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VIRTUAL PUBLIC HEARING

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SUPPLEMENTAL RULE ON EPA PROPOSAL

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STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE

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

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Tuesday, April 14, 2020

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21 REPORTED BY GARRETT LORMAN

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1 P R O C E E D I N G S

2 5:00 p.m.

3 MICHAEL HALPERN: All right. Good  
4 afternoon. My name is Michael Halpern. I am the  
5 deputy director of the Center for Science &  
6 Democracy at the Union of Concerned Scientists.  
7 Welcome to this virtual public hearing hosted by  
8 the Union of Concerned Scientists on the  
9 Environmental Protection Agency's proposed  
10 supplemental rule titled *Strengthening*  
11 *Transparency in Regulatory Science*. This session  
12 is being recorded and should post to the Union of  
13 Concerned Scientists YouTube page shortly after it  
14 ends.

15 We do appreciate you taking the time to  
16 provide public comments on the proposed  
17 supplemental rule. Close to one hundred people  
18 registered to provide public comment at the three  
19 sessions today. We are going to begin hearing  
20 publics shortly at this third of three sessions,  
21 and we do have a little bit of space at the end.  
22 So, if you would like to register to speak at the  
23 end of the session, please E-mail [ucsvph@gmail.com](mailto:ucsvph@gmail.com)

1 as quickly as you can. That's [ucsvph@gmail.com](mailto:ucsvph@gmail.com).

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

5 Ken, go ahead.

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

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

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

12 MICHAEL HALPERN: Yes.

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

1 glad we're all here. This is an important day for  
2 science. It's also an important day for  
3 democracy.

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

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

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

22 During normal times, the government  
23 recommends a minimum sixty-day public comment

1 period for the simplest of proposals. But these  
2 are not normal times, and this is not a simple  
3 proposal. Numerous science and public health  
4 organizations including the Union of Concerned  
5 Scientists urge the EPA to extend the public  
6 comment period to at least run thirty days beyond  
7 the end of the declared national public health  
8 emergency. We also asked for virtual public  
9 hearings. Unfortunately, EPA refused both of  
10 those requests. So, we decided to hold this  
11 hearing on our own. We invited EPA to send staff  
12 today to listen to today's hearing and ask  
13 questions. They declined to do that also.

14 Now, the COVID-19 crisis provides -- has  
15 caused profound challenges to our country and our  
16 communities in the world. The virus has disrupted  
17 all of our lives. Many people are working  
18 remotely while caring for children who are out of  
19 school. Others are taking on the crisis directly  
20 and working extra hours at great risk from health  
21 care specialists to sanitation workers. Public  
22 health organizations are working overtime to  
23 provide scientific advice to protect individuals

1 and communities throughout the country. Some  
2 people have reduced access to technology. So, all  
3 of these conditions make it more difficult for  
4 public comment.

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

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

22           Now, we expect the EPA to do its job and  
23 seek feedback on proposals. But when the agency

1 fails, as is the case today, we will step in to  
2 make sure that the agency receives as much  
3 feedback as possible, and all of us look forward  
4 to reviewing the public comments that are made  
5 today.

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

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

20           MICHAEL HALPERN: Thank you, Ken, for  
21 those remarks, and I'd like to provide everybody  
22 with some background information and briefly  
23 describe the proposed rule on which we are taking



1 comments today.

2           So, the EPA describes the rule as  
3 follows: *This Supplemental Notice of Proposed*  
4 *Rulemaking proposes that the scope of the*  
5 *rulemaking apply to influential scientific*  
6 *information as well as significant regulatory*  
7 *decisions. This notice proposes definitions and*  
8 *clarifies that the proposed rulemaking applies to*  
9 *data and models underlying both pivotal science*  
10 *and pivotal regulatory science.*

11           *In this SNPRM, EPA is also proposing a*  
12 *modified approach to the public availability*  
13 *provisions for data and models that would*  
14 *underline significant regulatory decisions and an*  
15 *alternate approach.*

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

21           So, for both oral and written comments,  
22 EPA will only consider feedback that directly  
23 addresses this supplemental proposal. So, please

1 do your best today to speak to the changes to the  
2 rule that are made in the supplemental proposal  
3 and its impact on EPA's ability to complete its  
4 mission and protect public health and the  
5 environment.

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

13           We're here today to hear comments on that  
14 proposal supplemental rule. We will not be able  
15 to respond to questions from attendees or have any  
16 dialogue among speakers.

17           In order to accommodate all speakers,  
18 testimony is limited to four minutes. After your  
19 name is called, we will ask you to proceed with  
20 your testimony. A transcript from this public  
21 hearing will be submitted to the docket and the  
22 recording will be made publicly available.

23           If you have any written comments or other

1 documents you would like to submit for the record,  
2 including your testimony as prepared for delivery,  
3 please E-mail them to the E-mail address you  
4 received on your confirmation form, which is  
5 [ucsvph@gmail.com](mailto:ucsvph@gmail.com). That's [ucsvph@gmail.com](mailto:ucsvph@gmail.com).

6 If you are watching this broadcast, you  
7 can also register again to speak today by E-  
8 mailing [ucsvph@gmail.com](mailto:ucsvph@gmail.com) as quickly as possible,  
9 and we will do our best to add you to the queue.

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

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

21 Today's hearing is broken into three  
22 separate sections. The first one began at 9 a.m.  
23 this morning, the second one at 1 p.m. this

1 afternoon, and this one at 5 p.m. Eastern Daylight  
2 Time. Each session is being streamed live through  
3 the Union of Concerned Scientists YouTube channel  
4 and can also be viewed on the UCS website.

5           And finally, we ask for your patience  
6 with this virtual hearing. People will have  
7 varying internet bandwidths and familiarity with  
8 the technology and experience providing testimony.  
9 If someone has technical difficulties when it is  
10 their turn, we will move on to the next speaker  
11 and return to the person with technical  
12 difficulties later in the session.

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

17           JASON JACOBSON: Thank you, Michael. As  
18 a reminder, all attendees are muted automatically.  
19 We will unmute you when it is your turn to speak.  
20 If you wish to turn on your video, you may do so.

21           We will now begin our public comments.  
22 The first speaker will be Hayden Hashimoto,  
23 followed by Dr. Lisa Patel, and after that we will

1 hear from Kyla Bennett.

2 Hayden Hashimoto, please go ahead.

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

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

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

23 EPA fails to show why the current process

1 for considering available cutting-edge science  
2 including relying on currently available peer  
3 review for influential scientific information is  
4 problematic.

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

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

19 EPA's proposal forces health researchers  
20 to decide between ignoring federal privacy  
21 requirements that protect the confidentiality of  
22 the human subjects of scientific study or  
23 producing health studies that will be ignored

1 because they don't satisfy EPA's new standard.

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

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

18 While EPA tries to claim that this is a  
19 procedural rule, the substantive impact of this  
20 rule is clear. Denying access to the best science  
21 will have a substantive impact on federal public  
22 health regulations by removing support from our  
23 health protective rules.

1           Indeed, the fact that the original  
2 proposal, which EPA is reporting now to  
3 supplement, was not described as procedural is  
4 very revealing. EPA well knows that its intention  
5 with its original proposal was to limit the access  
6 to significant scientific work based on human  
7 health data because that work demands stronger  
8 regulatory actions and this supplemental proposal  
9 expands that effort.

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

15           The Supreme Court made clear in Chrysler  
16 Corporation v Brown that the Housekeeping Statute  
17 cannot be used as authority for substantive  
18 regulations that limit the scope of another  
19 statute. Limiting the agency's ability to  
20 consider research that relies on confidential  
21 human health studies would impede environmental  
22 regulations under several statutes, not least of  
23 which is the Clean Air Act.



1           For example, the National Ambient Air  
2   Quality Standards Program, bedrock of our National  
3   Clean Air Law, requires EPA to issue air quality  
4   criteria that accurately reflect the latest  
5   scientific knowledge useful in indicating the  
6   extent of all identifiable effects on public  
7   health or welfare which may be expected from the  
8   presence of such pollutants in the ambient air.  
9   This proposal directly undermines that directive.

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

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

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

18           JASON JACOBSON: We can and see you.  
19   Thank you.

20           DR. LISA PATEL: Great. So, I'm Dr. Lisa  
21   Patel. I'm a former environmental scientist at  
22   the Environmental Protection Agency, Advocacy and  
23   Policy Lead at the Sean Parker Center for Allergy

1 and Asthma Research at Stanford University, and a  
2 physician. I work as a pediatric hospitalist who  
3 is on the front lines of the coronavirus pandemic.

4 I'm here to testify because the EPA  
5 would, in essence, create its own avoidable health  
6 crisis by moving forward with this supplemental  
7 rule, which substantially limits science used to  
8 keep our children healthy. Rigorous scientific  
9 studies whose patients are subjects in trials to  
10 study, measure, and track a variety of biomarkers  
11 and health outcomes due to environmental  
12 pollution.

13 Researchers have an ethical directive to  
14 protect the identify of these patients by not  
15 disclosing their personal health information or  
16 PHI. The supplemental rule mandates that the use  
17 for its internal scientific assessments and rule-  
18 making be publicly available, a logistical  
19 impossibility for studies using PHI. The EPA  
20 could essentially ignore these studies under the  
21 rule. I would like to talk about what this means  
22 for air pollution and children's health in  
23 particular.

1           New research shows us that pollutants  
2   like PM2.5 affect us down to our very genes,  
3   altering our epigenetic programming in ways that  
4   increase our risk for asthma and activate a pro-  
5   inflammatory cascade that places us at higher risk  
6   for a range of cardiopulmonary disease. This  
7   starts in utero, and data from our center shows  
8   that exposure to PM2.5 also changes epigenetic  
9   programming and immune regulation in young kids  
10  that are potentially heritable.

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

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

1 susceptible to environmental toxins.

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

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

14           Our best available science is showing us  
15 that pollutants like PM2.5 are more dangerous than  
16 we previously knew at even lower levels than we  
17 previously understood. Data shows that even at  
18 the lowest detectable PM2.5 levels of 2.8 still  
19 result in excessive of thirty thousand deaths per  
20 year. A study from [inaudible 32:12] evaluating  
21 air pollution in six hundred and fifty-two cities  
22 found that an increase in just 10 mcg/meter in a  
23 2-day living average was associated with 0.44

1 percent increase in daily all-cause mortality,  
2 0.36 percent increase in daily cardiovascular  
3 mortality, 0.47 percent in daily respiratory  
4 mortality.

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

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

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

22           We talked about the data, but I just want  
23 to take my last minute to talk about what this

1 looks like as a practicing physician in a  
2 hospital. The terrified eyes of a child who is  
3 suffocating in front of you because of the severe  
4 asthma exacerbation landing in an intensive care  
5 unit again for impending respiratory failure. The  
6 expectant mother who the day before was preparing  
7 her nursery, now finds herself in premature labor  
8 being told by a physician like myself about her  
9 infant's chance of survival -- survival without  
10 significant morbidity, the possibility of putting  
11 an endotracheal tube down her little baby's  
12 throat, of chest compressions, of a central line  
13 to keep her baby alive. We should do our all to  
14 prevent these outcomes, not increase their number.

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

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

1 Kyla, go ahead.

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

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

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

23 Our primary concerns are:

1           1. The Federal Housekeeping Statute does  
2 not give authority for this rule. According to  
3 its legislative history, the Housekeeping Statute  
4 is never intended by Congress to authorize an  
5 agency to use it for substantive regulations.

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

11          3. Consideration of studies only of the  
12 underlying -- if the underlying data is publicly  
13 available in a tiered-access approach is still  
14 indefensible. The tiered-access approach by which  
15 data that cannot be made public can be shared with  
16 a few for independent validation is still  
17 unworkable. It is illegal to share personal  
18 health data with anyone. So, sharing it with just  
19 one or a handful of people is just as illegal as  
20 sharing it with the general public. Giving less  
21 consideration or no consideration to studies where  
22 underlying data are not publicly available is a  
23 political decision that has nothing to do with



1 science. This is contrary to EPA's mission to  
2 protect human health and the environment based on  
3 best available science.

4           4. EPA does not have the resources to  
5 re-analyze all of the data used in decision-  
6 making. The supplemental rule clarified that by  
7 saying all studies had to be reproducible, they  
8 meant be analyzed. EPA does not have necessary  
9 statisticians and data analysts to do such work.  
10 Moreover, this will delay all EPA decision-making.  
11 When studies are sent to the FDA, statisticians do  
12 re-analyze all the data. Expedited FDA review  
13 takes roughly six months. Normal reviews can take  
14 up to two years. How will EPA deal with the lack  
15 of resources within the agency and the timing?  
16 How much will this cost, and what will delays mean  
17 in terms of impacts to human health and the  
18 environment? Here in the US, chemicals are  
19 innocent until proven guilty. In other words, new  
20 chemicals such as novel PFAS can be used unless  
21 and until they are proven to adversely affect  
22 human health and the environment. What will the  
23 human cost be to these delays?

1           5. This supplemental rule is simply a  
2 continuation of this administration's war on  
3 science. Peer review of scientific articles  
4 should be enough to establish the strength of the  
5 study. Scientists are able to evaluate the  
6 strength of the study by looking at the data  
7 transformation, sample size assumptions, and the  
8 model. These safeguards already exist in peer  
9 review. This rule invents a new arbitrary and  
10 political standard by which a study is judged  
11 unrelated to scientific merit.

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

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

23           JASON JACOBSON: Thank you, Dr. Kyla

1 Bennett. Next, we'll hear from Roy Gamse.

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

6 I'll start with what the supplement  
7 doesn't do. It doesn't provide any reason why  
8 this self-regulation is needed, no examples of EPA  
9 rules that are faulty because data or models  
10 aren't available to the public. It's based on a  
11 theory with no supporting evidence, which results  
12 in very high implementation costs and likely lost  
13 health benefits to the public. EPA has not  
14 provided the costs for this rule and claim that it  
15 is not a major rule costing at least \$100 million  
16 a year as defined by the executive orders. But  
17 the Congressional Budget Office estimated a very,  
18 very similar House of Representatives proposal,  
19 the Secret Science Reform Act of 2015, would cost  
20 \$250 million annually. So, where is the economic  
21 impact analysis that's required of every other EPA  
22 action over \$100 million? Not in this supplement.

23 What is in the supplement on pages 9 and

1 10 are two alternatives for dealing with studies  
2 for which data or models aren't available for  
3 independent validation. EPA asks, "Which do you  
4 prefer: (a) Tiered access used to reduce the risk  
5 of re-identification of private information; or  
6 (b) The agency giving greater weight to studies  
7 where the underlying data and models are available  
8 than to those for which they are not.

9 To understand the choice, consider the  
10 reality that we're anonymizing human health data.  
11 EPA says it can take a data set of personal health  
12 information obtained in research studies with the  
13 promise of confidentiality and disguise it so that  
14 individuals are anonymous. Sounds good but no  
15 longer feasible in these days of big data  
16 analysis. The International Society of  
17 Environmental Epidemiologists submitted comments  
18 showing how weak the promise of anonymized  
19 confidentiality really is. They showed that in  
20 the Harvard Six Cities Study, most individuals in  
21 one of the cities could be identified without name  
22 and address information but just the information  
23 needed for independent validation. For Medicare

1 cohort with exposures by zip code and the data  
2 needed for validation, most of the individuals who  
3 died would be identifiable.

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

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

18           EPA didn't address those ISEE comments in  
19 the supplement and the alternatives it proposes  
20 don't solve the problem. EPA wouldn't know if the  
21 anonymization will indeed protect confidentiality  
22 when an ISEE expert or malicious hacker tries to  
23 crack it, so it cannot guarantee confidentiality.

1 It can only promise best efforts.

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

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

20           Look at the track record of health  
21 studies used by EPA as a basis for its regulation  
22 and ask, how many would be given lower or no  
23 consideration? Why hasn't EPA answered that

1 question? They may be reluctant to reveal the  
2 answer. Hence, we have no hard data or even  
3 estimates of real-world impact of the regulations,  
4 health, or cost.

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

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

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

22           (Break)

23           JASON JACOBSON: Thank you for joining

1 the UCS-sponsored virtual public hearing regarding  
2 the supplemental rule on EPA proposal,  
3 *Strengthening Transparency and Regulatory Science*.  
4 We are taking a short break in will resume public  
5 comments at 5:40 starting with Dianna Burdett and  
6 followed by Dylan Burdett after her. Thanks.

7 (Break)

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

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

22 It is concerning that there are rollbacks  
23 regarding our environmental regulatory system



1 because I'm coming from a community where one  
2 child out of every three will end up in the  
3 hospital with respiratory issues. It's higher  
4 than the national average. And now we are in the  
5 middle of a pandemic, which attacks our  
6 respiratory processes. So, this rollback is  
7 asking us to disregard the science that will keep  
8 our community healthy and allow our respiratory  
9 systems to be attacked even further. We have no  
10 safeguards when we disregard science, and our  
11 lives are being touted -- the lives of this  
12 community are being touted as essential lives.  
13 Our community provides essential workers, yet our  
14 day-to-day life isn't being respected. It's a  
15 shame when publicly we are told we are essential  
16 and we need to be out there and we need to be  
17 providing services for individuals who aren't able  
18 to come out and for individuals to stay home and  
19 be comfortable and publicly they give us cartoon  
20 figures with capes. But they don't even provide  
21 safeguards using our best science.

22           And it's a problem to the future of our  
23 children, the health of our essential workers who

1 are out there on a regular basis providing the  
2 services to the remaining of the communities  
3 around us knowing full well that when we come out  
4 of this, we come out of it worse than when we  
5 entered.

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

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

23 We need to enter the next year with

1 stronger science and stronger regulations. Thank  
2 you.

3 JASON JACOBSON: Thank you, Dianna.  
4 Next, we have Dylan Burdett.

5 DYLAN BURDETT: Hello.

6 JASON JACOBSON: Dillon, go ahead.

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

17 As a scientist whose primary research is  
18 currently pivoting in an attempt to create an  
19 effective therapeutic for the disease, COVID-19,  
20 among the [inaudible] only to be brought back up  
21 as an amended rule. This is another example of  
22 the administration taking advantage of a bad  
23 situation in order to devalue and sideline science

1 and put our people at risk when our medical and  
2 scientific professionals are needed more than ever  
3 to protect and ensure the health of our population  
4 moving forward.

5           This is a rule that should not apply to  
6 pivotal regulatory decisions but also has no  
7 business being applied to influential scientific  
8 information. When considering any type of  
9 scientific information, the EPA must use the best  
10 science available. Due to the rules of most  
11 institutional review boards or IRBs, this rule  
12 would sideline nearly all basic science research  
13 to date [inaudible] actual scientific analysis,  
14 allowing important studies to be devalued for mere  
15 political reasons. It would drastically decrease  
16 the amount of participants that would participate  
17 in research moving forward, as tests using the  
18 anonymization protocols suggested by the EPA have  
19 been shown to not protect the true anonymity of  
20 most research subjects. This could expose  
21 research subjects to potential retaliatory  
22 actions, employment problems, or unwanted press  
23 attention. This would also allow the elimination

1 of longstanding and well-accepted studies as the  
2 research subjects may have already passed away.

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

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

17           When we look at who will be most affected  
18 by this amended rule, it is once again the most  
19 vulnerable communities within our country --  
20 fence-line communities existing at the  
21 intersection of immigrant communities, communities  
22 of color, and working-class communities are the  
23 ones who have suffered disproportionately under

1 the administration's EPA rule changes and  
2 rollbacks.

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

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

18           JASON JACOBSON: Thank you, Dillon. As a  
19 reminder for all of the public comments that have  
20 been provided today, we will attempt to get  
21 written testimony supplements as well to ensure  
22 that if anyone did have their audio pause, we will  
23 -- we will capture the entirety of their remarks.

1 We will now take a short break while we wait for  
2 other speakers to join, and we'll check back in  
3 every five minutes. Thank you.

4 (Break)

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

13 (Break)

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

22 (Break)

23 JASON JACOBSON: You are listening to

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

9 (Break)

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

18 ZIGMUND PLATER: Good. Let me see.

19 JASON JACOBSON: We can hear and see you.  
20 Good, marvelous. I am Zigmund Plater. I have  
21 been a professor for more than fifty years on  
22 public health, administrative law, environmental  
23 protection law, and I want to say the practical



1 effect of this proposed rule would clearly be to  
2 deter, to diminish, to prevent EPA from issuing  
3 strong public health and public safety  
4 protections. It's not just the likely effect,  
5 however, it also appears to be the likely intent  
6 of the agency's political leadership. It's a  
7 cynically clever trick.

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

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

21           So, EPA says the supporting studies  
22 cannot be used unless there can be an intensive  
23 independent validation down to the raw data of

1 confidential information of all the human test  
2 subjects. But EPA knows that virtually all human  
3 subject studies give their subjects strict  
4 confidentiality.

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

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

21 The purpose of the proposed rule is to  
22 allow EPA to bypass its statutory duties and  
23 disingenuously transparency rule is not just

1 housekeeping. Housekeeping rules aren't allowed  
2 if they legally affect people external to the  
3 agency, and scientists external to the agency are  
4 affected in having their embargoed and may violate  
5 their first amendment right to petition the  
6 government.

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

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

19 It would be nice to ask, please explain  
20 how this proposed rule can avoid the legal taint  
21 of a highly partisan regulatory agenda for cutting  
22 back on public protections that EPA is supposedly  
23 sworn to protect. I think I got it into four

1 minutes, and as you can see, there are important  
2 problems with this rule, and most of them are the  
3 EPA is not serving EPA's purpose but undercutting  
4 it. Over and out.

5 JASON JACOBSON: Thank you, Zigmund.

6 ZIGMUND PLATER: Thank you.

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

12 (Whereupon, the session was concluded.)

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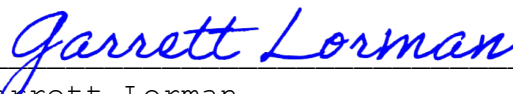
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C E R T I F I C A T E

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

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