronted by the Department of Energy management that they accused you of lobbying on behalf of the program, is that correct?

Dr. METTING. Yes.

Chairman LOUDERMILK. Okay. Thank you.

Dr. Weatherwax, was one of your goals for the October 16, 2014, briefing with the Congressional staff to dissuade the Senate from offering a companion bill to the House bill?

Dr. WEATHERWAX. Chairman Loudermilk, I had no explicit goals for the briefing other than to provide information that was requested at the briefing. The briefing—I did not personally attend the briefing.

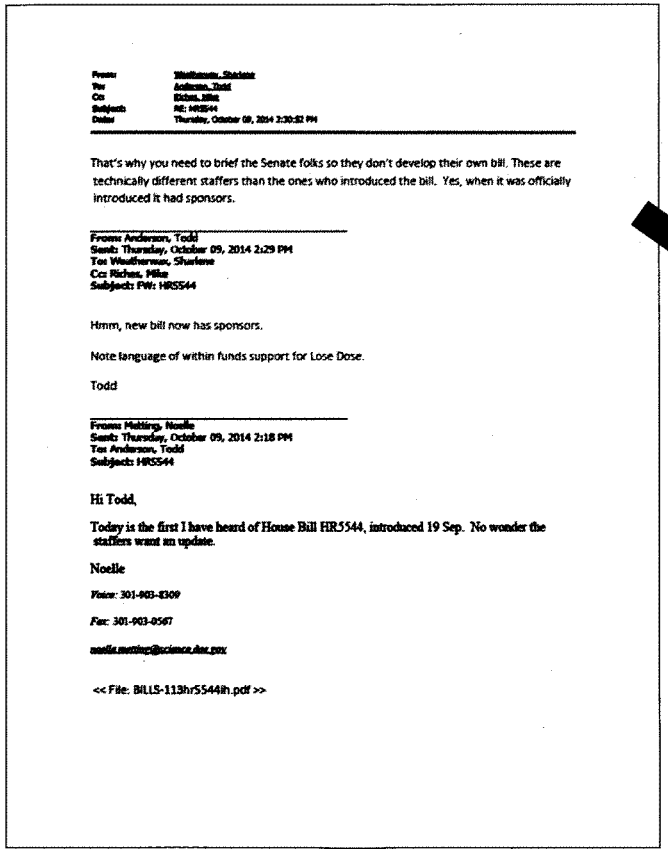
Chairman LOUDERMILK. So if the intention would have been to dissuade the Senate from introducing their own bill, then would you consider that a form of lobbying?

Dr. WEATHERWAX. I am not aware of the official definition of lobbying, but since I had no intention of doing any of that activity, I can't really answer to it.

Chairman LOUDERMILK. Well, someone in the DOE must know what the official definition of lobbying is since they accused Dr. Metting of doing the same.

Could we bring up the slide, please?

[Slide.]



That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced it had sponsors.

From: Anderson, Todd
Sent: Thursday, October 09, 2014 2:29 PM
To: Weatherwax, Sharlene
Cc: Riches, Mike
Subject: FW: HR5544

Hmm, new bill now has sponsors.

Note language of within funds support for Lose Dose.

Todd

From: Nolting, Noelle
Sent: Thursday, October 09, 2014 2:18 PM
To: Anderson, Todd
Subject: HR5544

Hi Todd,

Today is the first I have heard of House Bill HR5544, introduced 19 Sep. No wonder the staffers want an update.

Noelle

Voice: 301-903-8309

Fax: 301-903-0567

noelle.nolting@science.doe.gov

<< File: BILLS-113hr5544ih.pdf >>

From: Weatherwax, Sharlene
To: Anderson, Todd
Cc: Riches, Mike
Subject: RE: HR5544
Date: Thursday, October 09, 2014 2:30:52 PM

That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced it had sponsors.

Chairman LOUDERMILK. Dr. Weatherwax, in this email from you to Todd Anderson to whom I understand—and according to Dr. Metting's testimony—was the one that you preferred to speak to the Congressional staff. In this email you directed Dr. Anderson to conduct the briefing so that he would dissuade the Senate from offering their own bill with regard to low-dose radiation research.

Now, that seems contrary to what you just told me in answering that question. In fact, the email says, "That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced, it had sponsors."

Can you explain the purpose of this email if it wasn't to lobby Congress to do something?

Dr. WEATHERWAX. So in the body of the email the question arises around a House bill, so my understanding is that the briefing was designed to inform the staffers about the Low Dose Radiation Program in general. So my understanding is that scientific issues are presented by the Program Manager, but the responsibilities of the Division Director, who was Dr. Anderson, are to communicate the strategic direction and the portfolio balance that he has developed so——

Chairman LOUDERMILK. Well, I appreciate that but that is not what the text of the email says. The text of the email says, "That's why you need to brief the Senate folks so they don't develop their own bill."

Dr. WEATHERWAX. So since it's Dr. Anderson's responsibility to communicate what is in his portfolio and to convey the program priorities that he has balanced for all of the competing scientific opportunities, his job was to present that to House and Senate so that they can see how he arrived at his conclusions for presenting his particular portfolio.

Chairman LOUDERMILK. Okay. I'd like to go to Dr. Metting now. And I think it's clear that—and I think that's why you're having a hard time answering the question is that this was indeed an intention of going and persuading Congress to do something, which is a practical definition of lobbying, which Dr. Metting was fired for doing. I think there's some hypocrisy here.

Dr. Metting, is the narrative that Dr. Weatherwax instructed Dr. Anderson to lobby against H.R. 5544 consistent with your memory of how the briefing went?

Dr. METTING. Actually, the briefing—it wasn't. It wasn't because I believe that my management—and Todd is my—Todd Anderson is my manager and with the help of Dr. Carruthers, I think they were trying to inform—they were trying to lobby against this bill itself. They were trying to—they told me to——

Chairman LOUDERMILK. Okay. To make clear that you were directed to basically lobby against the Senate introducing their own bill? Are we clear? Or that was the intention?

Dr. METTING. Actually, I don't think anything was mentioned to me about the Senate in any way. I was told that I would be doing the science and that's it, but I was told in the pre-briefing that we are against this bill and we don't want this bill to pass.

Chairman LOUDERMILK. So as you stated in your testimony that the result of you being released—or fired was that you honestly an-

swered the questions by the staff, which you said you were impressed that they had the knowledge they had, and you were not lobbying to—or you—they felt you were lobbying to keep the program just because you were answering the questions honestly?

Dr. METTING. Yes. Yes, Mr. Chairman. I was only answering the questions.

Chairman LOUDERMILK. Dr. Weatherwax, Congress relies on briefings with federal agencies and in particular a scientist like Dr. Metting to provide candid technical expertise on matters. Would you agree with that?

Dr. WEATHERWAX. Yes.

Chairman LOUDERMILK. It also seems that when it came to a briefing on the Low Dose Radiation Research project you viewed this briefing not as an attempt to inform Congress with technical expertise but an attempt to prevent legislation. Is that accurate?

Dr. WEATHERWAX. As I stated previously, our intent was to provide information about how we develop our budget priorities to balance the program portfolio that includes many broad elements of which the low-dose radiation research is one. So we were there to provide a full accounting of all of the science that's presented so that Congress can make its own determinations about how we come to our decisions.

Chairman LOUDERMILK. Thank you. And I have exceeded my time. I apologize, members of the committee, but I'll extend that same latitude to the other members because I was not very well in managing my own time.

I now recognize Mr. Beyer.

Mr. BEYER. Thank you, Mr. Chairman.

Over 40 years of managing employees, I've had the unfortunate responsibility of sometimes having to fire people. Rarely though do I fire people on the spot. It's usually—on the spot it tends to be because they just got into a fistfight with somebody or were caught lying outright to a customer.

So, Dr. Metting, we've heard a lot about your firing. Is it your sense that you were removed because you were advocating for a program that you lead for more than ten years or were you removed because of "insubordinate defiance of authority," that you were argumentative, that you called their actions idiotic? Was it basically because you disagreed with them on the science or because they saw you as unmanageable?

Dr. METTING. I—at the time I thought that they were actually reacting to the $16 million question that I talked to them with after the briefing, but I also knew that they were very upset with me talking about the science in the briefing itself, which was a wonderful—actually a good opportunity to talk about the program and I was—that's why I was just very surprised when they were upset about that. That was not lobbying. That was talking to the science.

Mr. BEYER. Okay. Thank you. Dr. Weatherwax, it's hard for us it—for any of us here to know what happened in that briefing after the fact. We have the transcripts and stuff, but I'm curious to know what you and others took at DOE to help mediate this and resolve the tensions between Dr. Metting and Dr. Anderson and other DOE employees.

You know, it's a big step to take someone out of a career they've devoted a significant part of their life to. So did you seek mediation? Was there anything else that attempted to resolve the bad blood between Dr. Metting and the other folks at DOE?

Dr. WEATHERWAX. So, Congressman Beyer, so the process works to actually defend the rights of the employee and also the interests of the Department. And in this case, the supervisor, Dr. Todd Anderson, submitted the proposal to remove Dr. Metting. So he issued the proposal. At that point, it was deemed that it had to go for human resources to actually advise on what the process—what the next steps would be, and so we followed the process at the Department, which is that the proposing official submits some kind of request and then the human resources and general counsel provide advice as to whether or not there are sufficient grounds to take any action, any kind of personnel action.

And so in this case it's a process as with all personnel actions is that it has to be then handed over to HR and GC, and at that point if they feel that it's—there is sufficient grounds to warrant further action, then the process—the entire matter goes to the deciding official, who is a neutral third party.

Mr. BEYER. Well, let me simplify. Does it seem to you in retrospect that it's an overreaction to fire somebody for advocating for a program that she spent perhaps 14 years of her life working on?

Dr. WEATHERWAX. So I believe that the proposal to dismiss Dr. Metting enumerated a number of issues, and some of those issues obviously—there are a number of those issues which are not related at all to the briefing. And so I think that that was something then that the process had to look at, and that's what the deciding official was viewing. And so I feel it's not my position to make the determination of what course of action should be taken on something that is so serious, and so we relied on HR to advise us.

Mr. BEYER. So who was the deciding official?

Dr. WEATHERWAX. In this case the deciding official was Dr. Steve Binkley. He's another Associate Director in the Office of Science. He manages the Advanced Scientific Computing Research Office.

Mr. BEYER. Thank you. Dr. Metting, prior to October 2014, had you ever been disciplined or reprimanded by your supervisors at DOE?

Dr. METTING. Mr. Congressman, actually never. I have never had anything written against me or had any disciplinary action neither at the—at—as a fed or——

Mr. BEYER. So was the first time in your career then that any supervisor had sought to reprimand or punish you?

Dr. METTING. Oh, yes. That's the first time. I was shocked.

Mr. BEYER. Do you feel your actions immediately after the briefing, that heated exchange, were appropriate?

Dr. METTING. The heated exchange was in response to what they were saying, and after Dr. Anderson had raised his voice and then we—it was—there was actually some scientific content there. We were actually talking about the use of the—you know, of science in BER, so it was under the rubric of a scientific exchange after everyone was gone in the privacy of the—of BER really.

And it was—I was—I really actually feel like I was goaded, and I did say that I thought the—I thought their decision was idiotic

on there and I was—I was also not—I didn't like the way some of the questions were in the briefing itself. The question of—well, actually, Dr. Carruthers brought up the fact that DOE does not have regulatory—does not set regulatory standards and that was not true. And so I did correct that in a—kind of a collegial fashion, and I think that was what Dr. Carruthers was reacting to at the—after the briefing in the post-briefing.

Mr. BEYER. All right. Thank you very much, Mr. Chair.

Chairman LOUDERMILK. Thank you, Mr. Beyer.

I now recognize the fine gentleman from the great state of Texas, Mr. Weber.

Mr. WEBER. Thank you, Mr. Chairman.

Dr. Weatherwax, you stated in your discussion with Chairman Loudermilk that you didn't go there to lobby, you were—you didn't go there at all to the meeting but that you felt like your intent was to actually impart the scientific facts. And in your opening statement, in your testimony you went through a litany of scientific facts.

But let me ask you this. At what point did you become aware of the fact that there—this was indeed—there was a lobbying attempt going on, to use the term "subtly yet firmly" dissuade the Senate from filing their companion bill? When did you become aware of that?

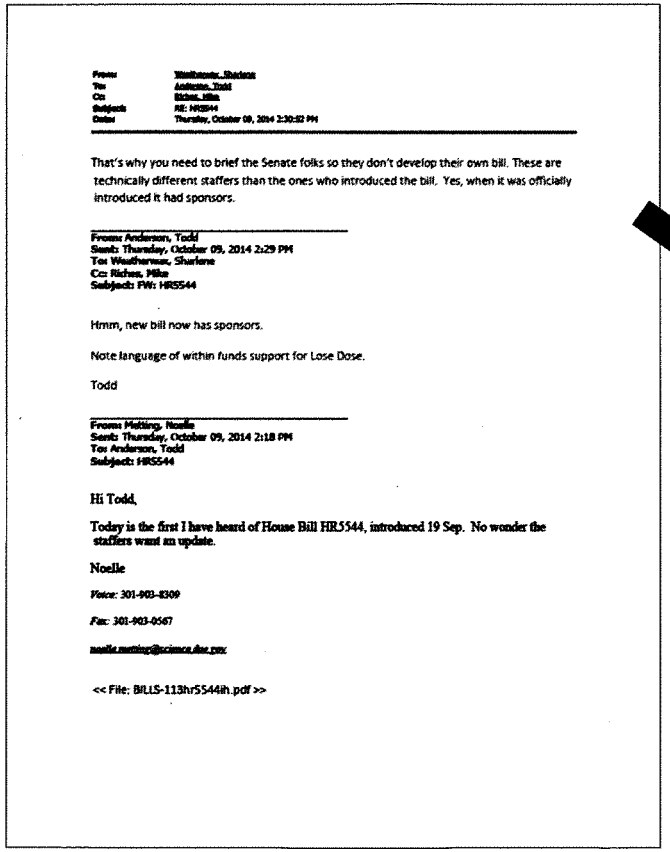
Dr. WEATHERWAX. I can't recall when I became aware of any——

Mr. WEBER. Okay. Well, let me help you with that. It——

Dr. WEATHERWAX. —lobby.

Mr. WEBER. Let me help you with that. On your email—can we put the email back up on the slide?

[Slide.]



That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced it had sponsors.

From: Anderson, Todd
Sent: Thursday, October 09, 2014 2:29 PM
To: Weatherwax, Sharlene
Cc: Riches, Mike
Subject: FW: HR5544

Hmm, new bill now has sponsors.

Note language of within funds support for Lose Dose.

Todd

From: Melting, Noelle
Sent: Thursday, October 09, 2014 2:18 PM
To: Anderson, Todd
Subject: HR5544

Hi Todd,

Today is the first I have heard of House Bill HR5544, introduced 19 Sep. No wonder the staffers want an update.

Noelle

Voice: 301-903-8309

Fax: 301-903-0567

noelle.melting@science.doe.gov

<< File: BILLS-113hr5544ih.pdf >>

From: Weatherwax, Sharlene
To: Anderson, Todd
Cc: Riches, Mike
Subject: RE: HR5544
Date: Thursday, October 09, 2014 2:30:52 PM

That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced it had sponsors.

Mr. WEBER. It says—Dr. Carruthers writes—and this is, by the way, October the 4th, 2014. That's the exact date. "I think this is an opportunity to subtly yet firmly let the Senate know" blah, blah, blah, blah, blah. So you did become aware on October the—you knew at least before October the 4th, 2014, or on that date that there was this effort going on. Is that accurate?

Dr. WEATHERWAX. So, yes, I obviously knew——

Mr. WEBER. Okay. Well, let me move on.

Dr. WEATHERWAX. But I don't see the word "lobby."

Mr. WEBER. Let me move on. Well, to let the Senate firmly know, I mean that is the definition, as our Chairman pointed out. Dr. Metting had said she—in the pre-briefing she had been informed of some things. Did you attend any kind of pre-briefing?

Dr. WEATHERWAX. No.

Mr. WEBER. Did you have emails about the pre-briefing?

Dr. WEATHERWAX. I might have been copied on them, but I don't recall actually engaging——

Mr. WEBER. So if we sent you a request for more emails about this briefing, you could find this for us?

Dr. WEATHERWAX. Of course. If you inquired about any emails, we would provide them.

Mr. WEBER. Okay. Well, let me do it this way then. Why was it thought that Dr. Anderson was better on staying on message in this particular instance? Do you have any knowledge of that, email written communication as to why Dr. Anderson needed to be chosen?

Dr. WEATHERWAX. So typically, when we have briefings to Congressional staff, it is the Division Director who usually attends. And so in this case the Division Director is more experienced.

Mr. WEBER. Okay. That's what I need. So if he's more—and if he can stay on message, particularly if the message is to subtly yet firmly—to use the email's terminology—basically lobby the Senate against filing the companion bill, he was the logical choice?

Dr. WEATHERWAX. So he's the appropriate choice to convey what our program priorities are.

Mr. WEBER. Okay. It's my understanding committee staff meets with technical experts all the time. Our gentlemen over here on the other side of the aisle said it was unusual or the Democrats weren't—but I'm sure that they've met with committee—their staff has met with technical experts, too. In your opinion is Congress entitled to the opinion of experts or just the ones that maybe Dr. Todd Anderson and the others in this instance agree with? Are we entitled to the opinions of experts or just the ones that you all agree with?

Dr. WEATHERWAX. Congress is entitled to what they ask for.

Mr. WEBER. Okay. So you would agree with me, then, that this lobbying effort—apparent lobbying effort to subtly yet firmly dissuade the Senate was inappropriate?

Dr. WEATHERWAX. I don't believe that's what my statement says.

Mr. WEBER. Well, I wasn't asking you about your statement, Dr. Weatherwax. I'm asking you about what occurred in the email and your obvious apparent attempt to convince the Senate—dissuade them from not filing their companion bill. That is lobbying in its truest form. Do you think that's inappropriate?

Dr. WEATHERWAX. So since I never actually said that Dr. Anderson should lobby, his job is to provide——

Mr. WEBER. But that's—I didn't ask—that's not my question. My question is this attempt to subtly yet firmly influence the Senate, is that not improper to you? Yes or no?

Dr. WEATHERWAX. Dr. Anderson was there to convey the overall program priorities.

Mr. WEBER. You're not going to answer the question. I'm going to move on.

Dr. Weatherwax, it appears that you and other DOE officials wanted to ensure that Congress would not receive information about the Low Dose Radiation Program in an attempt to prevent legislation, and thus, that's the subject hearing matter for this hearing. Is that accurate to say? It at least appears that you all wanted to dissuade this Congress from getting—Senate particularly from getting that information. Would you agree that it appears that way?

Dr. WEATHERWAX. The Senate—if the Senate asked us to provide information, we provided the briefing.

Mr. WEBER. Well, according to this, you have to have someone staying on message to subtly yet firmly let the Senate know. You did read that in the email, I take—you do read your emails?

Dr. WEATHERWAX. Yes, sir, I do.

Mr. WEBER. Okay. That did not raise a red flag for you?

Dr. WEATHERWAX. If the intent is to provide information about the science, we did not interfere with that whatsoever.

Mr. WEBER. All right. Let me do it this way real quick. On your testimony—you referred to your testimony on page one. You say competitive funding on their BER—I'm going from memory now—programs. Was is so competitive that it seemed to justify an attempt to lobby the Senate not to file a companion bill and in order to direct that funding that Congress was seeking to establish? Is it that competitive?

Dr. WEATHERWAX. It is a very highly competitive funding——

Mr. WEBER. So it sounds like that you all might have thought it was justifiable. I get that. And then on page three you go into the technical stuff and you say that a lot of the things that you all do is to "provide an analysis" and then you list some groups that can draw their own conclusions. And I won't go through it and bore you. It's on page three if you want to read it.

So my question is should Congress be allowed to draw conclusions as well?

Dr. WEATHERWAX. Of course.

Mr. WEBER. So you admit that. And so—but you don't say that the attempt to subtly yet firmly dissuade the Senate was a contravention of that idea that they can draw their own conclusions?

Dr. WEATHERWAX. No.

Mr. WEBER. Wow. Okay. Very good. Let me go to you very quickly, Dr. Metting. You said that somebody was your boss. "Todd Anderson is my manager." Is that still true today?

Dr. METTING. Well, he's not supervising me today. I'll just say that I'm still a member on—of BER in Todd's—in Dr. Anderson's division——

Mr. WEBER. Okay.

Dr. METTING. —but I am on detail with the Office of Environment, Health, and Safety.

Mr. WEBER. Okay. And you still as of this date have not been able—allowed to get your personal effects back?

Dr. METTING. No, not at all. When I—the second day after I got back—actually finally got back to DOE I asked—I called up BER. I was calling Kathy Holmes, Dr. Weatherwax's admin person, to see if I could go—come in finally and get my things.

Mr. WEBER. Okay. And I don't mean to pry but do you have grandchildren?

Dr. METTING. Yes, I do.

Mr. WEBER. Were there pictures of your grandchildren included in that?

Dr. METTING. There could have been some pictures. There could have been so——

Mr. WEBER. Yes. Yes. Okay. So you mentioned that somebody was seen pushing a dumpster into your office to get rid of this stuff. And who was that?

Dr. METTING. I'm sorry, that—I have to admit it's hearsay but I have the email from a colleague——

Mr. WEBER. Okay.

Dr. METTING. —in BER who watched my Associate Director actually personally pushing a dumpster——

Mr. WEBER. Is it the norm that they push around these dumpsters and do these kinds of things?

Dr. METTING. I have never heard of such a thing.

Mr. WEBER. No? Okay. Thank you, I yield back, Mr. Chairman.

Chairman LOUDERMILK. I thank the gentleman from Texas.

I find it very interesting that the statement was that it was appropriate for Dr. Anderson to brief Congressional staff, but the DOE did not find it appropriate for Dr. Anderson to be here for the Full Committee.

At this point I'd like to recognize the gentleman from California, Mr. Rohrabacher, five minutes.

Mr. ROHRABACHER. Thank you very much. And so you do have grandchildren? You know, I have children and I got married later on in life and one of my daughters has had some health problems. And I just want you to know that this research on low-dose radiation is vital to a lot of people's grandchildren and children, including my daughter. And I thank you for your dedication to finding out about this issue because it is just essential for the health of so many people. And thank you very much for—my daughter had leukemia so we know what that's about.

And I am very, very honored and pleased that we have someone like yourself that is going to withstand pressure to go beyond your scientific responsibilities but to basically try to achieve a political end, meaning that they—trying to stop someone from achieving a political end by compromising your scientific commitment because that's what it sounds like to me.

And what this whole thing sounds like, Mr. Chairman, to me is that what we have here is an example of where scientists are feeling, at least in the Department of Energy and this Office of Science are feeling that they have to go in a certain direction in order to placate the—basically the priority of the Administration and—

which obviously did not—was not holding low-dose radiation research as a priority.

I am a cosponsor of the legislation that would have basically formalized that the money being spent—this money that's being spent be spent there in the Department of Science on low-dose radiation research.

Dr. Weatherwax, could you tell me, do you agree that those of us who are elected officials have the right to have those kind of—set those type of priorities with the spending—with money that's being spent on federal research?

Dr. WEATHERWAX. Congress certainly has the right for——

Mr. ROHRABACHER. Right. So we have the right——

Dr. WEATHERWAX. —generating legislation.

Mr. ROHRABACHER. And so we do and it's recognized, yet we have someone here who has dedicated her life to a specific research area that is being talked about now and she is being given direction beforehand as what direction her answers should be to the people who constitutionally have responsibility of making the decision.

This type of—you know we hear all the time from our colleagues on the other side of the aisle that we because we have doubts about manmade CO_2 warming the planet that we are politicizing science, and I will have to tell you my feeling here is what we've got is an example of politicizing science. Someone there in the Department in your Office of Science, although not a political appointee, feels compelled to try to placate the rest of the Department of Energy's commitment to global warming as being a manmade situation that they're going to—and that goes all the way down that—what I call fanaticism on the global warming issue is being felt the effects of that all the way down to this very honorable scientist who spent 14 years of her life trying to do something that would be important for her grandchildren and my children and children all over the United States.

This is—and I realize that you're trying to be as honest with us as you can, but it also—quite frankly, your answers indicate to me that there's a lack of willingness to take on other people in the Department of Energy who would be upset if you said anything to back her up.

And, Mr. Chairman, this type of politicization has impacts not only in our responsibility because what we're talking about now today is our responsibility as elected people in a democracy, the people elect someone to make major decisions as to how money will be spent. Not only does it undermine democracy, but in the end it hurts people. In the end this research, which we believed was vital, much more vital than proving that CO_2 causes the earth to get warm, that we felt that that money should go to low-dose radiation research. And instead, someone in the Department of Science tried to pressure her so that we couldn't back up that concept that we have, that that scientific investigation is more important than spending it on manmade global warming.

So with that said, I thank you, Mr. Chairman, for this hearing, and I would like to compliment Dr. Metting for your courage, for your willingness to say the truth as you see it which is what all science has to be. And undermining that and having someone trying to tell you what you should emphasize and shouldn't emphasize

in order to obtain a political goal, which is basically to influence the decision-makers who are elected to make the decision, you showed great courage and great patriotism. Thank you very much for being with us today.

Dr. METTING. Thank you, Mr. Congressman.

Mr. WEBER. [Presiding.] The Chair now recognizes Congressman Randy Neugebauer from also the great State of Texas.

Mr. NEUGEBAUER. Well, thank you, Chairman.

Dr. Weatherwax, you're a scientist, is that correct?

Dr. WEATHERWAX. That's correct.

Mr. NEUGEBAUER. At the Department of Energy?

Dr. WEATHERWAX. Yes.

Mr. NEUGEBAUER. And so I think your title is Associate Director of Science for Biological and Environmental Research, is that correct?

Dr. WEATHERWAX. That's correct.

Mr. NEUGEBAUER. Yes. So when you're doing research or investigations, are the facts important?

Dr. WEATHERWAX. Yes.

Mr. NEUGEBAUER. Why are they important?

Dr. WEATHERWAX. So scientific research is all predicated on obtaining facts. Facts obtained from experiments, often using controlled hypotheses, and collecting the facts helps us to refine our theories and then suggests further experiments.

Mr. NEUGEBAUER. So what if you were working on a scientific project and you were evaluating some previous projects that had been done, scientific research, and someone was directing you as to what science that you were able to view and precluded you from looking at, say, other experiments that had been done in the same area? Would that be productive to your work?

Dr. WEATHERWAX. I don't think that typically that's how science is done so——

Mr. NEUGEBAUER. Well, no, but I mean answer the question. I'm not asking your opinion on how you think it's a done or not. Would that be productive to your scientific research?

Dr. WEATHERWAX. No.

Mr. NEUGEBAUER. No. So if you're a Member of the United States Congress and you're trying to evaluate how we spend the taxpayers' money and what are the things that are in the best interest of the American people, wouldn't you think the facts are important?

Dr. WEATHERWAX. Yes.

Mr. NEUGEBAUER. Now, you know, do you think your opinion on an issue should influence the facts that you're willing to share with me?

Dr. WEATHERWAX. I—if you ask me for a fact, then I'll provide it. I don't think my opinion——

Mr. NEUGEBAUER. Yes. Yes.

Dr. WEATHERWAX. —matters.

Mr. NEUGEBAUER. Well, that's what we asked for, and I think that's what we expect. And I think what members of this committee find very troubling is that there was an effort here that we had an oversight committee trying to, you know, do its job and then we had people within the Administration—and what's more

troubling it's—I expect it from the Administration, but from professional scientists I don't expect that.

And I think what's discouraging here is that we had professional scientists trying to filter or influence the information and how that was presented to the United States Congress. And, you know, I find that distasteful, and I also find it very unprofessional that you, from the scientific community, don't rely on the facts. It's important to have the facts because we're counting on you to—both in your research and in your investigations to make sure that, you know, we are doing everything we can to keep the American people healthy and safe and that this kind of behavior is counterproductive to that.

And so I would say that I'm hopeful that this is not a pervasive culture within the Department of Energy or any other department of the United States Government. With that, Mr. Chairman, I yield back.

Mr. WEBER. I thank the gentleman.

The gentlelady from California is now recognized for five minutes.

Ms. LOFGREN. Well, thank you, Mr. Chairman. And I'm sorry I'm late. The Judiciary Committee is having a hearing at the exact same time.

You know, I want to explore how we can improve our scientific integrity policy at the agency. As you know, I'm sure the Union of Concerned Scientists has made an observation that the policy is rather short and it's just three pages. And although I think it hits all the high points, it—compared to the scientific integrity outlines of some other agencies, you know, it's on the short side.

And I'm wondering how we might move forward and use this observation as a way to further improve the agency and whether you have comments on that, either one of you?

Dr. WEATHERWAX. I can't comment on how the Department has developed the scientific integrity policy, but I can certainly say that as a scientist and the daughter of a scientist who worked on the space missions, I certainly agree that scientific integrity is important.

Dr. METTING. I'm just a scientist. I'm not a—in the management chain, but I would think that management could do better at Department of Energy.

Ms. LOFGREN. All right. So it's not something that you as scientists would necessarily want to weigh in on. I just think, you know, the need—when you get to scientific integrity or any integrity policies, it's important that they be robust, but it's also important that they be communicated to—not only to management but to every person in the institution so that everybody knows what the rules are.

And I think that, you know, I have great regard for the current Secretary of Energy. I mean, he's a fabulous scientist and individual. Steve Chu was—and also, I mean, a Nobel Prize-winner, I mean, was the Energy Secretary when the current integrity policy was adopted. And I think that to ask—well, I don't know if there's time left in this Administration, but to ask that this be reviewed and amplified would be a good outcome from this hearing, a productive outcome rather than just a negative one.

And I'm hoping that we might—I'll—if I could, I would ask unanimous consent that we put into the record the analysis undertaken. It's entitled "Federal Agency Scientific Integrity Policies, A Comparative Analysis" and it's done by the Union of Concerned Scientists. It's dated March 2013, but I think it's still pertinent and would be helpful to be part of the record.

Mr. WEBER. Without objection.

[The information appears in Appendix I]

Ms. LOFGREN. And with that, Mr. Chairman, I think my time is nearly expired and I'd be happy to yield back.

Mr. WEBER. I thank the gentlelady.

The gentleman from Illinois is recognized.

Mr. HULTGREN. Thank you, Chairman. Thank you both for being here.

Mr. Chairman, at this time I'd also ask unanimous consent to be able to insert into the record three different letters. The first is dated March 18, 2013. It's from a group of researchers in Madison, including Columbia University, which states "Our limited understanding of low-dose health risks seriously impairs the nation's decision-making capabilities both in the short- and long-term after a large-scale radiological event."

The next—I'd also like to include letters from the American College of Radiology and the Health Physics Society supporting my legislation, which passed the House in January 2015. This bill is H.R. 35, the Low Dose Radiation Research Act of 2015. This is another quote from the Health Physics Society letter. "A greater understanding of the effects of low-dose radiation on humans will not only add to our body of knowledge on the subject but it would also enable us to make better decisions on what are the proper levels, procedures, and protections needed when our citizens are subject to exposure to sources of low-dose radiation."

So I'd ask for unanimous consent to be able to enter those into the record.

Mr. WEBER. Without objection, so ordered.

[The information appears in Appendix I]

Mr. HULTGREN. Thank you. Questions—if I could direct initial questions, Dr. Weatherwax, if I could direct it to you. Was it your intention and the intention of other such as Dr. Anderson, Dr. Carruthers, and Dr. Huerta to attempt to prevent the benefits of low-dose radiation research from being presented to Congress?

Dr. WEATHERWAX. No.

Mr. HULTGREN. Dr. Weatherwax, if Dr. Metting provided that information in response to questions from Congressional staff, then why was she removed from her position?

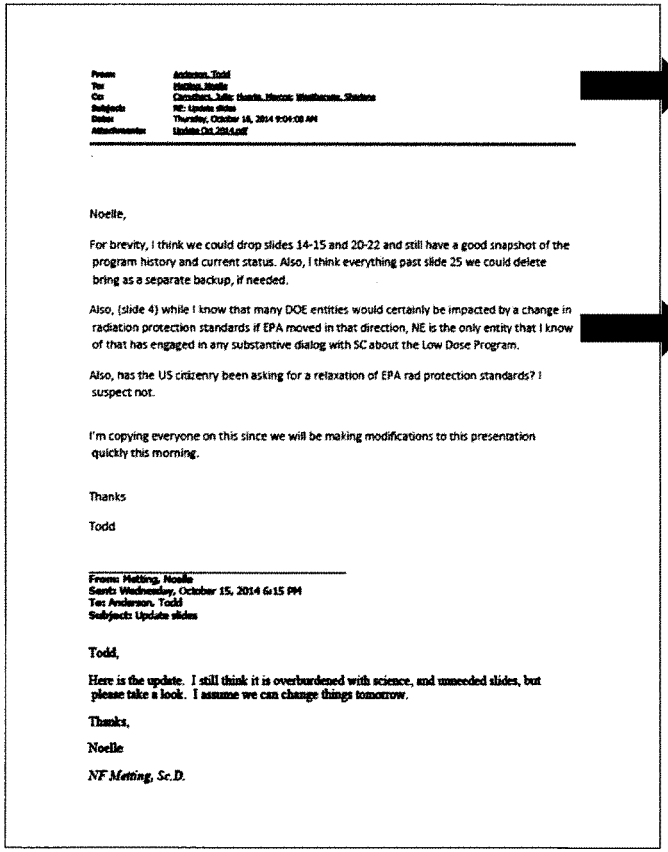
Dr. WEATHERWAX. So my understanding is that the proposal to dismiss Dr. Metting details all of the issues, and those were the issues that were actually reviewed by general counsel and human resources, and the procedures were followed. The deciding official is the one who viewed the entirety of all of those issues and made the decision.

Mr. HULTGREN. Dr. Weatherwax, is it the role of the federal agency officials to prevent information from being accurately presented to Congress, as it was in this case?

Dr. WEATHERWAX. I don't believe that the federal government inaccurately presented information in this case.

Mr. HULTGREN. Well, clearly, there was a slide that was removed and I guess—I think I have a slide that we can put up.

[Slide.]



From: Anderson, Todd
To: Metting, Noelle
Cc: Carruthers, Julie; Huerta, Marcos; Weatherwax, Sharlene
Subject: RE: Update slides
Date: Thursday, October 16, 2014 9:04:00 AM
Attachments: Update Oct 2014.pdf

Noelle,

For brevity, I think we could drop slides 14-15 and 20-22 and still have a good snapshot of the program history and current status. Also, I think everything past slide 25 we could delete bring as a separate backup, if needed.

Also, (slide 4) while I know that many DOE entities would certainly be impacted by a change in radiation protection standards if EPA moved in that direction, NE is the only entity that I know of that has engaged in any substantive dialog with SC about the Low Dose Program.

Also, has the US citizenry been asking for a relaxation of EPA rad protection standards? I suspect not.

I'm copying everyone on this since we will be making modifications to this presentation quickly this morning.

Thanks

Todd

Also, (slide 4) while I know that many DOE entities would certainly be impacted by a change in radiation protection standards if EPA moved in that direction, NE is the only entity that I know of that has engaged in any substantive dialogue with SC about the Low Dose Program.

Mr. HULTGREN. Dr. Weatherwax, this is an email from Dr. Anderson to Dr. Metting, which you were copied. It appears to suggest that Dr. Metting remove slide 4 from the briefing documents, a slide that lists all the federal agency uses for low-dose radiation research. Isn't that precisely the information that Congress would want to know in a briefing about the program?

Dr. WEATHERWAX. So I cannot comment as to why Dr. Anderson recommended removal of a particular element within a briefing. It could have been for brevity. I can't actually speak to why he suggested removal.

Mr. HULTGREN. Yes, I wish Dr. Anderson again were here to be able to respond to that directly.

Also, I guess I think I've got another slide.

[Slide.]

Who is interested in Low Dose Program research?

- **Department of Energy**
  - Office of Nuclear Energy (nuclear power sustainability)
  - Office of Environment, Health, and Safety Security (AU) (setting implementation standards for DOE workers and public)
  - Office of Environmental Management (clean up levels; high cost)
  - National Nuclear Security Administration (emergency response)
  - General Council (GC-70) NEPA documentation
- **Environmental Protection Agency**
  - Setting of general regulatory standards
- **Nuclear Regulatory Commission**
  - Setting of regulatory standards for nuclear power industry
- **Departments of Labor, Transportation; NASA**
  - Worker safety
- **Department of Homeland Security**
  - Emergency response
- **Department of Defense**
  - Military action, emergency response
- **Citizenry of the U.S.** (fear levels: Fukushima, Chernobyl, TMI, …)

Mr. HULTGREN. There it is, the slide that notes the beneficial nature of low-dose radiation research for Homeland Security and the Department of Defense in responding to radiological attacks.

Dr. Metting, in your scientific opinion could the research developed by the Low Dose Radiation Research Program benefit federal emergency response agencies?

Dr. METTING. Yes, very much so in setting evacuation standards, the levels at which we need to address different types of emergencies, yes.

Mr. HULTGREN. Again, it's a great disappointment. I do look towards these hearings and the requests that we make to agencies as our ability to be able to be educated on what is happening, how funding ought to happen, what important programs ought to continue to be funded. And in this case it seems like we were not given that opportunity. In fact, very directly certain things were excluded from our ability to see.

Dr. Metting, last question. Is this the sort of information that you think DOE management preferred to keep from committee staff during the briefing? And did the DOE management tell you to stick to talking points that excluded the sort of information?

Dr. METTING. Yes, it did.

Mr. HULTGREN. Again, thank you so much. This is disturbing. This is frustrating. And I hope we can continue to get to the bottom of this and make sure that this never happens again but also that there is justice in this.

So with that, I will yield back. Thank you, Chairman.

Mr. WEBER. I thank the gentleman.

The gentlelady from Virginia is recognized. No? You're good? Okay.

All right. The gentleman from—on my right here from Virginia, which is not often you're on my right. He wants to do another round so we will do that.

Let me start by simply saying—I'll tell you what. You go.

Mr. BEYER. You sure?

Mr. WEBER. You bet you. You go.

Mr. BEYER. Thank you, Mr. Chairman.

I'd first like to respond to my friend Mr. Rohrabacher from California who talked about the fanaticism of climate change science and just point out that 97 percent of the scientists in the world—China, India, Europe, et cetera—believe often reluctantly that climate change is real and that it's manmade and that we represent an enormous threat to mankind. This is not fanaticism, nor is it politics. It's just what the science is.

I know there are three percent that agree that it's—believe it's not real. Two good friends of mine sent me pieces that believe that climate change is not manmade or there's nothing we can do about it. I don't think they're fanatics either. These are—we should let the science be what the science is and then together try to make good decisions about how to move forward.

Dr. Weatherwax, is it the responsibility of the Department of Energy to communicate the Administration's science priorities to Congress? And would—it seems like we got off on the wrong foot when someone accused of Dr. Metting of lobbying, which then led to lots of accusations of you and Dr. Anderson of lobbying. Isn't this more

just the responsibility to communicate what the executive branch believes the priority should be and then the legislative branch can do what they want to do?

Dr. WEATHERWAX. Yes.

Mr. BEYER. Thank you. Let me ask this, the same question of both of you. Dr. Weatherwax, is there obviously more to learn from the Low Dose Radiation Program after a quarter billion dollars' worth of research or have we had a plateau period where we know most of what we think we need to know?

Dr. WEATHERWAX. So I believe that, as with many scientific areas, always more can be gained. However, in this case the program's priorities were certainly shifting more towards large epidemiological studies, which is studies of humans and populations and their exposure. And so those kinds of studies are probably the future of where this research is—field is going, and I believe that that type of research is ongoing. We are continuing to support a study, and those studies are being done by entities such as the National Cancer Institute.

Mr. BEYER. So, Dr. Metting, the same question. Do you believe that the research had plateaued after a quarter billion dollars or did you feel you were on the cusp of dramatic new insights?

Dr. METTING. Actually, I don't believe there was a plateau at all. We were—we had basically gone through all of what we could do with cell culture and we were going into whole systems biology. And when—once we started moving into that, what we did—what we realized is that for very low doses there's really not a cancer aspect to it. There is real interesting science that is asking what is actually—what does the low-dose actually do. And so we were looking at adaptive responses, we were looking at really excellent—like the metabolic shift that occurs at very low doses that actually triggers an adaptive response.

And it has very exciting directions to go because low doses—they affect your immune surveillance and at the very low doses it's much different from the types of mechanisms that occur at very high doses.

And I'm—I agree with Dr. Weatherwax that we need a new way to look at the epidemiology. We've been only having the high-dose epidemiology for so long. Now, we're looking at low-dose epidemiology, and that is exactly the type of science that we need to compare our new biology to, that the old—the A-bomb survivor epidemiologists are still using old biological assumptions. We have a whole new set of assumptions. The low-dose area is getting very exciting.

Mr. BEYER. I'm about to run out of time. I'd like to submit for the record, if there's no objection, the Department of Energy's response to the Inspector General and the Office of Special Counsel regarding the $16 million disclosure where the Department of Energy details how that $16 million was spent according to the Congressional appropriation if there's no objection, Mr. Chair.

Mr. WEBER. Without objection.

[The information appears in Appendix I]

Mr. BEYER. And then one last question for you, Dr. Metting. Is there anything inappropriate with both you for radiation, the low-dose radiation, Dr. Weatherwax, Dr. Todd Anderson, and others

communicating those understandings to Congress and then let Congress authorize and allocate the money it wishes to spend in its legislative wisdom? I mean, shouldn't——

Dr. METTING. I don't——

Mr. BEYER. Is there a reason why it's bad to have the necessary conflict between the Administration's perspective and Congress' perspective?

Dr. METTING. Mr. Congressman—Ranking Member, I really don't think there is anything wrong with a conflict. Both sides should be looked at. Both sides should be heard but——

Mr. BEYER. And hopefully the wisdom will emerge, right?

Dr. METTING. Yes.

Mr. BEYER. Okay. Thank you, Mr. Chair. I yield back.

Mr. WEBER. I thank the gentleman.

The Chair from Ohio is recognized.

Mr. DAVIDSON. Thank you, Mr. Chairman.

Dr. Weatherwax, I'm curious what is the process like when you prepare for meeting for Congress?

Dr. WEATHERWAX. So typically, when the request comes in, it will come to the Department's Congressional Affairs and they will then notify us as to what the request is and direct it to the appropriate office. If it's a matter of briefing appropriation staffers, then it would be budget-related and then the most senior person will typically go, the person has who has authority to develop the budget priorities and responsibility for justification.

Mr. DAVIDSON. Okay. So when you come to a hearing before Congress, do you have objectives for the meeting?

Dr. WEATHERWAX. So this is actually my first meeting with Congress, so clearly my objective is just to answer your questions.

Mr. DAVIDSON. Okay. So how—in the Department of Energy when you talk about the culture and you talk about—surely you've prepared others to come and give testimony before Congress. What's considered success? What's that like in the—you know, hey, you did a good job or you didn't do a good job?

Dr. WEATHERWAX. I think if Congress is satisfied with the information that the Department has provided, then that would be a successful outcome.

Mr. DAVIDSON. Why then was Dr. Metting's testimony before Congressional staffers not viewed as success?

Dr. WEATHERWAX. I don't believe that we actually made any kind of decision about success or no success after that particular briefing. I believe that the decision to—the proposal to remove, as I said, included other aspects that were not related to the specific briefing to Congress.

Mr. DAVIDSON. Thank you. Dr. Metting, after your October 16 briefing were you officially removed from your position at the Department of Energy?

Dr. METTING. Yes, I was.

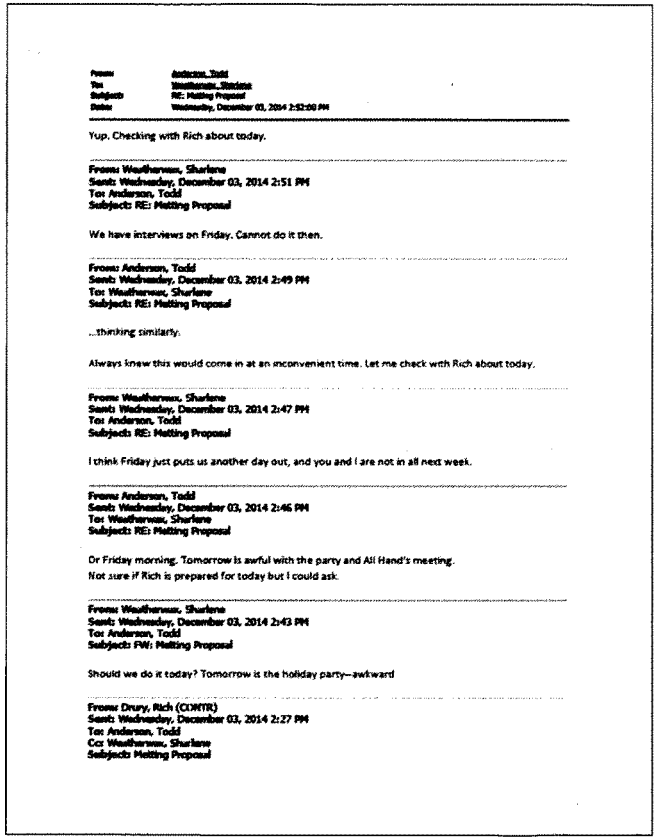
Mr. DAVIDSON. Without objection, I'd like to share an email exchange between Dr. Weatherwax and Dr. Anderson. They appear to be debating whether to provide Dr. Metting with an official notice of proposed removal from federal service on the day of the office holiday party. So this was December.

Dr. Metting, when were you informed about your dismissal from the Department, and could you please elaborate on how that happened?

Mr. WEBER. Without objection, so ordered. You wanted that in the record?

Mr. DAVIDSON. Thank you.

[Slide.]



Yup. Checking with Rich about today.

From: Weatherwax, Sharlene
Sent: Wednesday, December 03, 2014 2:51 PM
To: Anderson, Todd
Subject: RE: Metting Proposal

We have interviews on Friday. Cannot do it then.

From: Anderson, Todd
Sent: Wednesday, December 03, 2014 2:49 PM
To: Weatherwax, Sharlene
Subject: RE: Metting Proposal

...thinking similarly.

Always knew this would come in at an inconvenient time. Let me check with Rich about today.

From: Weatherwax, Sharlene
Sent: Wednesday, December 03, 2014 2:47 PM
To: Anderson, Todd
Subject: RE: Metting Proposal

I think Friday just puts us another day out, and you and I are not in all next week.

From: Anderson, Todd
Sent: Wednesday, December 03, 2014 2:46 PM
To: Weatherwax, Sharlene
Subject: RE: Metting Proposal

Or Friday morning. Tomorrow is awful with the party and All Hand's meeting.
Not sure if Rich is prepared for today but I could ask.

From: Weatherwax, Sharlene
Sent: Wednesday, December 03, 2014 2:43 PM
To: Anderson, Todd
Subject: FW: Metting Proposal

Should we do it today? Tomorrow is the holiday party--awkward

From: Drury, Rich (CIWTR)
Sent: Wednesday, December 03, 2014 2:27 PM
To: Anderson, Todd
Cc: Weatherwax, Sharlene
Subject: Metting Proposal

From: Anderson, Todd
To: Weatherwax, Sharlene
Subject: RE: Metting Proposal
Date: Wednesday, December 03, 2014 2:52:00 PM

Or Friday morning. Tomorrow is awful with the party and All Hand's meeting. Not sure if Rich is prepared for today but I could ask.

Should we do it today? Tomorrow is the holiday party--awkward

Dr. METTING. Yes, Mr. Congressman. I—okay. So it had been very tense, you know, since the October 16 and then when I was taken off of my duties as managing the Low Dose Program. And I had talked to my union representative, and everyone knew I was a little upset, but then there wasn't anyone who would really—Dr. Anderson, Dr. Weatherwax would not talk to me about the subject so it was very tense.

The morning of the—of December 4 we had a big potluck. It's a lot of fun. We're out in Germantown so we can bring large amounts of food. And I was tasked—or I volunteered to bring the turkey dressing, the mashed potatoes and gravy, and we had our party. And then directly after the party I was informed that there would be a personnel action in 2 hours and that—or something like that. I don't really remember the exact thing I was so shocked, and that you should probably bring your union representative with you at that time.

Mr. DAVIDSON. Was this consistent with the culture that something like this would happen or was this kind of a new trend or new event, new single data point in the culture?

Dr. METTING. Oh, you mean the personnel——

Mr. DAVIDSON. Yes, just the—you know, you're coming right off of a holiday party, you're coming off of testimony where you gave——

Dr. METTING. It was shocking.

Mr. DAVIDSON. —testimony?

Dr. METTING. It was shocking and it was out of the ordinary for me. I mean, I've never, ever had anything even against anything that I've done. I've always had very fully successful program reviews.

Mr. DAVIDSON. Thank you. Dr. Weatherwax, in your experience at the Department of Energy is it general practice for an agency scientist to be told what they can and cannot say during their Congressional testimony?

Dr. WEATHERWAX. No.

Mr. DAVIDSON. Have you ever been instructed to censor scientific opinions when communicating with Congress or other agencies?

Dr. WEATHERWAX. No.

Mr. DAVIDSON. So is it your opinion that this was an outlier of an event with Dr. Metting?

Dr. WEATHERWAX. We never told Dr. Metting to—we never attempted to censor scientific content.

Mr. DAVIDSON. Okay. It does appear that you—you were dissatisfied with the way the conversation went and took action, and it seems to have potentially had a stifling effect.

So my time is expired. Thank you.

Mr. WEBER. I thank the gentleman for yielding back.

Dr. Weatherwax, in your exchange just—the last exchange with the gentleman from Virginia, he talked about an opinion on climate change and it's okay if the Administration has an opinion and you think they ought to be free—he asked you didn't you think they ought to be free to pursue what they thought was important. Do you remember that exchange?

Dr. WEATHERWAX. Yes.

Mr. WEBER. Okay. So the gentleman from—well, let me do it this way. Just hold that thought. Dr. Metting, did you feel attacked after that meeting and obviously leading up to the party you were talking about?

Dr. METTING. After the briefing?

Mr. WEBER. Yes.

Dr. METTING. I was completely attacked. And at the time it felt like it was—you know, it was a surprise and it was——

Mr. WEBER. Okay.

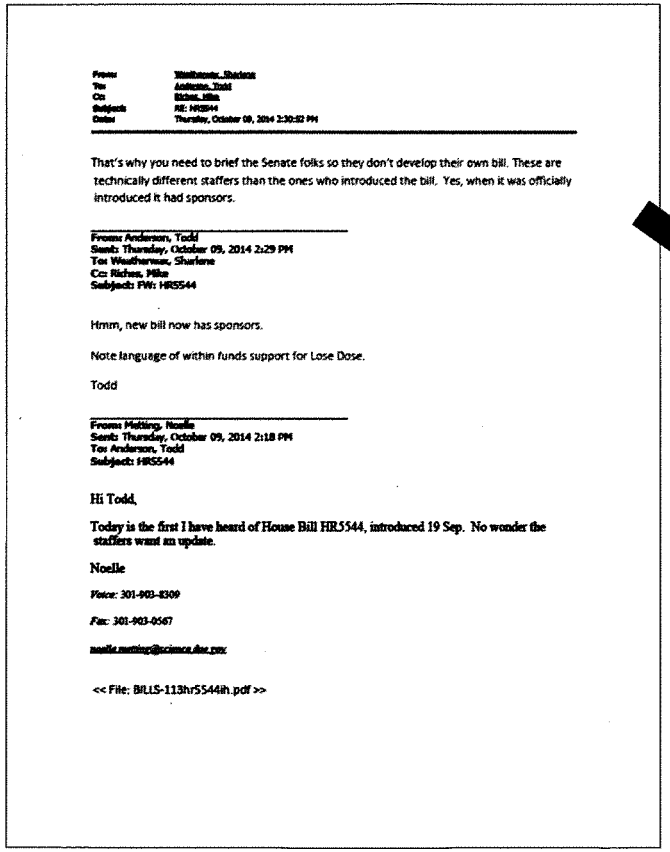
Dr. METTING. —unforeseen.

Mr. WEBER. Well, I apologize to you for that. And from what I know, that should not have occurred and you should not have to endure that. And I hope you get the pictures, if there are some, of your grandchildren back.

But suffice it to say that I agree with an earlier comment. Thank you for coming up here because more—as important is the fact that the process has been attacked, and I think we're seeing that today.

Now, Dr. Weatherwax, we talked earlier and you—I asked you a couple questions about the lobbying intent and you said you didn't have an opinion and you weren't sure that was lobbying, but we have another email. And I use the word subtle, you know, to keep the Senate from filing a bill. Can we get that email up on the screen? Can we get that one up on the screen? The email I had originally, yes. There you go.

[Slide.]



That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced it had sponsors.

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: [redacted]
Sent: Thursday, October 09, 2014 2:30:52 PM

That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced it had sponsors.

From: Anderson, Todd
Sent: Thursday, October 09, 2014 2:29 PM
To: Weatherwax, Sharlene
Cc: Riches, Mike
Subject: FW: HR5544

Hmm, new bill now has sponsors.

Note language of within funds support for Lose Dose.

Todd

From: Melting, Noelle
Sent: Thursday, October 09, 2014 2:18 PM
To: Anderson, Todd
Subject: HR5544

Hi Todd,

Today is the first I have heard of House Bill HR5544, introduced 19 Sep. No wonder the staffers want an update.

Noelle

Voice: **301-903-8309**

Fax: **301-903-0567**

noelle.melting@science.doe.gov

<< File: BILLS-113hr5544ih.pdf >>

From: Weatherwax, Sharlene
To: Anderson, Todd
Cc: Riches, Mike
Subject: RE: HR5544
Date: Thursday, October 09, 2014 2:30:52 PM

That's why you need to brief the Senate folks so they don't develop their own bill. These are technically different staffers than the ones who introduced the bill. Yes, when it was officially introduced it had sponsors.

Mr. WEBER. So, you know, I talked about the subtly yet firmly, which is the third bullet point, but if you go up to the second—or fourth bullet point, but if you go up to the second bullet point, it says "If the goal is to squash the prospects of Senate support for the HSST." So I want to come back and say to you now you've expressed an opinion about climate change and what the Administration ought to be free to do or not do. Now do you also have an opinion that the goal to squash the prospects of Senate is inappropriate?

Dr. WEATHERWAX. Dr. Anderson is responsible for conveying the program——

Mr. WEBER. But I'm not asking about—I'm asking you, Dr. Weatherwax, do you have—you expressed an opinion with Congressman Beyer about whether or not we disagree on global warming. We can get into that later. So there's discussion about that. Do you have an opinion that the goal to squash the Senate action is inappropriate? The email—now, this email came to you, I will remind you.

Dr. WEATHERWAX. That's correct. The email came——

Mr. WEBER. Okay.

Dr. WEATHERWAX. —to me.

Mr. WEBER. So did you not have an opinion at that point that this might not be the best policy of this department?

Dr. WEATHERWAX. So my interpretation of that comment was that Todd's job was to provide the broad overall context——

Mr. WEBER. Okay.

Dr. WEATHERWAX. —for how the program priorities within this area of——

Mr. WEBER. Yes, it's not about his—your interpretation of him. It's about the attempt to squash—it clearly says squash it. You're a scientist. You have a Ph.D. You know what squash is. Do you have an opinion on that?

Dr. WEATHERWAX. I guess——

Mr. WEBER. You're just not going to—you're not going to offer an opinion on that?

Dr. WEATHERWAX. I think I did not interpret that comment as squashing any scientific content.

Mr. WEBER. Okay. Well, then, let's—let me move on. So Congressman Beyer and yourself had the exchange about whether or not you agree with global warming. I think you said the fantasism——

Mr. BEYER. Fanaticism.

Mr. WEBER. There we go. Thank you. I have to get—according to Mr. Rohrabacher, yes. But the fanaticism in their opinion—and there's been some Attorneys General, as you're probably aware from reading the news accounts, that have gone after ExxonMobil because in their opinion they think they've suppressed some things. But isn't the fanaticism of suppressing what a scientist can say in a Congressional committee meeting as dangerous as the purported climate change no matter where you fall on that side of—isn't that fanaticism just as dangerous? Do you have an opinion about that?

Dr. WEATHERWAX. I don't see that Dr. Anderson was squashing the conveying of science.

Mr. WEBER. It's interesting that you bring him back up because I was asking about a broad overall perspective about the fanaticism of suppressing a scientist from testifying before Congress committee staffers. That's just as bad as the purported fanaticism of denying global warming. Wouldn't you say that's just as bad?

Dr. WEATHERWAX. I don't believe that we ever squashed a scientist presenting scientific views to Congress.

Mr. WEBER. All right. Well, let's do it this way. There's another—there's actually an excerpt from Dr. Todd Anderson in the transcribed interview that the question—and it's up on the screen that says, question, "Is President Obama's Climate Action Plan a priority for the Department of Energy?" Can you see the answer there? Are you able to read that? What does it say?

Dr. WEATHERWAX. The answer that Dr. Anderson gave is yes——

Mr. WEBER. Yes, it is. And what's that second question? Can you read that for us?

Dr. WEATHERWAX. The second question says, "And is that a greater priority than the Low Dose Radiation Program?"

Mr. WEBER. And he says, "To the extent that we align our basic research efforts toward that goal, yes." So clearly they're prioritizing, right? Now, the question is this. This is testimony provided by Dr. Todd Anderson in a transcribed interview with committee staff. Dr. Anderson asserts, if you're following his question-and-answer here, "Research that benefits the President's Climate Action Plan is a higher priority than low-dose radiation research." So here's my question. Is the DOE ending the Low Dose Radiation Research Program to divert funds—and I would say to subtly yet firmly encourage—if that's a better word for you—the Senate to divert funds towards research in furtherance of the Climate Action Plan? Does that look like that to you?

Dr. WEATHERWAX. No.

Mr. WEBER. It doesn't? Okay. Well, then, Dr. Weatherwax, the DOE fired an employee—in your exchange with Mr. Davidson of Ohio, he said, did you think that the meeting was a success or a failure? She got fired because of it, so obviously somebody thought that what occurred in the meeting was bad. Do you have opinion on that?

Dr. WEATHERWAX. I believe that the justification for dismissal was outlined in the proposing documents and that there were issues greater than——

Mr. WEBER. So——

Dr. WEATHERWAX. —what transpired during the briefing.

Mr. WEBER. So the operation was a success but the patient died. Okay. So you don't have an opinion that that was a bad meeting.

Is the Department of Energy in this process sending a message to research scientists that they better somehow tow a political party—a particular—I'll do it that way—party line? And if they don't agree, if they express a difference of opinion, it is in peril of their careers. Would you agree with that?

Dr. WEATHERWAX. No.

Mr. WEBER. You don't agree with that? Okay. Last question, that's for you, Dr. Weatherwax. In your opinion is it okay for the Department of Energy to lobby the Senate to firmly but subtly prevent them from filing a bill?

Dr. WEATHERWAX. If the Department of Energy actually lobbied for something, then I—you know, I don't believe that that's what happened.

Mr. WEBER. Okay. And so to follow up the last email, the goal to squash the Senate prospects is inappropriate, of filing that bill?

Dr. WEATHERWAX. I think that the goal is to convey the broader context of how we set our budget priorities.

Mr. WEBER. Well, there certainly seems to be some control there. Dr. Weatherwax, I appreciate your testimony but it just looks like you're more focused on, I guess, the science—your part of the science research instead of the topics here today that would say, look, this is inappropriate.

There is some inappropriate behavior going on, as one of my members over here said earlier, and we want to make sure that that stops. And the fact that you don't recognize that and won't provide at least an opinion that it was categorically inappropriate and that it might need to be a little attitude adjustment in the Department of Energy is frightening to me.

But anyway, I appreciate you being here.

Dr. Metting, anything you'd like to say before we close?

Dr. METTING. Mr. Chairman, I think you've done a fabulous job at laying out all of the issues.

Mr. WEBER. Well, thank you. How many grandchildren do you have?

Dr. METTING. I do have two grandsons.

Mr. WEBER. Two grandsons. They need a sister.

Dr. METTING. That's what I'm telling my other son.

Mr. WEBER. Well, thank you both for being here, and this hearing is adjourned.

[Whereupon, at 11:40 a.m., the Subcommittees were adjourned.]

Appendix I

Additional Material for the Record

STATEMENT SUBMITTED BY FULL COMMITTEE
CHAIRMAN LAMAR SMITH

COMMITTEE ON
SCIENCE, SPACE, & TECHNOLOGY
Lamar Smith, Chairman

For Immediate Release
September 21, 2016

Media Contact: Kristina Baum
(202) 225-6371

Statement of Chairman Lamar Smith (R-Texas)
Markup of H.R. 6076, H.R. 6066, and H.R. 5829

Chairman Smith: The first bill, H.R. 6076, the "TREAT Astronauts Act," establishes an occupational healthcare and enhanced monitoring program for former American astronauts.

This bill ensures that our courageous men and women who venture into space receive support for medical issues associated with their service. It also allows NASA to get more data on the effects of human spaceflight.

I thank Space Subcommittee Chairman Brian Babin for introducing this first-of-its-kind legislation.

Since NASA selected the first group of astronauts in 1959, more than three hundred American astronauts have ventured into the cosmos as explorers.

In an age when spaceflight has come to seem almost routine, it is easy to overlook how dangerous it is and how little we know about the long-term health effects of spaceflight.

Today, through its Lifetime Surveillance of Astronaut Health program, NASA screens and monitors astronauts for occupational related injury or disease.

This program contributes to our scientific knowledge of long-term health effects and assists participating astronauts in monitoring for spaceflight related illnesses and disease.

However, this program does not provide for diagnosis or treatment of those no longer serving. It also does not include retired and "management" astronauts because NASA is not explicitly authorized to provide such services.

Current astronauts receive full medical treatment. Former astronauts benefit from the Federal Employee Claims Act. And ex-military astronauts are afforded even more services.

This legislation will fill any potential gaps to ensure that our country fulfills its obligation to care for medical conditions that may be associated with human spaceflight.

Filling those gaps for former astronauts will encourage their expanded participation in the data research, evaluation, and assessment program.

The "TREAT Astronauts Act" is also fiscally responsible. It establishes NASA as a secondary payer to existing obligations of the United States or any third party.

I again thank Chairman Babin and urge my colleagues to support the TREAT Astronauts Act.

The second bill we will consider this afternoon is H.R. 6066, the "Cybersecurity Responsibility and Accountability Act of 2016." I thank the sponsor, Congressman Ralph Abraham, for taking the initiative on this legislation.

During this Congress, the Science Committee has held close to a dozen hearings related to oversight, policy and budgetary aspects of federal cybersecurity issues.

The hearings included the examination of data breaches at the Office of Personnel Management, the Internal Revenue Service and the Federal Deposit Insurance Corporation.

These hearings have underscored a need for accountability, responsibility and transparency within these agencies and within the federal government as a whole relative to the cybersecurity of information and information systems.

The Science Committee's jurisdiction over the National Institute of Standards and Technology (NIST) has broad and meaningful potential for improvement of federal government IT security.

The Federal Information Security Management Act of 2002 (FISMA 2002) and the Federal Information Security Modernization Act of 2014 (FISMA 2014) task NIST with establishing cybersecurity standards, guidelines, and associated methods and techniques for use by the federal government through research and development.

The hearings held by this Committee have identified several shortcomings by agencies in fulfilling FISMA requirements. Dr. Abraham's bill serves an important purpose and addresses these shortcomings through more research, agency-head accountability, and Office of Management and Budget enforcement.

I thank Dr. Abraham for his work and I urge my colleagues to support H.R. 6066.

The final bill we will consider is H.R. 5829, the ADVISE Now Act. This bill requires the EPA to finally create an already authorized Agriculture Committee to its Science Advisory Board (S-A-B) within 30 days of enactment.

If the EPA fails to meet the deadline, the authority is transferred to the Secretary of Agriculture who then has 15 days to appoint members to the EPA S-A-B Agriculture Committee.

The establishment of the EPA Agriculture Science Committee will provide farmers with an important and strong voice in the federal rule-making process and gives them a seat at the table.

The EPA has a history of advancing regulations that impact the agriculture community without proper input from those who are directly affected by the EPA's regulations. The ADVISE Now Act is an important first step to help remedy this situation.

I thank my colleagues, Agriculture Committee Chairman Michael Conaway and Congressman Rodney Davis, for their work on the bill. I support it and urge my colleagues to support it as well.

Committee approval of these three bills will advance America's future security through increased space activity, hardened information infrastructure, and an expanding food supply.

###

STATEMENT SUBMITTED BY FULL COMMITTEE
RANKING MEMBER EDDIE BERNICE JOHNSON

OPENING STATEMENT

Ranking Member Eddie Bernice Johnson (D-TX)

House Committee on Science, Space, and Technology
Subcommittees on Oversight and Energy
"Examining Misconduct and Intimidation of Scientists by Senior DOE Officials"
September 21, 2016

Good morning, and thank you to Chairman Loudermilk and Chairman Weber for holding this hearing today.

I will be very brief in my remarks. The title of today's hearing is quite provocative. It ostensibl references a personnel action against a DOE employee that ultimately was resolved by the Department and Dr. Metting reaching a settlement almost a year ago. It is my understanding tha under the agreement, the terms of the settlement remain sealed. As a result, I would hope that Members will not spend today's hearing trying to re-litigate that dispute.

Without question, we want to ensure that our federal agencies and departments maintain open and clear communication channels with Congress, and that our scientists are able to provide thei best scientific assessments when asked by Congress to do so. I have no doubt of DOE Secretary Moniz's commitment to scientific integrity, and I expect that any shortcomings identified as a result of the 2014 incident will be taken to heart and addressed by the Department. If this hearing delivers that message to DOE management, it will have performed a service.

However, I cannot close without expressing the hope that this Committee will follow up this hearing by taking a look at its own actions. It is more than a little ironic that the Majority has framed this hearing around protecting federal scientists from intimidation when the Majority itself has taken extreme steps to intimidate scientists at NOAA, making unsupported allegations of scientific misconduct against them and even accusing them of altering their climate science research results to promote a political agenda. Those false allegations have tarnished this Committee, and I think NOAA's scientists are owed an apology by our Majority. But I'm not holding my breath that one will be forthcoming any time soon.

With that, I want to welcome our witnesses to today's hearing, and I yield back the balance of my time.

DOCUMENT SUBMITTED BY REPRESENTATIVE ZOE LOFGREN

Knopinski, Jenny

From: Venneri, Janet
Sent: Friday, August 28, 2015 8:51 AM
To: Dehmer, Patricia
Cc: Carruthers, Julie
Subject: RE: New Sensitive IG Management Referral
Attachments: SC response 15-0201-C.PDF

Hi Pat,

Attached is the response we sent back to the IG. It was prepared by BER and Kathleen reviewed it. On February 18, the IG sent me an e-mail saying that based on our response they plan no additional action, and the matter will be closed.

Janet

-----Original Message-----
From: Dehmer, Patricia
Sent: Thursday, August 27, 2015 7:42 PM
To: Venneri, Janet
Cc: Carruthers, Julie
Subject: FW: New Sensitive IG Management Referral

Janet,

Can you tell me what the followup was on this IG Management Referral? I don't seem to have the response in my electronic archives.

Thanks,

Pat.

****
Patricia Dehmer
Acting Director, Office of Science
U.S. Department of Energy
1000 Independence Avenue, S.W.
Washington, DC 20585-1290
Phone: (202) 586-5430 in Forrestal
Phone: (301) 903-5316 in Germantown
Fax: (202) 586-4120 in Forrestal
E-mail: patricia.dehmer@science.doe.gov

-----Original Message-----
From: Dehmer, Patricia
Sent: Tuesday, January 20, 2015 3:50 PM
To: Venneri, Janet
Cc: Weatherwax, Sharlene; Klausing, Kathleen; Dehmer, Patricia; Carruthers, Julie
Subject: FW: New Sensitive IG Management Referral

Janet,

Please send this one to Sharlene Weatherwax in BER, with a copy to Kathleen Klausing.

Thanks,

Pat.

****
Patricia Dehmer
Acting Director, Office of Science
U.S. Department of Energy
1000 Independence Avenue, S.W.
Washington, DC 20585-1290
Phone: (202) 586-5430 in Forrestal
Phone: (301) 903-5316 in Germantown
Fax: (202) 586-4120 in Forrestal
E-mail: patricia.dehmer@science.doe.gov

-----Original Message-----
From: Venneri, Janet
Sent: Tuesday, January 20, 2015 8:24 AM
To: Dehmer, Patricia
Cc: Carruthers, Julie
Subject: New Sensitive IG Management Referral

Pat,

Attached is a new IG management referral which requires a response back to the IG within 30 days.

Who should handle this one?

Thank you.

Janet

-----Original Message-----
From: Mapeso, Bella [mailto:Bella.Mapeso@Hq.Doe.Gov]
Sent: Tuesday, January 20, 2015 8:17 AM
To: Venneri, Janet
Cc: Schaible, Jean-Marc (HQ); Gardner, Nicole (HQ)
Subject: Referral Letter 15-0201-C

Good morning Ms. Venneri

Please see the attach referral letter for your review and response.

Please reply to Agent-in-Charge Nicole.Gardner@HQ.DOE.gov

Thank you,
Bella Mapeso

Department of Energy
Office of Inspector General
202-586-1050

Department of Energy
Office of Science
Washington, DC 20585

January 30, 2015

MEMORANDUM FOR John Hartman
Acting Assistant Inspector General for Investigations

FROM: Patricia M. Dehmer
Deputy Director for Science Programs
Office of Science

SUBJECT: Response to Management Referral Concerning Possible Misuse of Funds (OIG File No. 15-0201-C)

In response to your memo of January 16, 2015, the Office of Science (SC) has evaluated the issues concerning the alleged misuse of funds intended for research related to the Fukushima plant disaster in 2011. Our response follows.

FY 2012 appropriations stipulated in the Conference Report:
"Within available funds, $16,000,000 is provided for radiobiology to help determine health risks from exposures to low levels of ionizing radiation to properly protect radiation workers and the general public, and to conduct studies of health impacts at and around the Fukushima Daiichi nuclear plant."

The table on the next page provides a relevant breakdown of SC spending of FY 2012 appropriated funds; all projects were relevant to radiobiology research. Some funding was provided for scientific workshops on radiobiology topics, and some for ensuring adequate oversight of funded research on human subjects (Institutional Review Board).

This information was communicated by the SC Budget Office Director to the Senate Energy and Water Development committee on September 5, 2012, in response to a specific inquiry on how the funds were allocated. Since no response requesting further information or disputing the relevance of any funded activity was received, the budget execution was deemed acceptable and responsive to the appropriation.

Printed with soy ink on recycled paper

INSTITUTION	PI	AMOUNT (in thousands)	TITLE
LBNL	Blakely	120	Non-Invasive Early Detection & Molecular Analysis of Low Dose Effects in the Lens
LBNL	Pluth	68	Systems Biology Model of Interactions Between Tissue Growth Factors and DNA Damage Pathways
LBNL-SFA	Karpen	5,600	Low Dose Scientific Focus Area
ORNL-SFA	Palumbo	945	ORNL Lowdose SFA
ORISE	Viator	17	Central DOE Institutional Review Board
PNNL	Bolton	2,502	Linear and Nonlinear Tissue Signaling Mechanisms in Response to Low Dose and Low Dose-Rate Radiation
American Statistical Assn	Crank	28	The ASA Conference on Radiation and Health, June 10-13, 2012
California, Univ of SF	Balmain	344	A System Genetics Approach to Identify Low Dose Radiation-Induced Lymphoma Susceptibility
Duke University	Jirtle	345	Epigenomic Adaptation to Low Dose Radiation
Gordon Research Conf	Demple	10	2012 Mutagenesis Gordon Research Conference, August 19-23, 2012
Lovelace Biomedical & Environmental Research Institute	Scott	1,500	Biological Bases for Radiation Adaptive Responses in the Lung
NASA	Cucinotta	133	Systems Biology Model of Interactions Between Tissue Growth Factors and DNA Damage Pathways: Low Dose Response and Cross-Talk in TGFBeta and ATM Signaling
Northwestern University	Woloschak	1,466	Effects of Low Dose Irradiation on NFKB Signaling Networks and Mitochondria
Oxford Brooks University	Kadhim	11	International Workshop to Address the Application F Systems Biology Approach in Radiation Research, September 2012

Radiation Research Society	Williams	70	Student Travel/Workshop Support for Meeting of Radiation Research Society
Steward Research & Specialty	Hlatky	1,500	Multi-Scale Systems Biology of Low-Dose Carcinogenesis Risk
		14,659	**Subtotal**
Epidemiologic Study of One Million U.S. Radiation Workers and Veterans Projects			
National Council Rad Prot	Boice	444	Epidemiologic Study of One Million American Workers and Military Veterans Exposed to Ionizing Radiation
ORNL (with Boice)	Leggett	200	Dose Reconstruction for One Million US Workers and Veterans Exposed To Radionuclides
ORISE (with Boice)	Ellis	225	Scientific Support to the Study of One Million American Workers and Veterans Exposed To Radiation
		869	**Subtotal**
SBIR/STTR		472	
		16,000	**Total**

The exact language in the Office of Science's FY 2013 Congressional Budget (page 140) states "Funding for research informing the exposure outcomes of the Fukushima Daiichi nuclear reactor is completed in FY 2012."

SC awarded $2.9M (DE-FG02-12ER65387) over 24 months for an epidemiology project (shown in the above table as "Epidemiologic Study of One Million U.S. Radiation Workers and Veterans Projects." All DOE funding was provided in FY 2012; other federal agencies (NASA, NRC, and EPA) contributed subsequent funding to the project.

The project objectives state the relevance of the work to determining the health impacts at and around the Fukushima Daiichi nuclear plant:

"The single most important question in radiation epidemiology is determining the level of risk associated with exposures that occur gradually over time. The nuclear reactor accident at Fukushima, Japan has emphasized the scientific and societal interest in understanding the health risks of low-level radiation exposures. Existing studies, however, have not provided robust estimates of risk following low dose rate exposures. The study of one million early U.S. radiation workers and veterans will provide information on risk following chronic exposures by focusing

on five occupational groups with differing radiation exposure patterns, including intakes of radionuclides: (1) uranium workers at multiple Department of Energy (DOE) locations; (2) nuclear weapons test participants (atomic veterans); (3) nuclear power plant (NPP) workers; (4) industrial radiographers, radiologists and other medical practitioners; and (5) plutonium workers at multiple DOE locations. The study is cost efficient because it builds on the investments made and foundations laid by investigators and government agencies over the past 30-40 years, which have established early worker cohorts that can now provide answers to questions on the lifetime human health risks associated with low-level radiation exposures."

We find no evidence of misuse of appropriated funds.

If you have any questions, please contact Sharlene Weatherwax at 301-903-3251.

DOCUMENTS SUBMITTED BY REPRESENTATIVE RANDY HULTGREN

COLUMBIA UNIVERSITY
College of Physicians and Surgeons

Center for Radiological Research
630 West 168th Street,
New York, NY 10032
212.305.5660 Tel
212.305.3229 Fax
www.crr.columbia.edu

March 18, 2013

The Honorable John P. Holdren
Assistant to the President for Science and Technology
Director of the White House Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Dr. Holdren:

The Fukushima nuclear accident in 2011 emphasized major gaps in our understanding of the health effects of low doses of ionizing radiation. These gaps seriously impact our ability to make optimal science-driven decisions in response to a major nuclear event in the United States, accidental or otherwise. It follows that the United States has a critical need to enhance research on low-dose health effects and to ensure that the nation maintains a sufficient pool of relevant expertise. Because these issues are of such national significance, and the potential health and economic consequences so major, we have joined together to outline our concerns and to suggest a practical way forward.

Our limited understanding of low-dose health risks seriously impairs the nation's decision- making capabilities, both in the short and the long term, after a large-scale radiological event. For example, differing strategies for evacuation after Fukushima ultimately relate to our limited quantitative knowledge of low-dose radiation risks. But it is also true of our understanding of the long-term health consequences of a radiological event involving large populations: while the regulatory agencies assume that there is no radiation dose below which the health risk is zero, we really do not have sufficient data or sufficient understanding to know whether this is really the case, or whether, as some assert, low radiation doses may even be beneficial. Setting permissible standards too stringently will result in a major and unnecessary economic burden to the nation, whereas setting standards too low would present an unacceptable cancer burden for the population.

While a large-scale radiological event is perhaps the most obvious issue of concern here, other issues such as the rapid increase in medically-based radiation exposures, cleanup of radioactively contaminated sites, as well as the need for science-based policies regarding the possible expansion of nuclear power, require a level of research and scientific expertise that the US is rapidly losing – in universities, in national labs, and in industry. Apart from the human health issues, all these topics have, of course, major economic consequences for our nation.

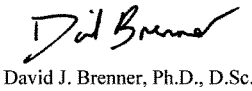
For many years the US has been the world leader in the field of low-dose radiation research, but more recently the US has lost significant momentum, noticeably so in comparison with Europe and Asia. Whilst a few small US research programs still exist in this area, such as at NASA and NIAID, the single US program principally dedicated to supporting US-based extramural low-dose radiation research, the Department of Energy's Low Dose Radiation Research Program, is clearly winding down. The overall outcome will not only be a diminution of research on the key issues outlined above, but also a critical decrease in the pool of US subject-matter experts who will be available to assist in high-level policy and decision making.

Moving forward, therefore, we suggest that the National Academy of Sciences be asked to prepare an expert report on the future of low-dose radiation research in the US. The objectives of such a report would be to:

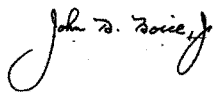
- assess the current status of low-dose radiation research in the US at all levels;
- formulate overall scientific goals for the future of low-dose radiation research in the US;
- develop a long-term strategic research agenda to address these scientific goals, ideally in concert with programs in other countries;
- define the essential components of a sustainable program that would address this research agenda within the universities and the national labs;
- assess the cost-benefit effectiveness of such a program.

We would of course be happy to meet with you at your convenience to discuss these issues in more detail.

Yours Sincerely,



David J. Brenner, Ph.D., D.Sc.,
Higgins Professor of Radiation Biophysics, Columbia University
Director, Columbia University Center for Radiological Research



John D. Boice Jr., Sc.D.,
Professor of Medicine, Vanderbilt University School of Medicine
President, National Council on Radiation Protection and Measurements (NCRP)

William F. Morgan, Ph.D.
Chair, Committee 1, International Commission on Radiological Protection (ICRP)

James E. Cleaver, Ph.D.
Professor Emeritus, University of California, San Francisco
Member, US National Academy of Sciences

Tom K. Hei, Ph.D.
Professor and Vice-Chairman of Radiation Oncology, Columbia University Medical Center
President, U.S. Radiation Research Society

Hedvig Hricak, M.D.
Chair, Department of Radiology, Memorial Sloan-Kettering Cancer Center, NY, NY
Member, Institute of Medicine of the National Academies

S. James Adelstein, M.D., Ph.D.
Paul C. Cabot Distinguished Professor of Medical Biophysics, Harvard Medical School
Former Chair, NAS Board on Radiation Effects Research
Member, Institute of Medicine of the National Academies

Jonathan M. Samet, M.D.
Professor and Chair, Department of Preventive Medicine, University of Southern California
Member, National Cancer Advisory Board
Member, Institute of Medicine of the National Academies

c.c. *Dr. Ralph J. Cicerone, National Academy of Sciences*
Mr. Charles F. Boden Jr., NASA
Dr Steven Chu, US DOE
Mr. Daniel B. Poneman, US DOE
Dr. Anthony S. Fauci, NIAID
Dr. Thomas Frieden, CDC
Dr. Nicole Lurie, ASPR
Dr. Allison M. Macfarlane, NRC
Mr. Kenneth A. Myers III, DTRA

c.c (cont) *Dr. Tara O'Toole, DHS*
Dr. Bob Perciasepe, EPA
Dr. Arati Prabhakar, DARPA
Dr. Robin Robinson, BARDA
Dr. Harold E. Varmus, NCI

HEALTH PHYSICS SOCIETY

"Specialists in Radiation Safety"

Barbara L. Hamrick, CHP, JD
President, Health Physics Society
1313 Dolley Madison Blvd, Suite 402
McLean, VA 22101
Tel: (703)790-1745
Fax: (703)790-2672
Email: HPS@BurkInc.com

February 10, 2015

Sen. Lisa Murkowski
Chairperson
Energy and Natural Resources Committee
United States Senate
Washington, DC 20510

Sen. Maria Cantwell
Ranking Member
Energy and Natural Resources Committee
United States Senate
Washington, DC 20510

Dear Senators,

As the President of the Health Physics Society, I am writing you to express the Society's strong support of H. R. 35, the Low-Dose Radiation Research Act of 2015, which passed the House of Representatives on January 7, 2015.

The Health Physics Society is a nonprofit scientific professional organization with over 4,000 members nationwide whose mission is excellence in the science and practice of radiation safety. Since its formation in 1956, the Society has represented the largest radiation safety society in the world, with a membership that includes scientists, safety professionals, physicists, engineers, attorneys, and other professionals from academia, industry, medical institutions, state and federal government, the national laboratories, the military, and other organizations. Society activities include encouraging research in radiation science, developing standards,

and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits it offers the general population.

As passed by the House of Representatives, H.R 35 ensures the continuance and enhancement of the Department of Energy's (DOE) Low-Dose Radiation Research Program, which focuses on the health effects of ionizing radiation in the low dose range. The bill also directs the National Academies of Science to formulate a long-term strategy to resolve the extent to which low-dose radiation may pose health risks to humans, and requires DOE to develop a five-year research plan that responds to the Academies' recommendations.

A greater understanding of the effects of low dose radiation on humans will not only add to our body of knowledge on the subject but it will also enable us to make better decisions on what are the proper levels, procedures, and protections needed when our citizens are subject to exposure to sources of low dose radiation.

Previously, while the program was fully funded by DOE, great strides were made in understanding the biological responses of human (and other animal) cells to low dose radiation. The research identified several protective responses by the cells exposed to low dose radiation, in contrast to the damaging changes in cells induced by high radiation dose. It is critical that additional research be conducted to link these responses at the cellular level to changes in cancer frequency in humans. The United States was once the leader in radiobiology research, but due to DOE's decision to withhold funding from the program, we have fallen woefully behind, and the vast amounts of data generated by the research already performed is sitting idle, waiting for more study and analysis.

Please feel free to get back to me with any questions you may have on this legislation or any subject involving radiation safety. Both the entire Health Physics Society and myself stand ready to assist you as issues of radiation safety come before you and your staffs.

Sincerely,

Barbara L Hamrick, CHP, JD
President, Health Physics Society

QUALITY IS OUR IMAGE

acr.org

James A. Brink, MD, FACR
Chair, Board of Chancellors

Massachusetts General Hospital
Juan M. Taveras Professor of Radiology
Harvard Medical School
55 Fruit Street, FND-216
Boston, MA 02114-2699

Phone: 617-724-9634
Fax: 617-726-3077
Email: jabrink@partners.org

August 1, 2016

The Honorable Lamar Smith
Chairman
House Committee on Science, Space, and Technology
2321 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Smith:

The American College of Radiology (ACR), representing more than 35,000 radiologists, radiation oncologists, medical physicists, interventional radiologists and nuclear medicine physicians, supports HR35, the Low-Dose Radiation Research Act of 2015. As such, I am writing to you in your capacity as conferee for S.2012 to urge that the language of HR35 be retained in conference.

As you know, HR 35 would require the Director of the Department of Energy (DOE) Office of Science to carry out a research program on low dose radiation for the purpose of enhancing the scientific understanding of and reduce uncertainties associated with the effects of exposure to low dose radiation. Further, it would require the Director to enter into an agreement with the National Academies to conduct a study assessing the current status and development of a long-term strategy for low dose radiation research.

The National Academies Board on Radiation Effects Research has played an integral role in the study of the biological effects of ionizing medicine over the last several decades, having published a series of reports (BEIR report series) that are frequently cited in professional literature, regulatory and policy-making venues. However, its most recent report was issued in 2006. Given the extensive volume of research that has occurred since the publication of the last BEIR report, there is a need for an update to the BEIR report series that critically looks at the research and provides a balanced perspective on the significance of research and knowledge in this field over the past decade.

As medical providers who utilize ionizing radiation in the diagnosis and treatment of disease, we value the role the National Academies has played in distilling volumes of research related to ionizing radiation. The

knowledge garnered from BEIR studies helps to guide our understanding and decision-making as we strive to optimize the care we provide our patients.

The ACR urges your support in including the language of HR 35 in the conference of the energy bill.

Sincerely,

James A. Brink, MD, FACR
Chair, ACR Board of Chancellors

DOCUMENT SUBMITTED BY REPRESENTATIVE DON S.BEYER

Federal Agency Scientific Integrity Policies: A Comparative Analysis

Prepared by Francesca T. Grifo

Senior Scientist and Science Policy Fellow

Union of Concerned Scientists

March 2013

The following pages contain analysis of 22 federal agency scientific integrity policies developed in response to a December 9, 2010 memorandum by Dr. John P. Holdren, director of the Office of Science and Technology Policy.

We evaluated the policies to see how effectively they would advance the goals we outlined in our 2009 comments on President Obama's March 2009 memo to Dr. Holdren, which began this process: protecting government scientists, increasing the transparency of government science, and strengthening the quality of government scientific information and advice.

Six agencies submitted policies that actively promote and support a culture of scientific integrity; five submitted policies that also promote and support scientific integrity but need additional work to ensure long-term change at the agencies. Eleven agencies submitted policies that do not make adequate commitments to achieve the preservation and promotion of scientific integrity. The agencies are presented on the following pages in alphabetical order within these three groups.

To find out more about our scientific integrity work, visit www.ucsusa.org/scientific_integrity

Centers for Disease Control and Prevention

Summary: Great policies on releasing and sharing data. Although it does not explicitly allow scientists the right of last review, it has many useful aspects to its media and communications policies.

Strengths

- Media and communications policies are broad and detailed
- Thorough guidance regarding timely dissemination of data to the public
- Establishes clear procedures for how allegations of scientific misconduct will be investigated and resolved
- Contains specifics on how to make scientific information more accessible and transparent
- Addresses conflicts-of-interest in the peer review process and on federal advisory committees
- Excellent provisions for training
- Repeats the principles from December 9, 2010 Holdren memorandum

Weaknesses

- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- This passage is a red flag "Although CDC may conduct research in areas relevant for making policy decisions, the goal of such research is to provide the best evidence to drive policy in the right direction."
- Although the clearance process is initiated by the first author, there is no explicit provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document for which they are not authors but that relies on their research or identifies them as a contributor.
- Although the policy states CDC accepts scientific debate, we could find no procedure for reporting and resolving differing scientific opinions outside of or before the clearance process.
- No commitment to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.

Department of the Interior

Summary: One of the most detailed and comprehensive policies. It explicitly states that it applies to all employees – not just scientists!

Strengths

- Applies to all employees including political appointees, supervisors, contractors, and career employees.
- Establishes clear procedure for how allegations of scientific misconduct will be investigated and resolved
- Contains procedures for reporting and resolving differing scientific opinions
- Asks employees to distinguish between official public communications and other communications made in their private capacity
- Provides supplemental forms and procedures including conflict of interest statements and waivers and scientific misconduct notifications.
- Repeats the principles from December 9, 2010 Holdren memorandum

Weaknesses

- Missing details in the communications policy (470 DM) such as disclaimer language and publication policy.
- Supports but does not adequately explain scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Right of last review limited to news releases to the extent practicable and no explicit rights regarding allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No commitment to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.
- No user-friendly online portal dedicated to scientific integrity where the policy and supplemental information could be found.

Environmental Protection Agency

Summary: Breaks new ground in the areas of personal views exception and giving scientists the right of last review.

Strengths

- Applies to all employees including political appointees, supervisors, contractors, and career employees. Makes roles and responsibilities of each explicit.
- States clearly and comprehensively scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Grants scientists the responsibility to review, approve and comment on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Repeats principles from December 9, 2010 Holdren memorandum.
- Made a draft policy available for public comment and incorporated many comments into the final policy.

Weaknesses

- While the Scientific Integrity Policy "mandates the Scientific Integrity Official to develop a transparent mechanism for Agency employees to express differing scientific opinions" we could not locate this on EPA's website. This policy should also include more details on procedures for resolving differing scientific opinions.
- The Scientific Integrity Policy promises "the EPA Scientific Integrity Committee will develop an Agency wide framework for the approval of scientific communications". We could not locate this document on the EPA website.
- Commits to developing procedure for how allegations of scientific misconduct will be investigated, resolved and publicly reported.
- Provides for annual publicly available reporting on the status of scientific integrity within the agency but these reports could not be located on the website.

NASA

Summary: This is a list of existing policies with little narrative. Although there are good elements, agency scientists would have to spend hours to find and understand them.

Strengths

- References strong NASA policies with regard to communications and whistleblower protections.
- Provides clear and concise guidance on data sharing.
- Referenced media policy allows scientists to express personal opinions with appropriate disclaimers.
- Repeats some principles from December 9, 2010 Holdren memorandum

Weaknesses

- Policy is a list of extant policies. Many agencies such as the CDC drew on multiple existing policies, but they summarized them into a user-friendly document.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.

National Oceanic and Atmospheric Administration

Summary: Excellent policy that is easy to access on the NOAA website; so long as the weaker Department of Commerce policy does not supersede.

Strengths

- Applies to all employees including political appointees, supervisors, contractors, and career employees and makes roles and responsibilities of each explicit.
- Exceptionally easy to understand FAQ section on website.
- Released an annual report on implementation of the policy.
- States clearly and comprehensively scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Includes procedural handbook for addressing allegations of scientific misconduct.
- Draft policy was available for public comment and incorporated many comments into the final policy.
- Has a Scientific Integrity Commons section of its website with links to multiple resources.
- Repeats principles from December 9, 2010 Holdren memorandum

Weaknesses

- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No data sharing specifics or firm commitments.
- Should release a procedure for reporting and resolving differing scientific opinions.
- Less well intentioned Administrations could use Department of Commerce policies to restrict scientific integrity at NOAA.

National Science Foundation

Summary: The strongest media policy of all the agencies but missing some other key protections.

Strengths

- Very strong communications policy.
- States clearly and comprehensively scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Establishes responsibilities for both scientists and public affairs officials.
- Cites procedure on how allegations of scientific misconduct will be investigated and managed.
- Information is easy to find on the NSF website.
- Repeats principles from December 9, 2010 Holdren memorandum.

Weaknesses

- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- No commitment to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.
- Research publication guidance is weak.

Promotes and supports scientific integrity but needs additional work to ensure that the policy stands the test of time

Department of Commerce

Summary: Cedes important details to its bureaus with an interest in science so don't look here to see how the department will ensure the integrity of science.

Strengths

- Confirms scientist and researcher rights to express personal opinions to the public and the media.
- Repeats some principles from December 9, 2010 Holdren memorandum.

Weaknesses

- Not explicit that the policy applies to political appointees, supervisors, contractors in addition to career employees.
- Fails to address many guidelines put forth in the December 9, 2010 memorandum.
- Lacks specifics and details as to how stated principles will be enforced and upheld.
- Implies the scientists must seek approval from public affairs officials.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- No commitment to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.
- No procedure for reporting and resolving differing scientific opinions.
- Fails to provide specifics on open government requirements, research dissemination and data sharing.

Department of Homeland Security

Summary: This policy is missing many key elements.

Strengths

- Repeats some principles from December 9, 2010 Holdren memorandum

Weaknesses

- Fails to address most of the guidelines put forth in the December 9, 2010 memorandum.
- Not explicit that policy applies to political appointees, and supervisors, in addition to career employees.
- Policies excessively restrictive and vague, even given the nature of the Office.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No provision for scientist and researcher rights to express personal opinions with appropriate disclaimers.
- No procedure for reporting and resolving differing scientific opinions.
- No procedure for data sharing with other agencies or commitment to timely releases of scientific information.
- No commitment to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.
- Very scientist focused with little mention of the role of non-scientist supervisors.

Promotes and supports scientific integrity but needs additional work to ensure that the policy stands the test of time

Department of State

Summary: This policy fails to address many of the guidelines put forth in the December 9, 2010 memorandum and its communications policy is excessively restrictive.

Strengths

- Applies to all employees including, supervisors, contractors, and career employees.
- Allows scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Refers to established procedures for how allegations of scientific misconduct will be investigated and managed.
- Repeats some principles from December 9, 2010 Holdren memorandum.

Weaknesses

- Fails to address many of the guidelines put forth in the December 9, 2010 memorandum.
- All communication of scientific topics, policies, and research to the media must be cleared through the Bureau of Public Affairs.
- Unofficial scientific communications of official concern must be approved by the Bureau of Public Affairs and requires a disclaimer.
- No commitment to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.
- No procedure for reporting and resolving differing scientific opinions.

Food and Drug Administration (FDA)

Summary: Principles are there but specific provisions and guidance are missing.

Strengths

- Taking strong steps toward limiting conflicts of interest on scientific advisory panels.
- Repeats principles from December 9, 2010 Holdren memorandum.

Weaknesses

- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- Promises FDA written media relations policy but this could not be found on the FDA website.
- Requires permission from public affairs to speak to the media in an official capacity.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No procedure detailing how allegations of scientific misconduct will be investigated, managed and reported.
- No data sharing and dissemination specifics. Unnecessary hurdles prevent data and research from being made public.
- Especially important at the FDA – scientific integrity principles should pertain to scientific information submitted to the agency from interested parties.
- Lacks specifics as to how stated principles will be enforced and upheld.
- Less well-intentioned Administrations could use Department of Health and Human Services policies to restrict scientific integrity.

Marine Mammal Commission

Summary: Commissions were not required to create scientific integrity policies. Although some key features are missing, everything in here is good.

Strengths

- Confirms scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Contains clear and concise guidelines for the selection and retention of Commission staff.
- Has clear data quality and dissemination guidelines.
- Repeats principles from December 9, 2010 Holdren.
- Mandatory financial disclosure for commissioners and scientific advisory committee members.
- No current members have financial conflicts of interest.

Weaknesses

- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- Supports but does not adequately explain scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Scientists must seek approval from public affairs officials to speak to the media.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions.

Does not make adequate commitments to scientific integrity

Department of Defense

Summary: This policy is excessively restrictive and vague, even given the nature of the Office.

Strengths

- Repeats some principles from December 9, 2010 Holdren memorandum
- DOD approval to speak to the media or the public shall not be unreasonably delayed or withheld.

Weaknesses

- Fails to address most of the guidelines put forth in the December 9, 2010 memorandum.
- Not explicit that policy applies to political appointees, contractors, and supervisors, in addition to career employees.
- Policies excessively restrictive and vague, even given the nature of the Office.
- Scientists may only speak to the media or the public with appropriate coordination with their organization.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No provision for scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions.
- No procedure for data sharing with other agencies or commitment to timely releases of scientific information.
- Policy is difficult to find on DOD website.

Department of Education

Summary: This policy was released in draft form nearly a year ago and we could not locate a final policy or the draft policy on the department's website. The draft lacked many crucial details.

Strengths

- Applies to all employees including, supervisors, contractors, and career employees.
- Repeats principles from December 9, 2010 Holdren memorandum.
- Made draft policy available for public comment.

Weaknesses

- Lacks specifics and details as to how stated principles will be enforced and upheld.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No provision for scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions.
- Fails to provide specifics on open government requirements, research dissemination and data sharing.

Department of Energy

Summary: This policy is less than three pages long and hence has many significant gaps. Does not fully embrace the principles in the OSTP guidance memo and has many additional missing elements.

Strengths

- Repeats principles from December 9, 2010 Holdren memorandum.

Weaknesses

- Not explicit that policy applies to political appointees, supervisors, contractors in addition to career employees.
- Fails to address many of the guidelines put forth in the December 9, 2010 memorandum.
- Lacks specifics and details as to how stated principles will be enforced and upheld.
- Weak media and communications policy.
- States but does not adequately support scientist and researcher rights to express personal opinions with appropriate disclaimers.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions.

Department of Health and Human Services

Final policy

Summary: HHS could have set the gold standard by calling on the depth of experience with scientific integrity at the NIH. But they did not.

Strengths

- Repeats principles from December 9, 2010 Holdren memorandum.
- Allows individual HHS agencies to develop agency-specific scientific integrity principles, policies, and procedures of their own.
- States scientist and researcher rights to express personal opinions with appropriate disclaimers.

Weaknesses

- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Does not allow use of HHS title or affiliation even for identification purposes when presenting personal or individual views.
- Scientists must seek approval from public affairs officials to speak to the media.
- This policy does not address how allegations of scientific misconduct will be investigated, managed and reported.
- No HHS- wide guidance for reporting and resolving differing scientific opinions.
- Defers to HHS agencies for specifics on open government requirements, research dissemination and data sharing.
- Leaves all specifics and details as to how stated principles will be enforced and upheld to individual HHS agencies.

Department of Justice

Summary: Very decentralized draft policy that could lead to problems for scientists and very limited commitments to transparency. No final policy could be found on the DOJ website.

Strengths

- Applies to all employees including, supervisors, contractors, and career employees.
- Repeats principles from December 9, 2010 Holdren memorandum.
- Commitments to maintaining and strengthening scientific integrity and credibility are strongly stated.
- Prohibits employees from inappropriately suppressing or altering scientific research.

Weaknesses

- Implementation plans are left up to individual offices rather than establishing a department-wide policy.
- Communications policy is excessively restrictive even given the DOJ's position. The policy requires public affairs officers to coordinate all interactions with the media.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No provision for scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Commits to developing a procedure for reporting and resolving differing scientific opinions but does not indicate when it will be released.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- Limited transparency commitments.

Department of Labor

Summary: The final policy is exactly the same as the draft policy in spite of a large response to a public comment period. Although the principles from the December 9, 2010 memorandum are repeated, there are many flaws, weaknesses, and gaps.

Strengths

- Establishes clear procedure for how allegations of scientific misconduct will be investigated and managed.
- Repeats principles from December 9, 2010 Holdren memorandum.

Weaknesses

- Not explicit that the policy applies to political appointees, supervisors, and contractors in addition to career employees.
- Scientists may only speak to the media on matters related to their official work and only if assigned by their immediate supervisor and in coordination with their public affairs office.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Supports but does not adequately explain scientist and researcher rights to express personal opinions with appropriate disclaimers.
- No procedure to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.
- No procedure for reporting and resolving differing scientific opinions.
- No data dissemination commitments.
- Lacks specifics and details as to how stated principles will be enforced and upheld.

Department of Transportation

Summary: The draft policy is no longer available on the department's website, and it was not replaced by a final policy. The draft failed to address most of the guidelines put forth in the December 9, 2010 memorandum.

Strengths

- Repeats some principles from December 9, 2010 Holdren memorandum

Weaknesses

- Fails to address most of the guidelines put forth in the December 9, 2010 memorandum.
- Lacks specifics for any of the commitments.
- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- No provision for scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Scientists must coordinate with public affairs officials prior to speaking to the media.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Lacks procedures on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions
- Commits to developing an implementation guide but has not made this public.

Department of Veterans Affairs

Summary: The final policy could not be located on their website. There was a public comment period but there is no evidence these comments were ever used to create a final policy. Many important features are missing from this draft.

Strengths

The March 27, 2012 draft policy:

- Confirms scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Establishes that allegations of scientific misconduct will be investigated and managed in accordance with Federal Policy on Research Misconduct.
- Makes strong commitments to transparency and the dissemination and publication of scientific information.
- Repeats principles from December 9, 2010 Holdren memorandum.
- Made draft policy available for public comment but we could not locate a final policy on their website.

Weaknesses

- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- Scientists must seek approval from public affairs officials before speaking to the media.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No commitment to publicly report the aggregate number of scientific misconduct allegations and the specifics on cases of confirmed misconduct.
- No procedure for reporting and resolving differing scientific opinions.

Office of the Director of National Intelligence

Summary: This policy could not be found on the ODNI website and had to be obtained through FOIA. The policy is excessively restrictive and vague, even given the nature of the Office.

Strengths

- Repeats some principles from December 9, 2010 Holdren memorandum
- In principle supports the separation of fundamental scientific and technological information from nationals intelligence capabilities so that more science may be released.

Weaknesses

- Fails to address most of the guidelines put forth in the December 9, 2010 memorandum.
- Lacks specifics for any of the commitments.
- Not explicit that policy applies to political appointees, supervisors, and contractors in addition to career employees.
- No provision for scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Scientists must coordinate with public affairs officials prior to speaking to the media.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Lacks procedures on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions
- Commits to developing an implementation guide but has not made this public.

USAID

Summary: Implies that scientists must seek approval from public affairs before speaking to the media which could have a chilling effect on transparency.

Strengths

- Applies to all employees including, supervisors, contractors, and career employees.
- Confirms scientist and researcher rights to express personal opinions.
- Repeats principles from December 9, 2010 Holdren.
- Contains strong principles to protect science from inappropriate interference.

Weaknesses

- Weak communications and media policies.
- Scientists must seek approval from public affairs officials to speak to the media.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions.

USDA

Summary: This policy has significant gaps and expired over a year and a half ago with no indication of plans for revisiting it.

Strengths

- Applies to all employees including, supervisors, contractors, and career employees.
- Repeats some principles from December 9, 2010 Holdren memorandum.
- Makes some good commitments regarding federal scientific advisory committees

Weaknesses

- Fails to address many of the guidelines put forth in the December 9, 2010 memorandum.
- Implies scientists must seek approval from public affairs officials to communicate with the media.
- No provision allowing scientists the right to review, approve and comment publicly on the final version of any scientific document that relies on their research or identifies them as a contributor.
- No provision for scientist and researcher rights to express personal opinions with appropriate disclaimers.
- Lacks procedure on how allegations of scientific misconduct will be investigated, managed and reported.
- No procedure for reporting and resolving differing scientific opinions.
- Lacks specifics and details as to how stated principles will be implemented, enforced and upheld.
- States that the policy will only be in effect for one year defeating the purpose of the policy.

139

REPORT SUBMITTED BY CHAIRMAN LAMAR S. SMITH

Regulation under Uncertainty

Use of the Linear No-Threshold Model in Chemical and Radiation Exposure

Dima Yazji Shamoun, Edward Calabrese, Richard A. Williams, and James Broughel

September 2016

MERCATUS WORKING PAPER

MERCATUS CENTER
George Mason University

3434 Washington Blvd., 4th Floor, Arlington, Virginia 22201
www.mercatus.org

Dima Yazji Shamoun, Edward Calabrese, Richard A. Williams, and James Broughel. "Regulation under Uncertainty: Use of the Linear No-Threshold Model in Chemical and Radiation Exposure." Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016.

Abstract

This paper examines the use of the linear no-threshold (LNT) model in chemical and radiation exposure. The LNT model assumes that exposure to any level of a chemical or radiation is harmful, down to even the last molecule. Used primarily to be "public health protective," the model has been the backbone of chemical and radiation risk regulation for many decades. Given the current state of science and risk management tools, we challenge the notion that using the LNT as the default model is public health protective. First, more and more research has uncovered dose-response relationships that reveal either a threshold or, more importantly, a hormetic response, where exposure to low doses of a hazard actually yields health benefits. Second, given these more realistic alternative dose-response models, risk management tools including risk-risk analysis and health-health analysis show that regulating down to extremely low levels can have negative health consequences when ancillary risks are considered. Risk-risk analysis focuses on how reductions in target risks can lead to increases in risk from substitute chemicals or activities. Health-health analysis explores how costs of compliance are borne in part by consumers who are forced to reduce their own private risk-mitigating activities. Overestimating risk, a common feature of the LNT model, upsets the careful balancing of risks required of risk managers.

JEL codes: D62, D81, I18

Keywords: linear no-threshold, dose-response, health and safety regulations, benefit-cost analysis, risk assessment

Author Affiliation and Contact Information

Dima Yazji Shamoun
Associate Director of Research
Center for Politics and Governance
Lecturer, Economics Department
University of Texas at Austin
dshamoun@utexas.edu

Edward Calabrese
Professor of Toxicology
University of Massachusetts at Amherst

Richard A. Williams
Director, Regulatory Studies Program
Mercatus Center at George Mason University

James Broughel
Research Fellow, State and Local Policy Project
Mercatus Center at George Mason University

All studies in the Mercatus Working Paper series have followed a rigorous process of academic evaluation, including (except where otherwise noted) at least one double-blind peer review. Working Papers present an author's provisional findings, which, upon further consideration and revision, are likely to be republished in an academic journal. The opinions expressed in Mercatus Working Papers are the authors' and do not represent official positions of the Mercatus Center or George Mason University.

Regulation under Uncertainty:

Use of the Linear No-Threshold Model in Chemical and Radiation Exposure

Dima Yazji Shamoun, Edward Calabrese, Richard A. Williams, and James Broughel

1. Introduction

The linear no-threshold (LNT) model has been the standard risk assessment model used for both chemical and radiation exposure for decades, particularly for low-dose exposure. While many assume that using the model provides for a public health–protective risk management decision, this remains to be proven. This paper challenges the notion that the LNT model is protective of the public health under conditions of uncertainty, in particular with modeling low-dose exposure. The meaning of "public health–protective" becomes less clear when there are offsetting increases in risk either to the target population or to an entirely different population.

We argue that there are three related assumptions, which are central to many risk assessments, that may lead to poor public health decisions: the LNT assumption, which might be thought of as a zero threshold assumption; the zero substitution effect assumption; and the zero income effect assumption. The LNT model, a widely applicable dose-response model in risk assessment—especially in cancer risk assessment—hypothesizes that exposure to even a single molecule of a hazard is sufficient to induce harm. By contrast, a threshold model assumes that exposure up to a certain dose is harmless, and a hormetic model hypothesizes that exposure to low doses of stressors is protective (i.e., beneficial) and only becomes harmful at higher doses.

The zero substitution effect assumption is that there are no risk-risk tradeoffs and, thus, a reduction in a target risk yields no unintended increases (or decreases) in other risks. Finally, the zero income effect assumption is that there are no health-health tradeoffs, meaning that

regulatory efforts to mitigate a target risk yield no offsetting increases in personal risks when private income is reduced by regulatory spending on health and safety.

If any one of these assumptions (or a combination of them) is found to be false, then public health may be compromised. The use of the LNT model, especially with its emphasis on conservatism, may lead to choices that increase the expected cost of risk-risk and health-health tradeoffs. Its widespread use could, for example, contribute to a culture among regulators whereby focus is aimed narrowly at target risks, but to the exclusion of countervailing risks, without consideration of diminishing marginal returns to public risk-reduction attempts, and in ignorance of private risk-reduction efforts.

We begin this paper with a background discussion of the history and origin of the LNT model. We then present a brief review of the recent scientific literature on hormesis, DNA repair, preconditioning, and adaptive responses in biology, challenging the foundational validity of linearity. Finally, we conclude with a discussion of tradeoff analysis, namely risk-risk analysis (RRA) and health-health analysis (HHA), which sheds light on the role of unintended consequences and opportunity costs in magnifying the potential health consequences of using the LNT model. Despite its widespread use, the LNT model is due for a reevaluation. In addition, because much of the health effect we are discussing occurs in the very low dose range, dose-response uncertainty, risk-risk tradeoffs, and health-health tradeoffs should be analyzed as part of risk management to improve public policy decisions and outcomes.

2. Background of the LNT Model

When estimating the risk from exposure to chemical hazards, neither epidemiological nor animal studies generally provide dose-response data in the relevant region for the average

human level of exposure, that is, the low-dose region. Due to the limitations of existing study protocols, extrapolations to possible responses in the relevant low-dose region are usually made from the level of response observed in the high-dose region. The LNT model assumption, which roughly connects the lowest dose-response point observed in animal studies to the origin, is the most common model used for extrapolation. For cancer risk assessments, in particular, it is the regulatory default,[1] and, in effect, it implies that there is no safe threshold for exposure to a carcinogen; exposure to even a single molecule of a carcinogen could cause harm proportional to the dose.

The adoption of the LNT model for cancer risk assessment stands at odds with the founding principle of toxicology that "the dose makes the poison." To quote Paracelsus in full: "All substances are poisons; there is none which is not a poison. The right dose differentiates a poison from a remedy" (Kirsch-Volders, Aardema, and Elhajouji 2000). Yet the LNT model assumption eliminates consideration of a threshold and focuses only on the level of "presumed" poisonous effects. Recent work, however, continues to affirm the presence of repair, as the body has "demonstrated response to mitigate or eliminate [the] damage" from low dose radiation. (Sacks, Meyerson, and Sigel 2016).

Abandonment of the previously held threshold assumption constituted a significant paradigm shift in toxicology. Although "extraordinary claims require extraordinary proof,"[2] the LNT model was accepted as the default model for cancer risk assessment by US regulatory agencies without an extraordinary justification. In the following two subsections we provide a

[1] Some noncancer risk assessments make use of the LNT model as well, though they are more aberrational than customary. For example, the Environmental Protection Agency applies the LNT model to estimate the risk of exposure to low doses of some air pollutants, such as fine particulate matter ($PM_{2.5}$) and more recently to ozone (O_3).

[2] The original quote may have been from Marcello Truzzi (1987): "The more extraordinary a claim, the heavier is the burden of proof demanded."

brief history of the LNT model and its application by regulatory agencies to ionizing radiation and then to chemical carcinogens in general (a historical summary is provided in the table in the appendix).

2.1. Adoption of the LNT model in the Assessment of Risk of Ionizing Radiation

Ever since the publication of Darwin's 1859 work, *On the Origin of Species by Means of Natural Selection*, the question as to the cause of genetic change by which natural selection takes place has occupied the biology community (Calabrese 2013b). Evolution was seen to be driven by random mutations to individual genes, which would then be passed on to future generations (Muller 1922). But what was inducing the mutations?

Geneticists raced to discover this mechanism of evolution. They applied stressors ranging from temperature to ionizing and nonionizing radiation. In 1927, Nobel Prize–winning geneticist Hermann J. Muller initiated a discussion on the possibility that X-rays could lead to heritable mutations. Though the doses he used in his study were extremely high (200,000 times the background dose), he found a significant mutation rate, which led Olson and Lewis (1928) to speculate that naturally occurring ionizing radiation may be the process behind evolution (Calabrese 2013b).

Even given linearity in the low-dose region, however, the inducible mutation theory was ambitious, as it hypothesized that small doses of natural radiation could explain the full extent of evolution driven by genetic mutation. Despite the need for extraordinary proof and the emergence of several studies rejecting the LNT model interpretation (Patterson 1928), genetic mutation in response to ionizing radiation came to be the common assumption, requiring a new framework to accompany it.

This novel framework would emerge from a collaboration of geneticists and physicists. Before Muller's theory of inducible mutation, medical physicists had envisioned that each cell has a sensitive area, or a heart, and that when the heart dies, the cell dies. According to this theory, known as target theory, cells are dosed with radiation that may result in "hits" that can then kill the cell. A cell can potentially survive a number of radiation doses, as not every dose will hit the heart (of a cell); also the heart may withstand several hits before it dies. Thus, target theories are modeled as x-hit target theory, where "x" denotes the number of hits it takes to kill the heart of the cell. For example, a single hit theory implies that the heart will be killed on the first hit (Nomiya 2013)—that is, response occurs in proportion to the dose.

Applying target theory to radiation-induced mutation advanced both the state of target theory and the LNT model for ionizing radiation. The formal justification of the linear dose response within the target theory framework appeared in an influential paper by radiation geneticist Timoféeff-Ressovsky and physicists Delbruck and Zimmer (1935). The paper hypothesized a binary reaction mechanism where an observable response (i.e., mutation) takes place when units of energy are absorbed (or ionized) by the target region (the particularly sensitive region, or the heart) of a gene. Once an X-ray treatment excites an electron in the target region of the gene, a permanent effect takes place in the form of a mutation (Calabrese 2013b). The units of energy are generally referred to as hits and thus the target theory of ionizing radiation is often referred to as the one-hit target theory.

The one-hit target theory of mutation stood at odds with the general physiological understanding of the time that the elimination of one molecule out of a very large number of molecules does not generate an observable effect. Even after the 1953 discovery of the structure of DNA (Watson and Crick 1953) came to replace most of what had been assumed about gene

structure (e.g., its molecular stability), the one-hit target theory continued to be applied. And in 1956 the theory even made its way to the Biological Effects of Ionizing Radiation I (BEIR I) committee formed by the National Academy of Sciences. There the geneticists comprising the BEIR I panel made the seminal recommendation to switch from a threshold model to a linear model to estimate the risk of mutation from ionizing radiation (Calabrese 2013b).

Still, as understanding of low-dose-induced DNA repair and recovery was making its way through the scientific community, some challenged the BEIR I decision. These challenges, however, did not succeed in reversing the BEIR I decision, and regulatory agencies in America and around the world followed BEIR I's lead, adopting linearity in cancer risk assessment (Calabrese 2013b).

2.2. Adoption of the LNT Model in the Assessment of Risk of Other Stressors

In 1961 Nathan Mantel and W. Ray Bryan used a probit model to estimate the risk of developing cancerous tumors when exposed to carcinogens (Calabrese 2013b). They recommended a "safe dose" of 1 in 100 million. The common regulatory "tolerated" level of risk from exposure to carcinogens traces its origin to this publication. This safe-dose recommendation was adopted by the Food and Drug Administration (FDA) in its publication of the 1973 risk guidelines, but it was modified to 1 in 1 million in 1977.[3] In 1979, the FDA revised its cancer risk assessment policy, replacing the probit model used by Mantel and Bryan with the LNT model.[4]

[3] The 1 in 1 million level was the threshold below which no regulatory action was necessary.

[4] In fact, there have been many mathematically based models used to extrapolate from high to low dose for carcinogenesis. One significant method used by the EPA early on came from K. S. Crump (1984). There were two-stage models (Armitage and Doll 1957), three-stage models (Neyman and Scott 1967) and the one-hit model from Moolgavkar and Venzon (1979) and Moolgavkar and Knudson (1981). These are discussed in Thorsland, Brown, and Charnley (1987). A more general discussion can be found in Anderson and the Carcinogen Assessment Group of the EPA (1983). For a thorough analysis of the history and evolution of dose-response modeling, see Calabrese (2013b).

The EPA took several measures in the 1970s to limit exposure to carcinogens.[5] In its 1976 proposed guidelines on carcinogenic risk, the EPA recommended the use of quantitative risk assessments to estimate the risk of exposure to carcinogens. Based on limited epidemiological evidence on ionizing radiation and the link between smoking and lung cancer, the EPA also endorsed the use of the one-hit model (and thus a linear dose response) (Calabrese 2013b). According to EPA Administrator Douglas Costle, the one-hit model was chosen due to its conservative nature, that is, its perceived bias toward overestimation of risk in the presence of uncertainty (EPA 1976). Overestimation of risk was (and still is) considered consistent with the agency's mission to protect public health from environmental chemical exposures. A later publication suggested that wide application of the LNT model in regulatory risk assessment was due in part to its attractiveness to regulators, namely, "It is easy to apply and . . . it will generate an upper bound on the unknown, underlying cancer risk in most instances." (Office of Science and Technology Policy 1986). And the timing for the regulation of chemical carcinogens was simply right, following as it did on the heels of ionizing radiation, a mutagen with a readily available and widely used framework of analysis. So while the one-hit model was initially proposed for the mutational effects of ionizing radiation, it eventually became the default model for all chemical carcinogens.

In 1977 the Safe Drinking Water Committee (SDWC) of the National Academy of Sciences (NAS) recommended to the EPA the adoption of the LNT model in cancer risk assessment (Calabrese 2013b). The EPA followed this recommendation in 1979 in its assessment of the risk of chloroform in drinking water (Environmental Protection Agency 1979). The

[5] The EPA's website has a Quantitative Risk Assessment for Exposure to Vinyl Chloride (Kuzmack and McGaughy 1975) and Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens (Train 1976).

SDWC expressed skepticism on the grounds that the LNT model did not incorporate biological characteristics of the animal studies nor did it anticipate "newer developmental methodologies" (Calabrese 2013b). As a result, the SDWC briefly withheld its endorsement of the LNT model only to endorse it again in 1983, since the model was still in use by the EPA. From there, the LNT model became the default methodology for the assessment of risk of chemical carcinogens. These endorsements and the application of the LNT model, first by the FDA (1979) and then by the EPA (1979), were foundational steps in the history of regulatory risk assessments.

3. Recent Developments in Dose Response

Regardless of the reasons why regulatory agencies initially decided to use the LNT model, the debate should now be on whether there is sufficient evidence to justify maintaining its use. As we argue, there is mounting evidence in biology and toxicology (as well as risk management theories) to support reevaluation of the choice of dose-response model to optimize public health. The LNT model is difficult, if not impossible, to validate and, therefore, integrating other default models may allow for conducting validation exercises. Evidence of alternative dose-response models (e.g., hormesis) and biological mechanisms (e.g., DNA repair, preconditioning, and adaptive response) suggest that adherence to the LNT model may be imprudent, as it prevents public policy from achieving its full potential in protecting public health.

In fact, due to these issues of validation and plausibility, the Nuclear Regulatory Commission has recently started examining the validity of the LNT model as compared to the hormetic model for ionizing radiation (Nuclear Regulatory Commission 2016). In the next section we briefly outline three challenges from toxicology and biology to the LNT model,

namely, validation issues, hormesis as an alternative model, and, finally, research on DNA repair, preconditioning, and adaptive responses in biology.

3.1. Validation Issues

As noted above, it is extremely difficult, if not impossible in some instances, to validate the dose-response function at low doses, since thousands of subjects are required to uncover either a small response or a relatively infrequent event. This is particularly true when the adverse effect, such as cancer, occurs in both the test and the control group (Scala 1991). This task is made even harder when one potential response in the test group is a decrease in the incidence of the adverse event, that is, a hormetic response. To uncover such an effect would require a study design that would allow for such a response. Another difficulty for a dose-response researcher, and the more familiar one, is extrapolation. Extrapolation problems exist for both animal and human (epidemiological) studies. Even the most sophisticated epidemiological and animal studies are incapable of detecting low levels of risk, for example, below 1 percent, and so these risks must be imputed based on data at higher doses.

The validation issue is further magnified with the LNT model, as it predicts proportional risk to ever smaller and smaller doses. Much of the current justification for using LNT as the default dose-response model for exposure to ionizing radiation and chemical carcinogens is rooted in epidemiological studies. However, epidemiological studies are difficult to reproduce, hard to map to the general population due to the presence of confounders, and are often focused on cases where the population in question is exposed to high dose levels (Taubes 1995). Examples of such cases are studies of the effect of ionizing radiation that rely on evidence from radiation exposure following Hiroshima, Nagasaki,

Chernobyl, and Fukushima; occupational radiation studies; and medical studies on highly exposed individuals (Calabrese and O'Connor 2014).

Such high-dose exposure events and studies are therefore unsuited for extrapolation to the relevant day-to-day low-dose events like the use of X-rays and CT scans for medical purposes (Berrington de González et al. 2009). Even some of the more recent articles in the medical literature that predict high rates of disease and cancer-related deaths due to medical imaging in the United States rely on extrapolation from high-dose exposure to radiation (Berrington de González et al. 2009; Abbott 2015).

Moreover, there is a sizable stock of scientific research (epidemiological and medical) suggesting the possibility of a threshold model for radiation exposure for doses below 100 mSv (Ropeik 2013), while other studies have detected a beneficial response to low-dose exposure. For example, four epidemiological studies of subjects who are naturally exposed to background radiation did not detect any increase in cancer risk, with one study detecting a positive response to low-dose radiation (Tao et al. 1999).[6] Another study on the effect of radon exposure revealed beneficial effects to low-dose exposure (Cohen 1995). These results were affirmed in another more recent study on radon exposure, which detected the possibility of positive effects from low doses of radiation on lung cancer (Thompson et al. 2008). A multiple-country analysis of occupational exposure to X-rays and gamma-rays in nuclear power plants also did not detect negative health effects from exposure in workers; instead it showed a rate of all cancer mortality lower in the exposed workers relative to the general population (Cardis et al. 2007). A quick search on Google Scholar for hormesis alone generates 23,800 articles.

[6] The lack of statistical significance in these studies is nonetheless important, as it means that the effect of exposure to low-dose radiation on cancer risk is not different from zero. This finding of non-significance may imply a possible threshold and not an LNT model.

Much of the aforementioned research, which was unable to validate a linear response, also relies on epidemiological, occupational, and ecological investigations, which naturally suffer from the same shortcomings as the studies *supporting* linearity. Yet, regulatory risk assessment has lacked a systematic review of the evidence in support of each model. Such a review could shed light on the weight of evidence in support of each model while accounting for study design and quality. For example, lack of a systematic review is illustrated by the seventh committee on the Biologic Effect of Ionizing Radiation (BEIR VII) that attributed the beneficial response in the multiple-country study of occupational exposure to X-rays and gamma-rays to a "healthy worker effect and unknown differences between nuclear industry workers and the general public" (Calabrese and O'Connor 2014). These kinds of assertions are not helpful when equally plausible alternative explanations exist, but are ruled out without any review of the existing evidence.

The difficulty of validating models at very low doses drove the Health Physics Society and the American Association of Physicists in Medicine (AAPM) to conclude in December 2011 that the effects of radiation at very low doses (50–100 mSv) are either too minuscule to detect or virtually nonexistent. As a result, the two organizations issued statements recommending against quantitative estimation of health risks for doses of radiation below 50 mSv annually or below 100 mSv above that of background radiation in a lifetime. In the words of the AAPM (2011),

> Risks of medical imaging at patient doses below 50 mSv for single procedures or 100 mSv for multiple procedures over short time periods are too low to be detectable and may be nonexistent. Predications of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged. These predictions are harmful because they lead to sensationalistic articles in the public media that cause some patients and parents to refuse medical imaging procedures, placing them at substantial risk by not receiving the clinical benefits of the prescribed procedures.

As outlined, the low-dose region is one saturated with uncertainties and the choice of one model to estimate health risks gives "a false sense of precision" (Office of Management and Budget 2007) where none currently exist. Given that the use of the LNT model may lead to poor public health decisions, then integrating it with other plausible dose-response models moves us closer to optimizing public health protection (Calabrese et al. 2015).

The issue of model uncertainty and model validation in the low-dose region has been a challenge for decades. Ever since the publication of *Risk Assessment in the Federal Government: Managing the Process* in 1983 by the National Research Council (NRC), the choice of the low-dose model must be given to the one with the most biological plausibility (National Research Council 1983).

In the next subsection, we present recent developments in biology that support another low-dose model, namely, hormesis, or the biphasic dose-response model. In addition to having more biological support than the LNT model, hormesis, if correct, casts doubt on the supposed conservative nature of LNT.

3.2. Hormesis

In contrast with the LNT model, the hormetic dose-response model is a biphasic model where direction of response is not constant across doses. While response to exposure to a high dose of some substance may indeed be proportional to dose (i.e., harmful), response to exposure to a low dose of the same substance may be *inversely* related to dose (i.e., protective). In other words, exposure to a low dose of a carcinogen may—up to a certain threshold—*lower* the risk of developing a particular cancer. These characteristics are sometimes described as low-dose stimulation and high-dose inhibition.

As previously mentioned, all dose-response models encounter validation problems in the low-dose region; hormesis faces this issue as well. In hormesis, the hormetic effect is generally modest, that is, 30–60 percent greater than control values (Calabrese and Baldwin 2003). Given the small ratio of signal to noise and the modest effect, it is difficult to replicate hormesis and to distinguish between a threshold and a hormetic model in the low-dose region respectively (Calabrese and Mattson 2011). Considering, however, the significance of health implications of correctly identifying the type of dose-response model, efforts to design better studies have continued. As described in one paper, "The use of different default models has important implications in many areas, including the establishment of limits for chemical exposures" (Calabrese 2008).

Recent advances in clinical studies have begun to allow researchers to overcome some of the aforementioned obstacles. For example, shifting focus from whole-animal to cell-level investigation has allowed for more doses to be tested and results to be replicated, in addition to both allowing results more relevant to humans and to relying less on extrapolation (FDA 1993). These and other recent advances suggest that the dynamics of the low-dose region may be more nuanced than is predicted by the default LNT model.

Hormesis has been found to make more accurate predictions than both the LNT and threshold models using large independent data sets (Calabrese and Baldwin 2003). Some research has provided an explanation for the mechanism of action of hundreds of hormetic dose responses, suggesting that hormesis may be more of a rule than an exception. This claim was extended to both cancer and noncancer end points and is said to be independent of the biological model and the stressors tested (Calabrese and O'Connor 2014).

Studies in toxicology have revealed hormetic dose responses for both ionizing radiation and chemical carcinogens. One estimate for chemicals found a hormetic response in 37–50 percent of chemicals tested and also found that the hormetic responses exceeded those of the threshold by 2.5 to 1 (Calabrese and Baldwin 2003). In fact, a hormetic response is detected in nearly 2,000 chemical agents from a broad range of chemical classes (Calabrese et al. 2008, Calabrese 2013a). Some of the studies showing a beneficial health effect of ionizing radiation at low levels of exposure (discussed in the previous subsection) may also be an example of a hormetic dose response.

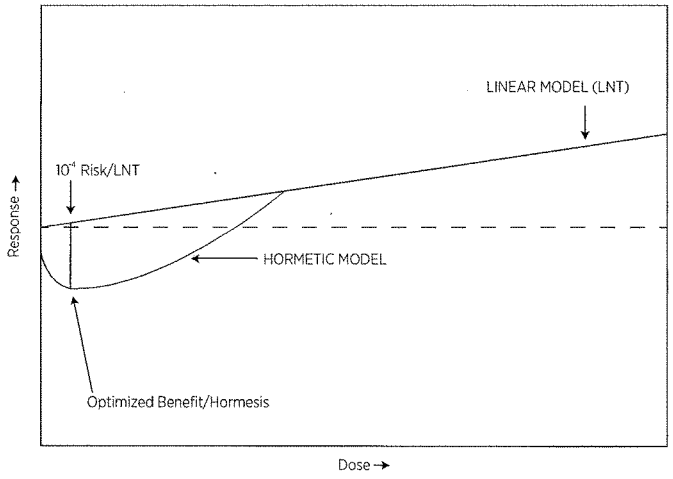
A major FDA-funded study (the mega-mouse ED01 study), which included 24,000 animals exposed to a known carcinogen (2-acetylaminofluorene, a derivative of fluorene), found evidence supporting a hormetic, or biphasic, dose response (Bruce et al. 1981). Additionally, a reassessment of the effect of DDT in an animal study—on which regulatory agencies had based their risk assessment—revealed a hormetic dose response (Sukata et al. 2002). Hormesis has also been detected in exposure to low doses of air pollutants, namely particulate matter (Cox 2012).

The LNT model is often argued for and justified on the basis that it is a conservative approach (EPA 2005).[7] However, hormesis alone casts doubt that adherence to linearity is necessarily conservative as we intervene to maintain lower doses. As recent research on model

[7] Some claim that the LNT model is not conservative. For example, Bailar et al. (1988) argue that a supralinear dose-response relationship is possible for some chemicals. Others have argued that the human population is heterogeneous in its susceptibility to cancer risks (Finkel 2014), such that some individuals will experience higher than average cancer responses. Bailar et al. (1988), however, did not consider the possibility of a J-shaped dose response in his study due to its lack of support at the time. Now, however, ample support for a J-shaped dose response is available, as mentioned above. Regarding variation in human susceptibility, at least for the purposes of calculating benefits in a benefit-cost analysis, it is the mean response in the population that should be considered. Some individuals will no doubt experience higher than average cancer responses, just as others will be lower than average. As will be discussed in more detail below, taking an upper bound of risk that accounts for humans having higher than average susceptibility or having a higher exposure is not conservative because there is a balance to be struck between target risks and the risks associated with risk-risk tradeoffs and health-health tradeoffs. Such balancing is impossible when upper bounds are used in place of mean population responses. Further, research on the integration of hormesis and the LNT model shows that setting a protection standard based on the response of the most sensitive populations can lead to a net negative health outcome (see Calabrese et al. 2016).

uncertainty suggests (Calabrese et al. 2015), the optimal hormetic response occurs at the nadir of the hormetic curve, which is illustrated in figure 1. As argued, the dose corresponding to a 10^{-4} response according to the LNT model is roughly aligned with the dose yielding the optimal hormetic response. Therefore, seen in light of model uncertainty and if the hormetic model is correct, then pushing exposure to a dose smaller than the dose corresponding to a 10^{-4} response as predicted by the LNT model will yield net health harm. Taking bladder cancer as an example, the health gains achieved by pushing exposure to a dose corresponding to a 10^{-6} LNT response (i.e., 100 bladder cancers less than a dose corresponding to a 10^{-4} LNT response), will be dwarfed by the health harm induced by eliminating the potential for protective hormetic effects (i.e., 3,150 more incidences of bladder cancer) (Calabrese et al. 2015).

Figure 1. Model Uncertainty and Health Protection when Accounting for Hormesis



Source: Edward J. Calabrese, Dima Y. Shamoun, and Jaap C. Hanekamp. 2015. "Cancer Risk Assessment: Optimizing Human Health through Linear Dose-Response Models." *Food and Chemical Toxicology* 81: 137–40.

3.3. DNA Repair, Preconditioning, and Adaptive Responses in Biology

When the LNT one-hit model was first proposed, it was assumed that a single change of DNA could initiate the carcinogenesis process and damage could not be reversed. In other words, DNA repair was ruled out. Scientific understanding has come a long way since then. In addition to recent developments indicating that displacing a large number of molecules is required to affect a mutational event (Weiss 1944), several types of cells are now found to successfully repair mutated DNA (Hanawalt 1994). And even if a carcinogen can initiate a carcinogenesis process in a linear fashion, the development of tumors may not necessarily follow. For instance, in one study Driver, White, and Butler (1987) demonstrated that a single administration of the mutagen/carcinogen dimethylnitrosamine (DMN) induced a linear dose response for renal mesenchymal DNA adducts (early cancer process stage), as well as for mesenchymal foci (later cancer process stage), observations consistent with the LNT model. However, the linear transition to the occurrence of tumor formation was not observed, as the foci at the lower doses failed to proceed to the tumor stage, yielding a threshold, rather than a linear dose-response relationship.

A similar point was made in a 1990 paper by Ames and Gold. The authors argued that cell division plays an important role in the carcinogenesis process, as cell division increases the vulnerability of DNA to mutation. Since animal testing is very expensive, rodents are generally subjected to chronic doses of hazards in order to better detect a carcinogenic effect. However, when high doses of a carcinogen are being administered in an acute manner—causing the destruction of some cells—then cell division is the natural bodily reaction to replace these dead cells, making DNA mutation more likely. As Ames and Gold have observed,

> By causing chronic cell division, a high percentage of all chemicals might be expected to be carcinogenic at chronic, near-toxic doses. . . . About half of all chemicals tested

> chronically at the MTD [maximum tolerated dose] are carcinogens. The fact that about 40% of rodent carcinogens are not mutagens is consistent with our understanding of the important role of cell division in carcinogenesis. Although toxicity at or near the MTD often induces cell division, below a certain dose no such effect is observed. (Ames and Gold 1990)

Research on DNA repair offers a significant challenge to the LNT paradigm: The notion of self-repair is inherently inimical to a linear theory. But while it could be argued that DNA repair does not on its own resolve the debate over the dose-response model, recent biological research on preconditioning and adaptive response seems to make a convincing case for hormesis.

Preconditioning and adaptive response research explores whether a low dose of a stressor induces a protective reaction in the body against higher doses of the same stressor and, in some cases, higher doses of other stressors. In other words, low doses of a stressor can increase resilience and promote survivability in the environment. Stressors can vary from environmental pollutants to chemical carcinogens to exercise to intermittent fasting. The ability of organisms to react adaptively to low doses of stressors has recently been argued to play a fundamental role in evolution (Mattson and Calabrese 2010). In fact, preconditioning and adaptive response is challenging two fundamental implications of the LNT model, namely that dose is cumulative and damage is irreversible (Calabrese 2015, Calabrese 2016).

Research on preconditioning and adaptive response is now proposing less invasive methods, both to treat present diseases and to prevent susceptibility to future ones. Recent studies argue that low doses of X-rays can induce a protective effect to treat pneumonia by promoting an anti-inflammatory response (Calabrese, Dhawan, and Kapoor 2014). Moreover, low-dose radiotherapy is argued to be highly effective on patients with shoulder tendonitis or bursitis (Calabrese, Dhawan, and Kapoor 2014). Low-dose X-rays have also been asserted not only to initiate an adaptive response to higher doses of radiation but also to nonradiation stress, such as oxidative damage,

which constitutes a major cause of diabetic complications. Low-dose radiation has been found to induce a maximal protective effect against kidney damage in diabetic patients (Shao et al. 2014).

Other research examines low-dose light therapy administered to the front lobe of the brain to stimulate brain and muscle activity and to sharpen memory (Hayworth et al. 2010). Additionally, low-level light therapy (LLLT) has been shown to be an effective treatment against subsequent heart attacks, and when administered to patients before surgery, it can promote healing of surgical wounds. In addition, LLLT administered on normal muscles may increase the amount of physical work that can be performed by extending the time that the muscle can function comfortably before fatigue starts (Agrawal 2014).

A comprehensive review of all the recent research on preconditioning and adaptive response and the biological basis of hormesis is beyond the scope of this paper, but one such study is Calabrese (2008). It is clear, however, that hormesis and preconditioning play substantial roles in public health. While massive uncertainties may fog up the low-dose region and make model selection a challenging endeavor, biological plausibility—as advocated by regulatory agencies and the NRC for many decades—must be the tiebreaker.

4. A Methodology to Alleviate the Uncertainty of Regulation in the Low Dose

Guidelines from the National Academy of Sciences can assist when reevaluating critical assumptions such as the LNT model. In addition, the NRC has dedicated numerous publications to risk assessment over the past three decades. For example, in 2009 the Council released *Science and Decisions: Advancing Risk Assessment* in which an entire chapter was dedicated to the "Selection and Use of Defaults." Choosing scientific defaults has been defined as "trans science," that is, "questions which can be asked of science and yet which cannot be answered by science" (Wagner

1995). By their nature, then, many of the default assumptions on which regulatory agencies generally rely in their risk assessments have been subject to controversy over the years (National Research Council 2009). This problem has been recognized in NRC publications dating back to the 1983 *Risk Assessment in the Federal Government: Managing the Process*—the famous Red Book—and the 1994 *Science and Judgment in Risk Assessment.* In the chapter on defaults in the 2009 publication, the NRC makes the case for selecting sound default assumptions as summarized in the following four recommendations (National Resource Council 2009):

1. Have a clear choice of defaults to prevent inconsistency resulting from an ad hoc interpretation of the data across the agency's analysis. Further, a default assumption may be well chosen in general, but it is necessary to maintain flexibility in the application of defaults, as substance-specific data may justify a departure from defaults.
2. Invoke defaults for the steps of the risk assessment where it is necessary to make "inferences beyond those that can be clearly drawn from the available data or to otherwise fill common data gaps." "Inferences are needed when underlying biologic knowledge is uncertain or absent."
3. Maintain criteria "available for judging whether, in specific cases, data are adequate for direct use or to support an inference in place of a default."
4. Report and compare alternative risk estimates in the presence of a "comparably plausible" alternative assumption; abandon a default assumption in favor of an alternative assumption when the latter is determined to be "clearly superior" to the former, that is, "its plausibility clearly exceeds the plausibility of the default."

The NRC makes the analogy between the "clearly superior" standard for alternatives to the legal concept of "evidence beyond reasonable doubt." A similar analogy can be drawn for

this point where "comparably plausible" can be interpreted as the legal parlance "preponderance of evidence," or the 50 percent range of plausibility. The two points can be reasonably summarized as follows: when an alternative is comparatively plausible, quantitative model uncertainty should be characterized and presented in the risk assessment; on the other hand, when an alternative is clearly superior, it should, then, replace the default. The NRC further clarifies the *clearly superior* standard by saying, "The term *clearly superior* should not be interpreted quantitatively, but the committee notes that statistical P values can also be used as an analogy. For example, rejecting the null in favor of the alternative only when $P < 0.05$ could be viewed as insisting that the alternative hypothesis is 'clearly superior' to the 'default null.'"

In a manner consistent with the recommendations from the NRC outlined above, regulatory agencies can make a well-justified fresh assessment of their LNT default assumption. Though choosing a default may be necessary in cases where data is lacking, the NRC encourages abandoning a default for an alternative when evidence accumulates and identifies the alternative as a more appropriate assumption. To follow an objective process for determining the appropriate default, regulatory agencies should consider both bodies of evidence validating the LNT, threshold, and hormetic models. Specifically, regulatory bodies can base their decision on a systematic review of evidence methodology[8] to determine whether hormesis is a "comparatively plausible" or "clearly superior" alternative model to LNT.

If neither the LNT nor the hormetic model are deemed "clearly superior," and the systematic review instead reveals them to be "comparatively plausible," then regulatory agencies

[8] Systematic review of evidence, instead of weight of evidence, is the latest recommendation from the NRC (National Research Council 2011).

can develop a quantitative model uncertainty analysis in their risk assessment and update their protection standards accordingly.[9]

The LNT model has long been the model of choice for cancer (and since 2009, for $PM_{2.5}$) risk assessment. Choosing and adhering to a particular dose-response model may have been necessary for many reasons: to ensure consistency in analysis and avoid ad hoc interpretation of the data; to prevent halting valuable scientific inquiry in the face of scientific uncertainty or lack of technical ability; or to ensure protection of public health and safety when knowledge and consensus are lacking. As argued in this paper, however, since certain assumptions may drive much of the results of a risk assessment, periodic reflection on the choice of assumptions is necessary to ensure that the resulting risk management decision is optimal, given the existing information.

5. Implications of Tradeoff Analysis

The analysis of tradeoffs is foundational to economics and sound decision-making. Tradeoff analysis looks at the consequences of making a choice or taking an action. Every choice taken eliminates another choice that could have been taken instead, and every choice taken has both intended and unintended consequences. Tradeoff analysis, therefore, attempts to calculate how the weight of the intended consequences of an action taken compares to the weight of the unintended consequences of that action as well as the weight of consequences of forgone alternative actions.

Below we will discuss two types of tradeoffs, namely, risk-risk and health-health tradeoffs, which are essential for consideration in any risk analysis based on an LNT hypothesis.

[9] One proposal on how LNT and hormetic models can be harmonized to maximize public health protection is suggested in Calabrese, Shamoun, and Hanekamp (2015).

5.1. Risk-Risk Tradeoffs

The doctrine of better safe than sorry is commonly invoked to justify the use of the LNT model because the "conservative" LNT is more likely to overestimate average risk than a threshold or a hormetic model, but it isn't so simple. Any regulation of risky behavior can push consumers into other, sometimes riskier, behavior. Thus, it is important not to develop tunnel vision, focusing only on the risk at hand. Risk policies must always take risk tradeoffs into account and, at a minimum, ensure that there are no negative public health consequences.[10]

A risk-risk tradeoff happens when risk-reducing actions increase (or decrease) a non–target risk at the same time that a target risk is decreased. These changes in non–target risks—so-called countervailing and coincident risks—are usually unintended but are also often discoverable. Any risk management action will cause people to make different choices, whether because of a change in relative prices or because of a need to employ a different technology (Williams and Thompson 2004).

Risk-risk analysis (RRA) is a formal analytical framework that compares reductions in target risks with unintended increases or decreases in other risks resulting from the mitigation efforts. Countervailing risks are the negative side effects of risk mitigation efforts, while coincident risks are those risks that are likely to fall in tandem with the target risk. A popular example of a risk-risk tradeoff is the increase in the risk of a stomachache as a consequence of taking aspirin to reduce the risk of a headache continuing (Graham and Wiener 1995).

RRA frequently involves both risk assessment and economic analysis, so it must involve a combined effort of risk assessors and economists (Williams and Thompson 2004). Risk-risk

[10] There may be an overall positive public health change resulting from a risk decision that may still fail a benefit-cost test because of non–health-related costs.

tradeoffs add to the uncertainty surrounding the choice of a dose-response model because they complicate the effort to identify a public health-protective policy. Just as there are many low-dose response functions that could be derived from high-dose animal studies, so too there could be many behavioral responses induced by a new regulation. Exposure to new risks as one takes actions to avoid proscribed risks can turn a regulatory action into a public health hazard.[11]

Thus, the issue of whether changes in exposure to risks are producing public health negative or positive outcomes is complicated. As we move to reduce exposure to one hazard, other risks will increase; the crucial risk management question is whether countervailing risks will increase by more than the targeted and coincident risk reductions. We suspect, as do Graham and Wiener, "that risk tradeoffs are quietly hindering the effectiveness of the national campaign to reduce risk" (Graham and Wiener 1995). If we ignore these countervailing risks, we increase the chances of moving in the wrong public health direction. The uncertainty with LNT models acknowledged by considering risk-risk tradeoffs is illustrated in figure 2.

Often, a countervailing risk will result from people using a substitute compound for the one being regulated. Looking at figure 2, if we presume that the target and the substitute both have LNT dose-response curves, then our concern is how the reduction in exposure to the target hazard (from A to B)—which results in a change in risk (here a decrease in response from 1 to 2)—compares to the risk posed by the use of the substitute compound (here an increase in dose from C to D with an increase in response from 3 to 4). The issue becomes even more complicated when there is the possibility that the target or the substitute compound or both might possibly have a hormetic dose-response function. This possibility is illustrated in figure 3.

[11] For example, an FDA warning label requirement for raw unpasteurized juice resulted in juice being pasteurized or ceasing to be produced rather than in the addition of the warning labels (Food and Drug Administration 1998).

Figure 2. Uncertainty Created by Risk-Risk Tradeoffs, Assuming an LNT Model

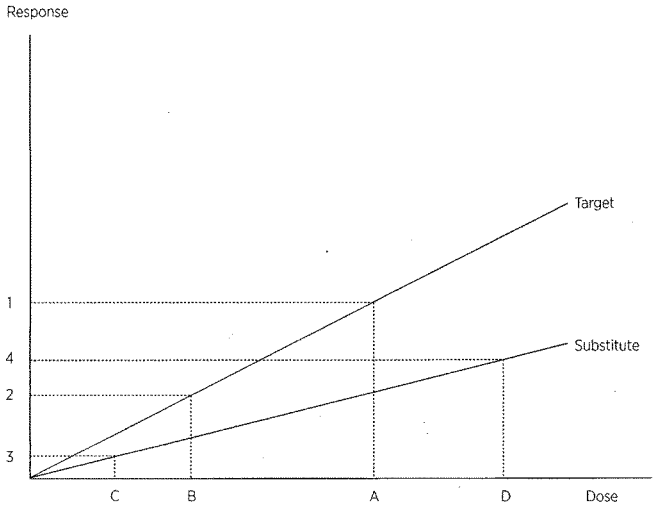
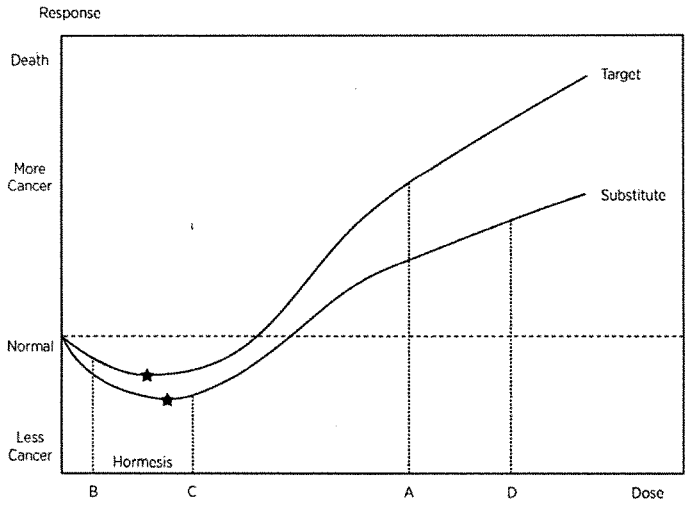


Figure 3. Uncertainty Created by Risk-Risk Tradeoffs, Assuming Hormesis



The stars at the bottom of the two curves represent the apex of the hormetic effect—that is, the optimal health response point. In this example, a decrease in exposure to the target compound from A to B not only decreases risk, it also increases the likelihood of a positive hormetic response, although past the optimal level. For the substitute compound, moving from C to D loses both the protective hormetic response *and* increases risk. Predicting the net effect on risk requires a great deal of information. Without such information, uncertainty may be so great as to make it unclear whether reductions in exposure to the target risk are producing public health positive or negative outcomes. Furthermore, the uncertainty involved in the shape and position of these functions on the two-dimensional dose-response plane makes decisions to improve public health considerably more uncertain.[12]

5.2. Health-Health Tradeoffs

As a general rule, the lower the level at which the mandated exposure to a risk is set, the higher the marginal cost of that mandate is likely to be, due to the economic phenomenon known as diminishing marginal returns. Since a large percentage of regulatory costs are translated into higher prices for goods and services, consumers will have lower real incomes and thus be less able to afford reducing the risks most relevant to them. The lower the levels of exposures chosen, the more it costs to comply (per unit of risk reduced) and the resulting higher prices reduce expenditures on private risk mitigation.

A subset of risk-risk analysis, known as health-health analysis (HHA), focuses on those countervailing risks that occur when regulatory costs reduce private expenditures that address

[12] Of course, consideration of the combined effects of multiple stressors, i.e., additive, antagonistic, and synergistic effects on either risk or hormetic effects, only further complicates the uncertainty.

personal health risks (Lutter and Morrall 1994). This effect alone can render a policy harmful to public health and, as discussed below, can also be regressive.

Vanderbilt Professor Kip Viscusi estimates that for each additional dollar of income earned (or lost), people tend to increase (or reduce) health-related expenditures by 10 cents; that is to say, an individual's marginal propensity to spend on health is roughly equal to 10 percent (Viscusi 1994). As people are obligated to incrementally spend more and more resources complying with regulations addressing public risks, they will respond by reducing expenditures on mitigating risks that they face in their private lives. At some point, if one takes enough income away from people and these losses are spread out across a large enough group, countervailing risks will increase by an amount sufficient to result in expected fatalities. One estimate of the magnitude of burden sufficient to induce one expected fatality is $92 million in 2016 dollars (Viscusi 1994).[13]

Such fatalities are not likely to be distributed evenly across society. Ralph Keeney has shown that such cost-induced fatalities fall disproportionately on those with lower incomes, including some minority groups (Keeney 1994). Conversely, if health and safety goods have diminishing marginal effectiveness, then spending the first dollars yields the largest return (e.g., spending on doctor's visits before spending on a car with a rear-view camera), which, in turn, means that the dollars spent by the lower-income population are the most effective at reducing health and mortality risks. As such, it is important to consider distributional effects in terms of who is bearing the costs and who is enjoying the benefits of risk mitigation. This is a more compelling

[13] This is known as a "statistical fatality" and refers to the adding up of small probabilities of death to one. That is, if 1,000 people stop making expenditures that will prevent a 1 in 1,000 risk of death, then there is the expectation that one "statistical death" will occur, although the identity of the deceased is unknown. The $92 million estimate is adjusted for inflation from $50 million in 1990 dollars, using the Consumer Price Index.

reason why inter-individual variability may be important. Indeed, presidential executive orders currently in effect also require agencies to consider such distributional impacts of regulations.[14] Since many of the benefits of reducing target risks will accrue to concentrated groups of the exposed population, while dispersed populations will realize increases in countervailing risks in addition to the costs of regulatory action,[15] policies with these kinds of differential impacts may be more likely to yield negative public health outcomes in the aggregate.

5.3. Risk and Health Tradeoffs in Practice

An example of how risk-risk and health-health tradeoffs can inform a decision to manage pathogenic risks comes from the consumption of raw oysters. Raw oyster consumption, especially from the warm waters of the Gulf of Mexico, results in approximately 30 deaths each year and more than twice that number of illnesses (Kuchler et al. 1999). One option to reduce this risk would be to restrict consumption of raw oysters during certain months of the year (e.g. March through November) when the pathogen is present at high doses. With perfect enforcement, this would essentially eliminate the target risk of vibrio Vulnificus, the pathogen in question. But two tradeoffs arise.

The first is a risk-risk tradeoff from switching to substitutes, that is, what people eat instead of raw oysters. All foods contain some risk from exposure to microbial, chemical, nutritional, and physical hazards, and there may be other kinds of raw seafood, such as sushi, with which people would replace oysters. One must account for the risks posed by these substitutes.

---

[14] See, for example, President Clinton's Exec. Order No. 12866, 3 C.F.R. 76 (1993); President Obama's Exec. Order No. 13563, 3 C.F.R. 58 (2011).

[15] For example, US ethanol rules increased corn prices, which reduced purchasing power for lower-income households around the world (Abdukadirov 2015). The general phenomenon of concentrated benefits and dispersed costs is discussed in Olson (1965).

The second is a health-health tradeoff from reduction in income. Because the typical oyster harvester's job skills are not readily transferable, these individuals would suffer an income loss—perhaps for prolonged periods—if oyster consumption were restricted (Kuchler et al. 1999). Research by Ralph Keeney and others has shown how income loss can cause health problems due to increased alcoholism, depression, and even suicide. Such income effects can lead to a reduction in expenditures meant to reduce personal risks, such as buying safer cars, living in safer neighborhoods, purchasing smoke detectors and baby gates, paying for preventive medical visits, and other risk-reducing products (Keeney 1994).

Pesticide standards are another nuanced example. If banning certain pesticides forces a switch to more expensive pesticides, the price of fruits and vegetables will increase (Gray and Graham 1997). Higher-priced fruits and vegetables may induce marginal consumers to switch to a cheaper but less healthful substitute. The inframarginal consumers, on the other hand—those who elect to keep eating fruits and vegetables despite the higher price—are now made poorer and less able to address their personal risks. Farmers' incomes may suffer as well, due to the higher production costs or a net decrease in demand.

6. Conclusion

Risk assessments were originally meant to give risk managers information that would allow them to choose policies that would unambiguously reduce risks and thereby protect public health. Risk assessments for both radiation and chemical exposure that employ conservative defaults, most particularly the LNT model, seemed to provide a ready-made safe level of exposure to a target risk to achieve this goal. The so-called "safety factors" were also meant to be conservative divisors to accomplish the same effect.

But as regulation has expanded and regulatory exposure limits have reached lower and lower levels, it is no longer possible to ignore the evidence of the biological implausibility of the one-hit model as well as the increasing evidence in favor of hormesis. A default model that inaccurately characterizes risk is a problem not just because the model could be wrong, but also because it could lead to adverse consequences to public health. This follows from the fact that risk management choices must take into account the health consequences of countervailing risks and health-health tradeoffs. These tradeoffs, in some cases, can be sufficient to offset the positive effects of target risk reductions, a consequence that becomes more likely when already-low target risks are overestimated.

Appendix: Major Historical Points Leading to the Adoption of the LNT Model

Year	Author/institution	Event
1859	Charles Darwin	• Publishes *On the Origin of Species*. • Initiates interest in the biological community to determine the cause of genetic change that drives natural selection.
1927	Hermann J. Muller	• X-rays induce mutation in fruit flies.
1928	Olson and Lewis	• LNT model proposed to account for evolutionary changes. • Follows Muller's discovery that X-rays can induce mutations in fruit fly germ cells.
1930	Hermann J. Muller	• Develops proportionality rule (i.e., linear dose response) for ionizing radiation-induced mutagenicity.
1935	Timoféeff-Ressovsky et al.	• Application of radiation target theory for mutagens. • Use target theory to propose a one-hit theory for ionizing radiation-induced mutation. The hit mechanism is used to explain the LNT dose response.
1956	Biological Effects of Ionizing Radiation Committee (BEIR I), Genetics Panel	• Proposes the use of the linear dose-response model for germ cell mutation, using the "doubling rule."
1961	Mantel and Bryan	• Develop carcinogen risk assessment model based on the probit model. • This is undertaken to advise US government agencies on chemical risk assessment.
1973	FDA	• Proposes a probit-based quantitative risk assessment method for cancer risk based on the 1961 Mantel and Bryan paper.
1976	EPA	• Proposes guidelines for cancer risk assessment based on quantitative risk assessment. • Recommends a linear dose-response model.
1977	FDA	• Retains the Mantel-Bryan model with some modifications. • Acceptable risk value is changed to 10^{-6}.
1977	US National Academy of Science's NAS) Safe Drinking Water Committee	• Recommends that EPA adopt LNT model for carcinogen risk assessment. • This recommendation is significant, given the widespread multimedia regulatory functions of EPA. Within two years of the recommendation, EPA applies LNT model to the regulations of trihalomethanes (e.g., chloroform) in drinking water.

continued on next page

Year	Author/institution	Event
1979	FDA	• Replaced the modified Mantel-Bryan model with the LNT model for carcinogen risk assessment, based on the following reasons: o Linear procedure is least likely to underestimate risk. o Linear extrapolation does not require complicated mathematical procedures. o No arbitrary slope is needed to carry out linear extrapolation. o Several significant limitations had been found with the application of the Mantel-Bryan model.
1979	EPA	• Establishes a national drinking water standard for trihalomethanes (including chloroform). • This is based on an LNT methodology as recommended by the US NAS Safe Drinking Water Committee (1977).

Note: Table is constructed from discussion in Edward J. Calabrese, 2013. "Origin of the Linearity No Threshold (LNT) Dose-Response Concept." *Archives of Toxicology* 87 (9): 1621–33.

Bibliography

AAPM (American Association of Physicists in Medicine). 2011. "AAPM Position Statement on Radiation Risks from Medical Imaging Procedures." December 13.

Abbott, Alison. 2015. "Researchers Pin Down Risks of Low-Dose Radiation." *Nature* 523 (7558): 17–18.

Abdukadirov, Sherzod. 2015. "Risky Business: When Safety Regulations Cause Harm." *William and Mary Policy Review* 6 (1): 1–21.

Agrawal, Tanupriya. 2014. "Pre-Conditioning with Low-Level Laser (Light) Therapy." In *Preconditioning: Adaptive Responses in Biology and Medicine.* 13th Annual International Conference on Dose-Response, University of Massachusetts at Amherst, April 22–23.

Ames, Bruce N., and Lois Swirsky Gold. 1990. "Misconceptions on Pollution and the Causes of Cancer." *Angewandte Chemie International Edition in English* 29: 1197–208.

Anderson, E. L., and the Carcinogen Assessment Group of the U.S. Environmental Protection Agency. 1983. "Quantitative Approaches in Use to Assess Cancer Risk." *Risk Analysis* 3: 277–95.

Armitage, P., and R. Doll. 1957. "A Two-Stage Theory of Carcinogenesis in Relation to the Age Distribution of Human Cancer." *British Journal of Cancer* 11 (2): 161–69.

Bailar, John C. III, Edmund A. C. Crouch, Rashid Shaikh, and Donna Spiegelman. 1988. "One-Hit Models of Carcinogenesis: Conservative or Not?" *Risk Analysis* 8 (4).

Berrington de González, Amy, Mahadevappa Mahesh, Kwang-Pyo Kim, Mythreyi Bhargavan, Rebecca Lewis, Fred Mettler, and Charles Land. 2009. "Projected Cancer Risks from Computed Tomographic Scans Performed in the United States in 2007." *Archives of Internal Medicine* 169 (22): 2071–77.

Bruce, R. D., W. W. Carlton, K. H. Ferber, D. H. Hughes, J. F. Quast, D. S. Salsburg, and J. M. Smith. 1981. "Re-Examination of the ED01 Study: Adjusting for Time on Study." *Fundamental and Applied Toxicology* 1 (1): 67–80.

Calabrese, Edward J. 2008. "Hormesis: Why It Is Important to Toxicology and Toxicologists." *Environmental Toxicology and Chemistry* 27 (7): 1451–74.

———. 2013a. "Hormetic Mechanisms." *Critical Reviews in Toxicology* 43 (7): 580–606.

———. 2013b. "Origin of the Linearity No Threshold (LNT) Dose-Response Concept." *Archives of Toxicology* 87 (9): 1621–33.

———. 2015. "Preconditioning Is Hormesis Part II: How the Conditioning Dose Mediates Protection: Dose Optimization within Temporal and Mechanistic Frameworks." *Pharmacological Research.* doi:10.1016/j.phrs.2015.12.020.

———. 2016. "Preconditioning Is Hormesis Part I: Documentation, Dose-Response Features and Mechanistic Foundations." *Pharmacological Research*. doi:10.1016/j.phrs.2015.12.021.

Calabrese, Edward J., and Linda A. Baldwin. 2003. "The Hormetic Dose-Response Model Is More Common Than the Threshold Model in Toxicology." *Toxicological Sciences* 71 (2): 246–50.

Calabrese, Edward J., Gaurav Dhawan, and Rachna Kapoor. 2014. "Use of X-Rays to Treat Shoulder Tendonitis/Bursitis: A Historical Assessment." *Archives of Toxicology* 88 (8): 1503–17.

Calabrese, Edward J., and Mark P. Mattson. 2011. "Hormesis Provides a Generalized Quantitative Estimate of Biological Plasticity." *Journal of Cell Communication and Signaling* 5 (1): 25–38.

Calabrese, Edward J., and Michael K. O'Connor. 2014. "Estimating Risk of Low Radiation Doses—a Critical Review of the BEIR VII Report and Its Use of the Linear No-Threshold (LNT) Hypothesis." *Radiation Research* 182 (5): 463–74.

Calabrese, Edward J., Dima Y. Shamoun, and Jaap C. Hanekamp. 2015. "Cancer Risk Assessment: Optimizing Human Health through Linear Dose-Response Models." *Food and Chemical Toxicology* 81: 137–40.

———. 2016. "The Integration of LNT and Hormesis for Cancer Risk Assessment Optimizes Public Health Protection." *Health Physics* 110 (3): 256–59.

Calabrese, Edward J., Edward J. Stanek III, Marc A. Nascarella, and George R. Hoffmann. 2008. "Hormesis Predicts Low-Dose Responses Better Than Threshold Models." *International Journal of Toxicology* 27 (5): 369–78.

Cardis, E., M. Vrijheid, M. Blettner, E. Gilbert, M. Hakama, C. Hill, G. Howe, et al. 2007. "The 15-Country Collaborative Study of Cancer Risk among Radiation Workers in the Nuclear Industry: Estimates of Radiation-Related Cancer Risks." *Radiation Research* 167 (4): 396–416.

Cohen, B. L. 1995. "Test of the Linear-No Threshold Theory of Radiation Carcinogenesis for Inhaled Radon Decay Products." *Health Physics* 68 (2): 157–74.

Cox, Louis Anthony. 2012. "Hormesis for Fine Particulate Matter (Pm 2.5)." *Dose-Response* 10 (2): 209–18.

Crump, K. S. 1984. "An Improved Procedure for Low-Dose Carcinogenic Risk Assessment from Animal Data." *Journal of Environmental Pathology, Toxicology, and Oncology* 5 (4–5): 339–48.

Driver, H. E., I. N. White, and W. H. Butler. 1987. "Dose-Response Relationships in Chemical Carcinogenesis: Renal Mesenchymal Tumours Induced in the Rat by Single Dose Dimethylnitrosamine." *British Journal of Experimental Pathology* 68 (2): 133–43.

EPA (Environmental Protection Agency). 1976. Health Risk and Economic Impact Assessment of Suspected Carcinogens. Interim Procedures & Guidelines. 42 Fed. Reg. 21402–5.

———. 1979. Control of Trihalomethanes in Drinking Water. National Interim Primary Drinking Water Regulations. 4 Fed. Reg. 231: 68624–710.

———. 2005. "*Guidelines for Carcinogen Risk Assessment.*" Washington, DC: EPA.

FDA (Food and Drug Administration). 1973. Compounds Used in Food-Producing Animals. Procedures for Determining Acceptability of Assay Methods Used for Assuring the Absence of Residues in Edible Products of Such Animals. Proposed rule. 19 Fed. Reg. 19226–30.

———. 1979. Chemical Compounds in Food Producing Animals. Criteria and Procedures for Evaluating Assays for Carcinogenic Residues [Docket No. 77 N-0026], 44 Fed. Reg. 17070–114.

———. 1993. "Advances in the Development of Alternatives to Whole Animal (Vertebrate) Testing." http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/IngredientsAdditivesGRASPackaging/UCM078780.pdf.

———. 1998. Labeling of Juice Products: Final Rule. 63 Fed. Reg. 37030 (July 8).

Finkel, Adam M. 2014. "EPA Underestimates, Oversimplifies, Miscommunicates, and Mismanages Cancer Risks by Ignoring Human Susceptibility." *Risk Analysis* 34 (10): 1785–94.

Fukushima, Shoji, Anna Kinoshita, Rawiwan Puatanachokchai, Masahiko Kushida, Hideki Wanibuchi, and Keiichirou Morimura. 2005. "Hormesis and Dose-Response-Mediated Mechanisms in Carcinogenesis: Evidence for a Threshold in Carcinogenicity of Non-Genotoxic Carcinogens." *Carcinogenesis* 26 (11).

Graham, John D., and Jonathan Baert Wiener, eds. 1995. *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment.* Cambridge, MA: Harvard University Press.

Gray, George M., and John D. Graham. 1995. "Regulating Pesticides." In *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment.* Edited by John D. Graham and Jonathan Baert Wiener. Cambridge, MA: Harvard University Press.

Hanawalt, Philip C. 1994. "Evolution of Concepts in DNA Repair." *Environmental and Molecular Mutagenesis* 23 (Suppl 24): 78–85.

Hayworth, C. R., J. C. Rojas, E. Padilla, G. M. Holmes, E. C. Sheridan, and F. Gonzalez-Lima. 2010. "In Vivo Low-Level Light Therapy Increases Cytochrome Oxidase in Skeletal Muscle." *Photochemistry and Photobiology* 86 (3): 673–80.

Keeney, Ralph L. 1994. "Mortality Risks Induced by the Costs of Regulations." *Journal of Risk and Uncertainty* 8: 95–110.

Kirsch-Volders, Micheline, Marilyn Aardema, and Azeddine Elhajouji. 2000. "Concepts of Threshold in Mutagenesis and Carcinogenesis." *Mutation Research* 464 (1): 3–11.

Kuchler, Fred, Jackqueline L. Teague, Richard A. Williams, and Don W. Anderson. 1999. "Health Transfers: An Application of Health-Health Analysis to Assess Food Safety Regulations." *Risk* 10 (4): 315.

Kuzmack, Arnold M., and Robert E. McGaughy. 1975. Quantitative Risk Assessment for Community Exposure to Vinyl Chloride. Environmental Protection Agency.

Lutter, Randall, and John F. Morrall III. 1994. "Health-Health Analysis: A New Way to Evaluate Health and Safety Regulation." *Journal of Risk and Uncertainty* 8 (1): 43–66.

Mattson, Mark P., and Edward J. Calabrese, eds. 2010. *Hormesis: A Revolution in Biology, Toxicology, and Medicine*. New York: Springer.

Moolgavkar, Suresh H., and Alfred G. Knudson Jr. 1981. "Mutation and Cancer: A Model for Human Carcinogenesis." *Journal of the National Cancer Institute* 66 (6): 1037.

Moolgavkar, Suresh H., and David J. Venzon. 1979. "Two-Event Models for Carcinogenesis: Incidence Curves for Childhood and Adult Tumors." *Mathematical Biosciences* 47 (1–2): 55–77.

Muller, H. J. 1922. "Variation Due to Change in the Individual Gene." *American Naturalist* 56: 32–50.

National Research Council. 1983. *Risk Assessment in the Federal Government: Managing the Process*. Washington, DC: National Academy Press.

———. 1994. *Science and Judgment in Risk Assessment.* Washington DC: National Academies Press. Doi:10.17226/2125.

———. 2009. *Science and Decisions: Advancing Risk Assessment.* Washington, DC: National Academies Press.

———. 2011. *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde.* Washington, DC: The National Academies Press.

Neyman, Jerzy, and Elizabeth L. Scott. 1967. "Statistical Aspect of the Problem of Carcinogenesis." *Berkeley Symposium on Mathematical Statistics and Probability* 4: 745–76.

Nomiya, Takuma. 2013. "Discussions on Target Theory: Past and Present." *Journal of Radiation Research* 54 (6): 1161–63.

Nuclear Regulatory Commission. 2015. Linear No-Threshold Model and Standards for Protection against Radiation. 80 Fed. Reg. 35870 (June 23).

Office of Management and Budget. 2007. "Updated Principles for Risk Analysis" (Memorandum M-07-24).

Office of Science and Technology Policy. 1985. Chemical Carcinogens: Review of the Science and Its Associated Principles. 50 Fed. Reg. 10372–442.

Olson, A. R., and G. N. Lewis. 1928. "Natural Reactivity and the Origin of Species." *Nature* 121: 673–74.

Olson, Mancur Jr. 1965. *The Logic of Collective Action*. Cambridge, MA: Harvard University Press.

Patterson, J. T. 1928. "The Effects of X-Rays in Producing Mutations in the Somatic Cells of Drosophila Melanogaster." *Science* 68 (1750): 41–43.

Ropeik, David. 2013. "Fear vs. Radiation: The Mismatch." *New York Times*, October 21.

Sacks, Bill, Gregory Meyerson, and Jeffry A. Sigel. 2016. "Epidemiology without Biology: False Paradigms, Unfounded Assumptions, and Specious Statistics in Radiation Science (with Commentaries by Inge Schmitz-Feuerhake and Christopher Busby and a Reply by the Authors." *Biological Theory* 11 (2): 69–101.

Scala, Robert A. 1991. "Risk Assessment." In *Casarett and Doull's Toxicology: The Basic Science of Poisons*. Edited by Mary O. Amdur, John Doull, and Curtis D. Klaassen. New York: McGraw-Hill, 985–96.

Shao, M., X. Lu, W. Cong, X. Xing, Y. Tan, Y. Li, X. Li, L. Jin, X. Wang, J. Dong, S. Jin, C. Zhang, and L. Cai. 2014. "Multiple Low-Dose Radiation Prevents Type 2 Diabetes-Induced Renal Damage through Attenuation of Dyslipidemia and Insulin Resistance and Subsequent Renal Inflammation and Oxidative Stress." *PLoS One* 9 (3): e92574.

Sukata, Tokuo, Satoshi Uwagawa, Keisuke Ozaki, Motome Ogawa, Takayuki Nishikawa, Syuji Iwai, Anna Kinoshita, Hideki Wanibuchi, Susumu Imaoka, Yoshihiko Funae, Yasuyoshi Okuno, and Shoji Fukushima. 2002. "Detailed Low-Dose Study of 1,1-bis(p-chlorophenyl)-2,2,2-trichloroethane Carcinogenesis Suggests the Possibility of a Hormetic Effect." *International Journal of Cancer* 99 (1).

Tao, Z., Y. Cha, and Q. Sun. 1999. "[Cancer Mortality in High Background Radiation Area of Yangjiang, China, 1979–1995]." *Zhonghua Yi Xue Za Zhi* 79 (7): 487–92.

Taubes, G. 1995. "Epidemiology Faces Its Limits." *Science* 269 (5221): 164–69.

Thompson, Richard E., Donald F. Nelson, Joel H. Popkin, and Zenaida Popkin. 2008. "Case-Control Study of Lung Cancer Risk from Residential Radon Exposure in Worcester County, Massachusetts." *Health Physics* 94 (3): 228–41.

Thorsland, Todd W., Charles C. Brown, and Gail Charnley. 1987. "Biologically Motivated Cancer Risk Models." *Risk Analysis* 7 (1): 109–19.

Timoféeff-Ressovsky, N.W., K. G. Zimmer, and M. Delbruck. 1935. "On the Nature of Gene Mutation and Gene Structure." Göttingen: Mathematische-Physikalische Klass, Fachgruppe VI, *Biologie* 1: 189–245.

Train, R. 1976. "Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens." Office of the Administrator, Environmental Protection Agency.

Truzzi, Marcello. 1987. "On Pseudo-Skepticism." *Zetetic Scholar*, 12–13: 2–4.

Viscusi, W. Kip. 1994. "Mortality Effects of Regulatory Costs and Policy Evaluation Criteria." *RAND Journal of Economics* 25 (1).

Wagner, Wendy E. 1995. "The Science Charade in Toxic Risk Regulation." *Columbia Law Review* 95 (7): 1613–723.

Watson, J. D., and F. H. C. Crick. 1953. "Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid." *Nature* 171 (4356): 737–38.

Weiss, Joseph. 1944. "Radiochemistry of Aqueous Solutions." *Nature* 153: 748–50.

Williams, R., and K. Thompson. 2004. "Integrated Analysis: Combining Risk and Economic Assessments While Preserving the Separation of Powers." *Risk Analysis* 24 (6): 1613–23.

Q **Is President Obama's climate action plan a priority for the Department of Energy?**

A **Yes, it is.**

Q **And is that a greater priority than the low-dose radiation program?**

A **To the extent that we align our basic research efforts towards that goal, yes.**

Document submitted by Representative Randy Weber