VIRTUAL PUBLIC HEARING

SUPPLEMENTAL RULE ON EPA PROPOSAL

STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE

5:00 p.m. to 6:32 p.m.

Tuesday, April 14, 2020

REPORTED BY GARRETT LORMAN
ATTENDEES

1 JASON JACOBSON, Moderator
2 MICHAEL HALPERN
3 KEN KIMMELL
4 HAYDEN HASHIMOTO
5 DR. LISA PATEL
6 DR. KYLA BENNETT
7 ROY GAMSE
8 DIANNA BURDETT
9 DYLAN BURDETT
10 ZIGMUND PLATER
11
12
13
14
15
16
17
18
19
20
21
22
MICHAEL HALPERN: All right. Good afternoon. My name is Michael Halpern. I am the deputy director of the Center for Science & 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 Union of Concerned Scientists YouTube page shortly after it ends.

We do appreciate you taking the time to provide public comments on the proposed supplemental rule. Close to one hundred people registered to provide public comment at the three sessions today. We are going to begin hearing publics shortly at this third of three sessions, and we do have a little bit of space at the end. So, if you would like to register to speak at the end of the session, please E-mail ucsvph@gmail.com
as quickly as you can. That's ucsvph@gmail.com.

Before we get started, I'm going to turn it over to Ken Kimmell, president of the Union of Concerned Scientists for some opening remarks. Ken, go ahead.

KEN KIMMELL: Hi, everyone. Michael, can you hear me?

MICHAEL HALPERN: Yes, I can. Please go ahead.

KEN KIMMELL: Great, and you can see me as well?

MICHAEL HALPERN: Yes.

KEN KIMMELL: Okay, terrific. Thank you so much. It's a pleasure to be with all of you today. But we're here for the wrong reason. We're here because the EPA, which is supposed to hold a public hearing on a matter of grave importance including one like this, has refused to do so. I have to tell you, it's very unusual that a non-governmental organization is in the position where it needs to sponsor a public hearing on a proposal by a federal agency. Typically, federal agencies do that work. But, that being said, I'm
glad we're all here. This is an important day for science. It's also an important day for democracy.

Interest in the proposal that we're going to talk about today is very strong. The initial iteration of this rule received more than six hundred thousand public comments over a three-and-a-half-month time frame.

This supplemental rule, which we will talk about today, significantly changes the initial proposal, but yet the opportunity for public input on it is currently severely limited, especially when one considers just how sweeping this proposal is and how different it is from the original proposal.

For this proposal, the EPA originally provided a thirty-day window for public comments with no public hearings. Now, EPA recently extended the public window to sixty days with a deadline of May 18th, but still with no public hearing, which is just grossly insufficient.

During normal times, the government recommends a minimum sixty-day public 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 the Union of Concerned
Scientists urge the EPA to extend the public
comment period to at least run thirty days beyond
the end of the declared national public health
emergency. We also asked for virtual public
hearings. Unfortunately, EPA refused both of
those requests. So, we decided to hold this
hearing on our own. We invited EPA to send staff
today to listen to today's hearing and ask
questions. They declined to do that also.

Now, the COVID-19 crisis provides -- has
caused profound challenges to our country and our
communities in the world. The virus has disrupted
all of our lives. Many people 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 health
care specialists to sanitation workers. Public
health organizations are working overtime to
provide scientific advice to protect individuals
and communities throughout the country. Some people have reduced access to technology. So, all of these conditions make it more difficult for public comment.

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

Now, today's public hearing, of course, is not the only opportunity to provide public comment. So, I encourage everyone to develop written comments to respond directly to the proposal. The Union of Concerned Scientists has developed a guide to providing effective public comments on this rule on its website.

Now, we expect the EPA to do its job and seek feedback on proposals. But when the agency
fails, as is the case today, we will step in to
make sure that the agency receives as much
feedback as possible, and all of us look forward
to reviewing the public comments that are made
today.

So, before I turn this back over to
Michael, I want to leave with this framing
question. I think we all know, especially in the
light of the crisis that we're in right now, that
having the best science, the best data, the best
analysis before governmental decision-makers is
not only important, it is literally a matter of
life and death. So, I hope and I trust that the
comments today will shed light on this crucial
question. Does the EPA's proposal advance this
imperative of having the best available science,
or does it undermine it?

And with that framing question, I'd like
to turn this back to Michael.

MICHAEL HALPERN: Thank you, Ken, for
those remarks, and I'd like to provide everybody
with some background information and briefly
describe the proposed rule on which we are taking
So, the EPA 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 significant regulatory decisions. This notice proposes definitions and clarifies that 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 underline 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.

So, for both oral and written comments, EPA will only consider feedback that directly addresses this supplemental proposal. So, please
do your best today to speak to the changes to the rule that are made in the supplemental proposal and its impact on EPA's ability to complete its mission and protect public health and the environment.

So, today's hearing is going to work as follows. Members of the public pre-registered to speak and were assigned a speaking time. They were asked to sign in on the webinar at least twenty minutes before their scheduled time in case we run ahead of schedule or in case different speakers cannot make it today.

We're here today to hear comments on that proposal supplemental rule. We will not be able to respond to questions from attendees or have any dialogue among 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. A transcript from this public hearing will be submitted to the docket and the recording will be made publicly available.

If you have any written comments or other
documents you would like to submit for the record, including your testimony as prepared for delivery, please E-mail them to the E-mail address you received on your confirmation form, which is ucsvph@gmail.com. That's ucsvph@gmail.com.

If you are watching this broadcast, you can also register again to speak today by E-mailing ucsvph@gmail.com as quickly as possible, and we will do our best to add you to the queue.

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

If you have additional comments after today, please follow the instructions on the Federal Register notice for this proposal and submit those comments by May 18th, 2020. Again, UCS has provided a guide for people on making effective comments on this proposal on the UCS website.

Today's hearing is broken into three separate sections. The first one began at 9 a.m. this morning, the second one at 1 p.m. this
afternoon, and this one at 5 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 your patience with this virtual hearing. People will have varying internet bandwidths and familiarity with the technology and experience providing testimony. If someone has technical difficulties when it is their turn, we will move on to the next speaker and return to the person with technical difficulties later in the session.

All right. With that, we are going to get started. I am going to turn it over to Jason Jacobsen, who is going to be running today's hearing. Jason.

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 our public comments. The first speaker will be Hayden Hashimoto, followed by Dr. Lisa Patel, and after that we will
hear from Kyla Bennett.

Hayden Hashimoto, please go ahead.

HAYDEN HASHIMOTO: Thank you. Good evening. My name is Hayden Hashimoto, and I am an attorney and legal fellow with Clean Air Task Force. CATF seeks to protect public health and the environment from the impacts of harmful air pollution through research, analysis, and public advocacy.

USC obtained a supplemental notice that contravenes the agency's mission to protect human health and the environment. This unlawful effort to tie the agency's hands behind its back limits its ability to consider the best available science in making regulatory decisions that affect public health and inserts politically motivated considerations into the decision-making process.

While couched as an effort to improve transparency, EPA provides little to no explanation as to how either the formal proposed rule or the supplement would actually achieve that goal.

EPA fails to show why the current process
for considering available cutting-edge science including relying on currently available peer review for influential scientific information is problematic.

EPA's argument about transparency does not hold water and certainly does not justify the drastic restriction on the agency's statutory duty to promote public health by taking a forward science-based approach in decision-making.

The idea promoted by EPA that peer-reviewed research based on confidential personal human health data is inherently suspect has no scientific basis. Any rule intended to encourage or pressure researchers not to guarantee the confidentiality of personal data or that would undermine potential subjects' willingness to participate in studies is likely to create significant impediments to future research.

EPA's proposal forces health researchers to decide between ignoring federal privacy requirements that protect the confidentiality of the human subjects of scientific study or producing health studies that will be ignored
because they don't satisfy EPA's new standard.

EPA has not provided a single compelling reason to explain why this kind of negative impact on public health research would further its statutory mission or otherwise be warranted.

EPA's reliance on its supposed housekeeping statute authority for this rule is particularly problematic as an initial matter. Because EPA is not listed in the law as an executive department, the statute does not directly grant any authority to EPA. And even if it did apply to EPA, this proposal is simply not a rational or reasonable exercise of that authority. That's because the statute provides authority for rules of practice or procedure, not those that affect the substantive outcome of a federal regulation.

While EPA tries to claim that this is a procedural rule, the substantive impact of this rule is clear. Denying access to the best science will have a substantive impact on federal public health regulations by removing support from our health protective rules.
Indeed, the fact that the original proposal, which EPA is reporting now to supplement, was not described as procedural is very revealing. EPA well knows that its intention with its original proposal was to limit the access to significant scientific work based on human health data because that work demands stronger regulatory actions and this supplemental proposal expands that effort.

This is an entirely outcome-determinate effort to limit access to cutting-edge science that explains the impacts of, among other things, exposure to air pollution and allows for its quantification in the name of transparency.

The Supreme Court made clear in Chrysler Corporation v Brown that the Housekeeping Statute cannot be used as authority for substantive regulations that limit the scope of another statute. Limiting the agency's ability to consider research that relies on confidential human health studies would impede environmental regulations under several statutes, not least of which is the Clean Air Act.
For example, the National Ambient Air Quality Standards Program, bedrock of our National Clean Air Law, requires EPA to issue air quality criteria that accurately reflect the latest scientific knowledge useful in indicating the extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutants in the ambient air. This proposal directly undermines that directive.

In sum, EPA has no legal authority to move forward with this role, and indeed by doing so, undermines the legal duties it does have under various environmental laws. Therefore, EPA should withdraw this rule. Thank you.

JASON JACOBSON: Thank you, Hayden Hashimoto. Next up, we have Dr. Lisa Patel.

DR. LISA PATEL: Hi. Can you hear me?

JASON JACOBSON: We can and see you.

Thank you.

DR. LISA PATEL: Great. So, I'm Dr. Lisa Patel. I'm a former environmental scientist at the Environmental Protection Agency, Advocacy and Policy Lead at the Sean Parker Center for Allergy
and Asthma Research at Stanford University, and a physician. I work as a pediatric hospitalist who is on the front lines of the coronavirus pandemic. I'm here to testify because the EPA would, in essence, create its own avoidable health crisis by moving forward with this supplemental rule, which substantially limits science used to keep our children healthy. Rigorous scientific studies whose patients are subjects in trials to study, measure, and track a variety of biomarkers and health outcomes due to environmental pollution.

Researchers have an ethical directive to protect the identify of these patients by not disclosing their personal health information or PHI. The supplemental rule mandates that the use for its internal scientific assessments and rule-making be publicly available, a logistical impossibility for studies using PHI. The EPA could essentially ignore these studies under the rule. I would like to talk about what this means for air pollution and children's health in particular.
New research shows us that pollutants like PM2.5 affect us down to our very genes, altering our epigenetic programming in ways that increase our risk for asthma and activate a pro-inflammatory cascade that places us at higher risk for a range of cardiopulmonary disease. This starts in utero, and data from our center shows that exposure to PM2.5 also changes epigenetic programming and immune regulation in young kids that are potentially heritable.

What does this mean for health? Mothers exposed to higher levels of PM2.5 are at higher risk for giving birth to premature or low birth weight infants or for a stillbirth. Premature infants and low birth weight infants are at higher risk for death, neurological disability like cerebral palsy, and chronic pulmonary conditions.

Children are particularly vulnerable to pollutants like PM2.5. They spend more time outside, have a faster respiratory rate compared to adults, which exposes them to more pollution. A majority of their lung maturity and growth occurs in the postnatal period, making them very
susceptible to environmental toxins.

In the short term, higher PM2.5 concentration results in a higher number of emergency room visits for asthma and increased upper respiratory infections in children.

In the long term, studies show that early and chronic exposure to air pollution places children at higher lifetime risk for developing asthma, hypertension, obesity, type 2 diabetes, dyslipidemia, and cardiac arrhythmias. This risk is not distributed evenly throughout our population with marked disparities for blacks regardless of poverty status.

Our best available science is showing us that pollutants like PM2.5 are more dangerous than we previously knew at even lower levels than we previously understood. Data shows that even at the lowest detectable PM2.5 levels of 2.8 still result in excessive of thirty thousand deaths per year. A study from [inaudible 32:12] evaluating air pollution in six hundred and fifty-two cities found that an increase in just 10 mcg/meter in a 2-day living average was associated with 0.44
percent increase in daily all-cause mortality,
0.36 percent increase in daily cardiovascular mortality, 0.47 percent in daily respiratory mortality.

When information from studies using PHI suggests we should be tightening our regulation, the EPA can easily ignore these studies to justify inaction or rollbacks that would worsen health outcomes.

The COVID-19 pandemic shows us the newest threat to human health and why research particularly on-air pollution matters. Data from Wu et al. this year shows us that from every 1 mcg per meter cube of PM2.5, there is a 15 percent increase in mortality from COVID-19.

Researchers at our center are starting to look at factors and associations that rely on PHI to better understand this link. The EPA's rule would essentially quash this type of much needed research if there was no hope for it to be utilized to change policy.

We talked about the data, but I just want to take my last minute to talk about what this
looks like as a practicing physician in a hospital. The terrified eyes of a child who is suffocating in front of you because of the severe asthma exacerbation landing in an intensive care unit again for impending respiratory failure. The expectant mother who the day before was preparing her nursery, now finds herself in premature labor being told by a physician like myself about her infant's chance of survival -- survival without significant morbidity, the possibility of putting an endotracheal tube down her little baby's throat, of chest compressions, of a central line to keep her baby alive. We should do our all to prevent these outcomes, not increase their number.

The EPA's rules have the ability to determine whether a child will live a long life of good health or shortened life of disease and disability. I urge the EPA to abandon this rule and continue to use the best available science to protect the health of our children.

JASON JACOBSON: Thank you, Dr. Lisa Patel. Next up, we'll hear from Kyla Bennett, and after Kyla Bennett, we'll hear from Roy Gamse.
Kyla, go ahead.

   DR. KYLA BENNETT: Thank you. My name is Dr. Kyla Bennett, and I am the science director for Public Employees for Environmental Responsibility or PEER. I am a former EPA employee, where I worked as both a scientist and a lawyer. I want to thank USC for holding these virtual hearings and filling the void that Trump's EPA has created.

   PEER commented on the original rule in August of 2018 and this supplemental rule does not alleviate our concerns. In fact, it only serves to increase our concerns.

   The bottom line is that both the original rule and this supplement are bad solutions searching for a problem that does not exist. This rule will impede both the speed and accuracy of EPA decision-making, something which is particularly important in times like these. EPA's core mission is to protect human health and the environment, and this supplemental rule will do the opposite.

   Our primary concerns are:
1. The Federal Housekeeping Statute does not give authority for this rule. According to its legislative history, the Housekeeping Statute is never intended by Congress to authorize an agency to use it for substantive regulations.

2. Expansion of the rule to cover all data studies and models, not just dose-response models is far too broad. This simply means that EPA will now have the ability to far more science and research than it originally proposed.

3. Consideration of studies only of the underlying -- if the underlying data is publicly available in a tiered-access approach is still indefensible. The tiered-access approach by which data that cannot be made public can be shared with a few for independent validation is still unworkable. It is illegal to share personal health data with anyone. So, sharing it with just one or a handful of people is just as illegal as sharing it with the general public. Giving less consideration or no consideration to studies where underlying data are not publicly available is a political decision that has nothing to do with
science. This is contrary to EPA's mission to protect human health and the environment based on best available science.

4. EPA does not have the resources to re-analyze all of the data used in decision-making. The supplemental rule clarified that by saying all studies had to be reproducible, they meant be analyzed. EPA does not have necessary statisticians and data analysts to do such work. Moreover, this will delay all EPA decision-making. When studies are sent to the FDA, statisticians do re-analyze all the data. Expedited FDA review takes roughly six months. Normal reviews can take up to two years. How will EPA deal with the lack of resources within the agency and the timing? How much will this cost, and what will delays mean in terms of impacts to human health and the environment? Here in the US, chemicals are innocent until proven guilty. In other words, new chemicals such as novel PFAS can be used unless and until they are proven to adversely affect human health and the environment. What will the human cost be to these delays?
5. This supplemental rule is simply a continuation of this administration's war on science. Peer review of scientific articles should be enough to establish the strength of the study. Scientists are able to evaluate the strength of the study by looking at the data transformation, sample size assumptions, and the model. These safeguards already exist in peer review. This rule invents a new arbitrary and political standard by which a study is judged unrelated to scientific merit.

Moreover, giving the EPA administrator -- who is often not a scientist him or herself, and also a political appointee -- giving them the authority to grant an exemption to the rule is pure politics.

In conclusion, this rule purports to increase transparency and good science, but it does exactly the opposite. It allows the agency to substitute its political will in the place of science. EPA should withdraw the rule immediately. Thank you.

JASON JACOBSON: Thank you, Dr. Kyla
Bennett. Next, we'll hear from Roy Gamse.

ROY GAMSE: Thank you to UCS. I'm Roy Gamse. I was deputy assistant administrator of EPA, responsible for overseeing the regulation development process.

I'll start with what the supplement doesn't do. It doesn't provide any reason why this self-regulation is needed, no examples of EPA rules that are faulty because data or models aren't available to the public. It's based on a theory with no supporting evidence, which results in very high implementation costs and likely lost health benefits to the public. EPA has not provided the costs for this rule and claim that it is not a major rule costing at least $100 million a year as defined by the executive orders. But the Congressional Budget Office estimated a very, very similar House of Representatives proposal, the Secret Science Reform Act of 2015, would cost $250 million annually. So, where is the economic impact analysis that's required of every other EPA action over $100 million? Not in this supplement.

What is in the supplement on pages 9 and
10 are two alternatives for dealing with studies for which data or models aren't available for independent validation. EPA asks, "Which do you prefer: (a) Tiered access used to reduce the risk of re-identification of private information; or (b) The agency giving greater weight to studies where the underlying data and models are available than to those for which they are not.

To understand the choice, consider the reality that we're anonymizing human health data. EPA says it can take a data set of personal health information obtained in research studies with the promise of confidentiality and disguise it so that individuals are anonymous. Sounds good but no longer feasible in these days of big data analysis. The International Society of Environmental Epidemiologists submitted comments showing how weak the promise of anonymized confidentiality really is. They showed that in the Harvard Six Cities Study, most individuals in one of the cities could be identified without name and address information but just the information needed for independent validation. For Medicare
cohort with exposures by zip code and the data needed for validation, most of the individuals who died would be identifiable.

A peer-reviewed study looked at an environmental health study in Northern California with data considered by HIPAA to be de-identified and identified 25 percent of the participants correctly. A study searched a Lexis Nexis database for stories mentioning hospitalization identified 43 percent of the patients without personal identification information provided.

The National Academy of Science's workshop reached the same conclusion. Attempts to anonymize health data with information that identifies individuals but leave enough for independent replication still allows participants to be identified.

EPA didn't address those ISEE comments in the supplement and the alternatives it proposes don't solve the problem. EPA wouldn't know if the anonymization will indeed protect confidentiality when an ISEE expert or malicious hacker tries to crack it, so it cannot guarantee confidentiality.
It can only promise best efforts.

Furthermore, future guarantees of confidentiality to research, for instance, couldn't be honestly made. If you asked me if my son could participate in a study with limited exposure on intelligence and you offer me best efforts by keeping his information secret, my answer is no, and yours would be too. So, getting participants in future environmental health studies will get much, much harder, if not impossible.

What about alternative B, giving epidemiology studies in which personal data is not available a lower priority than other studies? If the epidemiology study is the best study, then it should have the most weight. It is immoral under EPA's governing legislative mandates to not use the best available science, especially due to a rule with no justification.

Look at the track record of health studies used by EPA as a basis for its regulation and ask, how many would be given lower or no consideration? Why hasn't EPA answered that
question? They may be reluctant to reveal the answer. Hence, we have no hard data or even estimates of real-world impact of the regulations, health, or cost.

So, my answer to EPA's question -- do you prefer alternative a or b -- is a resounding neither.

In conclusion, EPA demonstrated no need for this rule, no examples for what problem is being fixed, no examples of what studies would be done creating the effect of doing so, no examples of improperly justified rules, no costs despite the executive orders. It has incurred the derision of almost every reputable health and science organization, and EPA should stop wasting its time and our time on this unnecessary rule.

Thank you.

JASON JACOBSON: Thank you, Roy. At this time, we will take a short recess, and we'll come back in five minutes to allow some additional speakers to join us in the hearing. Thanks.

(Break)

JASON JACOBSON: Thank you for joining
the UCS-sponsored virtual public hearing regarding
the supplemental rule on EPA proposal,
*Strengthening Transparency and Regulatory Science.*
We are taking a short break in will resume public
comments at 5:40 starting with Dianna Burdett and
followed by Dylan Burdett after her. Thanks.
    (Break)

JASON JACOBSON: Welcome back. You are
listening to a virtual public hearing regarding
the supplemental rule on EPA proposal,
*Strengthening Transparency and Regulatory Science.*
We are listening to public comments, in we will
now hear from Dianna Burdett. One moment. There
you go, Diana.

DIANNA BURDETT: Hello. Good afternoon.
Thank you for having me. I'm here on behalf of
Lake County in Illinois, and I'm speaking for the
community. I'm an organizer, an activist, and a
mother, a concerned resident of this Environmental
Justice community here in Lake County. I'm
speaking from Waukegan, Illinois.

It is concerning that there are rollbacks
regarding our environmental regulatory system
because I'm coming from a community where one child out of every three will end up in the hospital with respiratory issues. It's higher than the national average. And now we are in the middle of a pandemic, which attacks our respiratory processes. So, this rollback is asking us to disregard the science that will keep our community healthy and allow our respiratory systems to be attacked even further. We have no safeguards when we disregard science, and our lives are being touted -- the lives of this community are being touted as essential lives. Our community provides essential workers, yet our day-to-day life isn't being respected. It's a shame when publicly we are told we are essential and we need to be out there and we need to be providing services for individuals who aren't able to come out and for individuals to stay home and be comfortable and publicly they give us cartoon figures with capes. But they don't even provide safeguards using our best science.

And it's a problem to the future of our children, the health of our essential workers who
are out there on a regular basis providing the services to the remaining of the communities around us knowing full well that when we come out of this, we come out of it worse than when we entered.

I am a mother. I have a 4- and a 6-year-old child, and my neighbor has a young 9-month-old and my neighbor to my right has a 10-, 13- and a 16-year-old. We are a community with futures and all we ask is that our science -- our best science isn't disregarded and thrown away.

Our immune system is going to be left a wreck and the last thing that we need is the coal plant deregulated that is a mile away from me. If the ethylene oxide sterilizer deregulated, that is three miles away from us. We've already experienced several chemical emergencies in this last year in 2019. Now, we're dealing with a pandemic, and all of the essential workers in this area come from our community that is being ravaged. We are one of the highest hot spots in Illinois aside from Southside Chicago.

We need to enter the next year with
stronger science and stronger regulations. Thank you.

JASON JACOBSON: Thank you, Dianna.

Next, we have Dylan Burdett.

DYLAN BURDETT: Hello.

JASON JACOBSON: Dillon, go ahead.

DYLAN BURDETT: Okay, thank you. Thank you for your time and thank you to the Union of Concerned Scientists for taking on the responsibility of holding this public meeting while the decision-makers of the EPA have shirked their responsibility to protect the most vulnerable populations in our country. I am sorry that I was not present to hear the earlier comments from today. I'm coming to this hearing directly from work.

As a scientist whose primary research is currently pivoting in an attempt to create an effective therapeutic for the disease, COVID-19, among the [inaudible] only to be brought back up as an amended rule. This is another example of the administration taking advantage of a bad situation in order to devalue and sideline science
and put our people at risk when our medical and scientific professionals are needed more than ever to protect and ensure the health of our population moving forward.

This is a rule that should not apply to pivotal regulatory decisions but also has no business being applied to influential scientific information. When considering any type of scientific information, the EPA must use the best science available. Due to the rules of most institutional review boards or IRBs, this rule would sideline nearly all basic science research to date [inaudible] actual scientific analysis, allowing important studies to be devalued for mere political reasons. It would drastically decrease the amount of participants that would participate in research moving forward, as tests using the anonymization protocols suggested by the EPA have been shown to not protect the true anonymity of most research subjects. This could expose research subjects to potential retaliatory actions, employment problems, or unwanted press attention. This would also allow the elimination
of longstanding and well-accepted studies as the research subjects may have already passed away.

This amended rule could potentially give the EPA administrator discretion regarding the data that the EPA can consider. I would like to be perfectly clear on this. The administrator of the EPA and their office should not in any situation be given the ability or authority to weigh in and decide which studies should be exempt from this rule and which studies would have this rule applied to them.

[Inaudible] of the administrator for exemptions. This would create yet another unscientific tiered system by which scientists' findings could be used and abused after their creation.

When we look at who will be most affected by this amended rule, it is once again the most vulnerable communities within our country -- fence-line communities existing at the intersection of immigrant communities, communities of color, and working-class communities are the ones who have suffered disproportionately under
the administration's EPA rule changes and rollbacks.

This proposed rule change is no different. As a scientist and a member of a fence-line community and an Environmental Justice community, I know that this rule will hurt our community disproportionately. We have already been struggling economically and this [inaudible]. Our people have been forgotten or ignored as our elected representatives are more focused on their campaign contributions than the health of their most vulnerable residents.

We need protection from corporations that see our lives merely as line items on a balance sheet. For all of these reasons, I implore the EPA to not adopt this rule either in its amended or its original form. Thank you.

JASON JACOBSON: Thank you, Dillon. As a reminder for all of the public comments that have been provided today, we will attempt to get written testimony supplements as well to ensure that if anyone did have their audio pause, we will -- we will capture the entirety of their remarks.
We will now take a short break while we wait for other speakers to join, and we'll check back in every five minutes. Thank you.

(Break)

JASON JACOBSON: You're listening to a virtual public hearing sponsored by the Union of Concerned Scientists regarding the supplemental rule on EPA proposal *Strengthening Transparency in Regulatory Science*. We are taking a break while we wait for registered speakers to join our hearing. So, we will stay in this room for about another thirty minutes. Thank you.

(Break)

JASON JACOBSON: Thank you for joining the virtual public hearing sponsored by the Union of Concerned Scientists regarding the supplemental rule on EPA proposal *Strengthening Transparency in Regulatory Science*. We're on a short recess while we wait for our remaining registered speakers to join this hearing. We'll remain on recess until we have speakers join. Thank you.

(Break)

JASON JACOBSON: You are listening to
public comments at a virtual public hearing regarding supplemental rule on EPA proposal, *Strengthening Transparency in Regulatory Science*, sponsored by the Union of Concerned Scientists. We are currently on a break while we wait for registered attendees to join this virtual webinar, and we will keep this virtual webinar open for another ten minutes or so. Thank you.

(Break)

JASON JACOBSON: Thank you. You are listening to public comments at a virtual public hearing regarding supplemental rule on EPA proposal, *Strengthening Transparency in Regulatory Science*, hosted by the Union of Concerned Scientists. Our next speaker will be Zigmund Plater. Zigmund, you can go ahead when you're ready.

ZIGMUND PLATER: Good. Let me see.

JASON JACOBSON: We can hear and see you. Good, marvelous. I am Zigmund Plater. I have been a professor for more than fifty years on public health, administrative law, environmental protection law, and I want to say the practical
effect of this proposed rule would clearly be to
deter, to diminish, to prevent EPA from issuing
strong public health and public safety
protections. It's not just the likely effect,
however, it also appears to be the likely intent
of the agency's political leadership. It's a
cynically clever trick.

In court tests based on administrative
law, EPA can't issue binding rules without a solid
base in fact and science. And according to its
statutes, EPA must issue protective rules when the
facts and the science show potential threats to
public health and safety.

So, the political leaders of EPA have
come up with a way to avoid issuing strong
protections even when science shows a public
threat -- it's restrictive science -- by adopting
this policy here in this rule. It says even if
the science isn't good, that science can't be used
to regulate. EPA cannot be forced to regulate.

So, EPA says the supporting studies
cannot be used unless there can be an intensive
independent validation down to the raw data of
confidential information of all the human test subjects. But EPA knows that virtually all human subject studies give their subjects strict confidentiality.

So, human studies using all the most important EPA rule-making cannot be used, and so, the protective rules cannot be issued.

So now, look at this wording.

Independent validation. By whom? Not by EPA, not by science policy organizations. They don't have to look at confidential data. So, the raw data they say has to be pryable apart down to the individual personal identity so regulated industries can fight EPA on whatever rules EPA issues. So, it's to facilitate a tax against their own EPA rules that EPA leaders either prevent the rules from being passed in the first place or facilitate the attacks on their own rules. It's clear to anyone who understands political realism watching this charade.

The purpose of the proposed rule is to allow EPA to bypass its statutory duties and disingenuously transparency rule is not just
housekeeping. Housekeeping rules aren’t allowed if they legally affect people external to the agency, and scientists external to the agency are affected in having their embargoed and may violate their first amendment right to petition the government.

All this doesn’t come to us from rational public administrative process. It does not come to us from science. It comes from what political scientists call agency capture when agency officials aren’t motivated by the public's wealth -- welfare and health and safety, but rather by the interests of the very entities who they're supposed to regulate for the protection of the public.

But this rule will be readily reversed when an administration oriented to public service comes to clean up this feted mess.

It would be nice to ask, please explain how this proposed rule can avoid the legal taint of a highly partisan regulatory agenda for cutting back on public protections that EPA is supposedly sworn to protect. I think I got it into four
minutes, and as you can see, there are important problems with this rule, and most of them are the EPA is not serving EPA's purpose but undercutting it. Over and out.

JASON JACOBSON: Thank you, Zigmund.

ZIGMUND PLATER: Thank you.

JASON JACOBSON: This concludes the evening session. The recording of the session should be available on the YouTube page of the Union of Concerned Scientists shortly. Thank you again for your participation today.

(Whereupon, the session was concluded.)
CERTIFICATE

I, Garrett Lorman, 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.

Garrett Lorman
Professional Reporter

The foregoing certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or direction of the certifying reporter.