VIRTUAL PUBLIC HEARING

SUPPLEMENTAL RULE ON EPA PROPOSAL

STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE

9:00 a.m. to 11:00 a.m.

Tuesday, April 14, 2020

REPORTED BY ASHLEIGH SIMMONS, CER
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RICK BEIN  
THEODORE BROWN
MICHAEL HALPERN: Good morning everybody.

My name is Michael Halpern. I am the Deputy Director of the Center for Science & Democracy here at the Union of Concerned Scientists and we are about to get started. Welcome to this virtual public hearing hosted by the Union of Concerned Scientists on Environmental Protection Agency’s proposed supplemental rule titled Strengthening transparency in Regulatory Science. This session is being recorded, and should post to the Union of Concerned Scientists YouTube page shortly after it ends.

We appreciate you taking the time to provide public comments on the proposed supplemental rule. Nearly one hundred people registered to provide public comment today and so it should be a full day.

We will begin hearing public comments shortly. We do have some space at the end of this session and at the end of the two -- the afternoon and evening sessions. So, if you would like to register to speak at the end of any of them,
please email ucsvph@gmail.com. We will do our best to accommodate you. And that's ucsvph.com -- @gmail.com.

So first, I am going to turn it over to Ken Kimmell, president of the Union of Concerned Scientists. Ken, please go ahead.

KEN KIMMELL: Good morning everyone.

Michael, can you just verify that you can see me and hear me?

MICHAEL HALPERN: I can hear you. I cannot see you.

KEN KIMMELL: Okay. Let me start my video. How about now?

MICHAEL HALPERN: Yes.

KEN KIMMELL: All set?

MICHAEL HALPERN: Yes.

KEN KIMMELL: Great. Good morning everyone and welcome. Today the Union of Concerned Scientists is hosting this hearing for a simple reason, the Environmental Protection Agency has refused to do so.

I know that it is quite unusual for a
non-governmental organization to hold a public
hearing on an agency's proposal. Of course,
usually the federal agency that is responsible for
hosting -- for a proposal is responsible for
hosting the public hearing, particularly on major
proposals, while a comment period is open.

Interest in this proposal remains very
strong. The original draft of this rule received
more than six hundred thousand public comments in
over a three-and-a-half-month time frame.

This supplemental rule that we are here
to talk about today significantly changes the
initial proposal, but the opportunity for public
input has been severely limited. Especially when
one considers just how sweeping this proposal is
and how different it is from the original draft.

For this proposal the EPA originally
called for a thirty-day window for public comments
with no public hearings at all. They recently
extended the public comment to sixty days with a
deadline May 18th, 2020, without any public
hearings. This is simply grossly insufficient.
During normal times the government recommends a minimum sixty-day comment period even for the simplest of proposals. These are not normal times, and this is not a simple proposal. Numerous science and public health organizations, including UCS, urge the EPA to extend the public comment period by at least sixty days, plus a thirty-day period beyond the end of the declared national public health emergency.

We also asked for virtual public hearings. And unfortunately, the EPA has refused those requests. We also invited EPA to send staff today to listen to today's hearing and ask questions to those providing comment. The EPA has declined our invitation.

The COVID-19 crisis poses profound challenges to our country and to the world. The virus has disrupted all of our lives. Many of us are working remotely while caring for children who are out of school. Others are taking on the crisis directly and working extra hours at great risk, from healthcare workers to sanitation
workers. The public health organizations are working overtime to provide scientific advice to protect individuals and communities throughout the country. Some people don't even have access to technology. So, all of these conditions make it extremely difficult for public comment.

So, I should say, it's enormously impressive to me that more than a hundred people have registered to speak today. This is a testament to how many people realize just how significant this proposal is to EPA's ability to meet its mission and protect public health and the environment. We heard from many more who don't have the bandwidth today to provide comprehensive feedback on the proposal due to other commitments created by the pandemic.

I think we can all agree, especially in light of the crisis we are in right now, that the best science, the best data, and the best analysis is not only important, it's literally a matter of life and death.

So, I hope today that the comments will
shed light on this crucial question, does the proposal that EPA has made advance or does it undermine this imperative?

Today's public hearing, of course, is not the only opportunity you have to provide public comment. I encourage everyone to develop written comments to respond directly to the proposal. UCS has developed a guide to providing effective public comments on this rule on its website.

We expect EPA to do its job and seek feedback on its proposals. But when the agency fails, as it has here, we will step in to make sure that the agency receives as much feedback as possible.

I look forward to hearing and reviewing the public comments that are made today. Thank you all for participating. And I would like to turn it back to Michael.

MICHAEL HALPERN: Thanks, Ken. So, I would like to provide folks with some background information and briefly describe the proposed rule on which we are taking comments today.
The EPA described the rule — describes the rule as follows: This Supplemental Notice of Proposed Rulemaking proposes that the scope of the rulemaking apply to influential scientific information as well as the significant regulatory decisions. This notice proposes definitions and clarifies the proposed rulemaking applies to data and models underlying both pivotal science and pivotal regulatory science. In this SNPRM, EPA is also proposing a modified approach to the public availability provisions for data and models that would underly significant regulatory decisions and an alternate approach.

Finally, EPA is taking comment on whether to use its housekeeping authority independently or in conjunction with appropriate environmental statutory provisions as authority for taking this action.

For both oral and written comments, EPA will only consider feedback that directly addresses the supplemental proposal. Therefore, please do your best to speak to the changes to the
rule that are made in the supplemental proposal.

Today's hearing will work as follows:
Members of the public pre-registered to speak, and
were assigned a speaking time. They were asked to
sign-in to the webinar at least twenty minutes
before their scheduled time, in case we run ahead
of schedule.

We are here today to hear your comments
on EPA's proposed supplemental rule. We will not
respond to questions from attendees or speakers.

In order to accommodate all speaker’s
testimony is limited to four minutes. After your
name is called, we will ask you to proceed with
your testimony. The transcript from this public
hearing will be submitted to the docket, and a
recording will be made publicly available.

If you have any written comments or other
documents that you would like to submit for the
record, please email them to the email you
received on your confirmation form, which is
ucsvph@gmail.com.

If you are watching this broadcast, you
can also register to speak today at any of the
sessions and we will do our best to accommodate
you by emailing ucsvph@gmail.com and you will be
added to the queue.

We will make our best effort to ensure
that any comments spoken in languages other than
English will be translated into English in the
written transcript.

And if you have any additional comments
after today, please follow the instructions in the
Federal Register notice for this proposal, and
submit your comments by May 18th, 2020. Again,
UCS has provided a guide for people to make
effective comments on its website.

Today's hearing is broken into three
separate sessions which begin at 9:00 o'clock,
1:00 p.m. and 5:00 p.m. Eastern Daylight Time.
Each session is being streamed live through the
Union of Concerned Scientists YouTube channel, and
can also be viewed on the UCS website.

And finally, we do ask for patience with
this virtual hearing. People will have different
internet bandwidths and familiarity with the technology. And if someone has technical difficulties when it is their turn, we will move on to the next speaker, and return to that person who had technical difficulties later in the session.

All right. So, we are going to get started. I am going to turn it over to Jason Jacobson, who will be running today's hearing. Jason, please go ahead.

JASON JACOBSON: Thank you, Michael. As a reminder, all attendees are automatically muted. We will unmute you when it is your turn to speak. If you wish to turn on your video, you may do so. We will now begin our public comments. The first speaker is James Goodwin, who will be followed by Paul Billings and Andrew Rosenberg after that.

And now I am going to turn it over to James. James, are you ready?

JAMES GOODWIN: Yes, I am.

JASON JACOBSON: Go ahead.
JAMES GOODWIN: My name is James Goodwin. And I am a senior policy analyst with the Center for Progressive Reform. I thank the organizers for holding this shadow public hearing. But I also appeared today as a form of protest against EPA for its unconscionable decision to continue working on this dangerous rulemaking at all, let alone in the middle of a massive global pandemic.

I appeared today because I am among the few Americans fortunate enough to endure the hardships brought on by COVID 19 and still be able to participate in non-emergency government processes such as these. I also feel obligated to appear because as the father of two young children, I am extremely troubled by the harm that this rule might cause to them and others in their generation. And I feel obligated to appear since I have closely studied EPA's claimed legal basis for this contemptible rulemaking, which I will address now.

The failure of EPA to identify a colorable legal basis for this rulemaking is
emblematic of the Trump administration's brazen disregard for the rule of law. The original proposal laughably gestures at EPA's various authorizing statutes as legal authority. The ridicule this claim engendered appears to have spurred one of the most significant aspects of the supplemental proposal. Namely, the new claim that this rulemaking is authorized by the federal housekeeping statute. This argument has two critical flaws though.

First, the federal housekeeping statute doesn't apply to the EPA, only executive departments. Second, even if the statute did apply to EPA, it would not supply the legal basis for something like this rulemaking.

EPA acknowledges that it is not an executive department, but argues that it was nonetheless brought within the scope of the federal housekeeping statute through Reorganization Plan Number 3 of 1970, which created the agency.

The essay appended to my oral
presentation explains in greater detail why this argument should be rejected. For now, I will emphasize two points. One, Reorganization Plan Number 3 conspicuously makes no mention of the federal housekeeping statute. Instead EPA has left to infer the transfer of that authority to a vague catch-all provision. In essence, then the agency claims Congress implicitly intended for EPA to be considered a department, but just hasn't gotten around to officially declaring it.

Two, while Congress has updated the list of executive departments several times since 1970, it has never included the EPA. Most recently it did so with the Department of Homeland Security which, like EPA, was pieced together from several existing agencies.

Even if the federal housekeeping statute did apply to EPA, it would not supply the authority for something as radical and controversial as this rulemaking. While the appended essay addresses this argument in greater detail, I will emphasize two points now.
One, the censored science rule is a far cry from the kind of modest and noncontroversial internal operating procedures that Congress envisioned with the federal housekeeping statute. To wit: the original censored science proposal is so controversial it attracted over six hundred thousand public comments.

Two, even the Supreme Court case that EPA cites to support this argument that the rulemaking is covered by the federal housekeeping statute, *Chrysler Corp. versus Brown*, makes clear that the censored science rule exceeds the modest authority that the law provides. Among other things, the Court in *Chrysler Corp.* was troubled by how the rule at issue affected the relationship between the government and private sector entities.

Significantly, the operative function of the censored science rule is to affect the relationship between EPA and members of the public.

Specifically, it would fundamentally alter how the public participates in the
development of new rules by limiting the kinds of views that they can share on a scientific basis per those rules.

Today you will hear many reasons for why the EPA should abandon the censored science rule. As I have explained, the lack of a legal basis for the rule provides one more reason. Thank you for your attention.

JASON JACOBSON: Thank you, James. The next speaker will be Paul Billings, followed by Andrew Rosenberg and Chris Frey.

Paul, are you ready to speak?

PAUL BILLINGS: Yes. I am trying to start my video but it won't let me. Okay.

JASON JACOBSON: There you go. We can hear and see you.

PAUL BILLINGS: Good morning. I am Paul Billings, national senior vice president of public policy at the American Lung Association. The American Lung Association is the nation's oldest voluntary health agency. Today I am speaking on behalf of the nearly thirty-seven million
Americans with lung diseases, including asthma, lung cancer, and COPD. And everyone who wants to breathe clean, healthy air.

We want to thank the Union of Concerned Scientists for convening this hearing as the nation struggles with the COVID-19 pandemic.

Every day the news reminds us of how important lung health is for all of us. The American Lung Association and fifteen other health and medical organizations have asked EPA for a sixty-day extension to the comment and for EPA to convene three public hearings. We reiterate our request for at least sixty additional days to comment and for EPA to convene public hearings.

The American Lung Association opposes the proposed rule and we urge EPA to withdraw it.

Make no mistake, this proposal is not an effort to strengthen transparency or improve regulatory science. The proposal is an effort to exclude important studies whose conclusions, especially the studies that show that particulate air pollution causes premature death, are
inconvenient.

Later this morning we expect EPA administrator Andy Wheeler to announce that EPA is not strengthening the National Ambient Air Quality Standards for particulate matter. There is a strong insistent body of scientific evidence that supports strengthening the PM Standards. EPA should use this science to inform its policy decisions. It should not arbitrarily exclude studies or cherry pick studies.

Like the original proposal, a supplemental notice predicate is that studies that rely on confidential research participant data will be excluded from consideration or use to inform regulations or influential scientific -- scientific information. To be clear, studies that link air pollution with premature death would be excluded or diminished as the agency develop its regulations or influential scientific information. The administrator has the sole discretion to permit a study to be considered or be given full weight, but that is the exception under the
proposed framework.

In our written comments we will discuss our specific concerns with the supplemental's approach to the tiered access approach and the diminished in consideration approach. I'd like to spend my remaining time to share some of the history of this issue.

In January 1993 then EPA administrator Bill Reilly released the landmark paper, the Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders. The paper confirmed what we at the American Lung Association knew, that second-hand smoke harms health. That second-hand smoke kills. It sounds like common sense today. In fact, my adult daughters can't really even imagine a world that didn't think second-hand smoke was harmful. But the tobacco industry attacked in an attempt to make it controversial. The tobacco industry pulled out all of the stops to try to undermine and marginalize this report. They sued, they ran extensive PR campaigns, set up or funded front...
groups, and their lobbyists blanketed Capitol Hill.

They were terrified that we were going to get laws and ordinances passed to protect the public from second-hand smoke, including in all work sites, restaurants, bars, and other public places.

We know from discovery in later litigation that a tobacco industry lawyer, Chris Horner, wrote a memo to R.J. Reynolds seeking a second approach that would include the construction of explicit policy hurdles that EPA must follow. And to address process as opposed to scientific substance.

They wanted to create a process to limit the use of science that was inconvenient or lead to policies that could cut into their profits. The memo used the same terms, transparency, sound science, calls for reproducible science—the language the EPA is now using in its proposed rule.

The goal of the strategy as described by
Mr. Horner was to help R.J. Reynolds having to undo the agency’s work after the fact. The memo references EPA's pending proposal to set the first PM 2.5 standards and strengthen the ozone max as well. The goal was and is to censor science.

Make no mistake, the tobacco industry and polluters want to undermine science to stall public health safeguards. In addition to the specific limitations, this version of the EPA regulations, it may also have a chilling effect on research.

Many studies rely on patient volunteers, individuals who agree to share their most personal information with ethical researchers. NIH just announced a new study to see if patients to determine how many adults in the United States, without a confirmed history of infection, actually have the SARS COV-2 virus. Patients will sign up but they will have the expectation that their confidentiality will be protected. When patients fear their confidential information will be compromised, or the tobacco industry or some other
corporate interest will attempt to manipulate their information to support efforts that could result in say more exposure to second-hand smoke, it may stifle or reduce participation in studies. This could have far-reaching negative consequences for public health and the environment.

The supplemental proposal will censor science, together with efforts to discount or exclude benefits from pollution reductions and other rulemakings. This appears to be a coordinated effort by EPA to ignore science that is inconvenient to its regulatory rollback agenda.

We strongly oppose the supplemental proposal and we urge EPA to withdraw it. Thank you to UCS for convening this public hearing.

JASON JACOBSON: Thank you for your comments, Paul. The next speaker will be Andrew Rosenberg, followed by Chris Frey and Jennifer McPartland after that.

Andrew, go ahead.

ANDREW ROSENBERG: Thank you very much. Thank you for the opportunity to comment on the
EPA's supplemental notice of proposed rulemaking to the 2018 strengthening transparency and regulatory science rule.

I am Dr. Andrew Rosenberg, director of the Center for Science and Democracy at the Union of Concerned Scientists. So, I have over thirty years’ experience as a scientist and with regulatory decision making.

This supplemental rule sharpens the way in which this proposal would substitute political judgment and criteria for scientific method and best practice. It will do nothing to increase the transparency of the agency's decision making. Instead it clarifies that scientific evidence is a lesser importance than nullifying regulated industry and scoring political points.

By instituting completely non-scientific criteria of public availability of underlying data to weight scientific evidence, EPA's so-called transparency rule will severely restrict the agency's ability to protect public health and safety.
Under this proposal, not only will critical studies be ignored for no other reason than the inability to make all of the underlying data public because of personal or business privacy concerns, the administrator will have the authority to waive this requirement on a case by case basis with no specified reason. This makes a mockery of the process of relying on the best scientific evidence as required by statutory mandate for all of EPA's regulatory efforts.

These requirements for best scientific evidence cannot be waived away by a specious rule under supposed authority of the Housekeeping Act. This is not housekeeping. It is deconstruction of the agency's mission in a manner that is both arbitrary and capricious.

The scientific studies most directly targeted for exclusion by this rule are those analyzing medical information of individuals to understand population level effects. At no time in recent history, because of COVID-19, have we more clearly seen the importance of these
epidemiological analyses, yet these are the very studies this rule would cause EPA to ignore. Under no circumstances is the best or strongest evidence dependent upon public availability of underlying data to the degree required by this supplemental rule. Rather the best evidence depends on the methods, procedures, study, design, and execution, and the analytical approach.

As a reviewer for numerous journals and for regulatory science for multiple federal agencies, that is what I rely on, not the underlying unanalyzed data. The only purpose for making the raw data is raw data -- available for health studies, is to give industry interests a new opportunity to spin the science to meet desired regulatory outcomes. This is an old trick in the tobacco industry's playbook adopted by other unscrupulous actors.

Further evidence of the arbitrary and capricious nature of the rule is the requirement for reanalysis. Such a requirement redo the
calculations of all studies and perform pointless sensitivity analyses is not based on good scientific practice and only seeks to paralyze the agents who make work.

As with all other aspects of this rule, the agency has not provided analysis of what problem they are trying to solve. There is no analysis of the impacts on public health and safety nor of the cost of implementation. How can the EPA proceed without such detailed analyses?

Because this rule is clarified by the supplemental notice would ostensibly apply to all of the science the EPA would utilize from within and outside the agency. It will completely undermine the agency's fundamental mission. EPA, if you are listening, I urge you to immediately withdraw this proposal and stop this travesty.

Thank you very much.

JASON JACOBSON: Thank you, Andrew Rosenberg. The next speaker will be Chris Frey, followed by Jennifer McPartland and Representative Paul Tonko.
CHRIS FREY: Okay. Thank you. Yeah, I am Chris Frey. I am a distinguished university professor at North Carolina State University. I am a past chair of the EPA Clean Air Scientific Advisory Committee, a past member of the EPA Science Advisory Board, and the EPA Fit for Scientific Advisory Panel.

As a researcher in environmental engineering I have published over a hundred and thirty peer-reviewed journal papers. These comments are my own.

The EPA is proposing in the supplemental, new procedures for how science should be conducted within the agency without the benefit of a great many things.

One is the rigorous identification of what is the problem to be solved. Second is, without rigorous diagnosis of how to solve an actual problem, if any. Third is lack of rigorous interaction with scientists internal to the EPA, such as EPA career staff, and external to the EPA, such as via its scientific advisory boards,
including the ones I mentioned that I have served on, without development, demonstration, and evaluation of alternative approaches prior to arriving at proposals for a regulation. Without detailed evaluation of whether and, if so, how the proposed rule would conflict with existing statutes, such as the Clean Air Act in the case of the National Ambient Air Quality Standards. Without due consideration of alternative methods for changing internal practices to the extent that such practices merit changes, such as the development of internal working documents, white papers or guidance rather than a regulation. Without development of experience with the proposed measures by testing them prior to attempting to codify them into a regulation without engagement of program offices, such as the EPA Science and Technology Policy Council, to assess how the proposal would affect development of regulations across all environmental media throughout the agency. Without a background information document containing model case
studies, such as commonly provided in the development of many environmental regulations, it illustrates how the proposed rule would be applied in multiple context, the implications of the rule for the time and effort to conduct scientific analysis, and for the cost, not just to EPA but to stakeholders who produce scientific information.

And I think most egregiously, without seeking input from the National Academy of Science on a proposed rule that has sweeping implications for how science should be developed and used in regulatory decision making.

In the past EPA has sought input from the academy in advance of making large changes to its scientific enterprise, such as the famous 1983 Red Book report on Risk Assessment in the Federal Government and many others.

EPA should address each and every one of these deficiencies. The fact of the lack of due diligence by EPA is a confusing proposal that appears to be a solution in search of a problem and that will create problems potentially far
worse than the solutions it claims to provide.

For example, in the supplemental, the definition of terminology remains confusing with the term reproducible being used in a manner that directly contradicts the proper definition on the very same page of the Federal Register notice. It is clear that this proposal lacks input from the actual scientific community.

Given the origins of this proposal was some members of Congress, EPA should convince the public that this proposal is not nearly a politically motivated subterfuge aimed at excluding scientific evidence that would support health protective standards. Thank you.

JASON JACOBSON: Thank you, Chris Frey. Next up we have Jennifer McPartland, followed by Representative Paul Tonko and John Bachmann after that.

Jennifer McPartland, you may go ahead.

JENNIFER MCPARTLAND: Great. Thank you. I am just starting my video here. All right.

Good morning. My name is Jennifer
McPartland. And I am a senior scientist in the health program at Environmental Defense Fund.

EPA's supplemental censored science proposal continues to dismiss the agency's core mission, protection of human health and the environment.

Under the guise of transparency, the proposal would severely constrain the agency's use of best available science in violation of many of its statutes. If finalized, the rule will erode critical public health protections. And with them, the scientific integrity and public trust of the agency.

The fundamental premise of the proposal remains unchanged, to restrict EPA's use of critical scientific studies unless the data underlying those studies are publicly available. The data underlying many scientific studies are not publicly available and cannot be made publicly available.

For example, research involving human subjects often rely on medical or other personal
information, information that researchers cannot make public for legal, ethical, and practical reasons. Additionally, advances in data science have made it increasingly more challenging to effectively de-identify study subjects to protect their privacy. These are among the key studies we rely on to ensure our water is safe to drink, our air safe to breathe, and our land is safe for our children to play.

The supplemental proposal puts forward two new significant expansions. First, the proposal would now apply to all data and models, not just dose response data and models. And second, the proposal would apply to influential scientific information in addition to significant regulations.

With these sweeping expansions, EPA's unwarranted, burdensome proposal would apply to all scientific information the agency considers across its most important scientific outputs.

The supplemental proposal introduces troubling so-called alternative options for how
the agency would treat studies without publicly available underlying data. These options providing tiered access to underlying study data or assigning lesser weight to studies without publicly available underlying data still threaten the agency's use of best available science.

Moreover, EPA fails to provide even a modicum of analysis of how these options would actually be implemented, their associated costs, which would be significant, and their impacts on the scientific community, agency activities, and public health decision making.

The supplemental proposal continues to completely disregard established effective mechanisms used to vet scientific research, including peer review and consensus and findings across multiple studies. The EPA provides no explanation or justification showing that this proposal would improve upon these established mechanisms.

The supplemental proposal also continues to raise several troubling concepts that are
contrary to scientific best practices and chemical assessment, as discussed extensively in the Seminole National Academy's report, Science and Decisions.

Specifically, the proposed rule ignores the report’s conclusions that thresholds are the effects -- or chemical exposures are the exception rather than the rule given biological and exposure variability across a population. The proposal also gives more value to studies that employ a variety of dose response models and can be misleading. Multiple bad analyses does not make a study more credible.

Americans need and expect EPA to use the best available science. Right now, key organizations and institutes across the country are grappling with how best to respond to the COVID-19 crisis, including the EPA. Several groups, including Congress, have raised serious concerns around how the censored science proposal might impair EPA's use of critical studies to help address the current situation and its future use
of studies to improve preparedness.

EDF supports meaningful transparency in science and the ongoing efforts in the scientific community to provide that transparency. But this proposal is not about transparency, it is about political interests, roll back public health and environmental protections.

Finally, I would like to express dismay at EPA's decision to proceed with this proposal in the midst of an unprecedented health crisis that prevents key public health experts from engaging in this process. EDF strongly recommends that EPA withdraw the proposed rule. Thank you.

JASON JACOBSON: Thank you, Jennifer McPartland. Next up we have Representative Paul Tonko, followed by John Bachmann and Molly Rauch after that.

PAUL TONKO: Okay. Thank you, Jason.

Can you hear me?

JASON JACOBSON: We can you hear you.

PAUL TONKO: And can you see me?

JASON JACOBSON: I am starting your video
right now. You should be able to start your video.

PAUL TONKO: Okay. Are we -- do you see me?

JASON JACOBSON: Yes. Go ahead.

PAUL TONKO: Thank you. Thank you, Jason. And thank you to UCS for the opportunity to bring us all together. And it is an honor to join with so many of the environmental groups and environmental advocates that are so concerned about this issue. It's an honor to join with you.

So, I am Paul Tonko. I represent New York's 20th Congressional District. As Energy and Commerce on Environment and Climate Change Subcommittee Chair, I want to express great concerns about the Environmental Protection Agency's proposed rule supplemental published on March 3rd, 2020 entitled strengthening transparency in regulatory science.

Nearly two years ago I testified at EPA's public hearing strongly urging EPA to withdraw the earlier iteration of this selective science rule.
That rule would have allowed EPA to selectively exclude studies with conclusions they found unfavorable. I was joined by over one hundred members of Congress, a thousand scientists, and the leading scientific advocacy organizations in America in condemning this outrageous act. Clearly, EPA did not heed our call.

The path they chose given this blowback was to release a supplemental rule that effectively does the same thing. This supplemental allows EPA to prioritize studies, and not just for rulemaking, for all EPA activities. Let me repeat that, for all EPA activities.

They must have known this would be problematic because they are trying to get this rule adopted in the dark of night. EPA is rushing the rule with a shortened comment period, no public hearing, and during a pandemic. This is shameful behavior and I am glad UCS is giving us the opportunity to act.

EPA's new proposal, like the one before it, would severely limit the types of research
that EPA could take into account when developing policies. It has been cloaked in arguments about transparency. But let’s all admit here that this argument is bunk. This has nothing to do with transparency. They even admit in this rule text that EPA is looking for industry stakeholders to be able to reanalyze studies. Why would an industry stakeholder ever reanalyze a study unless it wanted its conclusions reversed?

This is a thinly veiled campaign, a thinly veiled campaign to limit serious and highly credible scientific research that supports critical regulatory action. Why would a science-driven public agency undertake such a radical departure from existing and widely accepted scientific standards?

EPA presents no evidence at all that peer reviewed, a system that has literally built American scientific might, is failing. In fact, only two out of ten thousand papers are retracted in the United States. The system is strong, the system is fair, and the system leads to positive
scientific and public health outcomes. Today's proposal and its false claims about transparency are consistent with that pattern, a fact that was put on full display when the administration realized its broad approach would hurt regulating industries too since many EPA chemical reviews relied upon confidential business information. To get around this, the rule would give the EPA administrator complete discretion to deprioritize studies, essentially guaranteeing that public interest will always matter more than science. That's why I refer to this policy as selective science.

This proposed rule will be used to erode landmark advancements -- achievements in public health and environmental safety. For example, we know the Clean Power Plan would have led to reductions in pollution that were predicted to prevent some three -- thirty-six hundred premature deaths, ninety thousand asthma attacks in children, and three hundred thousand missed school and work days each year. Many of these health
benefits were partially determined by landmark clean air studies like the Harvard Six City study. This is equivalent to telling CDC they can't use health data when fighting Corona virus. It is both insane and dangerous.

So, eighty-six of my house colleagues stand with me on this, as do countless everyday Americans. They are all aware of the reality here, that this is not about transparency. This is not about protecting human health or protecting our environment. This emperor simply has no clothes. I must again ask EPA to put science and public interest ahead of political and special interests and withdraw this rule based on its negative impacts on science, and its negative impacts on our public health.

With that, I thank you for the opportunity. And thank you again for bringing us together.

JASON JACOBSON: Thank you, Representative Tonko. Next up, we have John Bachmann, followed by Molly Rauch and Vijay Limaye
John, go ahead.

JOHN BACHMANN: Okay. I'm starting the video. Am I there?

JASON JACOBSON: Yes. We can hear and see you.

JOHN BACHMAN: Okay. Look, we are just eight days before the fiftieth anniversary of the first Earth Day and I have some questions. First, why is EPA in such a hurry to finish a rule -- no, I'm sorry. Why is EPA proposing to regulate science and rolling back regulations on pollution? Why is EPA in such a hurry to finish a rule for which there is not only no legislative mandate, but if actually adopted and implemented would cause the agency to violate many of its statutory mandates? Why do EPA's political leaders pretend that they actually care about science, and external science advice, or transparency in developing policy when again and again their own actions show otherwise?

A fair review of the supplemental
proposal must conclude that it would expand greatly the problems, cost, and wasted effort inherent in the original while continuing to weaken regulations and assessments by walling off access to many important scientific studies. Most importantly, EPA has still not demonstrated either the need for nor the benefits of regulating science, much less the cost.

A statement in the draft SAB report still stands. In general, the SAB finds that the EPA has not fully identified the problem to be addressed by the proposed rule.

Absolutely. The agency has not demonstrated the need for this proposed regulation. In the past, EPA has shown the flexibility to handle significant data issues, including reanalysis when they were risen. I played a role in promoting some of these in the fine particle stance. EPA can continue to use its existing procedures as it moves toward improving the transparency which we all would like, along with other federal agencies. The agency can
better address evolving scientific information related to dose response issues by issuing guidance without trying to crack the fixed regulation that would make the need for reanalysis more important than any other criterion for evaluating the scientific literature used for regulatory decision making.

The supplemental proposal offers several unattractive choices in the guise of trying to recognize the overwhelming objection from the scientific community on the original rule, publicly available tiered access versus restricted access, including studies completed before the rule or not.

The second most favored option is try to give an appearance of being reasonable. To quote one CASAC chair, bologna. Because EPA has done no assessment of cost and benefits of the proposal and options. I looked at a single set of important studies that play a major role in the current review of the science and policy for fine particulate air pollution standards. My purpose
was to determine what studies might essentially be excluded under the core rule options in 30.5.

Like the famous Six City and ACS programs, these are cohort epidemiology studies of fine particles and mortality. What Chris Frey calls soot. It's generally not possible to provide unfettered access to the personal information needed for reanalysis. EPA's assessment lists over forty such studies. Under the first option, I found that at least thirty of these would be excluded from consideration, just as in the original proposal.

Under the alternative, at least twenty-five would be downgraded to lower consideration solely on the basis of data availability. More consideration or weight are not that different from exclusion.

Finally, EPA's leaders' true disregard for science is obvious in their actions, like shortening SAB and CASAC terms, dumping scientists who have EPA funding but not industry consultants, cutting EPA's research budget, unilaterally
dissolving the expert panels long used in air
standards reviews. Failing to consult with SAB
before the 2018 transparency proposal and waiting
nearly a year to respond to SAB's request to
review the rule with a polite no. SAB went ahead
and did it.

Bottom line, this rule will fail. It
will lose in Court. Dump it, EPA. Thank you.

JASON JACOBSON: Thank you, John
Bachmann. Next up we have Molly Rauch, followed
by Vijay Lamaye and Deborah Wallace after that.

Just one second, Molly.

MOLLY RAUCH: Good morning.

JASON JACOBSON: Okay. Molly, go ahead.

MOLLY RAUCH: Good morning. Can you hear
me?

JASON JACOBSON: We can hear and see you.

MOLLY RAUCH: Good morning. I am Molly
Rauch, public health policy director for Moms
Clean Air Force. Thank you so much to the Union
of Concerned Scientists for hosting this hearing
today.
I am here on behalf of more than one million Moms Clean Air Force members to oppose this proposal and the supplemental which would prevent relevant peer-reviewed public health research from being considered when the agency is setting life-saving pollutants standards. Moms have been speaking out by the thousands against this proposal since it was first introduced and the supplemental has resolved none of our initial concerns.

The censored science proposal at issue today would force the EPA staff to ignore studies that use private datasets. This when much of the research on the health effects of pollution relies on data that needs to be kept private. Things like birth dates, home addresses, and medical diagnosis. It's precisely this kind of private data that has informed some of the most important large scale and groundbreaking research on the health impacts of pollution. In fact, it's the same type of data that underlies the research that told us that second-hand smoke was unsafe. And as
parents, we rely on this type of research to protect our children from pollutants and other health harms.

The censored science proposal is the cornerstone in a large-scale attack on health science at EPA. And specifically, the scientific process of Clean Air Act rulemaking. We have seen this so far most clearly with the science advisory process for the National Ambient Air Quality Standards. Some of the changes we have seen, as discussed by Dr. Bachmann, include disbanding -- disbanding advisory panels, lessen scientific review without adequate expertise, barring EPA funded scientists from serving on advisory panels, while creating no equivalent limits on the appointment of industry funded scientists, and so on.

If this EPA truly wanted to take more care with analysis and with considering science, we would not be seeing this kind of wholesale disregard for science in every other aspect of the NAAQS work. Indeed, Administrator Wheeler is
likely at any moment this morning to propose an 
update to the particulate pollution matter that 
refuses to tighten the standard.

And that current standard clearly allows 
for thousands of premature deaths and other health 
problems, thereby ignoring the best available 
science.

So, this rule attempts to solve a problem 
that does not exist. The EPA already has the 
capacity to evaluate the strength of studies. The 
process laid out is simply unnecessary. It would 
be a huge waste of time and a waste of resources. 
And as UCS experts have pointed out, this would 
provide the benefit of basically an arithmetic 
check. But it would also sideline crucial 
epidemiological research.

In the proposed supplemental the EPA 
administrator has the sole authority to exempt 
studies from this blanket censorship process. 
Putting this option in the administrator's hands 
means that this is not a scientific process, this 
is a political process. So, in the guise of
transparency, this rule attempts to shield heavy
industry from responsibility for lethal pollution.

Right now, the country is facing an
unprecedented global health crisis in the Corona
virus. People's lives are up-ended all across the
country. And we are relying on the scientific
expertise of health researchers more than ever.
We are seeing first hand in real time how strong
science helps us make the best decisions we can
for the health of our children, our families, and
our communities.

If we have learned anything in the last
weeks, it's that we must listen to scientists and
learn everything we can about threats to our
communities to make the best decisions. This is
really no time to engage in a stealth operation
aimed at censoring the scientific underpinnings of
our nation's health regulations.

Moms Clean Air Force strongly opposes the
censored science proposal and supplemental and we
urge EPA to withdraw it. And I want to again say
thank you to the Union of Concerned Scientists for
the (inaudible) rule. Thank you.

JASON JACOBSON: Thank you, Molly. The next speaker will be Vijay Limaye, followed by Deborah Wallace and Beto Lugo-Martinez after that.

Vijay, go ahead.

VIJAY LIMAYE: Hello. My name is Vijay Limaye. And I want to thank the Union of Concerned Scientists for organizing this virtual public hearing today. I am trained as a PhD environmental epidemiologist. I am also a former EPA scientist focusing on better understanding the harmful health effects of air pollution.

At the EPA I worked on air pollution and health science data and policy. I now work as a scientist at the National Resources Defense Council, NRDC. With regards to the supplemental proposed rule, it includes a number of glaring and foundational deficiencies. And there is a significant absence of any attempt by EPA to assess the major risks associated with actually implementing this proposal.

I am concerned by EPA's lack of
justification for this sweeping reach of the supplemental proposal, which is all-encompassing compared to even the original proposed rule. EPA now says that its science censorship rule would apply to any data and models used by the agency to craft its regulations. The change is significant. And it is an expansion of the net cast in the original proposal, which was limited to dose response data and models. And this change could weaken a wider range of current pollution controls all across this country. But that major change in scope was never justified in the proposal.

Moreover, this proposal is poorly conceived at a fundamental level. And as you have heard this morning, attempts to address a problem that simply does not exist. EPA has not in the original proposed rule or in this supplemental proposal adequately identified any particular problem to be addressed by this unprecedented agency action.

The concern was identified earlier by EPA's own scientific advisory board. This was
months ago in regards to the original proposal. But the agency did not address that concern in the supplemental proposal. EPA has not meaningfully engaged with the scientific advisory board in assembling its supplemental proposal. And in the supplemental proposal, EPA has not responded in any meaningful way to the major questions and concerns identified by the SAB about this rushed effort.

EPA has historically relied upon thousands of high-quality public health studies for decades in order to understand how environmental contaminants like air pollution affect human health. This approach based on the careful parsing of the best available scientific evidence, data that has been thoroughly reanalyzed and validated, has delivered profound health and economic benefits to the American public over the past fifty years to the tune of two trillion dollars by the agency's own estimate.

The monumental achievements of the Clean Air Act propel and strengthen by expert
application of epidemiology, toxicology, and interdisciplinary environmental health science should speak for themselves. Any attempt at this point to unsettle the agency's proven process and cast doubt on the integrity of overwhelming and thoroughly validated health evidence is simply not justified.

The supplemental proposal lacks any reasonable legal or scientific rationale. The recently finalized Integrated Science Assessment for Fine Particulate Matter, Soot Air Pollution demonstrates that the existing scientific review processes are fully functioning to capture and characterize the best available science as mandated by law.

In working to survey the available literature and identifying health effects caused by exposure to harmful air pollution, I know that the EPA staffers carefully review and follow the federal privacy protections, data integrity laws, and the agency's already high bar for consideration of scientific evidence. Thoughtful
attention is already paid to critically assessing the quality of each study's methods and results, including the quality of underlying data from which conclusions are made about causal effects.

And no decision at EPA is made on a basis of a single study alone. Rather, scientists work for years to painstakingly assemble and assess the evidence. This approach is working. But the supplemental proposal would up-end it by enabling political meddling in the agency's work.

EPA now proposes to prioritize its consideration of certain scientific studies over others without any clear criteria or transparent publicly accountable process. That's a recipe for bias and chaos in future EPA rulemaking because there is no clear explanation for how such important decisions will be made or implemented.

The supplemental rule proposes to give EPA the expansive new authority and the administrator to ignore the rules own unprecedented restrictions and make exceptions to allow for handpicked studies to be considered in
the agency's work. Moreover, administrator would not need to provide any robust explanation for such a drastic intervention.

In summary, the agency has not adequately shown the need for this proposed regulation. To the contrary, this defective supplemental proposal would ignite cascading waves of unnecessary, unworkable, and hugely expensive implementation issues. It would also directly enable selective interference in the science --

JASON JACOBSON: And that is time. Thank you, Vijay. Next, we have Deborah Wallace, followed by Beto Lugo-Martinez. And Patrice McDermott after that.

DEBORAH WALLACE: Well, I have no video. So, it is just going to be audio.

JASON JACOBSON: That is just fine. Go right ahead then.

DEBORAH WALLACE: Okay. My name is Deborah Wallace. I got my PhD in ecology in 1971. And have served in industry, government, academia, and the non-private sector. I have authored and
co-authored many peer-reviewed publications.

As a member of the environment section of the American Public Health Association, I am circulating a letter to Andrew Wheeler asking for rescinding of this rule. It has about a hundred signatures to date of environmental and public health scientists, doctors and nurses. The letter points out flaws in the rule that are not yet widely discussed. For example, one of the important tools in environmental health analysis is the meta-analysis. By excluding so many studies because of this raw data rule, there may not be enough admitted studies to support meta-analysis.

Secondly, the rule would create a massive database on a website inviting hacking by parties with commercial interests in lackness of standards and by hackers who are either pranksters or use ransomware. Hackers could falsify data and analyses, erase data and analyses, and reidentify individuals. Hacking has become one of the most expensive and disruptive crimes. Hacking by
corporations is so common that the Cyber Infrastructure Agency of Homeland Security gives it a class by itself.

Another point, the rule opens policy and standard setting processes to quote reanalysis, alternative models, and independent validation, including by well-funded consultants and direct employees of the regulated industries, thus the rule shows no recognition of the influence of conflicts of interests on scientific results and provides no assurance of testing and correcting for conflict of interests. Indeed, it invites distortion of science by conflicts of interest. There is a large literature on conflicts of interest that documents the bias they introduce into results and conclusions.

Another point, the rule fails to recognize the social science of informed consent, and a broad informed consent, which indicates that fewer volunteers would participate in environmental health research if they knew that their data would be posted and would be available
to for-profit industries. Privacy is very important to volunteers.

The new 2017 common rule with which EPA must comply requires use of the broad informed consent form for studies that would post data. Certain classes of potential volunteers, especially members of minority groups and people concerned about privacy, would shy away from giving broad consent. Thus, the rule would severely impair development of science. And there are papers out there in the literature about this.

This rule usurps the debate function of the larger scientific community in deciding what is influential and highly influential scientific information, what science is appropriate to support this scientific information and regulatory standards, and the methods for making these decisions.

The rule ignores the evolution of this debate and the knowledge of this important function of the scientific community that we gain from the disciplines of philosophy of science,
history of science, and sociology of science. There are at least half a dozen journals in sociology that explore the sociology of science and how we come to know what we know through the interactions within the scientific community. Thus, the proposed supplement would lead to failure of EPA to fulfil its functions of protecting the environment and environmental public health through subversion of environmental science and environmental health science by undue influence of regulated industries, and to strangulation of science both at the level of consideration of the studies used for policy and regulation, and at the level of producing science based on volunteers.

Thank you very much for allowing me to introduce these ideas.

JASON JACOBSON: Thank you, Deborah. Next, we have Beto Lugo-Martinez, followed by Cam Wejert-Depue. And after that is Patrice McDermott.

BETO LUGO-MARTINEZ: Hi. Good morning.
This is Beto Lugo-Martinez. I am based out of Kansas City. And I have a short comment letter that I put together. And I want to thank UCS for putting -- actually putting this virtual meeting together in spite of not having open public comment, you know, availability with the EPA or their agency.

So, a little bit of background of my organization or it’s -- my organization is called CleanAirNow. It's an environmental justice organization in Kansas City. We work on the front lines of environmental racism in communities fence line to industries, which have recently been given a green light to increase pollution during this -- during the current pandemic.

Our communities here are already struggling. Not just our community, but large communities around the country already struggled to survive. The COVID pandemic is making the usual challenges even more difficult to overcome. Decisions made about health and environment should be based on the best available science period.
The deceptively titled, *Strengthening Transparency in Regulatory Science* proposal does just little -- does just the opposite by keeping highly respected peer-reviewed scientific studies from informing government decisions on public health and environmental protection.

As its misleading name suggest, this rule’s intent and effect is to exclude from consideration scientific studies that examine the health impacts of environmental contamination and toxic chemicals that meet all scientific validity and rigor simply because they rely upon non-public data such as confidential medical information. These studies are possible because the researchers promise to protect communities, protect confidentiality of patients or subject matter participants.

Environmental justice frontline communities although always overlooked by Environmental Enforcement agencies have finally found a way to use scientific facts to redirect decisions that affect public and environmental
health. And one of these examples is through community based participatory research, the CBPR.

Communities have found a way to engage in a conversation with industry and environmental regulators and the people who make the laws. We are using data, quantifiable data and other evidence-based information to engage in the conversation to really protect the communities’ best interest. Now that communities have a way to engage in the conversation, beyond simply providing personal stories, now the government is trying to take this away from us.

It is hypocrisy. Before we were called vigilantes and emotional and too soft. Now that we are providing factual, hard science the government wants to exclude science and pick and choose when a rule does or doesn't apply. That is the opposite of a transparent process, excluding specific studies that make it harder to use science to put new safeguards in place.

When science-based facts are not taken into account into any permitting or land use
decisions or enforcement actions, our community members suffer the most.

This proposal echoes tactics the fossil fuel, Big Ag, and chemical industries to evaluate science. It exemplifies this administration’s abandonment of public protections entirely and has made access to the commons a free for all for the highest bidders. Showing the public once again it prioritizes profits over people.

I am outraged that we are even having this conversation in the middle of a pandemic. The situation around COVID is a perfect example, while the White House may at times attempt to redirect our actions to appease economic interests, ultimately governors and community leaders are looking to our healthcare professionals, our researchers and scientists who guide the decisions towards an outcome that is most suited to protect the general public. More than ever we should be listening to what science is telling us about our health. We should not be restricting the use of science in decision making.
Excluding science-based facts will adversely and disproportionately affect public health and impact communities of color, we should be prioritizing our ability to protect our air, water, climate and health. It is a critical time to embrace science-based protections for community health and keeping communities safe from chemical toxicants. Thank you. Thank you for the opportunity to speak today.

JASON JACOBSON: Thank you, Beto. Next, we have Cam Wejert-Depue, followed by Patrice McDermott and Michael Buza after that.

Cam, go ahead when you are ready.

CAM WEJERT-DEPUE: Great. Can you hear me?

JASON JACOBSON: We can.

CAM WEJERT-DEPUE: Great. Good morning everyone. Thank you for giving me the time to speak today on such an important issue. My name is Cam Wejert-Depue. I work for the American Lung Association's Healthy Air Campaign. Known as the nation's oldest voluntary health agency, the
American Lung Association's primary mission is to save lives, particularly by improving lung health and preventing lung disease.

The American Lung Association strongly opposes the EPA's so-called strengthening transparency and regulatory science proposal. Under this proposal many key studies that show the impact of air pollution on health will be downplayed or excluded. This proposal would not strengthen or clarify transparency within science or improve regulatory science. As I will discuss, this proposal would lead to the exclusion of critical studies within the rulemaking process and the agency more broadly. This includes studies that show that particulate matter air pollution causes premature death and elevated risks of respiratory illnesses. In fact, I would like to highlight two particularly important studies that this proposal would deem as not transparent and therefore could exclude from the EPA's rulemaking process.

First, in 1993 researchers at Harvard
University published a landmark air pollution study showing that particulate matter air pollution was linked to premature death. The Harvard Six Cities Study tracked the health of eight thousand, one hundred and eleven adults and fourteen thousand children in six small cities in the United States beginning in the 1970's. The results found that people in the cities with cleaner air were living two to three years longer than those living in cities with dirtier air. The findings added that residents in the city with the dirtiest air, in Steubenville, Ohio, were twenty-six percent more likely to die prematurely than were citizens of the cleanest city in Portage, Wisconsin. Another finding that stood out to researchers from the study was that the culprit was particulate matter and not sulfur dioxide as they had thought. Industry and their allies in Congress challenged the findings of this study and other similarly important studies.

Instead of blocking the studies as this proposal would do, EPA took a logical step and
referred the study to an independent third party to The Health Effects Institute for a deep dive review. There, autonomous reviewers examined the data and developed a report that confirmed their original findings.

In addition to the Harvard Six City Study, the American Cancer Society's Cancer Prevention Study two, which began in 1982, was a landmark piece of research that revealed some of the many risks to human health through breathing air pollution. Private health and medical data was used from hundreds of thousands of participants and shed light on the need to clean up emissions from power plants, diesel engines, and many other pollution sources in order to protect our public health.

These two studies with decades old patient data and others in the long list of studies that found evidence of harm from industrial emissions appear to be targets of this proposed rule.

Once published, these studies raised
alarms in the public health community about the increased likelihood of respiratory illnesses and premature deaths due to air pollutants like particulate matter, as well as the disproportionate effect of poor air quality on the most vulnerable communities. In response, industry used this same messaging developed by the tobacco industry to challenge the transparency of public health science. The same arguments used in this proposal.

Moreover, EPA's rushed process around this proposal, while missing adequate reviews, all highlight a key problem with this rule. It will not improve the use of science at EPA. Restricting the use of studies like the Harvard Six City Studies and the American Cancer Society would falsely downplay the impact of air pollution on health. It is essential to use the best public health science when it comes to making decisions about our public health.

On behalf of the millions of Americans who struggle with poor air quality and personally
suffer from the impacts, I urge the EPA to withdraw this proposal. Thank you.

JASON JACOBSON: Thank you, Cam. Next, we have Patrice McDermott, followed by Michael Buza. And after that is Dr. Bernie Goldstein.

Patrice, one moment. Patrice, go ahead.

PATRICE MCDERMOTT: Thank you. My name is Patrice McDermott. And I am director of Government Information Watch. And I have worked in the area of transparency and accountability for approximately forty years. My remarks today are intended to address those issues.

What the EPA is proposing is not transparency, nor is it transparent science. It has long been an underlying principle of advocates for government transparency and accountability.

The trust in government is dependent on both the openness of government policies, rules, or practices, and certainty that privacy-protected information, PPI, will be held confidential when it is given to government agencies.

We have become increasingly aware
moreover of the near impossibility of anonymizing personably identifiable information even with tiered access to independent validation when such validation includes the information necessary -- quote, necessary to understand, assess, and reanalyze findings by entities outside of the agency.

In the proposed rule, EPA reserves the right to itself to place less weight on the studies to the point of entirely disregarding them if the data and models underline pivotal regulatory science are not made available in full to EPA. Are not, quote, unquote, transparent by which EPA means that the underlying raw data is made publicly available in a manner sufficient for independent evaluation. Such raw data includes medical records and other PPI that are required to be held confidential.

At the same time, EPA would be required to, quote, give explicit consideration to a long list of models that could be prepared by outside stakeholders. The rule also proposes an
exclusionary test that eliminates individual studies based solely on whether the data is transparent. There is, however, no clear mandate that the models prepared by outside stakeholders be held to this standard. Worse, both the meaning of the exclusionary test itself and the decision to exempt a particular study from the requirement of public availability are explicitly left entirely to the discretion of the administrator to apply on a case by case basis. This is not transparency.

The following principles and recommendations are drawn from Rena Steinzor and Wendy E. Wagner with permission. Transparent science should make publicly available a conflict of interest disclosure statement if the study was privately sponsored, as well as the underlying contract governing that research in order to ensure that researcher’s independence to determine study design and report’s results was preserved. A clear statement of the methods for data collection and analysis used in the study to allow
for scrutiny, and even replication of the study. And all of the underlying data, presumably in digital form, that is not original specimens, et cetera. A proposal for a proposal for transparent science, should one apply the same standards to all scientific research and analyses used by the agency. Particularly research that is not published and that has escaped rigorous peer review.

Require that a list of all excluded research be shared with the public as decisions are made. Such disclosure could be accomplished by listing excluded or presumptively excluded information on a dedicated website in the course of a rulemaking agency decision. And three, be applied to all technical analyses prepared by the agency.

As this proposed rule neither conforms with the principles above, nor meets the requirements for a proposal for real transparent science, I urge that it be withdrawn in its entirety. Thank you.
JASON JACOBSON: Thank you, Patrice.

Next up we have Michael Buza, followed by Dr. Bernie Goldstein, and Tricia Dellolacocono after that.

MICHAEL BUZA: Hello.

JASON JACOBSON: Mike, go ahead.

MICHAEL BUZA: Yes. Can you hear me?

JASON JACOBSON: We can hear you.

MICHAEL BUZA: Okay. My name is Mike Buza. I am currently the chair of the Nepessing Group of the Sierra Club. I have also worked forty years in the past -- I am retired now, but worked forty years in the past in healthcare service in a variety of roles, including fourteen years as an administrator. My comments are as follows:

The EPA proposed rule to supplemental strengthening transparency in regulatory science appears to ignore the real-life world of doing research. The new rules would require scientists to disclose all raw data, including confidential medical records, before the agency could consider
an academic study's conclusions. These new proposed rules appear to ignore the HIPAA rules and state confidentiality laws that clinicians and medical researchers must live on. Any violation of the HIPAA or state confidentiality laws can result in stiff fines and loss of professional licenses.

In essence, the researchers could ruin their career to release their findings. All persons who have access to medical records are required to have annual training on HIPAA rules and state regulations on confidentiality so there is no room for denial of the laws and regulations.

The EPA has proposed supplemental rules -- a supplemental rule to strengthening transparency and regulatory science would make it virtually impossible to conduct research to ensure the environmental safety of the public, which the EPA is supposed to protect. To follow EPA rules and state confidentiality laws would require obtaining release of information from all subjects in the study. If a number of persons refuse to
sign the release, this could put into question the
reliability of the data. Also most likely limit
the number of subjects in the study. Again,
putting into question the reliability of data.

It appears that the current EPA rules is
to make it impossible to conduct research to
protect the citizens of the United States.

I would like to conclude by thanking the
UCS for providing me this opportunity to speak.

Thank you very much.

JASON JACOBSON: Thank you, Michael.
Next, we have Dr. Bernie Goldstein, followed by
Tricia Dellolacono, and Ben Levitan after that.

Dr. Goldstein, go ahead.

BERNIE GOLDSTEIN: First, my deepest
thanks for the Union of Concerned Scientists for
their hard work in putting on this hearing. I
will focus my remarks on fine particulates and
biomedical causability.

I have an influential scientific model
which I wish were wrong. It predicts that I am
the oldest person at this hearing with fifty-four
years of experience and the longest tenure in
performing what I personally believe to be highly
pivotal and scientifically influential
environmental post studies, all two hundred of
them.

Science is a web. Just untangling one
part of the web from another by artificial
definitions is impossible. For fine particulates,
it was Sidney Laskin in the 1940s who first showed
that they penetrated deeply into the lung and were
more toxic than coarse particles. But a fine
particle standard could not be set under the 1970
Clean Air Act until much, much later. Many
confirmatory approaches and laboratory animals
were needed and not all initially supporting the
Laskin (phonetic) findings. Also needed was a
robust monitor to measure fine particles, which
took years and also much controversy. But without
these studies, we could have not had either the
Harvard Six City Study nor the American Cancer
Society Study. These are the poster children for
the alleged need for transparency.
There are thousands of studies that have since confirmed the Harvard findings. Again, not unanimously. Let me emphasize that none of the studies that I have already referred to fit the supplement’s definition of replication or reanalysis, which seems to be its major impact. They think this new term called reproduction -- the definition is given in the supplemental, mostly hand waiving -- hand waving or not applicable to environmental epidemiology. One approach we do use in science, while imperfect, is to look at citations as a relevant indicator of influential science.

I will speak to biological causability, which is almost uniformly a factor in EPA's description of the scientific analysis underlining regulation. As much of the studies related to biological causability that are cited by EPA, are not dose response models, they would clearly be affected by the new supplement. As defined in the December 2019 particulate ISA, biological causability is part of the weight of evidence.
analysis that considers the totality of the health effects evidence, including consistency and coherence of effects described in experimental and observational health studies. Each of the six health effects chapters contains a section on biological causability.

    Basically, there is -- not only do they have additional references, I counted about twenty percent more in the chapter on cardiovascular facts, they also reference in the biological causability sections the previous ISA, which presumably references the previous ISA before that, are all of these scientific and influential since they have all been incorporated into the findings that EPA uses.

    Again, not always complete agreements. I have mentioned it is not surprising that is not complete agreement given the complexity and inherent challenges. But that is the crucial point, without a clear definition the administrator is free to cherry pick which studies he or she wishes to go on.
Finally, these decisions points and new definitions should be added to the many aspects of this overall proposal that should have been reviewed by EPA's congressional mandated scientific advisory board. Thank you.

JASON JACOBSON: Thank you, Dr. Goldstein. Next up we have Trisha Dellolacoano, followed by Ben Levitan, and Dr. Rick Bein after that.

Trisha, go ahead.

TRISHA DELLOLACONO: Hello. My name is Trisha Dellolacoano. And I am the national field manager for Moms Clean Air Force. We are a community of over one million moms and dads united against air pollution to protect our children's health. I'm also a mom to four young children. My family is currently practicing physical distancing in our home in New Jersey due to our public health crisis.

I am grateful to the Union of Concerned Scientists for organizing this public virtual hearing today. I joined this hearing this morning
to speak out in opposition to Administrator Wheeler's attempts to censor science in the name of transparency.

Right now, we are facing an unprecedented public health crisis. The American families are relying on the scientific expertise of health researchers to protect us now more than ever. We are seeing how strong science helps us make the best decisions we can for the health of our children, our families and our communities.

As the Corona virus crisis worsens across the country, the EPA should be making a special effort to listen to the voices of scientists and public health experts to make decisions that will protect our health in the face of this pandemic and not make us sicker.

This proposal put forth by the Trump administration constrains and undermines scientific integrity from the sound voice of scientists. This is an attack while the country is grappling with global pandemic.

The EPA's censored science proposal would
prevent relevant, peer-reviewed public health research from being considered when the agency is setting life-saving pollution standards.

Moms Clean Air Force members across the country have been speaking out by the thousands against this proposal since it was first introduced three years ago. The latest revision to the proposal is just as problematic as when it was first introduced. And we remain deeply concerned about the implications protecting children from pollution.

Science keeps our families safe. And the Trump EPA wants to cast it aside to benefit industry polluters. American families depend on EPA's consideration of high-quality science to protect us from the impacts of air pollution and toxic chemicals. This proposal would exclude certain types of public health research from consideration, placing the health of our children at risk. Limiting the scientific information, the EPA can use to identify public health threats and protect us from pollution is reckless and
dangerous. Not only does this proposal compel EPA
to subject high-quality research to extreme,
unnecessary, and untenable levels of disclosure,
but it also includes loopholes that would allow
the administration to exempt the industry from
having to disclose details of its own studies.

American families depend on the EPA and
high-quality science to protect families like mine
from the impacts of air pollution and toxic
chemicals. This proposal puts the protection in
jeopardy, placing the health of our children at
risk.

This proposal would also significantly
limit the research and data that EPA can use to
make informed policy decisions under major public
health and environmental laws.

Moms Clean Air Force members are highly
familiar with the impact that pollution has on
people and the devastating health impacts of
pollution. EPA's job is to protect human health
and the environment and not to pretend pollution
doesn't harm people. Moms Clean Air Force members
are highly familiar with the impact that pollution has on people -- sorry.

My own family was exposed to a toxic chemical after a horrifying accident in my community that left us breathing polluted air and poisoned my family. As a mom who has witnessed her children's health deteriorate due to polluted air they were breathing, I know personally what it is like to rely on scientific studies and sound science whose data informed us during that horrifying time. And again, during this Corona virus pandemic my family is relying on sound science to keep us safe.

On behalf of my family and the Moms Clean Air Force one million members, I strongly urge EPA to withdraw this dangerous proposal for the health and safety of our children. Thank you.

JASON JACOBSON: Thank you, Tricia. Next, we have Ben Levitan, followed by Dr. Rick Bein, and Theodore Brown after that.

Ben, please go ahead.

BEN LEVITAN: Good morning. My name is
Ben Levitan. And I am a senior attorney on the U.S. Clean Air Team at Environmental Defense Fund. On behalf of our more than 2.5 million members and supporters, EDF urges EPA to withdraw its reckless and unlawful proposal to censor the science that protects public health and the environment.

This supplemental notice greatly expands the reach of the original proposal, severely limiting EPA's use of the best available science to protect public health. Like the original proposal, the supplemental notice fails to remedy any problem, is not consistent with scientific practice, and inflicts grave harm on our communities, especially the most vulnerable.

If implemented, it would bar EPA from considering the best scientific evidence when making decisions about our health and environment, which would undermine bedrock protections that have saved millions of lives.

EDF's supplemental proposal fails to address the fatal deficiencies that EDF and others raised in comments on the original proposal while
creating additional problems. This supplemental proposal also underscores EPA's lack of legal authority to issue this deeply harmful rule.

EPA now asserts for the first time that an obscure federal law known as the Housekeeping Statute authorizes this sweeping attack on health science. This novel legal theory flouts the plain language and history of this statute, both of which make clear that EPA is not an executive department with housekeeping authorities.

Even if EPA were an executive department, the censored science rule is clearly substantive and would profoundly affect EPA's implementation of multiple environmental laws. It is therefore beyond the housekeeping powers granted by the statute for any agency.

In addition, today's virtual public hearing by no means excused EPA's unlawful failure to hold its own public hearing. Section 307(d) of the Clean Air Act requires EPA to hold a public hearing for the supplemental proposal, as the agency did for the original proposal in 2018. The
original proposal easily met the criteria for public hearing requirements. And the supplemental proposal only expands the scope of the action and heightens the necessity for public input.

While we greatly appreciate today's opportunity to express some of our many concerns, EPA's refusal to hold a public hearing remains unlawful and undermines the public's ability to weigh in on this harmful and consequential action.

Finally, EPA's decision to expand its attack on public health science during a national health crisis is dangerous and unconscionable. Our nation's healthcare and medical professionals are courageously working on the front lines of this crisis saving lives imperiled by COVID-19 while risking their own.

These experts' input on the supplemental proposal is critical, but they cannot and should not have to divert their attention from our national crisis to meet EPA's arbitrary comment deadline. Neither should citizens be demanded to address this outrageous attack on public health.
while grieving the illness and deaths of their loved ones, juggling remote work, home schooling, and child care. And confronting financial, mental health, and other personal challenges.

It's unacceptable to endanger the public health and welfare with this supplemental proposal at any time, but it is even worse during a period of unprecedented confusion and peril for the nation.

For these reasons and others that we will include in written comments, EDF call on Administrator Wheeler to immediately withdraw this proposal. Thank you.

JASON JACOBSON: Thank you, Ben. At this time, we are going to take a short break. We have had a couple of speakers that haven't been able to connect and we want to make sure that we ensure consistency with the schedule that has been posted. So, at this time we will take a short pause until 10:45. And we will pick it up then with Dr. Rick Bein. Thank you.

(Whereupon, a recess was taken.)
JASON JACOBSON: Okay. We are going to resume the virtual public hearing at this time. Next up we have Dr. Rick Bein.

Dr. Bein, go ahead when you are ready.

RICK BEIN: I don't have the video yet.

JASON JACOBSON: We can see you.

RICK BEIN: Okay. I am Rick Bein, Professor Emeritus Department of Geography at IUPUI, better known as Indianapolis University Purdue University at Indianapolis. My area of focus is environmental conservation and a number of other disciplines.

The action by EPA clearly reflects the self-interest to ignore science. The action -- this action reflects the attitude of the Trump administration making the EPA a puppet. The original mission of the EPA has become negated. Whatever science limits big business, science is recorded -- is ignored. Ecological concepts of population dynamics would show that periodic pandemics occur. Many history of these things as civilizations have collapsed. Diseases including
bubonic plague, Spanish flu, SARS is some more recent ones, but many, many times in the past. We have much writings where people like Rachel Carson, Thomas Malthus, Jared Diamond talking about the problem of this disease or diseases coming from time to time. This is the kind of thing that is being ignored and is a serious problem and because of the lack of peer review and transparency. That's all I have to say. Thank you.

JASON JACOBSON: Thank you, Dr. Bein. Next up we have Theodore Brown.

Theodore, you can go ahead when you are ready.

THEODORE BROWN: Okay. Is my video up?

JASON JACOBSON: It is.

THEODORE BROWN: Okay. Thank you for the opportunity to speak today. I spent a long career as a research scientist and as director of the Beckman Institute, a large interdisciplinary research center at the University of Illinois, Urbana-Champaign. And I have also written on
science’s role as a source of authority and expertise in society. The all-encompassing supplemental notice, Strengthening Transparency in Regulatory Science, is frightening in its obvious motivations and the dangerous directions in which it takes us.

The proposed new rules nod toward the idea that fully public data and analyses should override results that are not fully public, for whatever reason and that we can thus be assured of policy outcomes more closely aligned with the public interest. While others have spoken here this morning very eloquently on how the proposed restrictions will cripple effective rule-making, when results of relevance and reliability are cast aside even though they may be the most important or the only feasible source of useful data.

The proposal reeks of tipping the scale towards narrow interest. Somewhat like the moves we’ve seen on both the national and local levels to restrict access to voting by introducing artificial and arbitrary obstacles.
It couldn't have come at a worse time.

We have a very serious problem in front of us. We can ill afford such tactics in this world challenged by the changes wrought by global warming and now the Corona virus pandemic. Now more than ever, we must listen closely to what science can tell us. Policy and action will mean increasingly based upon or it should be increasingly based upon scientific results coming from powerful and reliable models in a constant state of evolution as the models themselves improve and as the inputs change. The supplemental proposal would place such work in limbo.

In other words, it doesn't take advantage -- in fact, it denies the efficacy of advances in computational science and other ways of creating reliable and complex models to help us solve these countless problems.

Science is at its best when it serves as an open forum to aid and analysis and policy formation. The new rules would make it much
easier to block consideration, and I emphasize the word block, of relevant data and model results. We can no longer fail to act while the damage is being done. And then only then make policy for mitigating it.

As the agency charged with protecting an increasingly besieged environment, the EPA must be free to draw upon the best that science can offer society. Many who’ve spoken today have made clear that the notion of transparency that drives this proposed change is deeply flawed. It takes us away from practices worthy of a free democracy, of considering all the evidence in forming rules and policies. Now our challenge is how to block the adoption of such a perversely wrong move. Thank you.

JASON JACOBSON: Thank you, Theodore. I will now turn it over to Michael Halpern from the Union of Concerned Scientists.

MICHAEL HALPERN: We have one or two more people we are expecting to log on in the next few minutes. So, we are going to take one more break
for about five to six minutes and see if they show up. So, again, we will be on a brief break for five minutes or so.

(Whereupon, a recess was taken.)

JASON JACOBSON: This concludes the morning session. The recording of this session should be available on the YouTube page of the Union of Concerned Scientists shortly. The afternoon session will begin at 1:00 p.m. and the evening session at 5:00 p.m. Eastern time. Thank you.

(Whereupon, the 9:00 a.m. session was concluded.)
CERTIFICATE

I, Ashleigh Simmons, Reporter, do hereby certify that I was authorized to and did report the Virtual Public hearing for the Union of Concerned Scientists; and that the transcript is a true and correct transcription of the testimony given by the participants.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

Dated this 28th day of April, 2020.

_________________________________________________________________
Ashleigh Simmons
Ashleigh Simmons
Professional Reporter

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