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Committee on Environment
and Public Works Washington, D.C.

HEARING ON OVERSIGHT OF THE ENVIRONMENTAL PROTECTION AGENCY'S IMPLEMENTATION OF SOUND AND TRANSPARENT SCIENCE IN REGULATION

Wednesday, October 3, 2018

United States Senate

Subcommittee on Superfund, Waste Management, and Regulatory Oversight

Committee on Environment and Public Works

Washington, D.C.

The committee met, pursuant to notice, at 2:20 p.m. in room 406, Dirksen Senate Office Building, the Honorable Mike Rounds [chairman of the subcommittee] presiding.

Present: Senators Rounds, Booker, Barrasso, Carper, Ernst, Sullivan, Whitehouse, and Van Hollen.

STATEMENT OF THE HONORABLE MIKE ROUNDS, A UNITED STATES SENATOR FROM THE STATE OF SOUTH DAKOTA

Senator Rounds. Good afternoon, everyone. The Environment and Public Works Subcommittee on Superfund, Waste Management, and Regulatory Oversight is meeting today to conduct a hearing entitled Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation.

Today we will hear testimony from experts and members of the scientific community in order to explore opportunities for greater transparency and the use of the best available science at the EPA. Regulations created by the EPA help to protect the American people from tainted water, dirty air, and chemical exposure. The essential work completed by the EPA should always have as its basis protecting human health and the environment.

However, in the past, I have been concerned that the broad discretion and lack of transparency at the EPA has led the Agency to seek out the science that supports a predetermined policy outcome rather than relying upon the best available science before coming to conclusions. Failing to do so results in regulations that overly burden our economy without having a substantial impact on human health or environmental protection.

On April 30th, 2018, the EPA published a proposed rule entitled "Strengthening Transparency in Regulatory Science."

This proposed rule would require the EPA to identify what science they used to come to regulatory decisions and to make those studies available to the public without compromising privacy protections.

The proposed rule would also require the EPA to take into account high-quality studies that challenge current scientific assumptions. The proposal seeks to accomplish this without excluding historically relied upon studies by allowing the EPA Administrator to waive certain data access requirements on a case-by-case basis.

I thank the EPA for taking this important step and I look forward to hearing from our witnesses today about the proposed rule.

In addition, on September 12th, 2017, I introduced S. 1794, the Honest and Open New EPA Science Treatment Act, commonly referred to as the HONEST Act. Companion legislation, H.R. 1430, was also introduced by Representative Lamar Smith. The HONEST Act passed the House of Representatives with bipartisan support on March 29th, 2017. Both bills have been referred to the Senate Committee on Environment and Public Works.

The HONEST Act would prohibit the EPA from proposing, finalizing, or disseminating regulations or guidance unless all scientific and technical information relied on to support those actions is based on the best available science. The bill also

requires this information to be specifically identified and publicly available in a manner sufficient for independent analysis and substantial reproduction of research results. Finally, the HONEST Act requires the EPA to redact sensitive information such as personally identifiable information, trade secrets, or commercial or financial information.

It has been suggested by some that the EPA is incapable of providing greater scientific transparency because of privacy concerns. We have a responsibility to be sensitive to that issue, in part because we do not want to dissuade individuals from participating in environmental studies.

I believe the EPA should use, as a model, the privacy protections already used by other Federal agencies, including the de-identification protocols employed by the Department of Health and Human Services.

The EPA has a long history of creating burdensome, unnecessary regulations without giving the public an opportunity to fully vet the reasoning behind their decisions. We should all agree with providing greater transparency if it can be done without excluding legitimate scientific studies or compromising privacy. This is especially true if we can turn to other agencies, like the National Institutes of Health, for guidance on best practices.

Sound, reliable science is vital to helping us make

important policy decisions that impact not just the health of American families, but their livelihoods. We should welcome vigorous debate on the science the EPA relies upon. Doing so will result in regulations that have the greatest benefit to human health and the environment, while doing the least harm to the economy. It will also result in regulations that can withstand legal challenges, providing industry with a level of certainty that allows them to make long-term investment decisions.

I would like to thank our witnesses for being here with us today, and I look forward to hearing your testimony.

At this time, I would like to recognize Senator Booker for a five-minute opening statement. Senator Booker.

[The prepared statement of Senator Rounds follows:]

STATEMENT OF THE HONORABLE CORY A. BOOKER, A UNITED STATES SENATOR FROM THE STATE OF NEW JERSEY

Senator Booker. Mr. Chairman, I am really grateful. Thank you for this opportunity and for calling the hearing.

I just want to give a quick opening statement and will submit a lot more of my remarks for the record.

One thing the Chairman and I agree with is how important it is for our regulatory agencies, including the EPA, to use the best available science to inform their decision-making. That is why so many of their Federal environmental laws include a best available science requirement, including TSCA, something that all of us worked well together on, which members of this Committee spent lots of time working on and came to an incredible bipartisan consensus on.

I think we can also agree that transparency in agency decision-making is very important. So, I am glad to have the chance to have a discussion about the need for transparent science-based decision-making at the EPA.

Unfortunately, the policy proposals that are the subject of today's hearing include the EPA's proposed rule to purportedly strengthen transparency and regulatory science. This rule is far more likely to hinder science-based regulation than help it. In fact, the EPA did not even consult with its own scientific

advisory board, which is charged with determining whether the best available science is being used as a basis for EPA regulatory actions, regarding this public rule. Instead, it has chosen to ignore fundamental concerns raised by its own advisory board members.

I believe that the proposed rule put forth by the EPA and the legislation called the HONEST Act actually conflicts with the EPA's directive to use the best available science. Examples of this are common sense. If the EPA could not consider scientific studies unless the underlying data is made publicly available in a way that is sufficient for validation, the Agency would not be able to consider science gathered in the aftermath of environmental disasters, such as the Deepwater Horizon oil spill, which is not a scientifically replicable event.

The Agency would not be able to consider studies that rely on private medical information or confidential business information because that data could not be made publicly available. Obviously, it would be unethical for anyone to attempt to replicate public health analyses that used data gathered from different exposures to certain populations and communities, exposures to lead, to PCBs, to mercury or other chemical contaminants. We would not want anybody to replicate those studies and that suffering.

For example, the EPA bases its standards for lead-based

paint hazards on long-term studies of children who were exposed to lead. Prohibiting the EPA from using these historical studies would cripple its ability to protect children and other vulnerable populations from lead, as one example.

I am looking forward to this afternoon's conversation, but I want to emphasize that if the EPA was truly concerned about transparency, there are actually meaningful actions the EPA could be immediately taking.

First, the EPA could release to the public the report that EPA completed more than one year ago regarding the cancer risks of formaldehyde, something we still have not released. Where is the transparency there?

Second, the EPA could convene an independent science advisory panel to recommend best practices for ensuring transparency in developing public health and environmental regulations, not ignore their own science-based advisory board.

Finally, the EPA could immediately withdraw its May 2018 proposed rule to modify the Risk Management Program amendments where EPA is now proposing to restrict the public's access to information about what chemicals are being stored in facilities in their communities and neighborhoods. The public has a right to know about dangerous chemicals. Why is the EPA withholding that information from them?

So, I look forward to hearing from our witnesses. I will

put more information for the record, but I again want to thank my colleague and friend for calling this important hearing having this discussion.

[The prepared statement of Senator Booker follows:]

Senator Rounds. Thank you, Senator Booker.

Our witnesses joining us for today's hearing are Dr. Edward Calabrese, Professor, University of Massachusetts at Amherst School of Public Health and Health Sciences; Robert Hahn, Visiting Professor, Oxford University Smith School of Enterprise and the Environment; and Dr. Rush Holt, Chief Executive Officer, American Association for the Advancement of Science.

Welcome to all of you.

I would like to also, at this time, yield to Senator Booker to introduce Dr. Holt.

Senator Booker. I could not let this moment go, Chairman, without trying to make Dr. Holt blush a little bit, because he is nothing short of a New Jersey treasure. He served eight terms in the House of Representatives and was the Congress's only legitimate rocket scientist who was in Congress. He has had an extraordinary career of public service even beyond his eight terms as a House member.

Right now, he is a publisher of Science Family of Journals. In this role, Dr. Holt leads the largest multidisciplinary scientific and engineering membership organization. Prior to joining AAAS, Dr. Holt was not only a Congressperson, but he was probably one of the best well known leaders in his State of New Jersey because he was the most nerd-chic guy in our State.

Dr. Holt has been named one of Scientific American magazine's 50 national visionaries contributing to a brighter technological future and a champion of science by the Science Coalition. From 1989 to 1998, Dr. Holt was Assistant Director of the Princeton Plasma Physics Laboratory and he previously taught physics and public policy at Swarthmore College.

And I just want to get rid of the rumor. In the TV show the Big Bang Theory, Sheldon's character was not based on Dr. Holt.

[Laughter.]

Mr. Van Hollen. Mr. Chairman, if I could just briefly add to that.

I want to welcome all the witnesses, but it is good to see my friend, Rush Holt. We served together for many years in the House, and everything that the Ranking Member said is 100 percent true, but he left out a very important fact, which I believe you are the only member of Congress who won Jeopardy or was a finalist on Jeopardy, as well.

I apologize because I am going to have to leave and I am going to try and come back, but I appreciate the opportunity. Thanks.

Senator Rounds. Thank you.

Once again, thank you, Senator Booker.

Thank you to all of our witnesses for taking the time to

participate today; we most certainly appreciate it.

We will now turn to our first witness, Dr. Calabrese, for five minutes.

I would share with you all your opening statements will all be included, without objection, for the record. We would ask if you could try to limit your opening remarks to about five minutes, that would be greatly appreciated by the Committee as well.

Dr. Calabrese, welcome, and you may begin.

STATEMENT OF EDWARD J. CALABRESE, PROFESSOR, UNIVERSITY OF MASSACHUSETTS AT AMHERST SCHOOL OF PUBLIC HEALTH AND HEALTH SCIENCES

Mr. Calabrese. Thank you very much.

Good afternoon, Chairman Rounds, Ranking Member Booker, and distinguished members of the Committee. My name is Edward Calabrese, and I am a Professor of Toxicology at the University of Massachusetts School of Public Health, Amherst, Mass. I am pleased to share with you my views on the EPA risk assessment transparency proposal.

Briefly, I have been at UMass for 42 years, teaching and researching in the areas of toxicology and risk assessment. I have authored nearly 900 papers in the peer-reviewed literature, about a dozen books, served on multiple National Academy committees such as the Safe Drinking Water Committee and the Air Cabin Safety Committee, which recommended to the FAA to eliminate smoking on commercial aircraft, a recommendation that was quickly adopted.

For the past 20 years, I have been funded by the Air Force Office of Scientific Research to assess the nature of the dose response of toxic substances in the low dose zone in order to protect the health and the wellbeing of Air Force personnel. These activities have led to a major dose-response revolution in

the area of biology, medicine, toxicology, and risk assessment.

The USEPA has proposed a general framework to strengthen its regulatory science procedures via enhancing transparency in multiple ways. I applaud EPA for this proposal as it is not only timely but requires scientific and administrative accountability. The proposal is broad, requiring the Agency to provide the scientific basis for proposed regulations, including underlying data. While this is an excellent start, the Agency should also commit to providing detailed explanations and public access to data that the Agency considered and decided not to use for regulation.

In addition, most EPA scientific decisions are based on multiple assumptions, some of which are frequently hidden, obscured, and often silent drivers of regulatory action, for example, the use of highly susceptible and often poorly predictive animal models. These assumptions need to be fully described, documented, and justified. This process should also include the basis for why EPA chose not to adopt the use of other or different approaches and/or assumptions. Thus, EPA's transparency proposal is excellent as far as it goes, but it needs to be expanded; it also requires an explanation of what was considered and why it was rejected.

Multiple high-profile controversies exist over the lack of availability of data sets used by EPA for regulatory decisions.

While I have not been involved in Agency disputes over such databases, I would like to note two personal examples that speak to data sharing with EPA and the scientific community, and the value offered to the Agency and the public. For example, in the 1980s I developed a database of 6,000 dose responses concerning whether carcinogens could cause cancer with but a single dose. I made many presentations on this topic across the Country, including several NAS Committees concerned with acute/short term exposures to toxic and carcinogenic agents in the aftermath of the 1984 Bhopal, India disaster. Following these presentations, EPA asked me to provide it with a copy of the single-exposure carcinogen database. These presentations and the shared database were intended to assist the NAS in guidance to EPA.

Second, my group at the University of Massachusetts conducted multiple studies on soil ingestion in children and adults. Subsequently, EPA used these data for clean-up standards of soil and dust contamination for the benefit of children and adults. Our group created a public website with all our data available for use by the EPA and the world, minus personal identifiers.

These are examples to enhance improved science and transparency in regulatory activities. The EPA transparency proposal is crucial to enhance public health and should have been adopted in some form 20 or more years ago.

With regards to risk assessment, "data transparency" should require the EPA to routinely receive and openly evaluate for accuracy any information that could significantly alter the key scientific assumptions underlying and dictating regulatory policy and practices. This current EPA proposal does just that by stating that EPA should no longer use the LNT, or linear non-threshold, model as the default in risk assessment.

Movement away from LNT as the accepted default model is long overdue. It is compellingly supported by many peer-reviewed scientific and historical studies and is badly needed to advance toward a more science-based approach in assessments of human and ecological risks.

Within this context, I have researched the nature of the dose response in the low dose zone for more than 30 years and have published about 500 papers on this topic in peer-reviewed journals. I have organized and conducted international conferences on the topic for over 25 years and have created a professional journal called Dose Response, for which I am the editor in chief. I have also written chapters on dose response for some of the major text books.

More recently, in the past decade, I have exhaustively researched the historical origins and scientific foundations of EPA's LNT model and have found it sorely wanting. LNT is important because it is the model upon which all our cancer risk

assessments and key health and ecological regulations are based. What I have learned was unexpected and it has turned more than 30 years of my understanding of toxicology upside down. It has revealed that what I taught for so many years at UMass and have written about so ardently in my many articles and books was factually wrong. What I learned in this reevaluation of LNT was that the field of toxicology and our regulatory agencies, such as EPA, had made a serious error in their understanding of LNT and incorrectly applied it to the assessment of human and ecological risks.

During my research and publication over a dozen peer-reviewed journal articles on the scientific origins of LNT, I learned that the LNT dose response model which drives cancer risk assessment was based on flawed science, on ideological biases by leading radiation geneticists, on scientific misconduct by National Academy of Sciences genetics panel during the atomic radiation scares of the 1950s, and on a 40-year mistaken assumption by yet another NAS committee.

I learned that these flaws, biases, misconducts, and mistakes ultimately gave rise to the EPA model and were perpetuated down to the present day by subsequent committees of the NAS and EPA. What began for me as a routine academic exercise to affirm the scientific origins and credibility of LNT ironically ended as a remarkable repudiation of its scientific

adequacy, challenging both the old guard and an EPA risk assessment process that is in need of significant revision.

My findings show that the EPA adopted LNT for all the wrong reasons and built their flawed risk assessment edifice upon it, failing to perform due diligence expected by Congress and the public.

Senator Rounds. If I could ask you to perhaps wrap it up. Everything will be included in the record.

Mr. Calabrese. It is one paragraph more, Senator.

Senator Rounds. Yes. Go ahead.

Mr. Calabrese. Secondly, extensive research findings that contradict EPA's LNT model have now been documented in the scientific literature.

With so many failed LNT predictions, EPA must not continue to use LNT as its default. A crusading EPA was young, impressionable, inexperienced, and somewhat blinded, and it adopted the flawed LNT model, believing that it would save the world. Not only was it wrong scientifically; the LNT in many ways has damaged public health and the economy, the worst of both worlds.

The present EPA proposal to consider non-linear models for risk assessment is a critical, positive development. Thus, I believe that the EPA has made a bold and constructive proposal that is scientifically sound and should be strongly supported,

approved, and implemented.

Thank you very much.

[The prepared statement of Mr. Calabrese follows:]

Senator Rounds. Thank you, Mr. Calabrese.

Now we will turn to Mr. Robert Hahn for your opening statement.

STATEMENT OF ROBERT HAHN, VISITING PROFESSOR, OXFORD UNIVERSITY SMITH SCHOOL OF ENTERPRISE AND THE ENVIRONMENT

Mr. Hahn. Thank you, Chairman Rounds, Ranking Member Booker, and distinguished members of the Committee.

Most of you folks are probably old enough to remember the movie The Graduate with Dustin Hoffman. There was a scene early on in The Graduate where he is wandering around aimlessly by the swimming pool and a gentleman comes up to him and whispers the word plastics.

Well, the word I want to whisper to you today, and Senator Booker and Senator Rounds touched on this in their opening remarks, is the importance of evidence. There is a virtual explosion going on in the Academy in which I work as an economist in developing evidence-based policy.

Just moving a little bit beyond the pros and cons of this legislation, which I will talk about in a minute and give my perspective on, I think there is a real opportunity politically to move forward in basing decisions that politicians and civil servants make about regulatory decisions and other programs, and basing them on evidence-based policy, and that is where I would like to see us going. That is sort of my big ax to grind. So, if I run out of my five minutes, I have at least made my political statement, which is probably a good thing to do if I

am going to run for President, which I am not.

I want to make a few points and conclude with a short plea for breaking the political logjam.

The first one is that I believe that the HONEST Act, as it is called, addresses a very important public policy issue, and it does so in a constructive way. That is not to say that it is perfect or can't be improved, but I am very sympathetic with the direction in which it and the EPA proposal is trying to move us.

The second point is why simply apply this to EPA? There are a lot of regulatory agencies and programmatic agencies in Washington, D.C. We might want to think about expanding the kinds of ideas that Senator Rounds and Senator Booker talked about.

And the third point I want to make is the point I just made about better evidence decision-making related to a commission I served on that President Obama was instrumental in starting, along with Congressman Ryan and Senator Murray.

So, point number one. The HONEST Act addresses an important public policy concern. I am just going to give you one example, so it is proof by anecdote. I have about three minutes.

So, I ran a center for about 10 years between two think tanks in Washington, D.C., the AEI Brookings Center on Regulatory Policy, or some such thing. I was doing a study with

Ted Gayer, who is now at Brookings, trying to figure out what was going on with mercury emissions in a proposed regulation that EPA had on mercury emissions, and it took us a really long time to figure out what was going on because we didn't have easy access to the data or the models. We found, in our independent analysis, that that particular rule, as it was tailored, probably wouldn't pass a benefit-cost test, and we published our findings in science. But that is of secondary importance.

What is of primary importance is the point that the Ranking Minority Member and the Chair pointed out, that we want to have these data made available and these models made available in a way that academics and other interested parties can check on the findings before they go into force.

Let me move on to a second point under this, and it relates to my specific views on the strengthening transparency and regulatory science proposal that EPA had.

There can be honest differences of opinion, but what would that proposal have done? It would have required the EPA to identify studies that are used in making regulatory decisions, it would have encouraged studies to be made publicly available to the extent practicable, and it would direct the EPA to clearly state and document assumptions made in regulatory analyses.

Now, if I were grading an exam, say, at the Kennedy School,

where I was on the faculty many years ago, and a student didn't do that, they probably would have gotten a C or less. In other words, these are things that make common sense, at least from my point of view.

Here is what, in my view, the EPA rule wouldn't do: it wouldn't nullify existing environmental regs, it wouldn't disregard existing research, violate confidentiality protections, or jeopardize privacy.

Let me move on to my conclusion, which is repeating my opening introduction.

I think there is a real opportunity here for the Congress to move forward in promoting a new era in terms of getting people to acquire and use data more intelligently to improve decisions in government and in the private sector.

For the government, I believe there is an opportunity to move things forward by promoting, as I said before, evidence-based policy. It is pretty hard for a politician or an individual of any political persuasion to object to the idea of evidence and using better evidence in decision-making. I think that is really important.

I think the HONEST Act represents a modest, albeit important step, in the direction of trying to move such policy, and I would urge legislators to move swiftly to consider this effort and other efforts that could vastly improve the quality

of decision-making in government and thus improve the welfare of American citizens.

Thank you.

[The prepared statement of Mr. Hahn follows:]

Senator Rounds. Thank you for your testimony, Mr. Hahn.

We will now turn to our third witness, Dr. Holt.

Dr. Holt, you may begin.

STATEMENT OF RUSH D. HOLT, CHIEF EXECUTIVE OFFICER, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

Mr. Holt. Thank you. And I do hope to stick to the evidence and to the topic at hand. Thank you.

Chairman Rounds, Senator Booker, I appreciate the opportunity to testify before you today on behalf of the American Association for the Advancement of Science.

The AAAS is the world's largest general scientific membership organization publisher of Science magazine, among other things, and our mission is to advance science, engineering, and innovation throughout the world for the benefit of all people. We also represent 250 affiliated societies.

The transparency rule that you are considering is opposed by many, I think most, scientists and scientific organizations because, contrary to the stated purpose of the rule, the rule would result in the exclusion of valid and important scientific findings from the regulatory process, as Senator Booker has said.

Transparency, openness, and peer review and regulatory science are essential ingredients of science, as espoused by AAAS since the founding in 1948. However, the so-called transparency rule is an insidious dodge.

Those who want to overturn the EPA procedures with this

rule provide no good evidence that there is any deficiency in the scientific research that has been used up until now. Excluding the kinds of peer-reviewed research that has been used is not justified.

To put it bluntly, the initiative you consider today is not about transparency or sound science; it apparently is about reducing regulations. We know this because the architects and proponents present their proposals as part of a deregulatory agenda.

But most important, whatever the ulterior purpose may or may not be, the effect of the rule would be a significant reduction in good, relevant science that could be used by EPA, and the change would likely result in harm to people and the environment.

The proposed rule and its strict application would allow only research that is made completely public, and this demonstrates either a deep misunderstanding of how science works, and should work, or an intention to cherry-pick evidence in the name of transparency.

There are numerous examples of excellent peer-reviewed research where some data cannot be published openly or where the experiment cannot be precisely repeated, and where redaction and anonymizing won't work. The most obvious examples are research projects that study human illness resulting from pollutants, for

example.

There are accepted procedures for testing results and verifying outcomes with methodologies that do not require access to all the raw data, so it doesn't need to be fixed. That is my point there.

The U.S. Department of Defense has said the EPA transparency rule would be problematic. EPA's own Science Advisory Board questioned whether it would be possible to implement the rule as proposed. The current Deputy Assistant Administrator of EPA's Chemicals Office stated that "such a requirement would be incredibly burdensome, not practical," and could justify all TSCA risk evaluations; not to mention the many, many scientists and scientific societies who see this rule as damaging.

The proponents of the rule want to eliminate secret science. There is no secret science here. The only secret that I see is the deficiency that the authors of the transparency rule see in the existing research used by EPA. The open secret is that the proponents of the rule are not seeking a better scientific process; they appear to be seeking a way to cherry-pick research in order to loosen regulations.

So, I recommend that you scrap these initiatives and work with the science community and other stakeholders to increase the use of science in the regulatory process, not to find ways

to decrease the science that can be used.

I thank you for your time and I will be happy to take any questions.

[The prepared statement of Mr. Holt follows:]

Senator Rounds. Dr. Holt, thank you for coming and testifying today.

Each of the Senators now has the opportunity for a five-minute Q&A with you, and I will begin at this time.

I would like to start with Mr. Hahn. I would just like to ask over a multi-period of time you have written extensively on the need for greater scientific transparency with regard to regulations that have an enormous impact on the economy and the quality of life for the American people. What do you believe has been the primary motivating factor behind not pursuing greater transparency prior to the current Administration?

Mr. Hahn. I am not sure I have a one-minute answer to that question, but I guess I think about it on a couple levels. Sometimes there is raw politics involved in particular issues where Congress may feel strongly about doing something and it may not be in its own interest to necessarily get to the heart of the scientific matter.

I think partly it is a matter that agencies don't always adapt to the latest technology, so we have the Internet now, we have easy ways of sharing things. It is worth, in my view, putting some resources into some of the issues that Dr. Calabrese mentioned earlier so that people can have access to the kinds of databases that he developed, but I am thinking of the government, the models on which they are building things.

So, for example, when we were writing the Administration's version of the Clean Air Act, EPA used a consultant that didn't share its model, and a lot of the Clean Air Act was being driven by the results of this model, in my opinion, and I don't think that was an appropriate way to conduct the development of that very important piece of legislation.

Senator Rounds. Thank you.

Dr. Calabrese, as a scientist, can you speak to the value of studies that can be replicated?

Mr. Calabrese. Replication is a pretty complicated question because it is really, in many ways, replication is the gold standard, especially when you are dealing with low dose exposures. High dose exposures is one thing, where you kind of overwhelm systems with massive exposures and you can see effects, but human exposures are going to be at much lower levels, and you really want to see if there are adverse effects that you are trying to prevent and you think might be occurring, then you want to be able, in your experimental systems, you want to be able to see if these findings are reproduceable or not.

The problem with these types of things is that, especially with regards to epidemiologic data and to somewhat minor effects, a lot of times a study comes out positive in one and then can't be replicated in many other studies. So the gold standard is that we really have to hold the scientific

researchers accountable for essentially providing reliable information to regulatory agencies and to society to give us confidence that the findings are sustainable and are believable, and this doesn't have to necessarily involve an exact replication, but would have to involve some type of confirmatory reliability that is substantial, that adds strong weight of evidence to any conclusion.

Senator Rounds. Thank you.

Dr. Holt, I am just curious. It would seem to me that for those of us that have to make decisions based upon recommendations from any type of an agency, in this case either Republican or Democrat, it seems to me the most data that we can get, and that which can be identified as being scientifically and peer-reviewed, would be welcome by the scientific community, but you have expressed a real doubt about the intent of moving forward with that and I am just curious. It seems as though the movement towards using sound science and one with as much transparency as possible would be a positive thing, and I am just curious.

I have heard your opening statement, but I am kind of surprised that there wouldn't be more of a welcoming to a peer-reviewed discussion with a number of different points of view that would be brought in, and I am missing something, I think, on it. Could you maybe elaborate a little bit, please?

Mr. Holt. Yes, thank you. Surely, you do want verification. EPA is required to base their work on science, actually different from most regulatory agencies. It is written into the laws. In other words, you should be using current science. And the science is not just the collection of data; it is collection of data in a way that removes bias, it is assembly of the data that -- I mean, it has to be empirical, based on experiment, observation, and then it has to be verified; and that is the key word.

It is really a red herring to say replication is what is necessary. The verification can come in various ways: through repeating the experiment, if it is an experiment. But even most experiments are hard to repeat exactly; and certainly natural disasters. Senator Booker referred to the Gulf oil discharge. Let's hope that isn't repeatable. There are many circumstances where it can't be repeated in exactly the same way.

But it can be verified; through peer review, through independent verification, through confirmation of the studies by putting them in the context of other studies. That is the way science works. And it is science, this whole process that you want to be maximized in the regulatory process.

Senator Rounds. Thank you.

Senator Booker?

Senator Booker. I am going to defer to my colleague and

friend, Senator Carper.

Senator Rounds. Senator Carper.

Senator Carper. Thank you so much for deferring.

A quick question of you, Dr. Holt. I am not going to ask a yes or no question of you, but anything that the other two witnesses said that you would say, yes, that is right, I agree with that? Have they said anything that you agree with?

Mr. Holt. Well, yes. I mean, certainly that we need --

Senator Carper. Briefly mention one of the things that you may heard.

Mr. Holt. Yes. More evidence. Clearly, we always want more evidence in this day and age, when evidence, opinion, and ideology are considered interchangeable.

Senator Carper. Good.

Same question, Dr. Calabrese, of you and Mr. Hahn. Anything that Rush said that you agree with even a little bit?

Mr. Calabrese. I would have to say I agree only a little bit with a couple of points that he made, and that is in many ways, I agree, the Agency is directed towards science-based regulation. But the problem with science-based regulation are the assumptions upon which the science essentially feeds into, and that is that we have national toxicology program studies that use very high doses, three doses at extremely high doses that may be 100,000-fold more than what people may be exposed

to, and we have unverified --

Senator Carper. I am going to stop right there. Thank you. We will ask you to continue to respond for the record, if you will. I have little time.

Mr. Hahn, anything that he said that you actually agree with? If you could be very brief in stating.

Mr. Hahn. The answer is yes, and I think we all agree that agencies should use the best science and they should have a transparent process so people and experts can understand what we are getting. I think the point of disagreement is about whether the proposals before us, the proposed rule and the HONEST Act, whether they move the ball forward or whether they don't, and my reading is that they do move the ball forward.

Senator Carper. Okay. Thank you.

A question, if I could, of Dr. Holt. I think it was in May of this year we learned that political appointees within EPA have stalled the release of EPA's formaldehyde risk assessment. The risk assessment reportedly concludes that formaldehyde causes cancer and leukemia. This health assessment has been years in the making and is ready to be peer-reviewed, but EPA's political folks are insisting on keeping it under lock and key in response to industry pressure.

My question of you, Dr. Holt, is how would you respond to the concern that EPA is keeping its own formaldehyde science

secret, while simultaneously claiming that it needs a new rule to "strengthen the transparency of EPA's regulatory science"?

Mr. Holt. Senator Booker pointed out the irony in this. There does seem to a double standard there. I am not expert on the formaldehyde study per se, and, in fact, much of it is not available for examination.

Senator Carper. All right.

Let me try another question, if I could, Dr. Holt. EPA's 23 Federal advisory committees were established, I believe, to advise the Agency on environmental science, on public health safety, and other subjects that are central and critical to EPA's work.

Last year, EPA announced that it would prohibit scientists who receive EPA grants from serving on its Federal advisory committees. In 1999, a Federal appellate court rejected a nearly identical approach at HHS, reasoning that members of these committees are "selected because they are experts in that field" and, therefore, it is not surprising that HHS would also fund their research.

My question: Given that EPA's advisory committees should include the best scientists, shouldn't EPA eliminate its seemingly unlawful effort to exclude anyone with an EPA grant from serving on them?

Mr. Holt. Senator, I would refer you to a statement that

we made, our organization made some months ago. I won't take much time from this hearing because that is somewhat apart from the subject of this hearing, but in EPA in particular, the science advisory process is essential. And I don't want to get into how much or if it is being degraded, but it is important to defend that scientific advisory process in the EPA.

Senator Carper. All right. One last question, Dr. Holt. Given that the rulemaking process, rewriting a rule or litigating a rule, are costly endeavors, shouldn't EPA either withdraw the rule entirely or perhaps remedy all the problems before finalizing it?

Mr. Holt. That is what I was trying to get at when I said I don't see the reason to change this. If there is deficiency in how it has worked up to now, then we can talk about what changes might be needed. But I don't see the deficiencies.

Now, some people have said, for example, the six cities Harvard study that found deadly effects of small particulates was a flawed study, but most people don't think it was a flawed study and, in fact, it has been verified in a variety of ways. And yet that has been the example that has been used for why we need a change in transparency, a change in procedures at EPA.

So, unless I am convinced that what has been done is wrong and needs to be changed, I don't see why we should have this or any variation on it.

Senator Carper. Mr. Chairman, thanks for allowing Dr. Holt to answer that question, and my thanks to Senator Booker for yielding his time to me. Thank you.

Senator Rounds. Thank you, sir.

At this time, I will turn to the full Committee Chairman, Senator Barrasso.

Senator Barrasso. Thank you, Senator Rounds. Thanks for holding this important hearing.

Mr. Hahn, I was wondering. President Obama issued an executive order seven, eight years ago, I think 2011, stating, he said regulations "must be based on the best available science." Does the EPA's current proposed rule to strengthen the transparency of the Agency's use of regulatory science, does this align with what President Obama asked for in 2011?

Mr. Hahn. I don't know exactly the text of what President Obama said, but, to me, we all agree, there is consensus, that rules should be based on the best available science. And I would even go further and say we should roll rules out slowly so we can learn about what works and what doesn't work, and do pilot studies and feed that back into our knowledge.

The real issue is what is happening on the ground at agencies like EPA, HHS, independent agencies like the Federal Communications Commission; and that is kind of my wheelhouse, where we do benefit-cost analyses. We see that some of the

regulations that come out of these agencies are incredibly beneficial, like seatbelt regulations, like the smoking regulation you talked about earlier; and some of them are not so beneficial, they are very expensive and actually don't improve overall consumer welfare.

So the short answer is yes, this rule, in my view, promotes the best available science, but I would like to see Congress more generally pushing in the direction of promoting evidence-based policy.

Senator Barrasso. Dr. Calabrese, your testimony notes a lot of health models currently used to inform regulatory decisions are based on data gathered 60 years ago. These models also use scientific assumption developed during that era.

How have the advances in science and technology improved the scientific community's ability to produce more accurate results and research?

Mr. Calabrese. There has been a wealth of scientific development since the first proposal for the use of LNT for cancer risk assessment back in 1956, and essentially what we have had since the 1950s to the present time is really policy-driving science. But we have such substantial scientific development that really has to be switched around, and science has to now drive policy. And my understanding of the dose response relationships in great detail is that the simplistic

linearized model of the 1950s did not take into account the plethora of biology that we have today, and the regulatory agencies need to be flexible to the science and let science drive policy, rather than the other way around.

Senator Barrasso. Mr. Hahn, EPA's proposal allows the Administrator to grant case-by-case waivers to use scientific studies which may not be able to meet the new transparency studies. Do you believe that the proposal's waiver is an appropriate method to provide flexibility, while maintaining the strong transparency standards that we are looking for?

Mr. Hahn. The short answer to your question is yes, but I haven't thought carefully about other ways of doing that that could potentially be better.

Senator Barrasso. Dr. Calabrese, your testimony also states that hidden assumptions in the EPA's secret science are often kind of silent drivers of regulatory action. Could you please describe how secret science can bias decisions made from a regulatory standpoint?

Mr. Calabrese. Yes. The so-called what I call the secret type sciences is essentially you might have really excellent studies that deal with an animal model that has very little relevance to a human population, yet we assume that the human population is responding exactly like the information provided by the animal. So, the science can be great, but the relevance

of a human population can be pretty much nil, and yet that is what the belief systems are based on and regulations are based on, and there are a whole series of other specific examples like that.

Senator Barrasso. Thank you very much.

Thank you, Mr. Chairman.

Senator Rounds. Senator Booker.

Senator Booker. I just want you to know, Mr. Chairman, I am not intimidated at all by going after the Chairman. He and I have a lot in common. He has a degree in science, biology, chemistry. I have a degree in science as well, political science.

[Laughter.]

Senator Barrasso. And we are both left-handed, as are several of the panelists today. It is a big day.

Senator Booker. Yes.

Senator Barrasso. What about you, Carper? We have three left-handers here and a couple left-handers.

Senator Booker. That is pretty good. That is pretty good.

Dr. Holt, Mr. Hahn used a football analogy which was an appeal to my more baser qualifications for the job I am in, as a former football player, where he talked about moving the ball up the field or not. He said that is what this is about.

Clearly, you want transparency. Clearly, you have talked

about the urgency for transparency, the urgency for good science. But I just don't think what is being clearly stated is that this very great tune of saying, hey, we want more transparency actually doesn't move the ball forward; it actually is going to move the ball back and hurt, potentially, the health and wellbeing of folks.

Could you succinctly explain one more time why such a proposed rule and the legislation actually could devastatingly hurt the safety and security of the American public?

Mr. Holt. The rule excludes the use of some kinds of research, and there are long lists of actual research or potentially relevant research that would be eliminated by any likely interpretation or application of this rule. I would direct the Senators to a letter I believe is available to you, I can certainly make it available to you, from the Emmett Environmental Law and Policy Clinic at Harvard Law School about the transparency rule. It is signed by presidents of hospitals and universities. They have a long list of valid research that they believe by any reasonable interpretation of this rule would be unusable in making regulatory policy.

And as I said in my prepared remarks, if you don't use all the good relevant science, people will be hurt.

Senator Booker. Right. And so the fact that the majority of your membership organization has spoken out against this, the

EPA's own Science Advisory Board has spoken out against this, you have universities and other science folks saying don't do this because you are going to exclude relevant science, you are going to undermine the safety of individuals because much of this is not replicable, all these things should scream to us that there is something wrong, even though the buzz words sound really good.

I want to bring your attention to a strategy that was used by those industries that were trying to prevent health and safety standards that we take, for example, cigarette smoking has been brought up. The EPA's proposed rule sounds so much similar. This secret science rhetoric that was used by the tobacco industry is the same rhetoric that is being used right now.

At the time, the tobacco industry lobbyists sought to create process-based hurdles that would make it harder for agencies to establish guidelines and safeguards for secondhand smoke exposure. Rumored proposals would have prohibited the EPA from using a study unless it was considered replicable and all the underlying data in that study was released to the public.

This is déjà vu all over again, as another New Jerseyan once said.

So here is industry, and this is the irony of this moment for me, is that you have industry working really hard to stop

the transparency on things like the methane rule, on what we are seeing right now with the methylene chloride, and then on other areas they are trying to stop us regulating things just like we did with the tobacco industry.

You have been, obviously, down here for 16 years of your career. Do you see this double standard and hypocrisy being used to try to do things that hurt the public health when it benefits industry, and doing things that undermine science?

Mr. Holt. Well, in my testimony I talked about a likely motivation of the people who are proposing this because they are proposing it as part of a deregulatory regime, but I wanted to get beyond that because really what I wanted to talk about is not whether it is a double standard and what the motivation is, but what would the effect be. And this is not just me saying this; I mentioned this Environmental Law Clinic, but the Thoracic Medical Society, the American Geophysical Union, the American Chemical Society; many, many organizations and even far more individual scientists are saying the effect would be that science that we know to be good science would likely be excluded.

Senator Booker. And just to make this last comment, exactly what you said is the issue with the methylene chloride, which people are dying from in the United States of America. It has been responsible for dozens of deaths. Under the TSCA law,

bipartisan TSCA law, the EPA proposed a ban on methylene chloride in paint strippers in 2017 and in 2018 the Agency said it would finalize a rule, yet they haven't acted. The scientific basis for the proposed ban on methylene chloride comes from an Agency risk assessment that received extensive interagency review and external peer review by independent scientists and relied on high quality studies, but, and the point of here, the underlying case studies are not publicly available because of protecting information.

So this is an example of what you are saying of how this would stop the banning of this chemical, which we know now needs to be banned; other nations have done it.

So I would just like to submit for the record, Mr. Chairman, if I can ask unanimous consent to submit for the record comments and letters from the Boston University School of Public Health, the California Environmental Protection Agency, the Project on Government Oversight Environmental Defense Fund, the Natural Resource Defense Council, all demanding that the rule be withdrawn immediately, and the Ecological Society of America, which opposes the EPA's rule.

Senator Rounds. Without objection.

[The referenced information follows:]

Senator Rounds. I would ask unanimous consent to include in the record several articles written by Dr. Calabrese and a letter in support of the proposed science transparency rule from the American Chemistry.

Senator Booker. He has published 900 articles. Are you putting them all in the record?

Senator Rounds. Five hundred.

Senator Booker. Just no requirement that I read them, please.

Senator Rounds. Not today, anyway.

Senator Booker. Not today. Okay.

[The referenced information follows:]

Senator Rounds. Senator Ernst.

Senator Ernst. Thank you to our witnesses today and thanks for holding the hearing, Mr. Chair.

Mr. Hahn, in your written testimony you stated that your research found that some of the EPA's environmental assessments were not always of high quality, and these assessments went on to form the basis for major regulations.

Can you go into a little bit more detail on this or specify which regulations you found to be based on low quality environmental assessments?

Mr. Hahn. So, I did that research about 10 years ago and I can't give you a list of a top 10, and journalists often ask me, but I can give you some examples of what the problems were.

Senator Ernst. Okay. That would be helpful.

Mr. Hahn. And some of these problems have been fixed. But you get a 200-page regulatory impact assessment, which is great for insomnia, on some chemical, and frequently the Agency doesn't summarize in a very clear way what their main findings are; they don't necessarily pay attention to the alternatives which they were supposed to think about in finding the best and cheapest way of achieving the result; they don't necessarily count all the benefits they should have.

So, there were real deficiencies in the analytical rigor that was underlying these regulatory proposals. And some of the

administrators at EPA and other agencies have tried to fix some of these things; I don't know how well they are doing.

But what I would say generally, and I am sorry Senator Booker had to leave, I think it is a really good idea to be able to share data and models, because even at the highest level of academia, even with peer-reviewed publications there are frequently errors.

A couple of professors from Harvard, who shall remain nameless but everyone knows who they are, wrote a very influential book about how long it should take to recover after the last Great Recession; and it turns out there were some fundamental errors in their analysis that wouldn't have been uncovered but for the fact that their data was shared, which is a good idea. So, I think it is a really good idea to be thinking about sharing data.

At the same time, I agree with you that we don't want to necessarily eliminate, by law or regulation, some very persuasive data that is published in peer-reviewed journals, but my bugaboo is it is really important to share this data so other people can take a look at it in sunlight so that, when you are passing a regulation that is going to impose costs on people or make them lose their job, that you have the best available evidence upon which to make those decisions.

Senator Ernst. No, I thank you for that. So, just going

back and maybe repeating in different terms some of what you just said, it is possible, then, that some of those assessments were made and they were the result of maybe shoddy work or perhaps errors, is that correct?

Mr. Hahn. To use a phrase that my three-year-old niece used many years ago when I was doing this research, some of it was stinky.

Senator Ernst. Well, that is a great way to describe it. Do you think that the EPA was trying to tailor the assessments to support the need for regulations in some of those cases, perhaps?

Mr. Hahn. I think it is possible. It is something that is very hard to prove, but we all live in Washington, D.C.

Senator Ernst. Certainly. And that is why I think that having transparency and peer review is important; a little bit of sunlight there. If a regulation is truly needed, then you shouldn't be opposed to having other people take a look at the methodology there.

Dr. Holt, this ties into this conversation as well. Some of those regulations turned out by various Federal agencies, including EPA, do pose economic threats to certain industries and, of course, a number of those communities that rely on those industries. If you were to be an employee of one of those industries or live in a community where a lot of that economic

thrust is involved, shouldn't you want to know every bit of information or data that is being used by those different agencies to develop the regulation that might threaten your very job or even your entire community?

Mr. Holt. Surely, there are regulations that don't work well, that are improper, that even should be removed, but the approach to making regulations is not to limit bad regulations by limiting the science that might lead to regulations, which is what is going on here. The full science should be available. And this is not to make science more available, the effect is to restrict the science that is available, because the whole rule is about removing some studies that cannot be used to make regulations. So, we should ask, are we throwing out some good science here. And the answer that is arrived at by science society after science society, science after scientist, is yes, it would be throwing out good research.

Senator Ernst. Well, I certainly appreciate all of the different opinions here today.

Thank you, Mr. Chair.

Senator Rounds. Thank you.

Senator Whitehouse.

Senator Whitehouse. Thank you, Chairman. I appreciate this hearing.

Dr. Holt, in a circumstance in which science discovers that

a substance or a chemical is harmful to human health and there is an industry involved in the manufacture or the distribution of that chemical or substance and that industry wants to fight back against the science, what sort of an apparatus does such an industry have at its disposal to take on the enterprise of science?

Mr. Holt. Well, let me stick to the subject at hand here. An approach that they might use is to say that their test results are proprietary. And under this rule, if it were in effect, the studies that might be available would not be available because they have a legitimate claim to keep their data proprietary, non-public; and, therefore, some good science that had been verified in appropriate ways would not be available to the regulatory agency.

Senator Whitehouse. Setting aside that question for a minute and back to my original question, does an industry in that predicament have access to an array of groups that have experience in trying to deprecate science and foment alternative views?

Mr. Holt. Well, as I have heard you speak often, there is an imbalance in access to resources, access to media, and access to public persuasion, so the regulatory agencies are set up in order to try to restore that imbalance, to make sure that all parties have input to the regulatory process.

Senator Whitehouse. The concern or a concern that I have about the very title of this hearing, Sound and Transparent Science, which in theory is a very good thing, goes back to a phrase that has been kicked around in this conversation called secret science, which I think is a highly misleading term. My understanding is that very often in public health, in order to get data, you look at people's public health records; you look at who got sick, who didn't. You look at the health records of human beings.

The condition of getting access to those records is that you don't give that private information out publicly. People's families might not want to know about it; people might not want their employers to know about it. There might even be cases where they don't want their insurance companies to know about it.

Will you agree with me that it should not be the price of having health records form the basis for scientific study that the individuals involved lose all their privacy with respect to their health records?

Mr. Holt. Still directed at me?

Senator Whitehouse. Yes.

Mr. Holt. Yes. You are right. As I said earlier, there really is no secret science. There should be fully available science when it comes to making regulation, and that science --

Senator Whitehouse. And the term "secret" really --

Mr. Holt. -- that science is not just the data. Some of the data must be kept non-public because of health records, because of legal proprietary information, because of a number of other things.

Senator Whitehouse. But if you were an industry --

Mr. Holt. But the science itself, the process of taking those data and verifying them should not be secret. But that is not what this rule or this legislation would deal with.

Senator Whitehouse. If you were an industry that wanted strategically to knock down public health science so that the dangers of your product were not understood or made public, then this would be a pretty handy way to go about it, because you disable an entire field of legitimate public health science by calling secret science science that actually only depends on people's health records.

Mr. Holt. I think it could be used that way.

Senator Whitehouse. May I ask unanimous consent that a curriculum vitae for Dr. Calabrese dated August 2013 be put into the record? I don't know if it is in the record already, but it is a pretty good summary of some of his industry clients and how much they have paid him over the years, and I think that is important in judging the witness's conflicts of interest here. So, if I could add that to the record.

Senator Rounds. Without objection.

Senator Whitehouse. Thank you.

[The referenced information follows:]

Senator Rounds. I am going to take just a little bit of liberty here. I really do appreciate the participation of all of our witnesses here today.

I look back at the time in which I have had an opportunity to serve on this Subcommittee, and the idea on it is to be able to provide oversight, and part of that is to ask questions about how the determinations are made.

Part of the discussion on that, and I think regardless of which side of the dais you sit on, you want sound science and you want the opportunity to be able to look at it and to ask the same questions that you would as if we all had scientific background; what would we be asking with regard to how that determination is made, and what data is available and how is it come up with, as much to be able to support the regulatory processes and say, look, we may disagree with the regulatory outcome, but we understand the science that was used behind it, and we can dispute it or we can agree with it, back and forth.

It seems to me that there must be a way for an agency with regulatory oversight responsibilities to be able to share over a period of time a process that could be agreed upon very similar to I am thinking about the National Science Foundation, where, time and again, there are different projects that are looked at, they are peer-reviewed, they are looked at objectively by outside groups who then discuss clearly how they come to a

conclusion as to which way they work; what should be included, whether or not the projects meet the appropriate funding guidelines, and so forth.

Speaking from experience as a former governor who worked on a National Science Foundation, at that point we were looking at National Science Foundation work for an underground laboratory to be located in Lead, South Dakota. Matter of fact, Princeton was one of the universities which participated in a lot of work. And we went through an extended period of time in which there were peer review processes to determine whether or not this was one of the sites at which an underground laboratory looking for neutrinos would be built; and I found it fascinating that although there was constant discussion among the different science organizations who were working on different locations, there was an acceptance that the basic process of sound science would win out.

Now, whether we use the terms of being able to replicate something or to be able to say that it is verifiable, become items that within the science community have clear and defined terms. But these are the types of discussions that we need to have if we are going to get to the point where, over a period of time, regardless of which administration it is, they should be held accountable for using the appropriate science, year in, year out.

And an oversight committee such as this, regardless of whether there are Republicans responsible for operating as a majority or Democrats, and regardless of whether the Administration is Republican or Democrat, there should be certain accepted standards that either Republican or Democrat Administrations should be held to adhere to with regard to how the regulatory processes are determined, and the accepted facts that are being used in making those regulations. That is what this is all about.

I don't think there is anything wrong with questioning the existing program which is out there, because most certainly there are questions that are raised on a regular basis. It does not mean that any one of the existing proposals is perfect, but most certainly I think the discussion that you all have held today, and the differing points of view that you have, has been very helpful to this Committee in trying to move forward and I would just thank you all for your input today.

Senator Whitehouse. Can I ask two more unanimous consents? One to put into the record a memorandum from the public relations firm of Bracewell and Patterson dating back to 1996 for the R.J. Reynolds Tobacco Company, and the other an action plan called The Secret Science Action Plan, prepared for Philip Morris.

Senator Rounds. Without objection.

Senator Whitehouse. Thank you, sir.

Senator Rounds. Thank you.

[The referenced information follows:]

Senator Rounds. With that, once again I want to thank all of our witnesses here today. You add to the discussion.

I would also like to thank our colleagues who have attended this hearing for their thoughts and questions.

The record will be open for two weeks, which brings us to Wednesday, October 17th.

With that, this hearing is adjourned.

[Whereupon, at 3:35 p.m. the committee was adjourned.]