VIRTUAL PUBLIC HEARING

SUPPLEMENTAL RULE ON EPA PROPOSAL

STRENGTHENING TRANSPARENTCY IN REGULATORY SCIENCE

1:00 p.m. to 3:00 p.m.

Tuesday, April 14, 2020

REPORTED BY ASHLEIGH SIMMONS, CER

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P R O C E E D I N G S

1:00 p.m.

MR. MICHAEL HALPERN: Good morning -- or good afternoon. My name is Michael Halpern. And I am deputy director of the Center for Science and Democracy at the Union of Concerned Scientists. Welcome to this virtual public hearing hosted by the Union of Concerned Scientists on the Environmental Protection Agency's proposed supplemental rule titled *Strengthening Transparency in Regulatory Science*. This session is being recorded and should post to the UCS YouTube page shortly after this session ends.

We appreciate you taking the time to provide public comment on the proposed supplemental rule. Nearly one hundred people have registered to provide public comment today. We are going to begin hearing public comments shortly. And we do have some space at the end of this session. So, if you would like to register to speak at the end of the session, please email ucsvph@gmail.com. That's ucsvph@gmail.com.

First, I am going to turn this over to Ken Kimmell, President of the Union of Concerned Scientists. Ken, please go ahead.

KEN KIMMELL: Hi. Good afternoon to some and good morning to others. Let me just check, can everyone see and hear me?

MICHAEL HALPERN: Yes.

JASON JACOBSON: Yes, we can.

KEN KIMMELL: Great. Well, I am going to start by saying that we actually shouldn't be here today. The Union of Concerned Scientists is hosting this public hearing because the Environmental Protection Agency has refused to do so.

It is highly unusual for a non-governmental organization like us to hold public hearings on a significant public policy proposal that's being advanced by a federal agency. Typically, of course, when a federal agency puts a rule out for public comment, it is their responsibility to hold a public hearing, particularly while the public comment period is

open.

Interest in this particular proposal is very, very high. The initial draft of the proposal went out for public comment and there were roughly six hundred thousand public comments that were entered into the record in a three-and-a-half-month time frame.

Now this supplemental rule that we are here today to talk about significantly changes the initial proposal, but the opportunity for public input on these changes is currently severely limited. Especially when one considers the sweeping nature of this proposal and the many ways that the EPA has made changes to the proposal since the original draft.

For purposes of this proposal, the EPA originally provided a thirty-day window for public comments with no public hearing. They recently extended the public comment window to sixty days with a deadline of May 18th, but with no public hearings. In our view, this is grossly insufficient.

During normal times, the government recommends a minimum sixty-day comment period for the simplest of proposals. But 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, preferably thirty days beyond the end of the declared national public health emergency.

We also asked for virtual public hearings. The agency has unfortunately refused both of those requests. We went an extra mile and invited EPA to send staff to listen in on today's hearing and ask questions of those providing comment. The EPA also declined that invitation unfortunately.

Now the COVID crisis poses profound challenges to our country and to our 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 this 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 even have reduced access to technology. So, all of these conditions make it extremely difficult for public comment.

And therefore, it is enormously impressive to me that more than a hundred people have registered to speak today. This is a testament to just how many people realize the significance of this proposal as to EPA's ability to meet its mission to protect public health and the environment.

We heard, by the way, from many more who don't have the bandwidth to provide comprehensive feedback on the proposal due to other commitments created by the pandemic.

Today's public hearing of course is not the only opportunity that you will have to provide public comment. I encourage everyone to develop

written comments to respond directly to the proposal. And UCS has developed a guide to providing effective public comments on this rule on its website.

So, let me leave you with a framing question. I know that all of us can and must agree, especially in the light of the crisis we are in now, that the best science, the best data, and the best analysis is not only important, it's not only essential, it is literally a matter of life and death.

So, the question for today is, is the EPA's proposal on the table likely to advance that imperative of having the best science available or will it undermine this imperative? And I think that is the key question to focus on.

So, I am going to turn it back to Michael. We expect the EPA to do its job and seek feedback on its proposals. But when the agency fails, as is the case today, it's our job to step in and make sure that the agency receives as much feedback as possible.

So, I look forward to the comments today. And I want to thank all of the people who have signed up to take part of this important endeavor. And with that, I would like to turn it back to you, Michael.

MICHAEL HALPERN: Thank you, Ken.

So, I would like to provide a little bit of background information and briefly describe the proposed rule on which we are taking comments today.

So, the EPA described the rule as follows: *The Supplemental Notice of Proposed Rulemaking proposes that the scope of the rulemaking apply to influential scientific information as well as significant regulatory decisions.*

The notice proposes definitions and clarifies that the proposed rulemaking applies to data and models underlying both pivotal science and pivotal regulatory science. In the SNPRM, EPA is also proposing that 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.

Now 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 in the rule that are made in the supplemental proposal.

Today's hearing will work as follows. Members of the public preregistered 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 speakers, 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 your confirmation from, which is ucsvph@gmail.com.

That same email, if you are watching the broadcast, you can also register to speak by emailing ucsvph@gmail.com and you will be added to the queue if time permits.

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

If you have any additional comments after today, please follow the instructions in the Federal Register notice for this proposal, and submit them by May 18th, 2020. And again, UCS has

provided a guide for people who want to make effective comments on its website.

Today's hearing is broken into three separate sessions, the first of which began this morning at 9:00 a.m. This session at 1:00 p.m. And one later today at 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 ask for patience during this virtual hearing, because we know that people have varying internet bandwidths and familiarity with this kind of technology. And if someone has technical difficulties when it is their turn, we will move on to the next speaker and return to the person who had technical difficulties later in the session. And people can always submit their testimony as prepared for delivery if they decide or if they have trouble overall.

All right. So, let’s get started. I am going to turn it over to Jason Jacobson, who is

going to be running today's hearing. Jason, please take it away.

JASON JACOBSON: Thank you, Michael. As a reminder, all attendees are muted automatically. 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 with our public comments. The first speaker will be William Reilly, followed by Nsedu Witherspoon. And after that we have Surili Patel.

William, you may begin.

WILLIAM REILLY: Thank you. It's extraordinarily constructive of the Union of Concerned Scientists to take on the responsibility of doing what EPA has chose not to do in this instance, which is to have this public hearing. Let me just say that looking back to the beginnings of EPA, the administrator, then Ruckelshaus, said that he felt constrained by the insufficiency of scientific and health information which he needed to set early standards and criteria. Since that time, EPA has given the

highest priority to ensuring the integrity of the science on which its regulatory decisions are made.

Enormous consequences flow from those decisions. Non-attainment of cities which have significant economic reverberations. The confidence of the public in the protection of their health, the trust to comply with difficult and sometimes costly regulations.

In 1989 the science advisory board at my request analyzed the policies of the agency. And the question was to what degree do they respond to the priorities that you see affecting the health and the ecology of the United States. They set out the criteria with a great deal of supporting data and analysis. And I used, and other administrators have used the science from them, from the National Academy of Sciences, from the National Institute of Health, through long-standing protocols which affect the quality and preparation of scientific opinion. Those are being called into question by EPA at this time.

It is enormously consequential that we reconsider elements of this proposal.

Other countries watch very closely of what we do. I can recall the Chinese chose to abandon their plan to build ten million refrigerators containing chlorofluorocarbons ozone depleters as a consequence of EPA research. The decision made in 1992 to declare side stream smoke a class A carcinogen was immediately accepted by the American public as a substantial decision based upon health criteria that deserved to be respected. And within two years, four hundred cities had changed their rules on side stream smoke and smoking indoors. What EPA does depends on the confidence of the public. It depends on the integrity of the science basis for its decision making. Both have been put into question by the current proposed regulation.

JASON JACOBSON: Thank you, William. Next, we have Nsedu Witherspoon, followed by Surili Patel. And after that will be Laura Bender.

NSEDU WITHERSPOON: Thank you so much to UCS for this opportunity. For over twenty-eight years, the Children's Environmental Health Network has been a national voice committed to protecting all children from the harmful effects of environmental hazards and to promoting a healthier environment. As the executive director, and on behalf of CEHN, I appreciate the opportunity to provide these comments on EPA's proposed supplemental rule strengthening transparency in regulatory science.

CEHN is strongly opposed to the proposed supplemental rule and believes it is even more harmful to children's health and safety than the previous version in many ways. The original proposal rule sets transparency standards that are too rigid and impossible to meet. It required that all data used in rulemaking be publicly available and allows EPA to exclude data that relies on confidential patient information.

Critical studies which have led to significant advancements in protective policies,

for example, from the EPA NIEHS's Children's Environmental Health and Disease Prevention Research Centers may certainly be excluded. This supplemental rule expands which studies can protect -- can be excluded even further. It now applies to an influential science at the agency -- to all influential science, not just the science used in regulatory efforts. The original exclusion applied only to those dose response research evaluating at what level a toxic chemical is toxic.

Further critical studies on health impacts which use medical information would also be excluded. The supplemental rule requires a lengthy and cumbersome reanalysis of already rigorously reviewed and analyzed raw data to make sure there are no errors in data calculations. This is a lengthy and unnecessary requirement, especially since scientific studies and data analysis undergo rigorous peer review and standard quality assurances and control. And EPA already has a review process in place. All of this

additional data analysis and number crunching is a waste of time and will result in delays to public health protections, not to mention the cost of the reanalysis to the agency and to researchers.

The new standard would also put greater weight on studies that make their raw data publicly available. This criterion is arbitrary and does not judge a study by standard scientific evaluation, such as the strength of its design or methods which are current acceptable metrics used to evaluate the merit of a scientific study.

Lastly, EPA has made no attempt to address the six hundred thousand comments received on the original proposed rule. And in doing so, has essentially ignored the scientific community, as well as leading public health organizations regarding valid concerns to the public's health and safety, given these comments were never addressed, the concerns, including those submitted by CHEN regarding children's health stand, including two very important comments.

The proposed rule would restrict EPA's

ability to set regulations informed by confidential data that cannot be replicated. This is of serious concern because from many older, longstanding landmark studies the original datasets were either not maintained or stored in outdated formats. And these could be eliminated under the proposed rule.

The proposed rule could also block the use of longstanding landmark studies on the harmful impacts of the toxic exposures and pollution, studies which were instrumental in the creation of the Clean Air Act, the Safe Drinking Water Act, the Food Quality Protection Act, and others.

Now more than ever CEHN is concerned with the supplemental rule that will adversely affect EPA's ability to use the best available science in decision making and negatively influence existing and future protections for children's health, such as clean air, clean water, and prevention of toxic exposures.

CEHN is also concerned about many aspects

of the supplemental rule that are cumbersome, unnecessary, and costly. As we did with the first proposed rule, CEHN requests that you withdraw the proposed supplemental rule strengthening transparency and regulatory science. Restricting EPA's ability to consider best available research will severely damage the integrity of evidence-based rulemaking. EPA will be unable to fulfil its mission to safeguard human health, especially the health of children and that of future generations. Thank you.

JASON JACOBSON: Thank you, Nsedu. Next up we have Surili Patel, followed by Laura Bender. And after Laura is Liz Hitchcock.

Surili, please go ahead.

SURILI PATEL: Thank you for the opportunity to speak on behalf of the American Public Health Association on the serious public health implications of the strengthening transparency in regulatory science supplemental rule. My name is Surili Patel.

APHA is a diverse community of public

health professionals that champions the health of all people in all communities. Together we speak out for science by bringing all disciplines of public health together so that we can work on cross cutting issues. And we publish a peer-reviewed research journal, the American Journal of Public Health, which is regarded as one of the leading scientific public health journals around.

We also speak out for action, to provide a collective voice to advocate at the federal level for laws and regulations that will advance the public's health and sound science. And we speak out for health because we believe in health equity and access to care for everyone in every community.

As APHA's director for the Center for Climate Heath and Equity, I work to inspire action and advance policy that addresses climate change at the nexus of health equity. And as the deputy director for the Center for Public Health Policy I advise the organization's environmental health program.

So today I speak on behalf of the association and our members, the reliable public health professionals that protect communities across the country when I say we uphold the transparency of science and support access to data. The scientific process is built on validation and peer review. The strengthening transparency and regulatory science supplementary rule would greatly limit the research used to inform national action to protect the environment and the public health effectively. And the scientific process has checks and balances to minimize methodological biases against certain populations. So, picking and choosing to admit certain studies would limit a comprehensive picture of the problem and possibly the solution thus perpetuating health and equity.

EPA should use the best available research to set limits on air pollution, exposure to toxic substances, and establish public health protections for other environmental threats. There are many instances where exposure of raw

data to the general public would mean reviewing patient information, which should remain confidential as an ethical measure to conduct research. However, excluding this research would substantially weaken the science needed to support environmental public health regulation.

By including influential scientific information within the scope of the rule, EPA restricts its ability to use the best science available in decision making. It also works towards biasing the scientific process and stacking the deck against vulnerable populations, like low-income communities and communities of color.

Some communities are exposed to both intrinsic factors like life stage, genetics, and underlying diseases, as well as extrinsic factors like social and life circumstances, such as poverty, that determine a biological response to chemical exposure. To protect communities faced with co-exposures, EPA must establish science to adequately identify and assess susceptible and

highly exposed groups.

Therefore, we join other leading public and environmental health organizations to urge EPA to withdraw the rule in a time where science and evidence-based strategies are the only way to protect communities across the country. Thank you.

JASON JACOBSON: Thank you. Next up we have Laura Bender, followed by Liz Hitchcock. And after Liz is Gretchen Goldman.

Laura, please go ahead.

LAURA BENDER: Good afternoon. Thank you so much to the Union of Concerned Scientists for holding today's virtual public hearing. My name is Laura Kate Bender. And I am the national assistant vice president for Healthy Air at the American Lung Association. The lung association's mission is to save lives by improving lung health and preventing lung disease.

We strongly oppose EPA's so-called strengthening transparency in regulatory science supplemental proposal. So, you have heard from

many representatives of the public health and medical community, including some of my colleagues, about the ways this proposal would undermine human health. I would like to take a few minutes to highlight the lack of transparency in EPA's work on this rule that got us to this point.

This is a sweeping proposal that would impact a wide range of public health safeguards, essentially affecting every future decision at EPA. And yet EPA's process in issuing it has been haphazard, rushed, and anything but transparent.

When the original version of this proposal came out in 2018, then Administrator Scott Pruitt prematurely announced it while it was still undergoing agency review and inter-agency review at the White House office of management and budget. Then when the media inquired about the discrepancy, OMB actually backdated the clearance by several days. If that date is accurate, it means that OMB only originally reviewed the proposal for forty-eight hours.

This rule was also originally proposed without a regulatory impact analysis. The EPA then originally failed to consult the agency's own science advisory board about the proposal. The SAB has since released a draft report finding significant deficiencies with the proposal and held public hearings.

We strongly urge EPA to wait until SAB has finished considering the rule and then take the recommendations from the board into account before moving to finalize it.

The supplemental rule is a significant revision and expansion of the original proposal and it merits an official EPA hearing of its own.

We appreciated the opportunity to participate in EPA's public hearing on the original proposal. We also appreciated that EPA extended the public comment on this version of the proposal from thirty to sixty days. However, that extension and the lack of official public hearing do not allow for adequate review of the rule, especially by the public health and medical

community.

Pulmonary and critical care physicians, nurses, and respiratory therapists and others who are on the front line of COVID 19 response, many researchers who study lung disease are very interested in the proposed rule are focused on testing and treating patients to prevent further spread extending the comment period further can push back the deadline to a time when these experts will have more opportunity to prepare meaningful comments.

My experience at the American Lung Association has been with the public health scientific and medical experts who I work with are more interested in offering input of this proposal than most other EPA actions that it ever worked on. Before the pandemic, when the supplemental proposal was under review at OMB, we organized a meeting with them by phone all together nine researchers and medical professionals from across the country. These lung health experts shared with OMB the many ways that the existing

scientific process is sufficient for ensuring transparency while protecting study participants privacy. They also shared the potential implications for patients if future air pollution standards are not based on the available health science.

Now, however, the health and medical professionals that volunteer their time for the lung association are stretched thin. This proposed rule has major implications for their work, but many are responding to the COVID 19 pandemic and simply need more time to weigh in meaningfully.

The lung association fundamentally disagrees with EPA's premise in both the original and supplemental proposal. The science that the agency uses to inform its decision making is already transparent. This rule is a solution in search of a problem.

However, even if EPA moves forward, we urge the agency to take the final SAB recommendations in account first, as well as to

allow additional time for public comment, taking into account the COVID 19 pandemic. Thank you.

JASON JACOBSON: Thank you, Laura. Next, we have Liz Hitchcock, who will be followed by Gretchen Goldman. And after Gretchen, we have Liz Borkowski.

Liz, you may go ahead.

LIZ HITCHCOCK: Thank you. My name is Liz Hitchcock. And I direct Safer Chemicals Healthy Families, a national campaign to protect Americans from toxic chemicals. We lead a coalition of local, state, and national organizations that came together out of our concern -- our common concern about toxic chemicals in our homes, places of work, and products that we use every day. This public hearing is magnifying the voices of the American public, a public that has had its health harmed again and again by our exposures to toxic chemicals.

We applaud UCS for stepping up and doing the job that the Environmental Protection Agency

should have done. And we are ecstatic that there are so many participants that I have got a strict four minutes limit, so I can't really spend enough time thanking UCS.

EPA's proposed supplemental rule is flawed and ill conceived. In the name of transparency, it will burden EPA scientists with unnecessary and costly processes that run counter to the agency's long-standing obligation to base public health decisions on the best available science. The damage that the rule will inflict on equality and timeliness of the EPA's science is not justified by any benefit of the proposed rule.

While its supporters have painted a bleak picture of EPA reliance on so-called secret science developed behind so-called closed doors based on data that has been withheld from the American people, is that really the problem or is this an effort to solve an imaginary problem, something that they call so-called secret science, something that in order to -- saying that in order to strengthen transparency, the EPA should only

use research if the public can see every last piece of underlying raw data.

If enacted, the censorship of the so-called secret science rule would allow EPA to ignore thousands of rigorous peer-reviewed health studies, making it harder for EPA staff to protect us from toxic chemicals and easier for the Trump administration to rollback regulations.

EPA scientists working on health -- risk and health hazard assessments collect and review thousands of studies. Published reports of these studies typically don't include all of the underlying data. Under this proposal, EPA would need to contact the researcher, ascertain the nature and extent of underlying data, and put in place a mechanism for the public to access the data.

Analyzing the house legislation -- house legislation that would impose similar obligations on EPA, the Congressional budget office and the EPA staff concluded that the cost of implementation would be at least two hundred and

fifty million dollars a year. Moreover, rather than devoting the time and effort to assure access to underlying data, EPA staff may follow the path of least resistance and simply drop many studies from consideration, shrinking the body of scientific evidence on which decisions are based.

EPA science assessments generally include an exhaustive and critical review of relevant studies and a full explanation of how they are being interpreted. Extensive information about each study is typically part of the public record even if all underlying data may not be included. EPA assessments are normally subject to public comment and independent peer review. And members of the regulatory community are free at any time to replicate studies they deem flawed, or to independently seek access to underlying data and reanalyze them.

In short, the so-called problem that the proposed seeks to fix is largely imaginary. Let's make no mistake. The stakes for EPA science and the protection of public health are simply too

high to finalize this deeply problematic and unnecessary proposal.

And as our lives are disrupted by the COVID-19 pandemic and resources are appropriately diverted to deal with the crisis, we should not be distracted from the fact that the Trump EPA is not skipping a beat on rolling back public health protections.

Thank you for holding this public hearing. And thank you for all of the work that UCS does.

JASON JACOBSON: Thank you, Liz Hitchcock. Next, we have Gretchen Goldman, who will be followed by Liz Borkowski. And after Liz Borkowski, we will have Liz Mueller.

Gretchen Goldman, go ahead. Gretchen, go ahead.

GRETCHEN GOLDMAN: Great. Thanks. Thank you for the opportunity to comment. I am the research director at the Center for Science and Democracy at the Union of Concerned Scientists.

Much has been said about the ways that

the EPA's April 2018 draft rule would undermine the ability of the agency to carry out its mission. Today I would like to focus on elements of the supplemental notice that worsen the impact of this rule.

First, the supplemental proposal expands what was already a sweeping proposal. With expanded definitions and more inclusive terms such as applying the rule to all models and all influential science, it is now crystal clear that the policy stands to fundamentally alter how the EPA can view science to protect public health and the environment.

Second, the tiered access approach proposed in the supplemental notice fails to address the central underlying concern with this rule, that it would require the disclosure of confidential data in order for the EPA to use the science. Even if a tiered access approach is implemented, researchers cannot share personal health data that they are legally and ethically bound to protect. The supplemental notice fails

to address this fundamental threat to the agency's ability to use the best available science.

Further, a tiered access system would be costly and near impossible for the EPA to implement with existing resources, let alone individual researchers if the responsibility were passed to them. The proposal provides no clarity on who will be responsible for the launch and maintenance of a tiered access system and how it would be managed, an endeavor that would require significant resources in order to mirror the CDC's research data center, which the supplemental notice cites as a model.

The alternative weighting approach proposed would unfairly and arbitrarily devalue legitimate scientific work that the EPA relies on. At an agency charged with protecting public health, studies involving health data are especially crucial. Many of these crucial health studies will be needlessly downgraded in EPA decision under -- decision making under this weighted approach.

Alarmingly, the supplemental notices states that the goal is for stakeholders to reanalyze the data and models that EPA uses. This is a waste of time and resources for an agency that already relies on extensive stakeholder and public input on rules and transparent ways. Hamstringing the agency's ability to use science for the purpose of providing industry-tied researchers the chance to unnecessarily reanalyze scientific work tips the scales against the public interest.

In the summer of 2018, I gave public comment on the draft rule with my one-month old infant in tow. I didn't have to be there, but I chose to be. This is a rule that will affect the ability of my children and all others in this country to breathe clean air, drink clean water, and enjoy a safe environment.

The EPA cannot do that under this proposal. I urge the agency to abandon this ill-advised and dangerous proposal. Thank you.

JASON JACOBSON: Thank you, Gretchen.

Next, we have Liz Borkowski, followed by Liz Mueller. And then -- and then Leonard Buckle.

Liz Borkowski, please go ahead.

LIZ BORKOWSKI: Thank you. Thank you for the opportunity to present comments. My name is Liz Borkowski. And I am the managing director of the Jacobs Institute of Women's Health at the Milken Institute School of Public Health at the George Washington University.

The Jacobs Institute is disturbed by EPA's supplemental notice of proposed rulemaking to strengthening transparency in regulatory science because its proposed changes are inadequate to address concerns about consideration of studies that involve confidential data. EPA's proposed changes fall far short of a system that would be practicable, while engendering confidence among both researchers and potential study participants.

To address the fact that participants in environmental health studies are typically assured confidentiality and that this precludes making

data publicly available, EPA suggests that when developing regulations or finalizing influential scientific information, it gives greater consideration to studies for which data have been made available.

Using non-scientific criteria to evaluate scientific studies is thoroughly inappropriate and at odds with established practices for evaluating study quality. For instance, the strengthening of the reporting of observational studies in epidemiology or STROBE checklist does not include public availability of data.

The threat of ignoring or down-weighting a study if its data are not available places pressure on scientists to release data, they might otherwise keep confidential. Given the rapidly developing evidence base about the possibilities of reidentifying anonymized data, scientists conducting research today might understandably prefer to err on the side of limiting data access. The supplemental language regarding tiered access by which authorized researchers can access

restricted data, and the public a less identifiable form, is far too vague and limited to engender confidence among researchers or those who might participating in studies.

For instance, it does not define authorized researchers or mention the institutional review boards that govern human subjects research in academia.

EPA's invocation of the National Center for Health Statistics Research Data Center, or RCD, acknowledges the necessity of establishing a way to provide carefully controlled access to identifiable data, but it fails to demonstrate that it has fully considered how such a model might be used for the many studies the agency ought to be considering.

The supplemental language merely states that the RDC is a model and that EPA is conducting a pilot study on how RDC might host EPA datasets. This falls far short of the kind of detail necessary before finalizing a rule.

Because RDC contains data collected by

CDC and other federal agencies, not by independent academic researchers, a great deal of additional work and infrastructure would be necessary before it could host the full range of data that should be informing EPA work.

The fact that RDC charges researchers three thousand dollars to access a single year's data hints at the substantial cost associated with the enterprise. EPA does not appear to have calculated the cost that the agency and outside researchers would incur in order to create a system that evaluates researchers' proposals and provides them with access to the appropriate level of data.

It also has not explained who would be in charge of making those determinations, a crucial issue given that communities disproportionately harmed by pollution might not trust EPA to make them.

EPA's proposal forces an untenable choice on researchers, know that their study will be inappropriately down-weighted or accept the

problems that can accompany submission of their research into a repository that has not been satisfactorily described. When environmental health researchers inform potential study participants that their data will be placed into such a repository, they will likely find it harder to recruit. The problem will be particularly acute in historically marginalized and disproportionately polluted communities whose involvement is essential.

If EPA moves forward with the rule it has proposed it will undermine science in decision making by making it difficult and potentially impossible to conduct and consider the best available science. This will have detrimental impacts on reproductive justice, health equity, and women's health.

The Jacobs Institute of Women's Health urges EPA to withdraw this rule. Thank you to the Union of Concerned Scientists for holding this hearing.

JASON JACOBSON: Thank you, Liz

Borkowski. Next up we have Liz Miller -- excuse me, Liz Mueller, followed by Leonard Buckle.

Liz, go ahead.

LIZ MUELLER: Thank you so much. Good afternoon. My name is Liz Mueller. And I am the National Director of Advocacy of the American Lung Association Healthy Air Campaign.

Today you have heard from individuals in the public health and medical community, including some of my colleagues, about the dangers of the strengthening transparency in regulatory science proposal.

Today I would like to talk about the processes already in place that review health studies, highlighting how the science in communities is already transparent.

The proposal excludes studies when underlying data cannot be shared with the public. It introduces alternative pathways that may be deployed to allow consideration of some studies. But make no mistake, case studies will not be fully considered if EPA finalizes this rule.

While studies involving laboratory animals might be able to meet this requirement, many studies examining the effects of environmental stressors on real people will not be able to meet the demand of public data sharing.

Publicly sharing information about diagnosis, hospitalizations or deaths, as well as where a study participant lives, works, or goes to school is not feasible because it would constitute a major breach of privacy.

Before a health study of humans can even begin, investigators must complete a rigorous review by an institutional review board to ensure that the risk to participants, including risk to privacy, are minimized. As part of its review, the institutional review board carefully scrutinizes the consent form that study participants will sign to ensure the form detailed how a participant's private data might be shared and what safeguards will remain in place to protect their privacy after the study's completion.

This proposed rule by EPA would prevent most research about the health effects of pollution in the real world from informing EPA policy because the underlying data about the participants of these health studies cannot be shared with the public.

On the question of replication, there already exists a mechanism within the scientific community to validate studies. Major health journals, including Lancet, the Journal of the American Medical Association, and the New England Journal of Medicine, and agencies like the EPA, require researchers to specify a data sharing plan as part of their research application.

The purpose of this sharing from scientist to scientist is to facilitate the replication of findings or to pool together data from multiple studies. There are strict requirements outlined in a signed agreement among those involved that the receiving scientist must demonstrate that she or he had the skills, resources, and safeguards to appropriately use and

protect the data. If there are questions, entities like the Health Effects Institute, or HEI, have conducted review.

For example, in July of 2000 the Health Effects Institute conducted a reanalysis of the two early air pollution studies, the Harvard Six City Study and the American Cancer Society's study on a link between particulate matter pollution and mortality. The reanalysis was conducted by a team of independent scientists, was overseen by a diverse ward of stakeholders, and affirmed the findings of the original studies.

Publishing a scientific health study is a year’s long process that involves intense scrutiny from others in the scientific community. To say that published studies that have gone through this process are not reviewed and validated is absurd. The science that the agency has used for years is already transparent and rigorously reviewed.

The EPA is trying to fix a problem that does not exist. Thank you so much for your time and for your attention today.

JASON JACOBSON: Thank you, Liz. Next, we have Leonard Buckle.

Leonard, go ahead.

LEONARD BUCKLE: Thank you very much for giving me the opportunity to make my comments about the EPA changes to its standards.

My background is forty years of doing research in methodological approaches to the study of interdisciplinary problems. My professional perspective is that of a philosopher of the -- of a pragmatic persuasion.

The science approach -- the approach to science that the EPA chooses to use to make distinctions between those science -- pieces of science will be regarded as acceptable and those that are not is something left over from preexisting Liechtenstein European philosophy.

It is a purely -- it is a purely objectivist point of view. And it is totally out of line with American thinking for the last century-and-a-half. The dichotomy draws flaws and invidious comparisons between most acceptable

pieces of social research, medical research, and biological research, and those pieces of research that would be appropriate for laboratory science of the physical, chemical, or possibly biological persuasion.

This dichotomy further is the wrong set of dichotomies is the wrong dichotomy to draw for the Environmental Protection Agency. Their choice of replicability private/public data and reproducibility is actually accomplishable only by a small fraction of all science. And the traction tends to lie outside the area of the EPA's involvement.

We are privilege -- in bench laboratory work and sacrifice of more -- more substantial and relevant material concerning environmental protection, public health, and general public safety.

The second -- the third major problem is that this research is at entirely at odds with the ethics and practical limitations set forth by other agencies as my previous colleagues have

discussed. This research is impossible -- research that would fit these standards is impossible under the guidelines of any IRB in any institution doing business with the United States government. This leaves the research available virtually nonexistent.

In effect, the EPA is defining away its very base. This opens the gateway to me for a concern for what alternatives the EPA chooses to imagine for its basis with making decisions. In particular, I am concerned in the extreme that instead of using scientifically based facts they are going to be building models built on speculation and public and private opinion.

My concern is raised -- is raised because for several years I have been involved in research into the operations research. And my concern is that one can build into the models one produces the assumptions one wishes to achieve, to set to accomplish the outcome one wishes to have.

In other words, the only proof of those models' success is that it ran, and that does not

prove that it has any correlation at all with reality. I fear the EPA is going to employ this as its major vehicle for decision making and alternative – as an alternative to science. Thank you.

JASON JACOBSON: Thank you, Leonard. Next up we have R. Stephen Berry.

R. STEPHEN BERRY: Yes. I have very little to contribute except one thing that I am I have become very embarrassed about the whole way that this administration has dealt with the -- with the EPA, with the environment, with all of the issues that we are discussing today.

And it seems to me that this administration has simply changed the name of the EPA. It's no longer the Environmental Protection Agency, it’s become the Environmental Pollution Agency. And that's my contribution, I'm afraid, my bitterness.

JASON JACOBSON: Thank you, R. Stephen Berry. Right now, we have a few attendees who haven't been able to join us electronically so we

will be taking a short break. We want to make sure that we stay consistent with the schedule and people's scheduled speaking times. So, we will take a short break until 2:10 p.m., at which point we will hear from Mark Peters. Thank you very much.

(Whereupon, a recess was taken.)

JASON JACOBSON: Hello, everyone. Welcome back. We will now hear from Mark Peters.

Mark, are you ready?

MARK PETERS: I am. Thank you very much. I appreciate your labor on all our behalf by the way. I have a degree -- are we ready to go?

JASON JACOBSON: Go ahead.

MARK PETERS: Thank you. I have a degree in philosophy and a degree in medicine. And have been a physician assistant for over forty years, primarily doing cardiothoracic and vascular surgery. And have been a researcher and managed datasets and data collection for national studies.

At any rate, when asked to explain the difference between a doctor and a P.A. I have

answered by explaining that if you want to know why something works, ask a doctor. If you want to know how something works, as a P.A.

Along those lines, I would like to talk about the work of scientists and statisticians. And rather than talking about confounding variables, randomization and matching observers or subjective bias, and on and on, not to mention at all the willingness of study participants to share personal data, like cholesterol levels or body mass index, I'd like to tell a little story. That story is of a small town where the town selectmen have been asked to try and consider some actions to increase the number of ministers in the town.

At the next town meeting, the selectmen bring the matter up. And someone notes the towns with more telephone poles have more ministers. That said, a motion is passed to add more telephone poles to the town. Of course, it is at great cost with -- from our outside view having a predictable result of knowing the increase in number of ministers.

Of course, this might be a hopefully humorous, but yet insightful story to consider the fact that science should be left to the scientists and data should be left to the statisticians. And as it has been pointed out by many other attendees, that the processes in place -- and in my own personal experience, scientists love nothing more than to prove each other wrong, do a great deal of review and study of data and the analytic processes to analyze that data to say here is where it should be done differently. And then that is done and the results of studies are confirmed or not. And that's just a superficial understanding of how the science works.

The other issue in my career, having done cardiothoracic and vascular surgery, I spent a great portion a great percentage of my time treating people with the diseases of tobacco use. And we know the end result of a long history of malfeasance by the tobacco industry to suppress, deny, obfuscate, and actually lie about the data that was privy only to them in the early years of

the twentieth century.

Historically back in the 1600's, in fact, an anonymous paper was published in London about chimney sweeps who were smokers, suggesting some correlation between lung disease and occupational and personal choice hazards.

At any rate, the legal status and the end result of that malfeasance is just an example of how industry might influence data even at the government level through lobbyists, as we know from that case. And so, there is great risk involved. Currently, as of 2018, the data suggests that four hundred and eighty thousand people a year have been dying from tobacco use. And that is even with all of the data available to show that it is potentially lethal.

So, in order to avoid those kinds of situations, we need to ask that this change in regulation not be implemented. Thanks.

JASON JACOBSON: Thank you, Mark. Next, we will take another short break. And we will come back at 2:25 to hear from Barry Gupman.

(Whereupon, a recess was taken.)

JASON JACOBSON: Thank you for joining us at the virtual public hearing for the supplemental rule on EPA proposal strengthening transparency and regulatory science.

Next up we'll be hearing from Barry Goppman, followed by Janet Ward.

Barry, you may begin your public comments. Barry?

BARRY GOPPMAN: Hi, my name is Barry Goppman. And I want to start out by saying I have no scientific background, but I do have a human functionality background, which has given me the belief to author this critical opinion of the EPA. So, I believe the EPA should change its -- change its name to the ENPA, Environmental Non-Protection Agency.

Twenty plus years ago I moved myself and my family to Smyrna, Georgia. It had all of the attributes I was looking for, but it also had a dirty little secret, EtO emissions. And my house was only three miles from the source of the

emissions, Sterigenics. Up until 2016, EtO was classified as a potential human carcinogen. In 2016, it was reclassified as a known human carcinogen. No warnings either written or posted existed to warn citizens then, as now.

Citizens and the politicians were completely in the dark. The new 2016 EtO classification was actually covered up by the EPA, Karen Hays, who is the director of toxicity here in Georgia, who never even sent out a press release, saying the public wouldn't understand.

Sterigenics has been operating emitting very high over the legal limit levels of EtO for forty years. It was allowed to hide in plain sight and operate on a storage facility operating permit, not a hazardous duty permit facility permit it should have been.

Who was the EPA protecting here, residents or big business? My lifestyle has always been one of health and fitness, including many Ironman triathlons and marathons.

Three years ago, I was diagnosed with an

incurable form of leukemia, which all but took my fitness lifestyle away. I spent more than fourteen thousand hours working out on the Silver Comet trail, which is a fitness trail located less than two miles from Sterigenics over the last twenty years.

I believe this long-term exposure to the unknown carcinogenic EtO gas at an increased lung level usage caused and/or directly contributed to my cancer. Others with the same lifestyle as I in other parts of the country report similar occurrences. The cancer has caused me side effects, including severe anemia, which sometimes leaves me breathless from just getting out of my car. It has also caused other types of cancers and neurological problems in many others who lived in close proximity of Sterigenics EtO plant exposure.

The EPA and the Georgia EPD have shielded this company from reprimand, including helping them craft a behind closed doors work order to upgrade and change their plant's emission system

without public knowledge or view. This breaks the law that they wrote. When the legality of this agreement was challenged, Sterigenics was banned from the building until a correct operating permit was replaced. Then the EPA looked the other way when they blatantly ignored that order and did the work anyway while they were still under the confines of this order.

Sterigenics has operated without consistent and reportable EPA supervision for forty years. And has multiple problems, including explosions and unreported leaks.

Are they above the law? The EPA and the FDA show an over-reliance on EtO and are listening to lobbyists to get information rather than doing true scientific inquiry about the problem. This creates a dramatic lap of two data points around EtO pollution.

I believe this shows chemical history capture of our regulatory agencies. Using data modeling based on industry's self-reported information subverts the ability of citizens

living near these EtO based facilities to know the full truth about the levels of poisoning that have occurred.

Lobbying efforts have created an environment at all levels of government that tips the scales steeply towards the industry and away from the health of our communities. They are protecting no one, just enabling criminal companies that are way more interested in profits over people to continue on that path.

The Environmental Non-Protection Agency is the correct name for the EPA. Thank you.

JASON JACOBSON: Thank you, Barry Goppman. Next, we will hear from Janet -- Janet Ward.

JANET WARD: Thank you. My name is Janet Ward. I am a resident of New Hampshire and a member of the board of a New England-wide environmental organization.

The Environmental Protection Agency was founded in December 1970 under the Republican administration of President Richard Nixon, who was

keenly aware of the environmental damage being done in the United States.

This damage represented a clear and present danger to public health. The EPA's mission was and ought to continue to be the protection of public health, and holding to account polluters whose actions endanger public health.

The proposed new rules on what studies the agency can cite in making regulations would be determined by a political appointee rather than by qualified scientists. These proposed rules gut the ability of the agency to oversee and establish necessary regulations to protect public health and safety.

The perpetrators of these new rules are banking on the inability of the public to understand and appreciate the danger these changes represent.

I am a member of the voting public. I understand the ramifications of these new rules. And I intend to publicize their dangers as widely

as possible.

These rules are unnecessary, dangerous, and crafted with political objectives in mind. Their implementation would destroy the ability of the EPA to do the work it was founded to do.

Thank you for the opportunity for sharing these reflections.

JASON JACOBSON: Thank you, Janet Ward. Next up we will hear from Andy Bessler.

Andy, go ahead.

ANDY BESSLER: Can you hear me okay?

JASON JACOBSON: We can hear you and it looks like your video is obscured.

ANDY BESSLER: I'm not too sure -- oh, sorry about that.

My name is Andy Bessler. I am the project director for the National Tribal Air Association. And NTAA was founded in 2002 under the Bush administration for improving air quality with the grant from the United States Environmental Protection Agency, with the mission to advance air quality management programs and

policies consistent with the needs, interests, and legal status of American Indian Tribes and Alaskan natives.

Tribes are important partners with federal, state, local agencies to protect ambient air quality, indoor air quality, and mitigate climate change. The National Tribal Air Association maintains a membership of one hundred and fifty-one member tribes around the country. And we are submitting comments on this proposal. And we have recently held an informational webinar for tribes around the country on this proposal last week. And that is all posted on our website, which is ntaatribalair.org.

The National Tribal Association has several comments regarding this proposal from EPA, this supplemental proposal on transparency in science.

For one, the comment period is inadequate -- is inadequate. Tribes are very much focused on protecting public health and maintaining a strong economy during this pandemic.

NTAA is opposed to the proposed expanded scope of this proposal. We oppose the EPA's administrator's exemption discretion. We oppose the lack of authority for the proposal and its failure to consider tribes and environmental justice communities.

The agency decision making must be based on best available science. Some environmental statutes explicitly say this, others it is implied, and others appear to be based on court decisions.

This proposal will cause valid and relevant science to be excluded or given less weight, which is out of bounds with EPA's mission to protect public health.

The proposal to address public health information is vague and doesn't concern feasibility or cost. Expanding -- expanding the applicability makes these problems worse and it doesn't fix any of the existing issues.

A big opposition that NTAA has is regards to the EPA's administrator's discretion. The

proposed exemption that the administrator can grant could put the trust in the administrator without mandatory standards. It could be used positively to exempt public health studies, or it could be used negatively exempting industry chemical regulation studies, for example.

Suggestive mandatory exemptions are there for certain studies or they suggest mandatory exemptions for certain studies, but all of this depends on the political (inaudible) on EPA administrator rather than really following what the science dictates.

We have opposition to the proposed expanded scope. The proposal expands applicability for significant regulatory actions and discusses other terms, like influential scientific information and dose response models. So, these are terms that are not really -- they are expanding applicability beyond what currently exists.

There is a proposal for tiered access based on other federal agency programs. And the

proposal applies regardless of when the study was performed. So, there is expanded scope that we oppose.

Also, there is a lack of authority. The proposal has changed the authority EPA seems to rely on. And it's solely on housekeeping authority statute for executive departments, in combination with corrective environmental statutes listed in the original proposal.

This really is a backward rulemaking proposing an action and then asking for help to determine authority. It is cited authority that doesn't authorize the rule. And it's -- in an event of a conflict, the proposal says that other statute or regulations may apply.

Finally, there is a failure to consider responsibility to Tribes and to environmental justice communities. There was no analysis performed of tribal implications or environmental justice implications.

EPA actions, whether they are significant regulatory actions or influential scientific

information, will impact tribal communities. And EPA must hear and address tribal concerns with this proposal.

Finally, EPA already has a strong system for using science in the rulemaking process. There is integrated science assessments, risk and exposure assessments, all involved in the policy making process. And if it's not broke, then don't fix it. So, we oppose this proposal and thank you for your time.

JASON JACOBSON: Thank you for your comments. At this point in the program we will be taking a short break so that we can stay consistent with our schedule.

Please come back and we will be checking in every ten minutes. Thank you.

(Whereupon, a recess was taken.)

JASON JACOBSON: Thank you for joining the virtual public hearing on the supplemental rule on EPA proposal strengthening transparency and regulatory science hosted by the Union of Concerned Scientists.

Next up we will hear from Claire Richards. Claire?

CLAIRE RICHARDS: Can you hear me okay?

JASON JACOBSON: Claire, we can hear you. You can begin.

CLAIRE RICHARDS: Hi. Thank you for having me. As a nurse scientist, my oath is to do no harm and to protect the health and safety of my patients. I am angry that the EPA is trying to further restrict the type of research that can be used in public health protection decisions and scientific assessments.

While as a nurse, I really need to be addressing the public safety concerns that are due to the Trump administration's fangled response to COVID-19 -- in particular, I have been trying to focus on how we can continue to provide high quality care in the context of a pandemic with a shortage of personal protective equipment, especially for the most vulnerable in long-term settings. So, I am pretty angry right now that I am unable to focus on this and that our government

is working to push through rules to benefit industries while I need to be working to protect patients and families right now.

I oppose the EPA's rule that states that all research used to support agency rules would be covered by these transparency requirements, not just dose response studies. This means that most research focused on the impact of contaminants on human health could not be used because they rely on information protected by HIPAA. This is atrocious and makes absolutely no sense. The HIPAA privacy rule governs public health information, which is individually identifiable information about an individual's care, health condition, or payment for care. I think transparency can be encouraged by making code available and can improve the quality of science, but not necessarily by requiring scientists to make underlying data available when there is more than minimal risk of being able to identify an individual.

I would like to refer the EPA to a paper

published called Big Data and Public Health Navigating Privacy Laws to Maximize Potential that was published by Thorpe and Gray in 2015. There are ways to modify the rules so that only identifiers, including city, state, and zip code are included in publicly available datasets.

Furthermore, a typical review of studies included in high impact journals rely on peer review rather than publicly available datasets, where the methods and summaries of dataset results and inferences, and limitations of studies are evaluated.

I think it should be noted that the lack of clarity as to how researchers can make their data available or how much it would cost creates a tremendous burden on researchers and should be addressed by the EPA.

Furthermore, the fact that the EPA administrator has the authority to waive the requirements for the data to be public on a case by case basis is a clear conflict of interest because the administrator is a political

appointee. And there is precedent for our government to favor industry and short-term economic rewards over human health.

So, thank you for having me. I clearly oppose this rule.

JASON JACOBSON: Thank you, Claire. We will resume a short break and have check ins every five minutes. Thank you.

(Whereupon, a recess was taken.)

JASON JACOBSON: Good afternoon. You have been listening to public comments provided by the UCS hosted virtual public hearing regarding the supplemental rule on the EPA proposal strengthening transparency in regulatory science. Thank you for joining us this afternoon. This does conclude the afternoon session. The recording of this session should be available on the YouTube page of the Union of Concerned Scientists shortly. The evening session will begin at 5:00 p.m. and run for approximately one-and-a-half hours. Thank you.

(Whereupon, the session was concluded.)

C E R T I F I C A T E

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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