

THE FUTURE OF LOW DOSE RADIATION RESEARCH

HEARING BEFORE THE SUBCOMMITTEE ON ENERGY COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY HOUSE OF REPRESENTATIVES ONE HUNDRED FIFTEENTH CONGRESS

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THE FUTURE OF LOW DOSE RADIATION RESEARCH

Wednesday, November 1, 2017

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

The Subcommittee met, pursuant to call, at 10:38 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Randy Weber [Chairman of the Subcommittee] 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

Subcommittee on Energy

The Future of Low Dose Radiation Research

Wednesday, November 1, 2017

10:00 a.m.

2318 Rayburn House Office Building

Witnesses

Mr. John Neumann, Director of Science and Technology Issues,
Government Accountability Office

Dr. Gayle Woloschak, Professor of Radiation Oncology and Radiology,
Northwestern University

Dr. James Brink, Professor of Radiology, Harvard Medical School,
Radiologist-in-Chief, Massachusetts General Hospital

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

Friday, October 27, 2017

TO: Members, Subcommittee on Energy
FROM: Majority Staff, Committee on Science, Space, and Technology
SUBJECT: Subcommittee hearing: “The Future of Low Dose Radiation Research”

The Subcommittee on Energy will hold a hearing titled *The Future of Low Dose Radiation Research* on Wednesday, November 1, 2017, at 10:00 a.m. in Room 2318 of the Rayburn House Office Building.

Hearing Purpose:

The purpose of this hearing is to explore the status of basic research on low dose radiation in the United States, including the previous Administration’s decision to cease funding for research in this area. This hearing will also examine the recommendations of the Government Accountability Office (GAO) study entitled “Low Dose Radiation: Interagency Collaboration on Planning Research Could Improve Information on Health Effects” released on October 26, 2017. Currently, there is a lack of consensus within the scientific community on the specific health risks associated with exposure to low doses of ionizing radiation.¹ This gap in understanding has profound implications for U.S. medical, industrial, commercial, and defense-related activities. Despite the apparent need for continued research in the field, DOE funding for low dose research steadily decreased from FY 2012 to FY 2015. In FY 2016, the DOE Office of Science ended its low dose program.

Witness List

- **Mr. John Neumann**, Director of Science and Technology Issues, Government Accountability Office
- **Dr. Gayle Woloschak**, Professor of Radiation Oncology and Radiology, Northwestern University
- **Dr. James Brink**, Professor of Radiology, Harvard Medical School, Radiologist-in-Chief, Massachusetts General Hospital

Staff Contact

For questions related to the hearing, please contact Hillary O’Brien of the Majority Staff at 202-226-8984.

¹ Preston et al. “Uncertainties in estimating health risks associated with exposure to ionizing radiation.” J Radiol Prot. 2013. Available at <https://www.ncbi.nlm.nih.gov/pubmed/23803503>

Chairman WEBER. The Subcommittee on Energy will come to order.

Without objection, the Chair is authorized to declare recesses of the Subcommittee at any time.

Welcome to today's hearing entitled "The Future of Low Dose Radiation Research." I now recognize myself for five minutes for an opening statement.

Good morning. Welcome to today's Energy Subcommittee hearing. Today, we will examine the status of U.S. research in low dose radiation and explore the effects of the previous Administration's agency-wide reduction in funding for this area of science.

Last Congress, the Science Committee explored the Department of Energy's decision to terminate the Low dose Radiation Research program, which, until its closure in 2016, was one of the largest and most effective programs in the world. In the course of staff briefings on this decision, a DOE employee was fired for speaking out in support of the Low Dose Radiation Research program. While this employee was eventually reinstated as a result of Committee oversight, the Department has yet to restart this important area of research.

The DOE's program explored the health impacts of low levels of radiation, allowing our Nation's researchers, industry, and military to safely handle nuclear material, maintain the nation's nuclear weapons program, and dispose of nuclear waste.

Low dose radiation research can also inform the authorities who set nuclear safety standards for the public, enabling federal emergency response agencies to more accurately set evacuation zones from radiological incidents.

This research is also particularly important to practicing physicians, who rely on knowledge about the impact of low doses of radiation to decide when and how to use diagnostics to detect cancer in patients.

This use-inspired, basic research leads to scientific discoveries and long-term benefits for the energy industry and our national defense.

Today's hearing is yet another opportunity to evaluate whether we as a nation are doing everything we can to ensure that the regulations, guidelines, and protections we put in place are indeed grounded in sound science.

We know a lot about the relationship between adverse health effects and high doses of radiation. At high doses, the dosage and risk are proportionally related. But the health risks associated with exposure to low doses of radiation are much more difficult to observe, and we are a long way away from understanding and accurately assessing this particular risk.

In the absence of conclusive evidence, scientists use what's called the linear-no-threshold (LNT) model to approximate the effects of low doses of radiation on the human body. This model takes what we know about high doses and applies it to low doses. Current federal dose limits and guidelines are based on the LNT model. Because this model is simply an assumption of the impact, not a validated mechanism for assigning risk, there is no definitive science to justify many of our nation's nuclear safety procedures or to set guidelines for medical treatments.

In order to best serve our nation's energy, medical and defense needs, we need foundational research in radiology and biology to directly define the impact of low doses of radiation.

Here on the Science Committee, we hear a lot of enthusiasm for next-generation technologies but we cannot forget about the questions we have left unanswered. The United States should not rely on a best approximation when it comes to our nuclear regulatory policies.

DOE must reprioritize basic research in low dose radiation so we know we are using the best available science to set these standards.

I want to thank our accomplished panel in advance, our witnesses, for testifying today, and I look forward to a productive discussion about the future of American low dose radiation research.

[The prepared statement of Chairman Weber follows:]



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

For Immediate Release
 November 1, 2017

Media Contacts: Thea McDonald, Brandon VerVelde
 (202) 225-6371

Statement from Chairman Randy Weber (R-Texas)

The Future of Low Dose Radiation Research

Chairman Weber: Good morning and welcome to today's Energy Subcommittee hearing. Today, we will examine the status of U.S. research in low dose radiation and explore the effects of the previous administration's agency-wide reduction in funding for this area of science.

Last Congress, the Science Committee explored the Department of Energy's (DOE) decision to terminate the Low Dose Radiation Research program, which, until its closure in 2016, was one of the largest and most effective programs in the world.

In the course of staff briefings on this decision, a DOE employee was fired for speaking out in support of the low dose radiation research program. While this employee was eventually reinstated as a result of Committee oversight, the Department has yet to re-start this important area of research.

The DOE's program explored the health impacts of low levels of radiation, allowing our nation's researchers, industry and military to safely handle nuclear material, maintain the nation's nuclear weapons program, and dispose of nuclear waste. Low dose radiation research can also inform the authorities who set nuclear safety standards for the public, enabling federal emergency response agencies to more accurately set evacuation zones from radiological incidents.

This research is also particularly important to practicing physicians, who rely on knowledge about the impact of low doses of radiation to decide when and how to use diagnostics to detect cancer in patients.

This use-inspired, basic research leads to scientific discoveries and long-term benefits for the energy industry and our national defense. Today's hearing is yet another opportunity to evaluate whether we as a nation are doing everything we can to ensure that the regulations, guidelines and protections we put in place are grounded in sound science.

We know a lot about the relationship between adverse health effects and high doses of radiation. At high doses, the dosage and risk are proportionally related.

But the health risks associated with exposure to low doses of radiation are much more difficult to observe, and we are a long way away from understanding and accurately assessing this risk.

In the absence of conclusive evidence, scientists use what's called the Linear-no-threshold (LNT) model to approximate the effects of low dose radiation on the human body. This model takes what we know about high doses and applies it to low doses.

Current federal dose limits and guidelines are based on the LNT model. Because this model is simply an assumption of the impact, not a validated mechanism for assigning risk, there is no definitive science to justify many of our nation's nuclear safety procedures or to set guidelines for medical treatments.

In order to best serve our nation's energy, medical and defense needs, we need foundational research in radiology and biology to directly define the impact of low doses of radiation.

Here on the Science Committee, we hear a lot of enthusiasm for next generation technologies. But we can't forget about the questions we have left unanswered.

The U.S. should not rely on a "best approximation" when it comes to our nuclear regulatory policies. DOE must re-prioritize basic research in low dose radiation so we know we are using the best available science to set these standards.

I want to thank our accomplished panel of witnesses for testifying today, and I look forward to a productive discussion about the future of American low dose radiation research.

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Chairman WEBER. I now recognize the Ranking Member, the gentleman, for his comments.

Mr. FOSTER. Thank you, Chairman Weber—

Chairman WEBER. I'm sorry. The—you're right, the Ranking Member.

Mr. FOSTER. Well, I'm the Ranking Member pro tem, I believe.

Chairman WEBER. I think that's what it is.

Mr. FOSTER. Well, I guess representing 100 percent of the Ph.D. scientists in Congress.

Chairman WEBER. There we go.

Mr. FOSTER. Anyway, I want to thank you for holding this hearing on a really very interesting and important topic, and thank you to all our witnesses for being here to provide us with your testimony and your expertise. I'm Congressman Bill Foster. I'm a scientist and a businessman, so I understand the importance of regulatory costs and getting the answer right.

This is an important issue because if you make the wrong decision or a decision not based on the best science, you know, frankly, people can die. If you set too conservative thresholds for chest X-rays, then patients may have non-diagnosed conditions because of X-rays that are not taken. If you, for example, set too conservative standards for nuclear workers, then it may impose—or nuclear bystanders—that may impose large costs on the nuclear industry and cause us to shift our energy balance, for example, to coal which we know kills tens of thousands of Americans each year.

And so it's important to get this answer right. The basis of our regulatory framework around radiation exposure has been the linear no-threshold model, which I'm sure we'll hear all about today, and that says the risk of cancer and other bad effects increases with every incremental increase in radiation exposure. So this conservative approach to regulation is not fully justified by the current body of peer-reviewed scientific literature in the low dose regime and investing into this research in this field is not just about the development of regulations, it's all about public understanding of an important issue.

Federal investments in radiobiology research have resulted in significant progress in our understanding of the health effects to low dose radiation, in particular, how cells respond to radiation exposure on a molecular level.

During the past 17 years, the Low Dose Radiation Research program at the Department of Energy has been responsible for several notable shifts in how scientists examine the impacts of radiation exposure including the impact on radiation not only on the cells directly deposited with energy but on the cells surrounding them, so-called bystander cells. There's also a new technology that has become available. The use of Big Data, for example, to perform virtual experiments on large human populations to try to tease out the signal here, or for example, gene sequencing of blood samples to detect cancer and precancerous cells at a preclinical level.

This work has informed our physicians and medical researchers as they try to design better treatments for cancer patients, and moreover, the implication of this research can be seen in the number and the breadth of different federal agencies that are investing in this work. In addition to the Department of Energy, there have

been federal investments in low dose radiation research at the Nuclear Regulatory Commission, the FDA, the Environmental Protection Agency, and the National Institutes of Health, NASA and the CDC. These agencies all see benefits from this work, and in their own areas of interest.

Yet the leadership in DOE under the past Administration and I should note, under the current Trump Administration as well, has decided to no longer support this research, and I'm happy to join my Majority colleagues with our questioning of this position, and we are not alone in our concerns. The GAO's report on this topic seemed very clear. They recommend that DOE take the lead in "the development of a mechanism of interagency collaboration on research on low dose radiation's health effects." Though I must observe that one of the, you know, glaring omissions from this hearing is a witness from the Department of Energy. We're reviewing a report from GAO that includes key recommendations for DOE, and it is sad that we're here without a representative from the Department to provide us with their input on these recommendations, and it's really a missed opportunity. I'm disappointed that we can't have a more complete conversation here, and hopefully make real progress in our oversight of the Department in this crucial area of research.

I hope the Majority will consider as we move forward with additional hearings on this topic or others directly under the purview of DOE the Department's lack of a Senate-confirmed leadership really shouldn't give us—give them immunity from Congressional oversight.

And with that said, I'm looking forward to this bipartisan dialogue on an important topic, and thank you again, Mr. Chairman and our witnesses.

[The prepared statement of Mr. Foster follows:]

OPENING STATEMENT
Representative Bill Foster (D-IL)

House Committee on Science, Space, and Technology
 Subcommittee on Energy
"The Future of Low Dose Radiation Research"
 November 1, 2017

Thank you Chairman Weber for holding this hearing on a very interesting topic. And thank you to the witnesses for being here to provide us with your testimony and expertise. I'm Congressman Bill Foster. I'm a scientist and a businessman and I'm glad to be with you today to discuss this important topic.

The basis of our regulatory framework around radiation exposure is the linear no-threshold model, which, as I am sure we will hear more about today, says that the risk of cancer increases with every incremental increase in radiation exposure. This conservative approach to regulation is frankly not well justified by the current body of peer-reviewed scientific literature in the low dose regime. But investing in research in this field is not just about the development of regulations. Federal investments in radiobiology research have resulted in significant progress in our understanding of the health effects of exposure to low dose radiation, in particular how cells respond to radiation exposure on a molecular level.

During the past 17 years, the low dose radiation research program at the Department of Energy has been responsible for several notable shifts in how scientists examine the impacts of radiation exposure, including the impact radiation has not only on the cells directly deposited with energy, but also the cells surrounding them, the "bystander" cells. This work has informed our physicians and medical researchers as they try to design better treatments for cancer patients. Moreover, the implications of this research can be seen in the number and breadth of federal agencies that invest in this work.

In addition to the Department of Energy, there have been federal investments in low dose radiation research at the Nuclear Regulatory Commission, the Food and Drug Administration, the Environmental Protection Agency, the National Institutes of Health, NASA, and the CDC. These agencies all see benefits from this work in their own areas of interest. Yet leadership at DOE in the past Administration – and I should note for the Majority, the current Administration as well – decided to no longer support this area of research.

I am happy to join my Majority colleagues in our unified critique of this position. And we are not alone in our concerns. GAO's report on this topic was very clear. They recommend that DOE take the lead in the "development of a mechanism for interagency collaboration on research on low-dose radiation's health effects." The only thing that is missing from this hearing is a witness from the Department of Energy. We are reviewing a report from GAO that includes key recommendations for DOE. Yet, here we are without a representative from the Department to provide us with their input on these recommendations. It really is a missed opportunity. I am disappointed that we cannot have a more complete conversation or make real progress in our oversight of the Department on this crucial area of research. I hope the Majority will consider this as we move forward with additional hearings on this topic or others that are directly under the purview of DOE. The Department's lack of Senate-confirmed leadership does not give them immunity to Congressional oversight. With that said, I am looking forward to continued bipartisan dialogue on this topic and to the testimony we will hear today.

Thank you again, Mr. Chairman. I yield back the balance of my time.

Chairman WEBER. I thank the Ranking Member pro tem, and now I'm going to introduce our witnesses.

Our first witness today is Mr. John Neumann, Director of Science and Technology Issues at GAO. He manages and oversees both federal R&D programs and federal efforts to support innovation. Mr. Neumann received a bachelor's degree in political science from the State University of New York at Stony Brook, an MBA from American University, and a J.D. from Georgetown University.

Our next witness is Dr. Gayle Woloschak—am I saying that right—a Professor of Radiation Oncology and Radiology at Northwestern University. Additionally, Dr. Woloschak is a Visiting Scientist at the Bundeswehr Institute for Radiobiology in Munich, Germany, and a lecturer at Rosalind Frank Medical School in North Chicago, and a Visiting Professor at Alexandria University in Alexandria, Egypt. And when do you sleep? She received a Ph.D. in microbiology at the Medical College of Ohio, Toledo, OH.

Our last witness is Dr. James Brink, Professor of Radiology at Harvard Medical School, and Radiologist-in-Chief at Massachusetts General Hospital. Dr. Brink was elected an honorary member of the American Association of Physicists in Medicine and a member of the International Society for Strategic Studies in Radiology. Currently, he serves as the Scientific Vice President on the Board of Directors of the National Council for Radiation Protection. He received a bachelor's degree from Purdue University and an M.D. from Indiana University. Dr. Brink joins us today to testify in his capacity as the Chairman of the American College of Radiology Board of Chancellors.

I want to say thank you to you all for being here, and we will begin our testimony, Mr. Neumann, by recognizing you for five minutes.

**TESTIMONY OF MR. JOHN NEUMANN,
DIRECTOR, SCIENCE AND TECHNOLOGY ISSUES,
GOVERNMENT ACCOUNTABILITY OFFICE**

Mr. NEUMANN. Chairman Weber, Ranking Member and Members of the Subcommittee, thank you so much for the opportunity to be here today to discuss GAO's report on federal protections against the harmful effects of ionizing radiation and federal support for related research.

To protect against cancer and other harmful effects associated with radiation exposure, the EPA, NRC, and other federal agencies have established requirements and guidance that apply to a range of settings in which exposure can occur. Agencies such as the Department of Energy have also funded research to determine how low doses of radiation affect human health. However, uncertainties remain about these effects. For example, in 2016, the Department of Energy's Biological Environmental Research Advisory Committee reported that further research on low dose radiation could decrease uncertainty in cancer risk estimates.

My statement today summarizes our report on low dose radiation, which examined two areas: first, how selected federal agencies have developed and applied radiation protection requirements and guidance for workers and the public, and secondly, the extent

to which federal agencies have funded and collaborated on research on the health effects of low dose radiation.

In our review of how federal agencies developed and applied radiation protection requirements, we focused on four settings in which radiation exposure can occur: the operation and decommissioning of nuclear power plants, the cleanup of sites with radiological contamination, the use of medical equipment that produces radiation, and lastly, the accidental or terrorism-related exposure to radiation, and we found that to develop radiation protection requirements and guidance for these four settings, agencies generally relied on the advice of scientific advisory bodies, and this advice included the use of the linear no-threshold model, which assumes that the risk of cancer increases with every incremental increase in radiation. However, advisory bodies have also recognized challenges in accurately estimating cancer risks from very low doses of radiation. For example, much of the data on health effects of radiation exposure come from non-U.S. populations such as the Japanese atomic bomb survivors. These populations received a large exposure to radiation over a short time, and there is uncertainty about the extent to which the health effects for them can be extrapolated to a U.S. population that may be chronically exposed to low doses of radiation.

In looking at federal agency support for research on the health effects of low dose radiation, we found that seven agencies obligated a total of about \$210 million from fiscal year 2012 to 2016 but their collective annual funding has decreased by almost 50 percent over that period.

We also found that agencies collaborated on particular research projects but they did not collaborate to address overall research priorities such as the research needs that the scientific advisory bodies we met with had identified regarding low dose radiation health effects. Such research needs include areas related to uncertainties in the linear no-threshold model, and by extension in the agency's dose limits and guidance levels that are based in part on that model.

In the past the Department of Energy provided leadership in this area. However, its leadership role has decreased since 2012 as the Department phased out funding for its main research program on low dose radiation health effects. We found that no other agency has stepped forward to fill this role.

Given these findings, we recommended that the Department of Energy take the lead in developing a mechanism for interagency collaboration on low dose radiation research. The Department disagreed with our recommendation, stating that it would be inappropriate for it to lead because other agencies have their own budget authorities and research priorities. However, given the Department's past leadership role, we continue to believe that the Department of Energy is in the best position to lead agencies in developing such a mechanism for addressing shared research priorities. Such an action would be consistent with the Department's responsibilities under the Atomic Energy Act to conduct research related to nuclear energy including the protection of health during activities that can result in radiation exposure.

This concludes my prepared remarks, and I'm happy to respond to any questions you may have.
[The prepared statement of Mr. Neumann follows:]

United States Government Accountability Office



Testimony
Before the Subcommittee on Energy,
Committee on Science, Space, and
Technology, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. ET
Wednesday, November 1, 2017

LOW-DOSE RADIATION

Interagency Collaboration on Planning Research Could Improve Information on Health Effects

Statement of John Neumann, Director,
Natural Resources and Environment

Chairman Weber, Ranking Member Veasey, and Members of the Subcommittee:

I am pleased to be here today to discuss federal agencies' requirements and guidance for protecting workers and the public from the harmful effects of ionizing radiation and agencies' support for research on the health effects of radiation at low doses.¹ Radiation comes from natural sources as well medical, commercial, and industrial activities. It has beneficial uses, such as treating cancer, but a large amount of exposure can cause sickness or even death within days, according to the Environmental Protection Agency (EPA). In contrast, low levels of exposure are not known to cause acute health effects but may increase a person's risk of developing cancer.

To protect against cancer and other harmful effects associated with exposure to radiation, EPA, the Nuclear Regulatory Commission (NRC), and other federal agencies have established requirements and issued guidance that apply to a wide range of settings in which such exposure can occur. For example, these requirements include limits on occupational dose, such as for workers in nuclear power plants, and limits on the dose that a facility, such as an industrial site with radiological contamination, can cause to members of the public.²

The Department of Energy (DOE) and other federal agencies have also funded research to determine the health effects of exposure to low levels of radiation. However, uncertainties remain about these effects, as DOE's Biological and Environmental Research Advisory Committee recognized in 2016, when it issued a report stating that further research on the cancer risk from low-dose radiation could decrease uncertainty in cancer risk estimates.

My statement today summarizes our September 2017 report on low-dose radiation,³ which examined (1) how selected federal agencies have

¹Ionizing radiation includes X-rays, gamma rays, and various types of atomic particles. Natural sources of ionizing radiation include certain foods, such as bananas and Brazil nuts, and soils rich in naturally occurring uranium. This statement uses the term "radiation" to refer to ionizing radiation.

²Radiation dose, as used in this statement, refers to the measured or calculated exposure individuals receive.

³GAO, *Low-Dose Radiation: Interagency Collaboration on Planning Research Could Improve Information on Health Effects*, GAO-17-546 (Washington, D.C.: Sept. 26, 2017).

developed and applied radiation protection requirements and guidance for workers and the public and (2) the extent to which federal agencies have funded and collaborated on research on the health effects of low-dose radiation. For our report, we reviewed agency documentation and interviewed agency officials on the development of their radiation protection requirements and guidance. In particular, we identified four federal agencies—EPA, NRC, DOE, and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS)—that have developed requirements or guidance for four settings in which radiation exposure can occur: operation and decommissioning of nuclear power plants, cleanup of sites with radiological contamination, use of medical equipment that produces radiation, and accidental or terrorism-related exposure to radiation. Findings from our reviews of these four agencies in the four settings we selected cannot be generalized to all agencies and settings in which radiation exposure can occur but provide illustrative examples. We also collected and examined data on support for low-dose radiation research from seven federal agencies that fund this research—the Centers for Disease Control and Prevention (CDC) within HHS, the Department of Defense (DOD), DOE, EPA, the National Aeronautics and Space Administration (NASA), the National Institutes of Health (NIH) within HHS, and NRC. In particular, we requested these seven agencies to provide data on obligations for low-dose radiation research for fiscal years 2012 through 2016 and information on the type of research funded.

More detailed information on the scope and methodology of our work can be found in our September 2017 report. We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, we found that EPA, NRC, DOE, and FDA have generally used the advice of scientific advisory bodies to develop and apply radiation protection requirements and guidance for workers and the public for the four radiation settings in our review. Specifically, the agencies relied on the advice of three scientific advisory bodies that supported the use of the linear no-threshold model for such requirements and guidance. This model assumes that the risk of cancer increases with every incremental increase in radiation exposure. Accordingly, the agencies have set regulatory dose limits and issued guidance to confine exposure

to levels that reduce the risk of cancer, while recognizing that scientific uncertainties occur in estimating cancer risks from low-dose radiation.

We also found that, for fiscal years 2012 through 2016, seven federal agencies—CDC, DOD, DOE, EPA, NASA, NIH, and NRC—obligated about \$210 million for research on the health effects of low-dose radiation, but annual funding decreased by 48 percent. During the period we reviewed, the seven federal agencies that funded this research collaborated on particular projects, but they did not use a collaborative mechanism to address overall research priorities, such as research needs that advisory bodies identified regarding health effects of low-dose radiation. In the past, DOE provided leadership in this area and advocated for greater coordination on research on low-dose radiation's health effects. However, since fiscal year 2012, its leadership role and funding have decreased because it has phased out funding for its main research program in this area, and no other agency stepped forward to fill this role. We recommended that DOE lead development of a mechanism for interagency collaboration on research on low-dose radiation's health effects. DOE disagreed with our recommendation, stating that agencies set their own research priorities. We continue to believe that DOE is in the best position to lead such an effort.

Background

According to NRC's website, the higher the radiation dose, the sooner the effects of radiation will appear, and the higher the probability of death. Radiation doses such as those received by survivors of the atomic bombs in Japan can cause cancers such as leukemia and colon cancer and, if levels are high enough, acute radiation syndrome. The symptoms of this syndrome range from nausea, fatigue, and vomiting to death within days or weeks. In contrast, the effects of low-dose radiation are more difficult to detect. In particular, below about 100 millisieverts (mSv) (10 rem)—the level below which the National Academies of Sciences, Engineering, and Medicine's (National Academies) 2006 report on radiation and human health considered radiation to be low dose—data do not definitively establish the dose-response relationship between cancer and radiation exposure.⁴

⁴National Research Council of the National Academies, *Health Risks from Exposure to Low Levels of Ionizing Radiation* (Washington, D.C.: National Academies Press, 2006). The millisievert (mSv) and rem are measures of effective radiation dose. One mSv is equal to 0.1 rem.

**Selected Agencies
Generally Used
Advice from Scientific
Advisory Bodies to
Develop and Apply
Radiation-Protection
Requirements and
Guidance**

In developing and applying radiation protection requirements and guidance for workers and the public—specifically, limits on dose or increased health risk and guidance levels on exposure—EPA, NRC, DOE, and FDA have generally taken the advice of scientific advisory bodies. In particular, they have relied on the advice of the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, and the National Academies' Nuclear and Radiation Studies Board.⁵ This advice includes the use of the linear no-threshold model, which assumes that the risk of cancer increases with every incremental increase in radiation exposure. For example, the National Academies published a report in 2006 stating that the balance of evidence from various types of studies tends to favor a simple proportionate relationship between radiation at low doses and cancer risk. According to the National Academies, the availability of new and more extensive data since the publication of its previous report in 1990 strengthened confidence in the 2006 report's estimates of cancer risk.

The advisory bodies have recognized challenges in accurately estimating cancer risks from very low doses of radiation exposure when using the linear no-threshold model. For example, much of the data on health effects of radiation exposure come from non-U.S. populations, such as Japanese atomic bomb survivors. These individuals received a large exposure to radiation over a short period of time (an acute exposure), and there is uncertainty about the extent to which the health effects for these populations can be extrapolated to a U.S. population that is regularly (chronically) exposed to low-dose radiation.

Nevertheless, NRC officials told us that, in the absence of convincing evidence that there is a dose threshold below which low levels of radiation are beneficial or not harmful, NRC will continue to follow the recommendations of scientific advisory bodies to use the linear no-threshold model. Similarly, officials from EPA told us that they would consider changing the use of the linear no-threshold model as the basis

⁵The International Commission on Radiological Protection is an independent, international organization with members consisting of scientists and policymakers in the field of radiological protection. The National Council on Radiation Protection and Measurements is a congressionally chartered, nonprofit educational and scientific body. The National Academies' Nuclear and Radiation Studies Board conducts studies on safety and other issues associated with nuclear and radiation-based technologies.

of their requirements and guidance only if there were a strong recommendation from scientific advisory bodies on radiation protection as well as an endorsement of the change by the National Academies.

Under this model, federal regulations set dose limits for radiation exposure that are below the level in the National Academies' 2006 report on radiation and human health for defining low-dose radiation. For example, NRC's annual dose limit for members of the public (excluding natural, or background, sources of radiation) from operation of nuclear power plants is a hundredth of the level the National Academies considers low dose. NRC based the dose limit on an advisory body recommendation that the cancer risk to the general public from exposure to radiation should be comparable to the public's risk from everyday activities, such as taking public transportation.

The low-dose radiation limits and guidance that federal agencies have developed and applied vary depending on the settings in which exposure can occur. For example, NRC has established limits on occupational dose that apply to nuclear power-plant workers; these limits are higher than NRC's annual dose limit for members of the public but are still below the level the National Academies considers low dose. In keeping with advisory body recommendations, NRC also applies the principle that doses should be kept as low as reasonably achievable (ALARA). NRC defines ALARA to mean making every reasonable effort to maintain exposures to radiation as far below dose limits as is practical. At a nuclear power plant we visited as part of our work, representatives told us that under their ALARA plan, the plant set its own dose limit for workers at 40 percent of the NRC's regulatory limit. Moreover, officials at the plant told us that they have been able to keep exposures below the plant's own limit by continuously seeking opportunities to reduce unnecessary worker exposure to radiation, such as using robots to perform maintenance work in radiation areas.

In contrast to radiation exposure received from nuclear power plants, FDA officials stated that the agency regulates the maximum radiation output of medical equipment, instead of setting limits on the total amount of radiation exposure to patients. According to FDA officials, FDA does not generally have the authority to regulate the total amount of radiation exposure a patient receives from medical imaging equipment.⁶ However,

⁶Under the Mammography Quality Standards Act, FDA has established a maximum dose limit to patients for mammography testing.

in keeping with the principle that radiation exposure should be kept as low as reasonably achievable, FDA encourages voluntary measures by health care providers, such as to investigate and determine whether it is possible to reduce radiation exposure to patients from the use of medical-imaging equipment.

Seven Agencies Have Funded Research on the Health Effects of Low-Dose Radiation but Have Not Collaborated on Overall Research Priorities

From fiscal year 2012 through fiscal year 2016, seven federal agencies obligated \$209.6 million for research on the health effects of low-dose radiation, but they did not use a collaborative mechanism to address overall research priorities in this area. DOE and NIH accounted for most of the funding, with DOE obligating \$116.3 million and NIH obligating \$88.6 million, or about 56 percent and 42 percent of the total, respectively. The five other agencies—NRC, NASA, DOD, EPA, and CDC—obligated the remaining \$4.7 million, or about 2 percent of the total.

DOE has two offices that have funded research on the health effects of low-dose radiation—the Office of Science and the Office of Environment, Health, Safety and Security—according to funding information DOE provided. The Office of Science established the Low Dose Radiation Research Program in 1998 and funded it through fiscal year 2016. A primary focus of this program was radiobiological research, which examines molecular and cellular responses to radiation exposure. According to DOE's website for the program, the program provided data and information about the low-dose range of exposure, producing 737 peer-reviewed publications as of March 2012. The Office of Environment, Health, Safety and Security provided funding for epidemiological studies, including studies involving Japanese atomic bomb survivors.⁷

NIH has funded and conducted both epidemiological and radiobiological studies on low-dose radiation, according to NIH officials. The officials stated that the studies are conducted through the National Cancer Institute's internal research program for radiation epidemiology, as well as through NIH's research programs for external funding of investigator-initiated research. Other institutes of NIH, including the National Institute of Environmental Health Sciences, also fund research related to the

⁷Epidemiological studies examine defined populations of workers and other individuals and the effects on their health after exposure to radiation.

health effects of radiation exposure as part of NIH's overall mission to fund medical research.

Among the other agencies that provided some funding to low-dose radiation studies, several provided funding to the Epidemiological Study of One Million U.S. Radiation Workers and Veterans (Million Person Study)—an ongoing study headed by the National Council on Radiation Protection and Measurements. DOE also provided funding for this study.

In fiscal years 2012 through 2016, the seven agencies who provided funding for research on health effects of low-dose radiation collectively decreased their annual funding obligations in this area by 48 percent, from \$57.9 million in fiscal year 2012 to \$30.4 million in fiscal year 2016. DOE accounted for a large portion of this overall decrease in annual funding. Specifically, over this 5-year period, DOE reduced its annual funding obligations for this area of research by 45 percent—from \$32.6 million in fiscal year 2012 to \$18.0 million in fiscal year 2016. According to DOE, the decrease was primarily due to DOE's reduction in funding for its Low Dose Radiation Research Program. According to DOE officials, decreases in funding for the program reflected a shift toward bioenergy and environmental research. Similarly, over the 5-year period, NIH's funding for low-dose radiation research decreased by 48 percent—from \$23.1 million in fiscal year 2012 to \$12.0 million in fiscal year 2016. NIH officials explained that funding levels for a particular disease or research area can fluctuate depending on several factors, including the number and quality of research proposals submitted and the outcome of NIH's peer reviews of the proposals, as well as the overall research budget.

The seven agencies that funded research on health effects of low-dose radiation for fiscal years 2012 through 2016 collaborated on particular research projects through various mechanisms, including joint funding of individual projects, but they did not use a collaborative mechanism to address overall research priorities. As previously noted, the 2016 report of DOE's Biological and Environmental Research Advisory Committee provided information about research needs in low-dose radiation and found that further research could decrease uncertainty in predicting cancer risk from low-dose radiation. The report stated that other agencies—including NRC, NIH, EPA, DOD, and NASA—could benefit from the reduction in uncertainty that could be obtained by this research.

In our September 2017 report, we recommended that the Secretary of Energy lead the development of a mechanism for interagency collaboration to determine roles and responsibilities for addressing

priorities related to research on the health effects of low-dose radiation. We made this recommendation because our previous work has shown that collaborative mechanisms can serve multiple purposes, such as leading interagency efforts to develop and coordinate sound science and technology policies across the federal government. Although collaborative mechanisms differ in complexity and scope, they all benefit from certain key features, such as leadership.

We directed this recommendation to DOE for several reasons. In the past, DOE took a leading role in advocating for greater communication and coordination between the fields of radiation biology and epidemiology. In addition, DOE is the federal agency that currently has primary responsibility under the Atomic Energy Act of 1954 for research related to the protection of health during activities that can result in exposure to radiation. DOE is well positioned to lead an effort to ensure that federal agencies have a mechanism for interagency collaboration to address overall research priorities related to low-dose radiation health effects because of the agency's past experience as a leader in this area of research. Such an effort could help DOE and the collaborating agencies determine roles and responsibilities, including leadership when addressing shared research priorities.

DOE did not agree with our recommendation. In particular, DOE stated that EPA and NRC also have legal mandates to research low-dose radiation exposure and that these agencies establish their research priorities in accordance with their respective budget authorities and recommendations from independent advisory bodies. DOE stated that as a result, it would not be appropriate for DOE to lead the development of a mechanism for interagency collaboration.

We believe that DOE's concerns stem from a misinterpretation of our recommendation, and we made several changes to our report and our recommendation to clarify DOE's role. We noted that we did not recommend that a mechanism for interagency collaboration serve as a replacement for agencies' legal mandates, budget authorities, and recommendations from independent advisory bodies. Instead, this mechanism would help agencies address shared research priorities. In making our recommendation, we did not specify the coordinating mechanism that agencies should use and instead left it to DOE to lead the development of an appropriate mechanism. We continue to believe that an interagency coordination mechanism for low-dose research is needed and that DOE is in the best position to lead agencies in developing the most appropriate mechanism.

Chairman Weber, Ranking Member Veasey, and Members of the Subcommittee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

**GAO Contact and
Staff
Acknowledgments**

If you or your staff have any questions about this statement, please contact John Neumann at (202) 512-3841 or neumannj@gao.gov. In addition, contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals who made key contributions to the report on which this testimony is based include Allen Chan, Kendall Childers, Joseph Cook, Richard Johnson, Cynthia Norris, Josie Ostrander, Amber Sinclair, and Jack Wang.

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Biography

John Neumann is a Director in GAO's Natural Resources and Environment Team, with over 25 years of experience leading performance audits of federal programs. He currently leads efforts in the science and technology area, including the management and oversight of federal research and development programs, protection of intellectual property, and federal efforts to support innovation. Mr. Neumann received his B.A. in Political Science cum laude from the State University of New York at Stony Brook, and holds an M.B.A from American University, as well as a J.D. from Georgetown University.

Chairman WEBER. Thank you, Mr. Neumann.
 Dr. Woloschak, you are recognized for five minutes. Thanks.

**TESTIMONY OF DR. GAYLE WOLOSCHAK,
 PROFESSOR, RADIATION ONCOLOGY AND RADIOLOGY,
 NORTHWESTERN UNIVERSITY**

Ms. WOLOSCHAK. Okay. Thank you. I'd like to mention that I used to work at Argonne National Laboratory, a DOE facility as well. I think that's important to mention.

I'm going to let some questions shape my discussion so the first question I'm going to ask is, what is low dose radiation? Before I describe what low dose versus high dose radiation means, I would like to remind everyone that ionizing radiation surrounds us daily. It is part of the natural background from sunlight and the Earth's crust, and radioactive chemicals are present in what we eat, drink and breathe including this cup of water I just drank. All of this constitutes natural background radiation, doses of radiation characterized as low dose radiation are higher than natural background. Most often, low dose radiation exposures occur when we are close to a nuclear cleanup site, or they might result from occupational or accidental exposures or exposure to medical low dose diagnostic procedures such as CT scans. Any of those low dose exposures are thousands of times lower than the radiation therapy doses used to treat cancer patients. These therapy doses belong to the category of medium- and high-dose radiation.

The next question is, what don't we know and why don't we understand low dose radiation? The most significant known risk from exposure to low dose radiation is considered to be cancer. If I ask a room of radiation biologists what is the risk for cancer formation from low dose radiation, I get every answer possible from a little bit of radiation is good for you, go sit in a radioactive spa and lap up those rays, to radiation risk for cancer decreases as the dose decreases, to risk from low doses is worse per unit dose than risk at high doses.

So the question is, we don't actually know the precise relationship between low dose radiation exposure and cancer induction. Why is there so much disagreement? Because we have contradictory data. One source of this problem is that many of the low dose studies done in the past were performed with cells in a test tube. A direct leap from cells to humans is never done in medicine because it is just not accurate. Before clinical trials of any sort with drugs or with radiation, we use—numerous animal studies are done in advance. In addition to the question of cancer risk, some of the recent low dose studies in Europe, Japan and China suggest that we may need to explore additional issues such as risk to unborn, risks to newborns that may have different effects for central nervous system or cardiovascular system. Until we have more research, questions will remain.

My next question is, why is closing the gap in understanding of paramount importance? My response is, our radiation protection policies deal with low doses of radiation because that is precisely the level of environmental and occupational exposures that can and should be regulated. Radiation protection is designed for a healthy population with the view of preserving health. With regard to low

dose radiation, these policies are based on the assumptions we make about low dose radiation effects. It is a matter of course that citizens must be protected from dangers associated with radiation exposure, but overprotection may be wastefully expensive and deplete funds that could be used for other strategic goals for the Nation.

Next question: What needs to be done in the research community to solve this issue? What was DOE's role in funding discoveries in the field? Work resulting from the DOE Low Dose Program led to many significant findings. For example, some unique biological responses to low dose radiation were found that are not evident at high doses. This means that a simple extrapolation from high-dose to low dose effects would not be correct. Much of this work was in the discovery phase and thus was done with cells in culture and never made its way to be tested in whole animals. This limits our ability to apply this work to human beings, which of course is our end goal. Since the time when the DOE Low dose program was terminated, biomedical science has continued to progress. New technologies have been developed and new discoveries have been made. Fine-tuned models could be developed to set the stage for fine-tuned decisions and evidence-based protection policies.

Before the DOE Low Dose Program, DOE was the leader in the radiation research science worldwide. Large-scale animal studies were done ranging from low dose occupational-type exposure to high-dose nuclear disaster-type exposures. I am in awe when I look at the volume, planning, design, and structure of these experiments done with animals for the entire duration of their lives. For reasons unknown to me, DOE terminated these studies without really completing a full analysis of the data. We are talking about data from 50,000 mice, 30,000 rats, 25,000 dogs.

Ultimately, this entire archive came to my laboratory at Northwestern, and it is the University that has supported it since the termination of the DOE Low Dose Program. What was the result of termination of the DOE Low Dose Program? I'm going to just go into the specifics here. For the U.S. radiation community, the loss of the DOE Low Dose Program has devastating effects. First of all, the radiation community for low dose has been decimated. Low dose radiation biologists participate in recommendations for radiation protection, for designing approaches to deal with radiation accidents, for dealing with population exposures. In the United States today, these committees are occupied predominantly by retired scientists. We are not able to train the next generation of radiation protection scientists in the United States and will be dependent on foreign support.

Secondly, NASA has a need for low dose work with radiation types unique to space exposure. Complementary work must be done with Earth-type radiation exposures. NASA reported to the NASA Space Radiation Discipline Working Group, which I chaired, that they were looking for collaborators in Europe to facilitate their work. In the past DOE was their partner.

We have lost much of the infrastructure to do low dose work in the United States. Many facilities are antiquated and have not been updated in some years. Some have even been decommis-

sioned. In many cases, the capacity to perform this type of research would take time to rebuild.

Finally, the United States is currently using low dose exposure effects data from science done in Europe, China, and Japan to support our regulatory policies. This is of concern because, one, other countries often have agendas in their research programs that are not consistent with our agendas. This is not to say that the research results are not correct, merely that the research design is set up to examine particular questions that may not be of equal priority in the U.S. Second, we do not have the capacity to reproduce any of those findings in the United States. And finally, in effect we are permitting other countries to set the radiation agenda for the world.

Thank you.

[The statement Ms. Woloschak follows:]

Introduction

My name is Gayle Woloschak. I am a Professor of Radiation Oncology and also Radiology at Northwestern University where I have worked for 15 years. Prior to that I was employed at Argonne National Laboratory (a DOE facility) for 13 years. At the time I left I was a Senior Scientist in the Biosciences Division. I am a radiation biologist and molecular biologist and active in a number of radiation societies, national and international radiation advisory agencies, and a member of other radiation-related teams.

I'm going to let some questions shape my discussion.

What is low dose radiation?

Before I describe what low dose (vs high dose) radiation means, I would like to remind everyone that ionizing radiation surrounds us daily. It is part of the natural background from sunlight and the earth's crust, and radioactive chemical elements are present in what we eat, drink and breathe. All of this constitutes natural background radiation. Doses of radiation categorized as low dose radiation are higher than natural background. Most often low dose radiation exposures occur when we are close to nuclear clean-up sites, or they might result from occupational or accidental exposures or exposure to medical low-dose diagnostic procedures such as CT scans. Any of these low dose exposures are thousands of times lower than the radiation therapy doses used to treat cancer patients. These therapy doses belong to the category of medium and high doses of radiation.

What don't we know? Why don't we understand low dose radiation?

The most significant known risk from exposure to low dose radiation is considered to be cancer. If I ask a room of radiation biologists what the risk is for cancer formation from low doses of radiation, I get every answer possible: from "a little radiation is good for you, you should go sit in a radioactive spa to boost your immune system" to "radiation risk for cancer decreases as the dose decreases" to "risk from low doses is worse per unit dose than risk at high doses". So – we do not know the precise relationship between low dose radiation exposure and cancer induction. Why is there so much disagreement on this question? Because we have contradictory data.

One source of this problem is that many of the low dose studies done in the past were performed with cells in a test tube. A direct leap from cells to humans is never done in medicine because it is not accurate. Before clinical trials of any sort (drugs, radiation, etc.), for example, numerous animal studies are routinely done.

In addition to the question of cancer risk, some of the recent low dose studies in the EU, UK, Japan and China suggest that we may need to explore additional issues. We may need to study low dose effects on the unborn and newborns in greater detail than we have before. We may need to study effects on the central nervous system and cardiovascular system. Until we have more research, questions will remain.

Why is closing this gap in understanding of paramount importance in the US?

Contradictory data (such as those on low dose induced cancer) make for contradictory assumptions. Our radiation protection policies deal with low doses of radiation because that is precisely the level of environmental and occupational exposures that can and should be regulated. Radiation protection is designed for a healthy population with the view of preserving health. With regard to low dose radiation these policies are based on the assumptions we make about low dose radiation effects. So, a small change in our knowledge can make for drastic changes in recommended policy with respect to acceptable levels of radiation for clean-up sites, radiation in water, and others. What this means is that closing the knowledge gap will allow us to balance spending money in cleaning up waste with optimal protection of the exposed public and workers. It is a matter of course that citizens must be protected from dangers associated with radiation exposure, but over-protection may be wastefully expensive and deplete funds that could be used for other strategic goals for the nation.

What needs to be done in the research community to solve this issue? What was DOE's role in funding discoveries in the field?

Work resulting from the DOE Low Dose program led to many significant findings. For example, some unique biological responses to low dose radiation were found that are not evident at high doses. This means that a simple extrapolation from high dose effects to low doses effects would not be correct. Much of this work was in the discovery phase and thus was done with cells in culture and never made its way to be tested in whole animals. This limits our ability to apply this work to human beings, which is our end goal.

Since the time when the DOE low dose program was terminated, biomedical science has continued to progress. New technologies have been developed and new discoveries have been made. Incorporating sensitive new techniques in low dose radiation research on animals would be essential as would modeling with new computational approaches. Fine-tuned models could be developed to set the stage for fine-tuned decisions and evidence based protection policies.

Before the DOE Low Dose Program, DOE was the leader in the radiation research science world-wide. Large-scale studies in animals were done ranging from low dose occupational-type exposure to high dose nuclear disaster type exposures. I am in awe when I look at the volume, planning, design and structure of these experiments done with animals for the entire duration of their lives. For reasons unknown to me, DOE terminated these studies without really completing a full analysis of the data (we are talking about data from 50,000 mice, 30,000 rats, 25,000 dogs). I was not involved in the studies at the time they were done, although I had a small project to evaluate some of the tissues from those projects immediately after DOE terminated the program.

When I moved from Argonne National Laboratory to Northwestern University in 2002, I asked for permission from Argonne to move the tissues to Northwestern since no one was using them at Argonne; I was denied permission. A year later, a colleague called to tell me that the tissues were

in the trash bin (literally). At that time, I called DOE to ask them intervene with the Argonne National Laboratory Biology Division to allow me to rescue the tissues for scientific studies. With DOE's help these materials were moved to Northwestern.

When DOE reinvigorated its interest in radiation with the Low Dose Program, I was able to obtain funding for two projects over 8y: Both were done jointly with Univ. Chicago, the latter also included Univ. California Davis. These projects included analyses of archival tissues and some new animals exposed to very low doses and low dose-rates of radiation.

However, by this time other institutions (Pacific Northwest National Laboratory near Richland, WA; Inhalation Toxicology Research Institute—now Lovelace—in Albuquerque, NM), similar to Argonne's Biology division, were closing their massive radiation research studies. As investigators who planned these studies were retiring, they contacted me as a means of securing that their work would be preserved. Their desire was to merge their materials with those from Argonne which we now curated. Part of our commitment to DOE was to make the tissues available to investigators around the world and the datasets available on a website that can be accessed by anyone. DOE agreed to fund the cost of the transport of the tissues, my University covered the costs so as not to lose the material, but the Low Dose program terminated and we never received reimbursement for the costs.

Ultimately, this entire archive came to my laboratory at Northwestern, and it is the University that has supported it since the termination of the DOE Low Dose Program.

What was the result of termination of the DOE Low Dose Program?

For my own group, the termination of the DOE Low Dose program means a constant struggle to preserve materials and data from DOE irradiated animal archive. There is great value in both the tissues and the datasets. As noted before, new techniques and new knowledge available to use today have allowed scientists to examine old tissues in new ways. Because of the continuing world-wide interest, we have made both the tissues and the datasets available to all interested investigators as much as possible. Nevertheless, the continued lack of funding from DOE has put the archive and the data in jeopardy, and much of the data we obtained particularly on the dogs and rats has not been made available online. When one thinks of the costs of doing life-long experiments with 50,000 mice, 30,000 rats and 25,000 dogs today (and the fact that animal husbandry at such a scale is not really possible in today's world), the fact that these data are sitting in a box in a storage facility feels horrible to me as a scientist. Thankfully, recently we obtained an NIH-NCI grant that may permit at least some additional curating of the data.

For the US radiation community, the loss of the DOE low dose program had devastating effects: -The radiation community for low dose has been decimated. Low dose radiation biologists participate in recommendations for radiation protection, for designing approaches to deal with radiation accidents, for dealing with population exposures. In the US today these committees are occupied predominantly by retired scientists. Very few new radiation biologists are coming

through the ranks who will be able to replace them. We are not able to train the next generation of radiation protection scientists in the US and will be dependent on foreign support.

-NASA has a need for low-dose work with radiation types unique to space exposure; complementary work must be done with earth-type radiation exposures. NASA reported to the NASA Space Radiation Discipline working group (which I chaired) that they were looking for collaborators in Europe to facilitate their work. In the past DOE was their partner.

-We have lost much of the infrastructure to do low dose work in the US. Many facilities in the US are antiquated and have not been updated in over 10y; some have even been decommissioned. In many cases, the capacity to perform this type of research would take time to re-build.

-The US is currently using low dose exposure effects data from science done in Europe, China and Japan to support our regulatory policies. This is of concern because: (1) other countries often have agendas in their research programs that are not consistent with our agendas; this is not to say that the research results are not correct, merely that the research design is set up to examine particular questions that may not be of equal priority in the US; (2) we do not have the capacity to reproduce any of those findings in the US to verify that they are accurate; and (3) in effect we are permitting other countries to set the radiation agenda for the world.

I would like to end this by summarizing with three key points:

1. Health effects of low dose radiation exposures remain ambiguous.
2. Policies regulating radiation exposures rely on models developed for high dose exposures; this may not be accurate
3. New technologies are changing science continually; their impact on our understanding of low dose radiation has great potential.

Chairman WEBER. Thank you, Doctor.
Dr. Brink, you're recognized for five minutes.

**TESTIMONY OF DR. JAMES BRINK, PROFESSOR,
RADIOLOGY, HARVARD MEDICAL SCHOOL;
RADIOLOGIST-IN-CHIEF,
MASSACHUSETTS GENERAL HOSPITAL**

Dr. BRINK. Chairman Weber, Ranking Member pro tem Foster, and distinguished Members of the Subcommittee, I want to thank you for holding this hearing today and for the opportunity to testify on this important topic. I am Dr. James Brink, Radiologist-in-Chief at Massachusetts General Hospital and the Juan M. Taveras Professor of Radiology at Harvard Medical School. I serve as Vice Chair of the National Academy's Nuclear and Radiation Studies Board and as Scientific Vice President for Radiation Protection in Medicine for the National Council on Radiation Protection and Measurement.

I am testifying today on behalf of the American College of Radiology as the current Chair of its Board of Chancellors. The American College of Radiology represents more than 36,000 radiologists, radiation oncologists, interventional radiologists, medical physicists, and nuclear-medicine physicians whose patients benefitted from diagnostic and therapeutic uses of radiation in medicine.

Without doubt, the use of ionizing radiation to diagnose and treat disease has revolutionized the practice of medicine. Millions of patients every year benefit from the use of radiation in diagnostic imaging, image-guided procedures, radiation therapies, and other applications.

The effects of high-level radiation exposure on the human body including the link between high-dose radiation and cancer are relatively well understood. Much of our knowledge is based on decades of atomic-bomb survivor data and the experiences of first responders to the Chernobyl disasters. Exposures to high doses of radiation have been associated with several types of cancer.

There is much greater uncertainty as to the link between cancer and exposure to low dose radiation. While exposure to lower doses may damage or alter a cell's genetic code, such exposure does not necessarily result in negative health consequences. This is because of the body's innate ability to repair itself and recover from cellular damage. This response is akin to your car's windshield wipers in the rain. In mild and moderate rainfall, your wipers keep everything relatively clear. In heavy and severe rainfall, your wipers can be overwhelmed and your vision blurred.

The National Academy's Board on Radiation Effects Research has played an integral role in the study of the biologic effects of ionizing radiation over the last several decades, having published a series of reports on this topic. These are frequently cited in the professional literature and in regulatory and policymaking documents. However, the most recent report was issued in 2006, and an update is needed to critically explore the latest research and provide a balanced perspective on its significance.

As medical providers who use 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 radi-

ation. To that end, the American College of Radiology endorsed the Low dose Radiation Research Act of 2015 in the last Congress. As this Subcommittee knows, the legislation would have required the Director of the Department of Energy Office of Science to carry out a research program to enhance our scientific understanding and reduce uncertainties related to the health effects of low dose radiation. Further, it would have required 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. We believe it is important for the National Academies to periodically assess the status and inform the development of a long-term strategy for low dose radiation research.

We also believe the Department of Energy and other federal agencies must be adequately funded to support low dose radiation research activities. Accordingly, we urge that similar legislation be introduced and passed in the current Congress. This is so important because it is very likely that someone you know will undergo a medical procedure that uses low dose radiation, and this research is necessary to better inform the potential risks of those procedures. We at the American College of Radiology and in the radiology community hope to continue to be a resource to this Subcommittee moving forward.

Thank you again for the opportunity to testify today and for holding this hearing on such an important topic.

[The prepared statement of Dr. Brink follows:]



**Statement of
James A. Brink, MD, FACR
Chair, Board of Chancellors, American College of Radiology**

**Before the Committee on Science, Space and Technology
Subcommittee on Energy**

DOE Funding of Basic Research on Low Dose Radiation

November 1, 2017

Chairman Weber, Ranking Member Veasey, and distinguished members of this subcommittee – I want to thank you for holding this hearing and for inviting me to testify. I am honored to be here today and welcome the opportunity to present the views of the American College of Radiology on the importance of Department of Energy-supported research on low-dose radiation.

My name is Dr. James Brink. I am Radiologist-in-Chief at Massachusetts General Hospital and the Juan M. Taveras Professor of Radiology, at Harvard Medical School. My professional career reflects a long-held interest in issues related to the monitoring and control of medical radiation exposure. As such, I currently serve as Vice Chair of the Nuclear and Radiation Studies Board (NRSB) of the National Academy of Sciences, Engineering and Medicine. I am also scientific vice-president for radiation protection in medicine on the National Council for Radiation Protection and Measurements (NCRP), having chaired the NCRP scientific committee that defined diagnostic reference levels for medical imaging in the United States (NCRP Report No. 172, 2012).

I am testifying today on behalf of the American College of Radiology (ACR) as the current chair of ACR's Board of Chancellors. ACR represents more than 36,000 radiologists, radiation oncologists, medical physicists, and nuclear medicine physicians whose patients benefit from diagnostic and therapeutic uses of radiation in medicine.

Sources of radiation exposure and beneficial uses of man-made radiation

In simple terms, “radiation” is energy that is emitted from a source as electromagnetic waves or as moving subatomic particles. “Ionizing radiation” is radiation with energy sufficient to strip electrons from atoms causing them to become charged. This displacement of electrons in a human cell has the potential to damage its DNA.

Although to some the term “radiation” may elicit extremely negative connotations, in truth radiation is a natural part of our universe. Humans are exposed constantly to radiation from natural sources including cosmic radiation from outer space and terrestrial radiation from soil and rocks. There is radiation in the air we breathe, the food and water we consume, the buildings in which we live and work, and even in our own bodies.

In addition to naturally occurring radiation, we are also exposed to man-made sources of radiation while enjoying the many benefits that come from medical uses, industrial activities, and commercial products. Consumer products such as fertilizer, welding rods, and smoke detectors, may contribute to our radiation exposure. Security systems such as those used at airports and for entry to Congressional office buildings and other federal buildings use low dose x-ray beams to visualize the contents of packages and baggage; this creates an extremely small amount of radiation exposure. Much higher doses of radiation are used to preemptively destroy biological agents such as anthrax although the irradiated mail does not itself expose the recipient to radiation.

Without doubt, the most significant source of exposure to manmade radiation in humans is that associated with medical diagnostic and therapeutic procedures. Such exposures include imaging tests that use low doses of radiation to allow radiologists to visualize the internal structure and function of the body as well as radiation therapy procedures that use high doses of radiation from radioactive material or external beams to destroy cancerous cells. A report by the National Council on Radiation Protection and Measurements (NCRP) calculates the average annual radiation dose per person in the U.S. at 620 millirem (6.2 millisieverts)(data reported for 2006). Approximately half of this exposure is naturally occurring radiation. A little less than half (48%) is associated with medical exposure (excluding radiation therapy) and includes Computed Tomography (24%), Nuclear Medicine (12%), Interventional Fluoroscopy (7%) and Conventional Radiography/Fluoroscopy (5%). I cannot overemphasize, however, the enormous benefits associated with the controlled use of radiation in medicine.

To be clear: the use of radiation in medicine saves lives, improves the quality of care, and the quality of life for millions of patients each year. Advances in medical imaging have rendered exploratory surgery virtually obsolete. Disease can be identified earlier and treatments monitored more readily to allow for optimal patient care. Additionally, image-guided procedures frequently replace more invasive surgical options, improving outcomes while reducing hospitalization and recovery times. Moreover, one million patients each year receive the benefits of radiation therapy for the treatment of cancer and other disorders; clinical trials and clinical experience have demonstrated the benefits of radiation therapy in curing cancer, extending life, and relieving pain and suffering.

Biological Effects of Radiation

The effects of high-level radiation exposure on the human body are relatively well-understood — learned from decades of atomic bomb survivor data as well as the experiences of first responders to the Chernobyl disaster. We know that high and extremely high radiation doses received over short periods of time can damage, modify, or kill cells—causing skin “burns,” nausea, bone marrow depression, rapid onset of cancer, gastrointestinal issues, cerebrovascular issues, cardiovascular issues, and even death.

Likewise, the data establishing a relationship between radiation exposure and cancer are primarily based on populations that have received high level exposures including survivors of atomic bombs in Japan and patients who have received high dose radiation therapy for the treatment of cancer. Exposures to high doses of radiation have been associated with several types of cancer including leukemia, multiple myeloma, and cancers of the breast, bladder, colon, liver, lung, esophagus, ovary, and stomach.

There is much greater uncertainty as to the link between exposure to low dose radiation and cancer. Lower doses occurring over a long period of time do not cause immediate health effects, and the biological effects of exposure to low dose radiation may be undetectable. While exposure to lower doses may damage or alter a cell's genetic code or DNA, such exposure does not necessarily result in negative health consequences. This is because of the body's innate ability to repair itself and recover from cellular damage. For example, human cells exposed to and damaged by low dose radiation can simply repair themselves or die off and be replaced by new and healthy cells. A problem can occur, however, when cells **incorrectly** repair themselves, causing a biophysical change that might eventually result in an adverse effect for the individual.

There are myriad variables that can influence whether exposure to low dose radiation might produce an adverse health effect, and because of the latency period between exposure and any resultant disease, researchers struggle to tease out the many confounding variables that might contribute to the disease. We know that there are numerous lifestyle factors (such as smoking, alcohol use, physical inactivity and obesity), as well as chemical exposures and physical hazards that can contribute to cancer risk. Moreover, we believe that certain factors such as age, gender, and life expectancy of the exposed individual can influence the level of risk associated with low dose radiation exposure to a particular individual. Additional research could add to our understanding in this area.

Theories Concerning the Health Effects of Low Dose Radiation – Policy Implications

In the absence of definitive data on the health effects of low dose radiation, those of us who use radiation in the practice of medicine, as well as those U.S. agencies charged with regulating the use of radiation and radiation exposure, have adopted the conservative approach of assuming that any amount of radiation exposure may pose some health risk. This theory is commonly referred to as the linear non-threshold model.

In keeping with the linear non-threshold theory, the medical community and regulators have adopted policies and practices to keep radiation doses “As Low as Reasonably Achievable”

(ALARA). As defined in regulatory schema of the Nuclear Regulatory Commission (Title 10, Section 20.1003, of the *Code of Federal Regulations* (10 CFR 20.1003), ALARA “means making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.” A complementary concept in medicine is “dose optimization” which entails using only the amount of radiation that yields the image quality necessary for a diagnosis (or the conduct of a procedure).

Not everyone in the scientific community agrees with the validity of extrapolating cancer risk for low dose radiation exposure based on data from individuals who have received high doses of radiation. Some believe there is a threshold below which radiation exposure should not be a concern. A somewhat controversial school of thought, known as Radiation Hormesis, hypothesizes that there could even be beneficial health effects of low-dose exposure.

The Need for Additional Study on the Health Effects of Low Dose Radiation

Given the current state of scientific understanding of the health effects of low dose radiation, the radiology community is committed to the principles of ALARA and dose optimization. Nevertheless, we also believe there is a compelling need to improve science’s direct understanding of low-level exposure and to apply new knowledge to radiation safety practices, professional guidelines, and regulatory policy.

The National Academies Board on Radiation Effects Research has played an integral role in the study of the biological effects of ionizing radiation 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.

Alongside its comprehensive risk assessments, the BEIR VII report identified a dozen needs for further research:

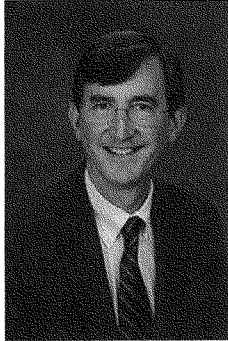
1. Determination of the level of various molecular markers of DNA damage as a function of low-dose ionizing radiation.
2. Determination of DNA repair fidelity, especially with regard to double and multiple strand breaks at low doses, and whether repair capacity is independent of dose.
3. Evaluation of the relevance of adaptation, low-dose hypersensitivity, bystander effect, hormesis, and genomic instability for radiation carcinogenesis.
4. Identification of molecular mechanisms for postulated hormetic effects at low doses.
5. Tumorigenic mechanisms.
6. Genetic factors in radiation cancer risk.

7. Heritable genetic effects of radiation.
8. Future medical radiation studies.
9. Future occupational radiation studies.
10. Future environmental radiation studies.
11. Japanese atomic bomb survivor studies.
12. Epidemiologic studies in general.

As medical providers who use 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.

To that end, the American College of Radiology endorsed the Low-Dose Radiation Research Act of 2015 in the last Congress. As this subcommittee knows, the legislation would have required 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 have required 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. We believe it is important for the National Academies to periodically assess the status and inform the development of a long-term strategy for low dose radiation research. We also believe the Department of Energy and other federal agencies must be adequately funded to support low dose radiation research activities. Accordingly, we urge that similar legislation be introduced and passed in the current Congress.

We hope to continue to be a resource to this subcommittee moving forward. Thank you again for the opportunity to testify today, and for holding this hearing on such an important topic.



JAMES A. BRINK is Radiologist-in-Chief at the Massachusetts General Hospital (MGH) and the Juan M. Taveras Professor of Radiology at Harvard Medical School. He earned a BS degree in Electrical Engineering at Purdue University and an MD at Indiana University before completing his residency and fellowship at MGH in 1990. He joined the faculty at the Mallinckrodt Institute of Radiology at Washington University School of Medicine where he rose to the rank of Associate Professor prior to joining the faculty at Yale University in 1997. Dr. Brink served as Chair of the Yale Department of Diagnostic Radiology from 2006 to 2013 prior to returning to MGH as Radiologist-in-Chief. Dr. Brink is Fellow of the Society for Computed Body Tomography/Magnetic Resonance, Fellow of the American College of Radiology (ACR), and Past-President of the American Roentgen Ray Society (2012). For the ACR, Dr. Brink serves as Chairman of the Board of Chancellors. For the National Council for Radiation Protection and Measurements (NCRP), he serves as the Scientific Vice-President for Radiation Protection in Medicine. For the National Academies of Sciences, Engineering and Medicine, he services as Vice-Chair of the Nuclear and Radiation Studies Board. Dr. Brink is an honorary member of the European Society of Radiology, the Italian Society of Medical Radiology, the American Association of Physicists in Medicine, and the International Organization for Medical Physics; he was also a recipient of the American Roentgen Ray Society's Gold Medal in 2015. Dr. Brink has broad experience in medical imaging, including the utilization and management of imaging resources, with specific interest and expertise in issues related to the monitoring and control of medical radiation exposure.

Chairman WEBER. Thank you, Doctor.

I now recognize myself for questions for five minutes.

Mr. Neumann, your report found that federal funding for low dose radiation research in the United States had declined by almost 50 percent from 2012 to 2016. I know some of the other testimony was about we had to depend on foreign research, as you heard from Dr. Woloschak, or was it Dr. Brink? What impact has that decrease in funding, in your opinion, had on the U.S. leadership in this area of research?

Mr. NEUMANN. Well, certainly when talking to all the agencies that are involved in this type of research, they all agree that there's a need to coordinate and better collaborate to identify and develop the research priorities to see that they are met, and so without this leadership, there's a potential of some of these gaps not being filled.

Chairman WEBER. Let me follow up on that. A couple of the testimonies said that there's no collaborative mechanism, and so Dr. Woloschak, I'll jump over to you real quick. What does a collaborative mechanism to you look like?

Ms. WOLOSCHAK. So in the days of the DOE Low dose program, what they would do is, if there was an interest from, say, DOE and NASA, NASA would help fund the same project. They would give a bit of the funding and expect that they could take advantage of the data that resulted from it. That I think was a very good collaborative arrangement between two different agencies working together that had similar goals. That's no longer possible. NASA's working alone. They don't have that sort of collaborative arrangement. I think similar arrangements between NIH and DOE actually existed for a period of time too. So I think those are the kinds of things that are very, very helpful.

Chairman WEBER. Do you agree with that, Dr. Brink?

Dr. BRINK. I do indeed.

Chairman WEBER. Okay. Now, Dr. Woloschak makes a very interesting point in her testimony that we don't have the next generation or whatever the term is of scientists. We're not getting them trained. Since you have a college nexus there, why is that, do you think?

Dr. BRINK. It's an interesting question. We have noticed that there's been a relative decline in what we call radiation professionals over the years, and it's certainly been a concern of the National Council for Radiation Protection and others, and it's not exactly obvious why there has been a decline but we've certainly made efforts to try and bolster and reinvigorate interest in this field really for the sake of the Nation going forward.

Chairman WEBER. Are you in possession of the numbers? Do you know what that looks like? Did we have a thousand scientists that have now gone to a hundred or fifty, or do you know what the—

Dr. BRINK. I don't. I'd be happy to find some numbers for you and get those to you.

Chairman WEBER. Well, I'm just curious because that's interesting why we're declining, and to your comments that we had to depend on foreign countries whose interests may not exactly align with ours.

Ms. WOLOSCHAK. I can comment on that as well. I mean, I know American Society for Therapeutic Radiation Oncology did a joint meeting at NIH about two or three years ago to try to talk about the decline, and I believe that the major result of that meeting was, was to say it's declining because we don't have people funded in low dose radiation research, so then to take students into the lab to do research and learn how to understand low doses, there were no training grounds.

Chairman WEBER. So let me paraphrase that if I understand. If we were to take and we were to have a more better funded program, a more collaborative approach where we focused on this, then we could perhaps induce students to be interested. Is that what you're saying?

Ms. WOLOSCHAK. Oh, absolutely. I see it with my own students.

Chairman WEBER. Okay. I'm going to change gears a little bit. You said in your testimony that there's a lot of naturally occurring low dose radiation. You went through some examples. Do we have any facts and figures as to maybe for the both of you doctors, do we have any facts and figures on what percentage of that occurs due to medical exams? I mean, is it five percent in the general population? Is it three percent. What percentage actually occurs due to medical exams?

Ms. WOLOSCHAK. We actually wouldn't call medical exams part of natural background.

Chairman WEBER. Well, I don't mean natural but natural was one. You know, you go through airports, you go through screening.

Ms. WOLOSCHAK. So medical exposures make up the highest percentage of human-made exposures that we have in the United States.

Chairman WEBER. What percentage is that?

Dr. BRINK. I think it's about 45 percent.

Chairman WEBER. 45 percent. Okay. And it's even in the water you drink. Before you take another drink, I wanted to make sure you remember that.

Okay. Another question. Dr. Woloschak, in your testimony you said you had considered that there were also risks to the unborn. Is that through the mother or is it through the medical exams? What do you—how do you consider that?

Ms. WOLOSCHAK. Actually the data out of the E.U. right now is suggesting that there are effects during pregnancy that are probably coming through the mother in some way, and we don't actually know the low dose mechanism but it looks as though the unborn maybe more sensitive, and even the data coming out of Hiroshima and Nagasaki studies suggest that the very young are more susceptible to cancer induction than very old from cleanup sites, from, you know, those sorts of things.

Chairman WEBER. Thank you. That reminded me. Two quick questions. I'm a little over my time.

Nagasaki, Hiroshima and the Japanese-related event, that population has to be going away because those survivors have to be diminishing almost daily. Do you know how many of those are left?

Ms. WOLOSCHAK. I don't know the exact numbers but you are exactly right. They are declining significantly. I was just there maybe 6 months or 8 months ago, and they are continuing to study the

population as long as they can. But one thing to realize is most of that population got sort of higher dose, what we would consider to be low moderate dose, not the very low doses that we would get, say, from, you know, occupational exposures here.

Chairman WEBER. All right. And then finally, I think it was you, Dr. Brink, who talked about Chernobyl. Do I remember right?

Dr. BRINK. Yes.

Chairman WEBER. So let's jump over to that population. When was that event, and how many were affected? Do you know that offhand?

Dr. BRINK. I don't know that off the top of my head. I'm sorry.

Chairman WEBER. So it's a more recent study.

Ms. WOLOSCHAK. The event was about 30 years ago. The problem with the Chernobyl studies is that the dosimetry is a little bit off. There's a lot of work being done with dosimetry.

Chairman WEBER. Right.

Ms. WOLOSCHAK. It's hard to analyze easily.

Chairman WEBER. Okay. Well, thank you. I'm over my time, so appreciate you all, and I now recognize Mr. Foster.

Mr. FOSTER. Thank you, Mr. Chairman.

I'm trying to puzzle out why it's been difficult to sustain an inter-agency collaboration on this. There has—you know, there's sort of—there's a bad reason this could happen, which is that bureaucracies under financial stress will often try to get rid of programs, shared programs, that they don't view as along their core line of business, and it's a natural thing. I think the only solution to that is to have the Congress say hey, this is something important that's slipping through the cracks between our agencies and basically knock heads to make sure that, you know, those are maintained.

There's another potential technical reason are the real differences in the type of radiation exposures that are of interest to different agencies. You know, if you're worried about healthcare, it's probably different than if you're worried about space-based exposure versus ingestion of radioisotopes from nuclear accidents and so on. So how much of that difficulty has to do with when you sit down to write the specifications of what you want to learn that you find different agencies have different specifications. Does anyone want to—

Ms. WOLOSCHAK. Yeah, you're exactly right in that different agencies do have different needs but a lot of times they overlap. So for instance, while NASA is going to care about space radiation and DOE is going to care about Earth-based types of radiation, you actually almost always need to use the Earth-based radiation as a control to understand space radiation. So they should actually be cooperating. They did for years. You asked the question why they stopped, and I have absolutely no clue. Probably you're right, having somebody from DOE at the table would have been useful.

Mr. FOSTER. Any other comments on sort of the technical differences between the types of exposures?

Mr. NEUMANN. Well, in talking the range of agencies that we met with, they all agree that there were some common areas of research that would be of use to each of the agencies, so that's why they would sometimes jointly fund some of these ongoing studies

the Million Person Study and other studies—where they can get research that would be useful to their particular settings.

Dr. BRINK. Just I agree with Gayle that there's a fair amount of overlap too which makes it a little bit puzzling but certainly there's obvious distinctions, NASA being very interested in cosmic radiation and so forth, but otherwise there's a fair amount of overlap in just how we address these.

Mr. FOSTER. Now, the other sort of big question here is, let's say that you're able to go to a less conservative, you know, zero intercept model for what you thought the human danger was. Is there anyone who's done, you know, an exhaustive, high-quality study of what the health and economic impact of that would be? Just assume that we declare a higher level of, you know, a de minimis exposure to be actually safe. What would be the economic impact? What would be the indirect health impact in terms of more, you know, more allowable chest X-rays, a shift in our energy mix, presumably towards nuclear and so on.

Dr. BRINK. It's an interesting question. I'm not aware of any such analyses but certainly as practicing physicians, most practicing physicians are still very much recognizing that the benefits typically outweigh the risks and so I don't know that there's been a huge reduction in the use of medical imaging, for example, because of whether there's the linear no-threshold intercepting the origin of the axis or whether they're considering there's a threshold effect or even a hormetic effect. Most physicians are still focusing on the benefits and practicing appropriately.

Mr. FOSTER. But there's still some limit. I mean, they reach a point at which, you've already had, you know, five X-rays this month and maybe we shouldn't have another one. Is there a sound scientific basis for that kind of decision?

Dr. BRINK. In my opinion, no, there's not, and when I'm faced with patients who are worried about those kind of thresholds, I'm going right back to the benefits and saying, you know, what is the reason why your physician needs these studies. Because the benefits are clear-cut. The risks are very much uncertain, and typically in almost all cases when there's a real sound medical reason to do the study, we're going to favor doing the study over a theoretical risk.

Mr. FOSTER. But it's your suspicion that, you know, to the extent that doctors are limiting, you know, things like X-ray or PET scans and so on that it's probably the conservatism, you know, related to radiation doses probably nets out harmful for patients?

Dr. BRINK. Well, we certainly will favor imaging tests that don't use ionizing radiation when we can so, for example, MRI or ultrasound don't have the same risks, and we certainly—and when we do need to use ionizing radiation, we're promoting using as low as reasonably achievable doses. But in terms of an economic threshold or economic benefit to a threshold, I'm just not familiar with any of those studies.

Ms. WOLOSCHAK. Yeah, where I would say where the economic threshold would probably come in, and I don't actually know the numbers, would be in how far do we have to clean up our nuclear-waste sites. It's probably a difference of trillions, at least billions of dollars if we accept the linear non-threshold or if we have a

lower threshold for cleanup. That's where I would think that there'd be a big savings in money.

Mr. FOSTER. I recall a paper by Richard Wilson of Harvard Physics Department who you may know. He was actually I believe one of the first Westerners allowed at Chernobyl and a real expert on this. He calculated the optimal radius of evacuation from Fukushima because you can mess up either way. If you—you know, there are two effects obviously. People suffer from exposure to radiation if they're too close. On the other hand, there's a well-documented probability of having people die, particular the elderly, if you move them, just relocate them, and so this allows you to calculate an optimal radius of evacuation. It was the conclusion of his paper at least that actually the Japanese evacuated too large a radius and ultimately had a negative health effect from that decision. And so this is just another example where getting the science right here is so important.

And now I'm over time myself so I'm happy to yield back.

Chairman WEBER. Okay. Thank you.

I now recognize the gentleman from Oklahoma.

Mr. LUCAS. Thank you, Mr. Chairman.

Dr. Wołoschak, one of the tendencies whether it's in Congress or the Executive Branch or, for that matter, anywhere out in the real world is, sometimes if we don't want the answer, we don't ask the question. So from that guise, let me quiz you and ask you for your opinion. The way that this research was determined to no longer be conducted, is that an example perhaps of someone not wanting the answers that would come from it? And if I look at this in the overall context, I mean, we've discussed health issues, we've discussed terrorism issues, we discussed the space program. From the perspective of my constituents back in Oklahoma, it seems that not knowing this information or taking the research to its ultimate conclusion puts us in a position to make perhaps decisions based on inaccurate facts. Could you expand on that a moment, I mean, from the perspective, say, of NASA? If we're going to the Moon or if we're going to Mars, we need to know these things, correct?

Ms. WOŁOSCHAK. Yes. In fact, when I ask astronauts, they say exactly that, that they care about the risks for cancer. They don't care as much about the risk of blowing up on a Launchpad which puzzles me.

Mr. LUCAS. Launchpad is instantaneous; cancer takes a long time.

Ms. WOŁOSCHAK. That's what they say.

Mr. LUCAS. I appreciate their point.

Ms. WOŁOSCHAK. But I think you're exactly right. The thing is, I can't actually speculate for why people don't want to know the answers to these questions or why it's been sort of stopped, but I will say it's been a pattern at least from my experience within DOE because we had a very large-scale program. I believe it was one of the best in the world for these—with these animals. They just terminated it, you know, spontaneously. Then they start up the Low Dose program and then again they terminated it very, very rapidly. I don't know what the reason for that is. It could just be something sporadic. Again, probably from DOE could answer that better than I could.

Mr. LUCAS. One of our responsibilities in Congress and most assuredly in our oversight capacities is to assess these situations and compel the right actions to take place to help provide guidance to the Executive Branch. I always remind my constituents in town meetings, no matter what anyone says at the other end of Pennsylvania Avenue, we write the laws. No matter what anyone says, the responsibility is for those laws to be implemented accurately and efficiently. So I find this a very concerning issue to me in a variety of ways. We have debated on this Committee as the Chairman knows and in Congress for years about how to store waste, whether a facility underneath a giant mountain in the West should be used, or it's better to store things down the street from me that I may not know about because that's where it was created or where we go ultimately with NASA.

Now, I appreciate your observations and the willingness to try and preserve as much of this research as could be done. Do any of your colleagues on the panel wish to address that question about what the background might or might not be that led to the decisions that have brought us to this point?

Mr. NEUMANN. Let me add the best answer we can get from DOE was that they had other research priorities in the bioenergy and environmental research that they wanted to fund. What was curious to us is that in 2016, the advisory committee report identified a number of areas that DOE thought would be useful to reduce the risk of cancer and understand better the low dose risk and also supported convening workshops between agencies to collaborate on a research agenda. But then the report ultimately concluded not to continue the research. So we couldn't get a better answer than that. It's just there were other research priorities.

Dr. BRINK. I have nothing to add to this one.

Mr. LUCAS. I think perhaps I've made my point, and I appreciate that, and I'll yield back the remainder of my time, Mr. Chairman.

Chairman WEBER. Which is by the way why we need a single collaborative mechanism to make that decision.

I recognize the gentleman from New York, Mr. Tonko.

Mr. TONKO. Thank you, Mr. Chair, and thank you to our witnesses for joining us today. I'm happy to see the Committee actively engaging on what I believe is a bipartisan issue where scientific research has an important role to play. Basic research on low dose radiation is of vital importance with far-reaching consequences for human health, future technology, certainly for human exploration and national security. So there's still a great deal in this field we do not fully understand, and I heard, I believe from just about all of you, that we need more attention to the research piece. Is that an agreement across the board that more research commitment is required? Mr. Neumann, I think you're—I see two heads nodded yes and—

Mr. NEUMANN. I would just say yes, that we identified—the agencies identified for us the research priorities, that there was obviously a number of areas that still had a great deal of uncertainty, and they believed there would be benefits to continuing that research.

Mr. TONKO. Okay. Now let's get into the GAO report. Mr. Neumann, the primary recommendation in the report is that DOE lead

the, and I quote, “development of a mechanism for interagency collaboration on research on low dose radiation’s health effects.” Now, DOE disagreed with your recommendation saying that it would not be appropriate for the Department to lead such an interagency initiative. Do you think it would be inappropriate for DOE to lead this interagency effort?

Mr. NEUMANN. Not at all. In fact, we thought they were in the best position to lead this effort given this past leadership as well as their responsibilities under the Atomic Energy Act, and it’s also consistent with GAO best practices that we’ve identified for interagency collaboration that if you don’t have someone leading such a mechanism, it’s difficult for agencies across the government to coordinate and make more-effective decisions.

Mr. TONKO. Is there a particular precedent you would point to for DOE to take on this role?

Mr. NEUMANN. Well, I think Dr. Woloschak also pointed out in one of her responses that DOE did do that in the past, and I think that’s what we also saw.

Mr. TONKO. And your testimony mentions GAO’s previous work has shown that collaborative mechanisms can serve multiple purposes, to develop sound science and technology policies. Can you further elaborate on the specific projects that GAO has examined to support this conclusion?

Mr. NEUMANN. Well, I can get back to you with specific examples but there’s been a range of examples in the past in various settings where there are multiple agencies involved in research areas that by having collaborative mechanism they can be more effective in achieving those goals. And without that leadership, those efforts are likely to not be as successful.

Mr. TONKO. And DOE has already responded that they do not concur with GAO’s recommendation. So are there alternative options that GAO considers or should consider or have considered when examining this issue that this Committee should be aware of?

Mr. NEUMANN. Well, I think we did consider whether or not other agencies would be in a position but we came to a conclusion based on the evidence that DOE was in that best position. Obviously additional direction from Congress might also encourage them to take a leadership role.

Mr. TONKO. And in the event that DOE does not implement your recommendation, are there other coordinating bodies or mechanisms outside of DOE such as OSTP that could potentially fill this void?

Mr. NEUMANN. In some of other work looking at OSTP, they usually are not in the position to direct agencies in some of these science efforts. They bring agencies together but then rely on the agencies to determine amongst themselves how to lead various efforts. So I would say that having an agency lead would be very effective.

Mr. TONKO. Thank you.

And Dr. Woloschak and Dr. Brink, most of the conversation in this field is about the detrimental effects of radiation exposure. Some researchers have indicated that there may be positive benefits from exposure to low doses of radiation but there’s still much

more that we need to learn. So my question is, what is your perspective on the possibility that there could be positive health effects as a result of exposure to low doses of radiation, and what could some of these positive effects be? Dr. Woloschak?

Ms. WOLOSCHAK. Yeah, so we for sure know that low doses of radiation boost the immune response, can actually add to health of people. The problem is, how do you balance that with potential risks of cancer and other effects. So the risk of cancer is something that's very questionable at low doses but there certainly are many studies that have shown that low doses also do boost an immune response, so it's that balance that I think is going to be hard to understand.

Mr. TONKO. Okay. Thank you.

And Dr. Brink?

Dr. BRINK. So the idea that radiation could actually be somewhat beneficial at low doses is called the hormetic effect, and it's yet another step beyond where we are today which is just accepting that there might be a threshold rather than the no-threshold hypothesis. So I tend to, as I alluded to in my windshield wiper analogy, that I tend to think that naturally occurring processes in many examples in nature do have non-linear responses whether they be that one or many others we can think of. And so to my way of thinking just getting to the point of acknowledging or understanding if there's a threshold through additional research that might show that would be the first step before even getting to the hormetic effect.

Mr. TONKO. I thank you all very much, and with that, Mr. Chair, I yield back.

Chairman WEBER. I thank the gentleman.

The gentleman from Illinois is recognized for five minutes.

Mr. HULTGREN. Thank you, Chairman. Thank you all for being here. I appreciate your work and appreciate your testimony today. Last Congress, the House unanimously passed legislation that I had sponsored. It was H.R. 35 to authorize a Low Dose Radiation Program. I was also glad this was included in the Committee's unanimously passed Energy Research and Innovation Act earlier this January. Hopefully we can see that get over the finish line in the Senate and a lot of other things too.

But coming from a state where more than half of our energy comes from zero-emission nuclear energy, the safe handling and storage of nuclear material is vital. The University of Chicago will be also celebrating the 75th anniversary of Chicago Pile-1 next month, so we've got the longest record of work in this space. Regulations based on science are necessary so that we're doing what's needed while not overburdening our research facilities and clean energy industry.

Dr. Woloschak, if I could address my first question to you. In your prepared testimony, you discuss new technologies that could be applied to this research. What are some of these new technologies, and in your opinion, how promising are these potential applications?

Ms. WOLOSCHAK. Yes. So actually the acting—Mr. Foster had mentioned that there are large-scale data analyses that are quite possible, and we actually are trying to take advantage of that now

looking at data sets from the United States, combining them with data sets from the E.U. in fact so we can look at 150,000 mice, being able to look at 31,000 dogs. That sort of data on a large-scale analysis was not even possible years ago. So statistical analyses have changed. Computational approaches have changed. That's one thing that's going to make a very big change.

The second thing is, is that as was noted before, we can do single-cell sequencing of cells so I think that that technology is going to be extremely important. We can also make new kinds of mice that we couldn't make before so if we wanted to try to create an animal with particular types of genetic susceptibilities, we can look at those with a far fewer number of animals. So there are a lot of new technologies that didn't exist when this program was even terminated 5 or six years ago. I mean, science is moving really fast.

Mr. HULTGREN. Dr. Brink, in March of 2013, Dr. Paul Cabot from Harvard Medical School cosigned a letter to the former Science Advisor, Dr. Holdren, detailing the gaps in knowledge on low dose radiation and the continuing need for this research. Do you know what response he received on that?

Dr. BRINK. I'm sorry, I do not, but I'd be happy to investigate and get back to you about that.

Mr. HULTGREN. That would be great if you would.

Dr. Woloschak, if I could, you testified that you have accumulated the archive of referenced animal tissue samples from DOE's closed Low Dose Program in your lab at Northwestern. What so far have you been able to determine? You kind of referenced that, but what else are you seeing? How do you plan to curate the data to make it publicly accessible to? And if DOE does restart the program, will that also make it so that your data—it'll be easier for you to make that public as well?

Ms. WOLOSCHAK. Yes, so these data are amazing. I mean, these were single—I mean, who does a 50,000-mouse experiment anymore? I mean, nobody—we don't have the capacity to do that. Twenty-one thousand dogs. I mean, so rather than throw it out, we actually took the data sets, and because of DOE's support through the Low Dose program, we were able to put much of that data up on a publicly available website now. The rat data are still not up on the website. Not all the dogs are up. We're trying to make it be publicly available so anybody can study it. That has been our goal. But the problem is keeping the data without having the tissues to go back to verify is a problem and that's why we have tried to keep the tissues as well, and I'm thankful to my university who has supported us through the hard times.

Mr. HULTGREN. That's great. Also Dr. Woloschak, a 21st century science workforce is something this Committee has been focused. We spend a lot of time discussing it, and I want to make sure that we're ensuring that we have it. In your testimony, you identified workforce issues in the field that the majority of radiation scientists are retired and that there are not enough young scientists to replace them. How do you recommend that our Nation and our world address this developing issue?

Ms. WOLOSCHAK. The reason why students don't want to go into radiation biology is because there's no funding so they feel like they're going into a dead-end position, and honestly, today, I can't

recommend for my students to go into that field. I also work in nanotechnology, and I push them in that direction because there's funding there. I believe that more funding for the field would really enhance capabilities to generate a workforce.

Mr. HULTGREN. That's great. In my last few seconds here, again, Dr. Woloschak, the National Council on Radiation Protection has been writing a commentary on recent research implications for the linear no-threshold model of radiation protection and expects to put a report out soon. Based on your review, what have been some of the major recent studies in radiobiology over the last five years and what impact, if any, are they likely to have on the current linear no-threshold model?

Ms. WOLOSCHAK. Right. So the report's not out. I'm actually on the board for the NCRP, and I don't—the report's not quite out so I'm not at liberty to say what they're going to say but certainly there have been—I believe they're going to still—they're using the human data as their primary mode for saying LNT is still the safest with today's current today. They will say that more data would be useful.

Mr. HULTGREN. Well, thanks again. Thank you all for being here. I yield back.

Chairman WEBER. I thank the gentleman. The gentleman from Florida is recognized for five minutes.

Mr. DUNN. Thank you very much, Mr. Chairman, and I want to thank our panelists. I was fortunate enough to capture them on the way into the room and had a chance to talk to them earlier, and I'm grateful for that. I appreciate the work that you do.

And also Mr. Neumann, we didn't get a chance to talk but I welcome you because I understand that you are the one person in the room who's most able to direct the Department of Energy to restart this research, and that's exactly what we would like to see you do. I think you've gathered that from all of us.

Congressman Foster suggested that we adopt a standard that has been called, I think Dr. Brink said it as low as reasonably achievable radiation, and I think that that is a great model for us to be thinking about. I can tell you as a practicing surgeon that we had a lot of pressure on us to limit radiation exposure even at the risk of being ignorant of the patients' underlying pathologies. So this work is very, very important.

My question—and this will be part Dr. Woloschak on the therapeutic side but part to Dr. Brink on the diagnostic side. So have we gone overboard in stressing the risks associated with the proper use of diagnostic radiation and therapeutic radiation?

Dr. BRINK. May I jump in first? I do think that as you probably experienced in practice that sometimes patients—there's been quite a lot of press that patients will be exposed to about the potential risk and sometimes they'll confound potential versus actual and will provide a lot of concern about even getting the necessary imaging that they need. And so very commonly I'll work hard to try and convince a patient that the benefit of what they would see from undergoing the test would greatly exceed the potential risk that they might face, and I imagine you've faced that in your practice as well.

Mr. DUNN. Every—it was just very, very commonly, and I think there's a sense of alarmism actually among the patients and they're getting this information from whatever sources that we're over-radiating them dangerously, and you're looking at somebody who might have something as simple as a kidney stone but if they're obstructed and they're infected beyond the obstruction, that's a potentially fatal problem.

Dr. Woloschak?

Ms. WOLOSCHAK. Yeah, I think for therapeutic radiation oncology where you're treating patients with cancer, most often they don't really worry about what the risks are going to be but where it comes to play is, because you're giving a dose all over the body, secondary cancers can come about as a result of the radiation exposure. So after they've been treated, then they're worrying either about am I going to have a recurrence or am I going to have a secondary cancer. So it becomes an issue after the fact. I don't think it influences therapy but certainly the one thing that does influence therapy is how can we make that treatment location be as small as possible to minimize dose to the rest of the body. So we do actually understand quite a bit about low doses because of the scatter of the radiation when we give therapeutic doses.

Mr. DUNN. So that's actually interesting subject for us. I mean, we obviously worry about bladder and rectal cancer following prostate radiation.

Ms. WOLOSCHAK. Absolutely.

Mr. DUNN. Can you give us a sense of how common that is—

Ms. WOLOSCHAK. Yeah, I mean—

Mr. DUNN. —rectal and bladder.

Ms. WOLOSCHAK. Yeah, I'm not really a radiation oncologist. I'm a radiobiologist that teaches radiation oncologists, but the worry is—there is a considerable risk, and in fact, that's what's affected the way that we deliver. So as you know, we're now using seed therapies, for instance, because of worries about radiation damage to the bladder and rectum mostly from late tissue toxicities that might result. Secondary cancers, there are quite a few studies that have been done looking at what percentage that you'll find in the field and then outside of the field, and there is a pretty considerable risk not as much to the rectum but to the other abdominal areas associated with particular prostate cancer.

Mr. DUNN. And finally, if I could—and one of the confusions is when we're talking about radiation, doses of radiation, we think we're measuring it in one type of measurement, and I'd like you to address a little bit either what measure we should be using or how confusing that subject is.

Dr. BRINK. That's a great question. You know, there's so many things that need to be investigated in research on low dose radiation and not the least of which is just how to measure it. There's much literature that reports the measurement to the entire body, the organism, the effective dose and others that really focus on the specific organ that's irradiated, and this alone actually creates a great deal of confusion, and some just owing to the uncertainty of the best way to measure the dose from any particular study or therapy.

Mr. DUNN. Any follow-up on that?

Ms. WOLOSCHAK. Yeah, and I would agree with that, and also add in that it's a big issue for discussion. I mean, at the National Council on Radiation Protection, we talk about what's the best way to try to calculate dose and figure out dose. It's controversial, and believe me, people—you could fill a room talking about it for days.

Mr. DUNN. So my time has run out but I hope, Mr. Neumann, what you take away from all of this is that we all are cheering for you to go, you know, get on this horse and ride it home. Thank you so much.

I yield back, Mr. Chairman.

Chairman WEBER. I thank the gentleman.

Mr. Foster, you're recognized.

Mr. FOSTER. If I could just—a point of clarification. In my remarks, I did not specifically advocate for ALARA, a low as reasonably achievable which is, you know, the rule under which I worked for many years at a national lab. You know, I view ALARA as largely an expression of our ignorance. It's what you do when you say since I do not know whether or not this may be dangerous, in the absence of better numbers, let us do as much as reasonably achievable, whatever that means, to minimize dose, and so it's an example of a real cost of not having the real numbers on this.

Chairman WEBER. You said it's the result of ignorance. Doesn't that apply to a lot of what Congress does? I'm just asking.

Mr. FOSTER. Well, it's also true that we work in the U.S. Capitol, which has—because of the stone that's used has radiation levels that would not be allowed for incorporation into a nuclear facility.

Chairman WEBER. Well, see, that explains what I'm talking about.

We're going to do a round two, and I don't know if the gentleman from Florida wants to hang for that, but at least Mr. Foster—are you good, Neal? Thank you.

So we would love to have the DOE in here as part of this discussion. We'd love to have the Under Secretary for Science from the DOE but we're waiting on him to get confirmed. So if we can make that happen, that would be helpful.

I did note in the testimony today that the Atomic Energy Act—and this is for you, Mr. Neumann. When the DOE said that they didn't think that they wanted to take that purview, the Atomic Energy Act of 1954, did they cite reasons from the Atomic Energy Act, or do you remember why they turned it down?

Mr. NEUMANN. They did not cite that. We pointed that out in our response to them, that they do have these responsibilities but—

Chairman WEBER. I saw that. Of course, it is at this point 63 years old so I guess the political question may be in part, do we need to revisit that Act? Do we need to clarify what their role might be in this instance?

Mr. NEUMANN. The language is pretty plain in the Atomic Energy Act that they're responsible to lead, you know, radiation research given—

Chairman WEBER. Which would include low dose?

Mr. NEUMANN. Right, which would include a range of—so, you know, you could always have more specificity but the language is pretty plain.

Chairman WEBER. Okay. Dr. Woloschak, you said that low dose radiation could boost the immune response.

Ms. WOLOSCHAK. There's certainly some studies that have demonstrated that in the literature, and it looks to be—that that's true.

Chairman WEBER. Okay.

Ms. WOLOSCHAK. The problem is, it may also cause cancer, and so do you want to tell somebody to go sit in a radioactive spa and enjoy and boost your immune system if at the same time they're at risk for cancer, and it's those unknowns that make it be so difficult for what to do with low dose radiation.

Chairman WEBER. Right. And is that probably true? One of the difficult parts of this in that research is because everybody's DNA makeup is different. How do you decide, you know, how everybody's going to be affected by that. Is there a time in a person's life generally speaking and an age—I think some of the testimony, I don't remember if it was you or Dr. Brink that said cells repair themselves. I think it was yours.

Ms. WOLOSCHAK. Oh, cells always repair themselves.

Chairman WEBER. Right.

Ms. WOLOSCHAK. So the question is, how much can they repair.

Chairman WEBER. But if they repair themselves inappropriately—I forget the terminology—then there's a—I guess they mutate and they create a problem in that regard. Is there an age—I mean, do you find that when a person gets older, midlife? Is it 30 years old, 50 years, 80 years old, or no? Do you have that research?

Ms. WOLOSCHAK. There's a lot of work that says that as people get older, their repair capacity decreases.

Chairman WEBER. Well, I know that's true.

Ms. WOLOSCHAK. Yes. We all know that. But the other thing is that in general, the young are more susceptible for cancer induction than the old because they're going to live longer.

Chairman WEBER. Okay. And then Dr. Brink, you brought up a new term for me. You said the idea of the beneficial low dose is called the hormetic effect.

Dr. BRINK. Yes.

Chairman WEBER. Spell that.

Dr. BRINK. H-o-r-m-e-t-i-c.

Chairman WEBER. Okay. Would you elaborate on that, please?

Dr. BRINK. It's a theory that I think was being alluded to earlier which is that low dose radiation could in fact be beneficial either through stimulating the immune system or what have you, and it's very much a theory at this point.

Chairman WEBER. So how did it come about and how long has it been around?

Dr. BRINK. I'm sure I can answer specifically. It's been — it's not new. The theory's been around for some time.

Chairman WEBER. Where does the name hormetic come from?

Dr. BRINK. Hormesis is the root term, and I'm sorry, I'm not a linguist. I'm not sure I can answer that.

Chairman WEBER. Okay. You just know that that's the term that was applied.

In Texas in Andrews County out by El Paso or actually I think it's maybe further north toward the panhandle is a company called

Waste Control Specialists, and they take on low-level radiation waste. Are any of you all aware of that facility or familiar with that facility? So when we're talking about, you know, doing research on low-level waste, were any of the low-level radiation waste facilities included in that research? Do you know?

Dr. BRINK. I'm not aware.

Ms. WOLOSCHAK. I'm not aware of any.

Chairman WEBER. So when we talk about doing research on low-level radiation, and maybe this is for you, Mr. Neumann, why wouldn't it be that the DOE or anybody that was involved prior to 2012 when the funding was starting to be diminished, why wouldn't they have included those facilities? Any idea?

Mr. NEUMANN. The research they've been conducted has been either epidemiological, you know, where they're looking at a population of people over time, or radiobiological, which involves lab work that Dr. Woloschak talked about.

Chairman WEBER. Right.

Mr. NEUMANN. That's how they were determining the potential effects of low dose radiation.

Ms. WOLOSCHAK. One approach would be to go to a site like the one you've mentioned and look at what the doses are, get a good dosimetry, and then do some lab experiments to try to answer what those effects might be in addition to studying the population.

Chairman WEBER. Dr. Brink, I think you were going to say something?

Dr. BRINK. Yeah. There certainly have been other efforts to look at radiation workers for their risks, and a more recent one is the Million Workers study looking at a million workers in the nuclear power industry that's underway.

Chairman WEBER. Right, and that was the reason I asked because those are typically associated with high-level radiation, right?

Dr. BRINK. Well, hopefully not for the workers.

Chairman WEBER. Well, I mean, you're hoping not but, I mean, you go in there and you think well, those would not be considered low dose radiation levels, right?

Ms. WOLOSCHAK. The Million Workers study is really about low dose workers—

Chairman WEBER. At nuclear—

Ms. WOLOSCHAK. —people that were exposed at low—

Chairman WEBER. At nuclear plants?

Ms. WOLOSCHAK. Yes.

Chairman WEBER. I would think the propensity would be to be—well, I guess any level—what did you call it? The lowest risk assessment level? But it's interesting to me that you only talk about nuclear energy plants, you don't talk about the waste facilities. Perhaps that's something that should be included.

So I appreciate that, and I'm going to yield to the gentleman from California.

Mr. ROHRBACHER. Let me apologize that, of course, as usual, we're scheduled with two important hearings at exactly the same time, and I will review your testimony later on. So if I ask a question or two that is repetitive, excuse me for that.

Let me—people are going to the dentist and then they're taking your pictures or you go to a doctor and they're taking X-rays of you. Is this the type of low dose radiation that deserves more research?

Dr. BRINK. So when we talk about low dose radiation, those kind of doses are extremely low, and more commonly, and you know, they're two or three orders of magnitude lower than the doses that we call low dose that we're focused mostly from computed tomography or nuclear medicine.

Mr. ROHRABACHER. So we don't—so one thing that came out of this hearing today is that you're not suggesting that we—this is a potential danger that needs further investigation in terms of the type of radiation that we are exposed to in the health industry, medical health?

Dr. BRINK. Well, the topic is very much about doses administered in the health industry. You were speaking more specifically I think about dental X-rays or—

Mr. ROHRABACHER. Right.

Dr. BRINK. —extremity X-rays, which are extremely low dose. But more commonly, the doses from an imaging procedure such as a CT scan or a nuclear medicine test would be also low dose but at a magnitude that we're really speaking about what would be the—where research would be helpful to understand better what the potential risk might be. At the moment we only extrapolate from high-dose exposures to kind of guesstimate what the risk would be at those kind of doses.

Mr. ROHRABACHER. And what about, is this idea that power lines—I guess power lines wouldn't be—I remember there were some complaints in the past that power lines could pose some sort of health threat. Was that due to radiation or something else?

Ms. WOLOSCHAK. You know, I was on a committee that investigated the effects of electric magnetic power lines, and that kind of radiation or the quality of radiation is different than the ionizing radiation that we're talking about now. Now, in fact, most of those studies said that there were no effects from living by the high-power lines but this is different type of radiation.

Mr. ROHRABACHER. All right. What about that?

Ms. WOLOSCHAK. And it's also a different kind of radiation than the cell phones have as well.

Mr. ROHRABACHER. Okay. So you aren't today testifying that a warning to all of us to put this on the speaker rather than next to your ear or that we better watch out when we go to the dentist or if you're—you have to get something X-rayed so the dentist—or so the doctor can figure out how to help you, we don't have to worry about those things?

Ms. WOLOSCHAK. So I think what we're trying to say is that cell phone, that quality of radiation, is something that we're not concerned about here. What we're concerned about is ionizing radiation, and ionizing radiation is dangerous because it breaks bonds, and that's—

Mr. ROHRABACHER. Can you give me an example of ionized—

Ms. WOLOSCHAK. So the dental X-ray is a type of ionizing radiation. The other types would be the CT scan, the chest X-ray, what we find in nuclear power plants, what we use for nuclear power. All of those would be examples of ionizing radiation. They're a type

of radiation that causes the breaking—has the potential to break our bonds in our genetic material.

Mr. ROHRABACHER. So is it a fundamentally different type of radiation that we're talking about?

Ms. WOLOSCHAK. It is fundamentally different than the cell phone or the power line, fundamentally different.

Mr. ROHRABACHER. So we're not just talking about dosage, we're talking about an actual difference in the type of thing that we're looking at?

Ms. WOLOSCHAK. Right.

Mr. ROHRABACHER. Well, we do know also—look, I'm here to learn, okay, so don't think less of me for asking stupid questions sometimes. Isn't—when you go and you're treated for cancer, aren't you being dosed with radiation, and if the cancer—if radiation causes cancer, what are we doing?

Ms. WOLOSCHAK. So that becomes one of the biggest questions in treatment of patients with cancer. You're absolutely right. The dose we're giving to the cancer to kill it is very, very high, but what happens is, high doses kill cells. They don't cause cancer; they kill cells. What causes cancer are lower doses where the cell still lives but it's picked up mutations. So when you treat somebody with cancer, you give this whopping dose, it kills the cells; they're gone. But around that dose there's often a lower dose, and then there's the risk of secondary cancer, a second cancer popping up. But the problem is the person's life is at stake so you just go in and you treat the cancer because you've got to save the life then, and then you worry about the effects later. But it is a risk. It is a risk.

Mr. ROHRABACHER. All right. Well, thank you very much for drawing our attention to this issue. Thank you, Mr. Chairman.

Chairman WEBER. Thank you, and I apologize to Mr. Foster. I should have recognized him next. Bill, you're up.

Mr. FOSTER. Thank you.

First, I just want to comment on these beneficial effects of radiation. You know, this has been speculated upon I guess as long as radiation was known. My mother, when she was growing up, I guess people thought it was a good idea to treat acne with very large doses of X-rays for which my mother enjoyed having various forms of skin cancer towards the later years of her life. On the other hand, you know, my brother who had stage IV esophageal cancer benefited tremendously from a focused dose of radiation on his tumor. And so better scientific understanding yields better health outcomes here, and one of the reasons that we really want to keep doing this research.

Now, in regards to the hormetic effects, you mentioned the immune system is activated in response to radiation dose. Is there also evidence that this can trigger autoimmune diseases as well? Is there a danger there as well as cancer?

Ms. WOLOSCHAK. Look, I want to stress that we don't understand enough about low doses to even say yes, there's this big hormetic effect. What I can say is, in the literature, you can find reports that when you treat with low doses, you stimulate animals to have a better immune response. Is there the possibility of autoimmune disease? You're absolutely right. That is a possibility that could come with it. So just as much as looks like there are positive ef-

fects, there may also be negative effects, and that's why we have the need to do research at that low dose range.

Mr. FOSTER. Okay. And similarly, DNA repair mechanisms are modulated by various factors inside biology. Are there documented effects of radiation on how active the DNA repair mechanisms are?

Ms. WOLOSCHAK. Certainly we know that the repair mechanisms are sitting there kind of raring to go, and when you irradiate, they go right to the site within almost nanoseconds to begin to repair. So the repair process is extremely rapid. It begins almost immediately following radiation exposure.

Mr. FOSTER. And it's my understanding that there is some scientific at least speculation, if not research, that you may be able to treat astronauts with drugs, for example, that activate the DNA repair mechanism to make them more radiation-resistant.

Ms. WOLOSCHAK. NASA's looking for mitigators exactly like that right now, so you're right on target.

Mr. FOSTER. It's sort of an infinitely complicated problem.

Now, I'd like to actually stand up in favor of DOE a little bit. It was not a completely thoughtless abandonment of this, and if I could have unanimous consent to enter into the record a letter—

Chairman WEBER. Without objection.

[The information appears in Appendix I]

Mr. FOSTER. —a letter to the Secretary of Energy Advisory Board dated—on this subject dated June 23, 2015, which makes two interesting observations. The first one is that, quoting from the letter, "it's highly unlikely and I would say impossible that a group of experts would after review and deliberation of the vast literature on this subject come to a consensus or that that consensus would resolve this issue to the satisfaction of the regulatory authorities or the public." You know, this has to do with is there a path to success here even if the science became clear, and I was wondering—I'll ask you for comments on that.

The second thing I want to point out is that this same letter from the SEAB says the SEAB does not believe that DOE should abandon its research on low level radiation effects. So although it expressed skepticism on a path to success both in convincing the regulators and the public that this could be a settled issue, they did also recommend this, and so the letter is, I think, interesting reading for anyone just trying to evaluate why the DOE went the way it did.

So any comments on that?

Ms. WOLOSCHAK. Yeah. I mean, so as a person that sits on a number of regulatory boards that discusses these and mostly makes advisory decisions, I mean, I think it is true to say that if you don't have data, then you always say well, we can't imagine what we can get to solve a problem. So DOE is exactly correct in saying we can't imagine what it would get to solve a problem. But at the same time what I'll say is, I've seen policies change because of data. So things I never expected like to have the limit for the dose for the lens of the eye, it's dropped because of new data and new results. It's dropped internationally—

Mr. FOSTER. The limit dropped in the sense of being more conservative?

Ms. WOLOSCHAK. Being more conservative in that particular example because cataracts were popping up at lower doses than people expected, and nobody would have imagine that happening five years ago. It was just not possible. So I think that it's easy for DOE to make that statement that things will never change, but the fact is, data do convince people, and that's why more data are needed.

Mr. FOSTER. You know, it used to be popular to tune up electron beam lines by looking at—staring the beam into your eyeball and looking at the track of radiation.

Anyway, I just wanted, in the time that I barely have here, to bring up the issue of money. I mean the reason that ultimately this program was discontinued is the stress in real terms of the budgets in the Department of Energy, so I have a lot of sympathy there. You know, I wish this could be a uniformly bipartisan issue. I was very disappointed when the Trump Administration proposed I think a 16 percent cut to the Department of Energy, and I was unable to get bipartisan support for a letter urging against that. It is not only authorization that counts, it is appropriations, and I think that everyone paying attention to this hearing should understand to watch votes on budgets and appropriations and not just authorizations.

Thank you, Mr. Chairman. This has been a really great hearing, and I yield back.

Chairman WEBER. Well, I thank the gentleman. I do want to point out that we didn't exactly—we're not enamored by those cuts either in every form, some cuts but not all of them, so I thank you for saying that.

I do want to ask probably a more technical question, Dr. Woloschak. Ionizing radiation, you specifically said as used in dental X-ray, they break bonds. Would you explain what you mean by that?

Ms. WOLOSCHAK. So ionizing radiation is defined by any radiation that can cause an electron to be ejected from an atom. That's actually the official definition. So if you think about the removal of an electron from an atom, so go back to high school chemistry—

Chairman WEBER. It's going to change the structure?

Ms. WOLOSCHAK. That ejection process causes bonds to break, and what we care about most, as a radiation biologist, is damage to our DNA. So when we break bonds to DNA, then we have to have processes in our cells that repair it and actually we have fabulous methods in our cells to repair it. It's incredible. But that is the definition officially of what ionizing radiation is.

Chairman WEBER. Okay. Are there other types of radiation?

Ms. WOLOSCHAK. Sure, sure. So ultraviolet radiation that we get from the sun when we get a sunburn. That's a different quality of radiation.

Chairman WEBER. So that's low level?

Ms. WOLOSCHAK. It's—but it's not ionizing. So we don't—so that's not what we've been worried about here because it's not ionizing. We can protect it with sunscreens and things like that. Electromagnetic radiation that comes from power lines, that's another type of radiation. It's not ionizing. Radiation that we get from our microwave is also radiation but it's not ionizing.

Chairman WEBER. I've often wondered about that, the microwave analogy. How many other types of radiation would you say? Are there six?

Ms. WOLOSCHAK. So yeah, they're probably about—from the electromagnetic spectrum, we go from extremely low-frequency radiation from the power lines, we go to radiation from infrared I mean, so there's a spectrum of probably like seven or eight types, and it depends on how you divide it.

Chairman WEBER. Okay. All right. That's actually probably, unless you have any other questions?

Mr. FOSTER. If I could have just one—

Chairman WEBER. You bet you.

Mr. FOSTER. —final comment. You know, this is a reminder of how great it is to have the GAO around, having an organization that provides high-quality, nonpartisan analysis is indispensable. You know, for good or ill, we've taken the size of Congressional staffs down to dangerously low levels, and that actually causes us to depend on organizations like yours, so thank you and thank everyone in your organization for existing and doing your job so well.

Mr. NEUMANN. Thank you.

Mr. ROHRABACHER. Mr. Chairman?

Chairman WEBER. The gentleman from California.

Mr. ROHRABACHER. One last comment as well. We all know that Madame Curie died, right? She died of cancer, I believe, from her experiments, and that's—we didn't even know anything about radiation then at all, and she was the one who discovered this, and about 40 years later, 50 years later, maybe, maybe 40, my father had cancer, and he was saved. Radiation saved him. He was one of the first chemotherapy guys, so Madame Curie died and my father lived, and we've been through this thing where you go to the shoe store and you're going to buy your shoes, I remember looking in the X-ray machine, so mankind has a lot to learn, and we have learned a lot, and I want to thank you guys for being at the forefront of this important lesson and try and see how we can use this to our benefit and take care of the dangers, so thank you very much.

Chairman WEBER. Well, thank you. I want to thank the witnesses for their valuable testimony and the members for their questions. The record will remain open for two weeks for additional comments and written questions from members.

This hearing is adjourned.

[Whereupon, at 12:01 p.m., the Subcommittee was adjourned.]

Appendix I

ADDITIONAL MATERIAL FOR THE RECORD

STATEMENT SUBMITTED BY RANKING MEMBER
EDDIE BERNICE JOHNSON
OPENING STATEMENT
Ranking Member Eddie Bernice Johnson (D-TX)

House Committee on Science, Space, and Technology
Subcommittee on Energy
"The Future of Low Dose Radiation Research"
November 1, 2017

Good morning and welcome to our witnesses. Thank you to Chairman Weber for holding this hearing to examine the future of low dose radiation research at the federal level.

This research is important to better understanding the health impacts of exposure to low doses of radiation that could result from medical tests, terrorism events, or materials associated with nuclear weapons and power production. Since its inception in 1998, the Low Dose Radiation Research Program at the Department of Energy had provided high-value scientific data to help determine these risks. In fact, just over a year ago the head of Biological and Environmental Research within DOE's Office of Science testified before this Committee and highlighted the accomplishments of this program. However, its funding levels have been cut since 2012, as the Obama administration informally expressed its intention to end the program, and it was finally terminated last year. Thus far the Trump Administration also has not indicated any interest in restoring DOE's stewardship of these activities.

With a proven track record of success, it is puzzling why such a program has been targeted for elimination. And it appears to make little sense to the Government Accountability Office as well. Earlier this year, GAO was asked to examine federal agencies' radiation protection requirements and guidance and related research. As we'll hear in testimony shortly, GAO responded to this request with a recent report which recommended that DOE lead the development of a plan for interagency collaboration on research into low dose radiation's health effects, citing a lack of coordination efforts among federal agencies after the Department began phasing out its program.

To help address this issue, I would like to note that I have cosponsored the bipartisan "Department of Energy Research and Innovation Act" that would, among many other important policy provisions, direct DOE to carry out a low dose radiation research program. This bill represents a bipartisan, bicameral agreement that we achieved as part of the comprehensive energy bill negotiations carried out late last year. I am pleased that so many members on this Committee from both sides of the aisle have also cosponsored this bill, which passed the House without objection in January, and I urge my colleagues in the Senate to act upon it soon.

So I look forward to hearing more from our excellent panel of witnesses on the need for more low dose radiation research and on the role that federal agencies should be playing in this field. That said, I'd be remiss if I did not note that there is a critical participant that we are not hearing from today – and that's the Department of Energy. Given that the primary reason that we're holding this hearing is because DOE has chosen to end its low dose radiation research program, it seems to me that we should have a representative of the Department here to defend this decision and discuss whether this remains the wisest course of action going forward. Therefore I

am deeply disappointed that the Department declined to offer a witness for this hearing, and hope that the Chairman and I can work together to ensure that we have representatives of the Administration testify before us on these and the many other issues relevant to our federal agency oversight responsibilities going forward.

Thank you and I yield back the balance of my time.

STATEMENT SUBMITTED BY MS. LAURA I. THEVENOT, CEO, ASTRO



AMERICAN SOCIETY FOR RADIATION ONCOLOGY
251 18th St. South, 8th Floor
Arlington, VA 22202

Main: 703.502.1550 • Fax: 703.502.7852
www.astro.org • www.rtnswers.org

November 7, 2017

House Subcommittee on Energy
Committee on Science, Space, and Technology
2321 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Weber and Ranking Member Veasey:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide comments on the House Committee on Science, Space, and Technology, Subcommittee on Energy's hearing on "The Future of Low Dose Radiation Research" (November 1, 2017).

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

ASTRO supports funding of basic research on low dose radiation in the United States, and the Government Accountability Office (GAO) recommendation that the Department of Energy (DOE) lead these efforts. Without this type of research, appropriate determination of health effects, as well as dose limits, cannot be easily determined.

As Gayle Woloschak, Ph.D., Professor of Radiation Oncology and Radiology at Northwestern University, stated in her oral testimony, currently "radiation protection policies deal with low doses of radiation because that is precisely the level of environmental and occupational exposures that can and should be regulated. Radiation protection is designed for a healthy population with the view of preserving health." Furthermore, the health effects of low dose radiation exposures remain ambiguous, and the policies regulating radiation exposures rely on models developed for high dose exposures, which may not be accurate. Reinstating funding of low dose research, coupled with the availability of new technology, would afford researchers the opportunity to understand the health effects of low dose radiation exposure and support the development of sound regulatory policies.

ASTRO appreciates the opportunity to provide comments on the future of low dose radiation research, and we look forward to continuing our work with the Committee on this, and other important issues. Should you have any questions, please do not hesitate to contact Margarita Valdez, assistant director of congressional relations at 703.839.7382 or margarita.valdez@astro.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

LETTER SUBMITTED BY REPRESENTATIVE BILL FOSTER

Massachusetts Institute of Technology

77 Massachusetts Avenue
Building 6-215
Cambridge, Massachusetts 02139

John Deutch Institute Professor**Department of Chemistry**

Tel: 617 253 1479
Fax: 617 258 6700
Email: jmd@mit.edu

Secretary Ernest J. Moniz
U.S. Department of Energy
1000 Independence Avenue S.W.
Washington D.C. 20585

June 23, 2015

Dear Mr. Secretary,

SEAB has requested that I respond to your letter of June 16, 2015 requesting

“...SEAB’s perspective on how DOE should pursue research on the question of a ‘linear’ or ‘threshold’ low-level radiation exposure model. Should DOE continue its efforts on this subject or leave it to other agencies such as EPA and NIH? Or is there a research effort that over time may lead to knowledge that will resolve the question of health effects of low-level radiation exposure to citizens and workers in the nuclear industry. Has the scientific community identified specific knowledge gaps that would be appropriate research priorities for DOE to pursue?”

This question of “linear” versus “threshold level” radiation exposure to low levels of radiation is important because its consequences for regulations governing radiation exposure to workers, and citizens in the vicinity of commercial nuclear power plants and associated fuel cycle activities, especially with regard to the increased likelihood of cancer fatality.

For human populations a plausible case can be made for a threshold below which there is no harm to exposure because the human population has forever been exposed and therefore adapted, to natural background levels of radiation. Organisms in the natural environment evolve biological mechanisms to repair radiation damage to cells at the molecular level, thus avoiding or reducing adverse radiation response. This suggests research on radiation damage at the cellular level to identify natural thresholds for radiation damage. However, if a precise understanding of the cellular level dose-response were reached, the challenges of scaling up this understanding to enable establishing a quantitative threshold for human dose-response would remain.

The most direct way to investigate low-level radiation damage is epidemiological studies on human populations exposed to different levels of radiation in one context or another (Denver versus Miami). Such studies do not rely on ‘controlled’ conditions to establish dose and response but rather attempt to infer the dose-response relationship from statistical information. This is a formidable task because as the dose level approaches zero the “noise” of random fluctuations that reflect different exposure circumstances becomes proportionally larger than the signal that one is seeking to detect.

Massachusetts Institute of Technology

77 Massachusetts Avenue
 Building 6-215
 Cambridge, Massachusetts 02139

John Deutch Institute Professor**Department of Chemistry**

Tel: 617 253 1479

Fax: 617 258 6700

Email: jmd@mit.edu

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