Transcript of CleanLaw: Laura Bloomer Interviews Gretchen Goldman about EPA Science Advisory Committees, December 18, 2019

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Robin: Welcome to this episode of CleanLaw from the Environmental and Energy Law Program at Harvard Law School. In this episode, our EELP Legal Fellow, Laura Bloomer, speaks with Gretchen Goldman, Research Director for the Center for Science and Democracy at the Union of Concerned Scientists about the Trump administration's changes to EPA's process for reviewing the National Ambient Air Quality Standards or NAAQS.

They discuss the importance of revising these standards to keep pace with current science and the many ways in which Trump's EPA is undermining the ongoing reviews for air quality standards for ozone and particulate matter.

This podcast was recorded before the Clean Air Scientific Advisory Committee met from December 3rd to 6th. You will hear Gretchen mention the upcoming meeting in the interview. Consistent with her insight, the committee did not reach a consensus at their December meeting regarding whether or not the existing NAAQS for ozone and particulate matter adequately protect human health. We hope you enjoy this podcast.

Laura: Hi, Gretchen. I'm really excited to be talking with you today. Thanks so much for joining us here.

Gretchen: Thanks so much for having me, Laura.

Laura: I want to get started with a little bit more of a thank you. Your research, your blog, your advocacy with Union of Concerned Scientists has really made me as a non-science wonk, as a lawyer who hasn't taken a hard science class in about a decade, really understand the importance of this topic and become deeply interested in it. So I really appreciate the work that you're doing.

Gretchen: Well, thank you very much.

Laura: With that, let's dive in to our main event, the Trump administration's attacks on air quality standards. So most of our listeners are familiar with the NAAQS, the National Ambient Air Quality Standards that EPA sets for six of the most pervasive pollutants like ground level ozone, carbon monoxide, and particulate matter. As you know, by statute, EPA has to review those standards every five years to ensure that they adequately protect public health and the environment. Considering the broader environmental science or public health perspective, can you tell us a little bit about why that five year review mechanism is so important?

Gretchen: It's been really prescient and useful for NAAQS to have that five-year requirement because that's allowed us to continue to update air quality standards as the science advanced. And I don't think even when they passed the Clean Air Act in the '70s they even thought that we would be where we are today, where we have more and more science that tells us new and diverse risks from air pollutants. And that means that we have this legal mechanism that now allows us to make sure that the standards can continue to be based on science over the years.

So that was a really important point that was put into that law that allows us to do that. And because of the mechanisms that feed in to NAAQS and because it has to be based on what protects public health and welfare with an adequate margin of safety, then we know that those standards can be revisited again and again. And that has to happen whether or not it's politically convenient.

Laura: And so generally, do you see that the standards do keep up with the advancement of science?

Gretchen: They largely have. There's certainly been capacity constraints on EPA's side and they've struggled to meet this five-year requirement just given all of the work they have to do for each pollutant. So it's happened in varying degrees for the different pollutants. But by and large, I'd say, we have kept up having science-based standards and the results of that have been very dramatic. We've seen decreases in all of the criteria pollutants, all six of the pollutants regulated currently under this part of the Clean Air Act. And the science just keeps telling us more about the relationship between these pollutants and health. And that's allowed us to ensure we continue to have a health-based standard.

Laura: And it's worth noting, talking about the relationship between these pollutants and public health, that EPA is currently involved in two review processes for particulate matter NAAQS and for ozone. So could you give us a couple sentences on the importance of those two standards for public health?

Gretchen: Yes. Those are the two pollutants where we see the most health effects in terms of the number of people affected. So these are pollutants that the science has continued to show that we need to tighten the standards. So every time this has come up, in each cycle we have seen more evidence of the need to tie in both the particulate matter and ozone standards. Also, because those are pollutants that have been harder to decrease emissions of in recent years. As we try to cinch down the standard, we also have to try to meet that standard. That's why those tend to be the hot topics in this area where there continues to be a lot of policy interest and scientific interest in those pollutants.

Laura: Got it. We're recording today - It's November 15th. And earlier this week, the Clean Air Science Advisory Committee or CASAC recommended, spoiler alert, no changes to the particulate matter NAAQS, essentially declaring that the current levels adequately protect public health. Am I understanding that report that they sent to EPA correctly?

Gretchen: Right. So that is their draft letter to the administrator making recommendations on the particulate matter standards. And it has never been this split on a recommendations letter to the administrator in the history of NAAQS. So this is notable.

I'll say it is a draft. They're going to discuss the draft at their December meeting. So we'll see if anything changes. But based on their October meeting and this draft letter, it seems that CASAC is not in agreement about the standards. So that's notable and at least four of the people on the committee have said they don't think it needs tightening.

This is very interesting and we'll see what they discuss and if they decide anything different when they're finalizing the letter. But that does track with what we saw in their October meeting where they couldn't come to agreement about whether or not the new science warranted tightening the standard.

Laura: That's super interesting that this is the first time they've been this divided. I didn't actually realize that. And basically what I want to do is get us to the point where we can talk about how we got to a divided CASAC recommending no change to the standards.

Gretchen: Sure.

Laura: So if you don't mind, let's start back at the beginning. And to give some grounding, what did the NAAQS process look like before Trump took office?

Gretchen: NAAQS is my favorite example of a science policy and how things should work. It's this really great science-based law, and the way that it works or has always worked is there is a clear line between the science and the policy. And that five-year requirement means we are regularly checking to see if new science warrants tighter standards.

There is an external science advisory committee CASAC that we mentioned that handles this. They've always historically been supplemented with experts on the particular pollutants that they're looking at. And this is because CASAC is only seven people. They typically are experts in air pollution, but given the range of pollutants and disciplines that they need to review for each review cycle, it's necessary to have additional experts involved.

And so we always have a pollutant review panel that has been chosen specifically for their expertise on the key disciplines for that pollutant. And they would go to meetings with CASAC, they would weigh in, they would review the documents and a lot of that would happen together. So you'd get a room of 20 or 30 experts on any given review that could weigh in and make sure that you get a robust science-based review on any given NAAQS review.

So that's how it's typically worked and they would work together. In the end CASAC would make a recommendation to the administrator about where that standard should

be. And that final letter - informed by the panel - would then get to the administrator's desk. They'd have access to that letter. They'd have access to the integrated science assessment, which is the giant document that summarizes everything we know about a pollutant and health and welfare effects. And the administrator can then make a policy decision about what the standard should be.

And so because of that letter and that process, you know exactly where the scientific community lands on where the standards should be according to top experts that were involved in this review. And I should add that the whole review is very public. It is the closest that you get to a public peer review of a document. It's really a neat process. And in the end, the administrator has some legal authority to say what he thinks the standard should be, but the Clean Air Act says that he has to base it on science, on the science of what protects public health and welfare.

And so historically that's led us to have a very clear indicator of whether or not the administrator does in fact follow the science. In cases where the administrator has not followed the recommendations of the science advisors of CASAC, then we know that we should raise questions about whether or not it was a science-based standard.

So that's been a very good accountability mechanism. It's been a very good legal mechanism to ensure that we do have health protective standards. So that's how the process has historically worked. And I'll just add that it's worked remarkably well because this is an area of science policy where there is a lot of pressure to not follow the science because we know that it matters a lot to industries what these standards are. It matters a lot to states what these standards are because being not in attainment for the standards has consequences. It means things about permitting, about funding for highways.

So, there's financial incentives for places to be within the standard. And because there is that mechanism, that's what's allowed it to be effective in the US, because we do have consequences if you are not within the standard. And so we are incentivized to try to have cleaner air. So that's a very important piece of the Clean Air Act and it's what makes it very effective.

But because of that, the flip side of that is that it also means there's a lot of pressure to have the standard be a certain way. It affects a lot of people. But by and large that's worked over the past four decades, even with a lot of industry pressure and political pressure to do certain things because it's such a strong science-based process.

Laura: I like the cycles of accountability with CASAC to the public and to other scientific experts. Then between CASAC and the administrator. And then the third one, which is making sure that the states actually are held accountable for meeting these standards and providing cleaner air to their communities.

I actually attended a science advisory board meeting once, not CASAC, and I did find it interesting, but it was very difficult to follow. So just to make sure we're understanding just how massive the assessments are that CASAC is reviewing, what types of studies, this is a hard question, but just kind of broadly, what are they looking at?

Gretchen: So the integrated science assessment, that's the first step on all the reviews is a couple thousand pages of discussion of summary of all of the science that says what we know about that pollutant and health and welfare effects. So it typically is, and this was prepared by EPA staff, so I do want to give them a shout out because this is no small undertaking and it includes some history on the NAAQS and on the standard and where we are at the current policy juncture. And then it gets into all of the science.

So it's everything we know about measurement of that pollutant, what do we know about any measurement error involved in measuring that pollutant and how it's spatially distributed. And then it goes into what we know about health effects and what is the relationship that pollutant has with health effects. There's a really great part of it that looks at the degree to which we can be confident that this pollutant is causing different health effects.

They have a great system where there's degrees of confidence around each one. And so you get a really good picture of how well do we know the science between particulate matter and cardiovascular disease or ozone and neurological development. It goes through all the different end points and there are some where we know a lot. It is highly probable that this is a causal relationship. And then there are some where it's suggestive - where there's sort of some evidence that there might be something there and we don't have enough data to say.

So that's a really important part of it. They do that for all of the pollutants. It also looks at the way that we set the standards. So there's different ways you can do it. You can say, we're going to say the pollutant can't be greater than this level over one hour. We can say it can't be greater than this level over 24 hours. You can look at whether you want to look at the average or the maximum. So it goes through a few different ways of thinking about that because sometimes on the standard it's useful to think about that as well. And then it goes through and discusses all of the welfare effects.

And welfare in this case is essentially all of the other reasons that we might want to control air pollution other than health. So things like climate impacts, ecological impacts, building materials, visibility, and there's all the discussions of the science and what we know about those welfare effects. As you imagine, that gets into a completely different area of science than looking at the health effects. So you need additional expertise to review those. And that's part of the reason you need many people to do these reviews.

So that's the integrated science assessment. And then there is another large document that's a policy assessment.

Laura: I can't believe we're only at one right now. This is pretty impressive.

Gretchen: So normally there's also a risk and exposure assessment and a policy assessment, and those are separate documents. The risk and exposure one gets more into the kinds of standards that you could have, what do we know about who is at risk from those different ... Doing different things with the standard, it sort of helps the committee and the panelists understand who is being protected by the policy, and then the policy assessment will look at different options and help them figure out what is the consequence of setting the standards at different places.

So normally it is these three large documents. Each of those documents go through multiple drafts and the committee and the panelists together will review them. They'll have public meetings. They'll take public comment. And so it is a long exhaustive process where you would get to see EPA with its external science advisors really develop everything we know about a pollutant and its health and welfare effects and everything we could know about what standards would protect against it.

Laura: Wow. I am both exhausted and hyped listening to that and hearing about how much science goes into this. But I guess we should turn to how this administration is changing that review process, what we're really trying to get at today. So there's three main changes that I want to make sure we have time to talk about with you, which is the accelerating the process or speeding it up, changes to the advisory panels, and then limiting the science that EPA can consider. Since you just gave us a great explanation on how thorough and extensive this review process is, can you tell us a bit about what the Trump administration has managed to do to try to speed up this process?

Gretchen: The administration has sped up the NAAQS process, and as we just discussed it, it is a very long process. It requires a lot of layers of review and comment and revised drafts. And that's proven inconvenient to this administration since they want to get these done by 2020 they've said. So then-administrator Pruitt did a back to basics memo where he outlined the ways they were going to try to speed up this process, and the EPA has been attempting to follow that.

So all of those layers of documents and drafts that we just discussed have been condensed. And so far on the particulate matter and ozone standards, it seems they're following this. So we've only seen one draft of the integrated science assessment. So the administration, the EPA has not even provided a draft that takes into account all of the public comments and all of the comments from the science advisors on the science, despite not even getting a second draft that has the revisions and requests for more information that the science advisors asked for. They are still being asked to deliberate on the policy.

So they've already had a meeting to discuss the policy assessment. The policy assessment they combined with the risk and exposure assessment. So we've also only seen one draft of that document. So they have not seen any revisions or been anything that it's responsive to questions or concerns they raised on that, and yet they've already got a draft letter making recommendations to the administrator about the particulate matter standards and they're discussing that letter at a December meeting.

So we're really seeing a tremendous acceleration of the particulate matter process. There's been very little time for discussion or anything that would be considered a review of the science and having that feed into policy. So as a result, the committee's not going off of too much, but they are being asked to do this on a very accelerated timeline. And if you think about how large these documents are and how much diversity of expertise they require, it would be a challenging job for any seven people. And we're seeing committee changes that make it even harder.

Laura: Right. Okay. Maybe we should talk about those committee changes.

Gretchen: They go sort of hand in hand.

Laura: Give a brief overview of what the CASAC is and maybe the PM review panel as an example to talk about why those two roles are important and how they worked together.

Gretchen: So the Clean Air Scientific Advisory Committee reviews the standards. Typically, they would do this with an external pollutant review panel. So we'd augment the seven-member CASAC with another 20 or 30 experts that have expertise in that particular pollutant. That's always worked really well to make sure that you get this robust set of experts to review all of the different kinds of science that feed into the standards. But the pollutant review panel is not legally required and a year ago October, the administration cut off that panel for the particulate matter of review. They said we don't need those extra experts, CASAC is covered, they can do it themselves. So that left seven people to do the entire particulate matter review and so that would be challenging for any set of experts but they also switched up the composition of CASAC. So those seven people now include, the majority of them come from regulatory agencies at the state level, so that's a particular kind of expertise. There's only one remaining member who has an academic affiliation and who is regularly publishing in the scientific literature.

Gretchen: So that leaves a big gap in the kind of expertise that is needed to review particulate matter or any review on any pollutant. So we're left with just these seven people that have been tasked with doing the entire particulate matter review. The broader scientific community and public comments have expressed concern about this and raised that in public comments. Administrator Wheeler has been questioned about it directly in Congress and he's continued to say that CASAC can do it on its own. This is notable,

especially given that CASAC itself has said that they do not have the adequate expertise to conduct this review. They said that in an official letter they issued last March and they've continued to say it. It's been remarkable to see that the administration has completely ignored that. They've just expected the committee to push forward without the expertise.

In September, they did convene a pool of consultants to help with the review. So this was sort of what I would consider their sort of too little too late solution, in quotes, for this problem, where they got a pool of consultants to help with the review. The pool of consultants is a far cry from the way the particulate matter review panel would have engaged in the review process. They're only being tapped to provide input in writing in advance of the CASAC meeting. Whereas the panel would have gone along the process with the CASAC. They would have been at the meetings, they would have reviewed the documents and been present for a public discussion of the science. But instead, this pool of consultants, which does not have the same expertise that the panel would have had, has simply been asked questions in writing and they've responded, but they can't weigh in on any issue they weren't directly asked by CASAC. So as a result, it's largely been just the seven-member CASAC that's been alone trying to do this monstrous review of particulate matter.

Laura: So it sounds like a handful of changes. The first that you mentioned was that CASAC got reconfigured. There's still seven members, but they're not from the same expertise they used to have and many of them aren't independent researchers. Then the second is that they disbanded these auxiliary panels, so took away tons of additional expertise and instead replaced them with a group of consultants that CASAC could just go to with specific questions rather than actually engaging in this public process that has the accountability that we talked about at the beginning as really being essential to keeping the NAAQS protective of human health and responsive to the science. Is that right?

Gretchen: Yeah, that's right. I'll just add one specific example of why it's a problem with the pool of consultants is one gaping research area that CASAC does not have covered is epidemiology, which on the particulate matter review is a very essential part of setting the standards. CASAC doesn't have an epidemiologist and the panel has several. So before they nixed that, they would have had a few epidemiologists, but instead they replaced it with a pool of consultants which does not have the same power of epidemiology in terms of who the people are. So they've continued to have this large gap in a very much needed expertise.

Laura: Yeah. Seems pretty essential to have an epidemiologist on a public health-based clean air science advisory committee.

Gretchen: You'd think.

Laura: You would think. I guess it's also worth noting that the start of all these changes, if I'm not incorrect, was a memo where then Administrator Pruitt redefined what conflict of interest meant.

Gretchen: Yes. That's a good point. We should start there. So in 2017, then Administrator Pruitt decided that if you had an EPA grant that you could not serve on a advisory committee to the EPA, that that was a conflict of interest. At the same time, it was not considered a conflict of interest if you worked directly for a regulated industry, and this is very nonsensical from a scientific perspective. EPA grants are on all kinds of things. They are not tied to the standard directly in any way and as is, there's already a very good system of dealing with conflicts of interest around science advice to the EPA. People are asked to recuse themselves from discussion of their own research. They have to go through an ethics review by the EPA before they can even be put on a panel. EPA largely has addressed any concerns around conflict of interest and it's of course ridiculous that you wouldn't consider working for a regulated industry a conflict and yet would consider having an EPA grant a conflict.

So as a result, there were several scientists who at that time had to make a decision, "Do I want to give up my grant to be on this EPA committee or panel or do I want to say, 'No, thank you, I'd rather not inform the nation's air pollution standards.'" There were scientists that chose both of those options, which is just a very unfortunate position for them to have been in.

Laura: That is ... I really hadn't thought about that. That is really hard. But actually it's a nice segue to asking about how incredible some of these former panel members have then even though they have now lost their job. So it turns out scientists are dedicated to helping save our air.

Gretchen: They are.

Laura: You guys are great. Through the help of UCS, the PM independent panel did convene. Can you tell us a bit about that and what their conclusion was?

Gretchen: That's right. So we hosted the now independent particulate matter review panel to conduct the review that they would have done with CASAC if the administration hadn't disbanded them last October a year ago. This was completely unprecedented because never before had a pollutant review panel been disbanded and so of course they've never convened anyway despite their disbanding. This was a really incredible event that we had scientists who volunteered their time and a tremendous amount of work to inform the standards even though they were not doing that in an official capacity. The EPA had said they didn't need them and they weren't being asked to serve, but yet they chose to do this anyway to inform the standard and to make sure that robust science advice got into the standard even if EPA didn't want it there and even if it wasn't being done in an official capacity.

They had been writing and providing oral comments on the meetings of CASAC in any way informing them. Then that culminated in October where they did an in-person meeting and reviewed the policy assessment and made recommendations to the administrator in the same way that they would have if they hadn't been beaned. We got 20 out of 24 of the original panel members that had been disbanded and so it was really a remarkable group that we were able to get all of them to dedicate this time to conduct this review. We tried to mimic the way EPA would have done it the best that we possibly could. It was led by Christopher Frey, who's a professor at North Carolina State University. He had run, been the chair of CASAC in the past and so he knew how to run the meeting, took public comments the way that EPA would have, both written and oral options. We livestreamed the whole thing so that anyone could watch the meeting.

The panel, as a result of that process, has already done what is taking CASAC a lot longer to complete, which is they already provided comments on the policy assessment and have developed a final letter to the administrator that says, "Based on our review of the science and policy elements, we think the standard should be set at this level." They did that the best they could with the information they had and so now, even though they weren't doing it in an official capacity, we have that as a line in the sand that this is what an independent group of top scientists have said about where the standards should be.

Importantly, on the health-based standard, they found that the current particulate matters standards are not adequate to protect public health. That's an important finding and we should ask if CASAC or the administration come to a different conclusion why that is. Why do they disagree with an independent panel that has more expertise than you do? So far, it looks like we're going to have to ask that question because the draft letter from CASAC so far has said that the current standards are adequate and that is not what the independent panel has said. So we're already seeing this discrepancy between what the administration and CASAC are doing and what an independent is doing. So we intend to continue to hold their feet to the fire with this independent panel's conclusions because knowing what they have said, I think there should be a scientific justification from CASAC for why they would disagree with this panel.

Laura: How is CASAC and the panel looking at the science differently? Maybe there isn't a basic explanation but if there is, what is the difference in how they reach the conclusion, CASAC saying that the status quo is okay and the panel saying that we need to make those standards more stringent.

Gretchen: That's a good question and I wish we could get them all in the same room to have the conversation.

Laura: Good point.

Gretchen: Which is of course what they would have done, right? They would have had this really robust discussion of do you like the evidence in this study? What do you think about this

one? You know, what's sort of more reliable? We didn't get to have that because the administration hasn't allowed us to do it. I mean, I'd say in the October CASAC meeting, the discussion was much more basic than the panel. Having sat through both entire meetings, I can say it was just a very different conversation in terms of the level of detail they went into. And so we didn't really get a lot of the same kind of information out of the CASAC meeting because they didn't do things that the panel did, like discuss individual studies and look at the causality findings and look at the different epidemiology studies and decide what the merits of each were and what they felt like the interpretation should be.

I think at, at sort of a high level, what we know is that CASAC chair, Tony Cox, is not a big believer in epidemiology as a field. He has questions about what evidence comes out of epidemiologic studies, and in particular, he's very focused on what we call causality studies or accountability studies. These are studies that try to get at what health response you see from a particular change in pollution level where you can really try to pinpoint what exactly the effect is. It's very challenging to get these studies because we can't expose large groups of people intentionally to harmful levels of pollution. There's ethical and also just physical challenges to how to do that.

The way that we do get some of those studies is from exceptional events, so times where we were looking at the same population, but the pollution level suddenly change. One common one is Olympic studies, so times where a city is hosting the Olympics, they shut down many air pollution sources in the area so we can look at what is a similar population that changes their exposure in a short time. You get them, some from a factory shutdowns, so in places where much of the air pollution was from a single source and that source shuts down. There's other methodologies you can try to get at it in different ways, but it's a little bit harder and there's also some limitations to those kinds of studies because it's often one-time events or things that you can't control. You can't control if there were other confounding factors that might be attributed to different changes in health outcomes you see.

Gretchen: So there's a lot of challenges. They are very useful to tell us a little bit more about what we know, but the CASAC chair wants to focus on these as the sole marker of whether or not you should tighten standard. So given the limited amount of information that we have, because these are harder studies to conduct, he doesn't think the other kinds of evidence that we have that suggests tightening the standard is adequate, to say that the current standard is inadequate.

The panel felt differently. They looked at all of the different kinds of evidence. They looked at all of the epidemiology studies, several of which observed health effects, but even below the current standard. So they looked at pollution levels below the current standard and we're still able to observe health effects, even controlling for many other confounding factors that they would typically look at in an epidemiologic study. They looked at that weight of the evidence and said, think that it warrants lowering the

standard. CASAC, they didn't get as much into the weeds, but they have said they don't feel that's enough new evidence to say we should lower the standard.

Laura: So some of it goes back to the accelerating the process even in the way in which you're doing the scientific review is also less in the weeds and more top line and then reaching different conclusions because of that.

Gretchen: Right.

Laura: So that's a lot about particulate matter, but EPA is also working on ozone and recently put out the policy assessment. Can you tell us a few of the key takeaways from that assessment?

Gretchen: Sure. So the EPA just put out the policy assessment for ozone, which is the other active NAAQS review happening right now. It's a little further behind than the particulate matter panel or particulate matter NAAQS is, but it's still moving along on this accelerated timeframe. They just released the policy assessment for ozone and that suggested that the standard stay the same. It looked at all the evidence that we've collected since the last review, which was completed in 2015, and the EPA has recommended that we keep those standards the same. CASAC will be reviewing that document as well as the integrated science assessment for ozone at a meeting in December.

One important note about the ozone process that is different from the way the PM process has gone is that CASAC's going to be discussing both the science document and the policy document at the same meeting in December. This is not how it typically works. You want to discuss the science and get a finalized science document before you are being asked to deliberate and finalize a policy assessment review. But EPA, since they're trying to condense this process so much and don't have a lot of time given their self-imposed arbitrary deadlines, then what we're seeing is they're going to review both of them at the same time. So we'll see how CASAC that can do this. This is sort of a challenge because they're going to be talking about the science, deciding whether the document's an adequate review of the science and then they have to immediately then talk about what the policy should be. But it's sort of a, it's an awkward thing because normally they would be able to talk about the science, they would ask EPA questions, EPA would be able to give them a revised draft, provide any additional information that they request about the science and its interpretation. But now they won't have time to do that so they're going to have to scramble and just try to do it all in one. So it'll be interesting.

Laura: It's startling to think about trying to create a policy without getting answers to questions on the science.

Gretchen: And it is and we saw that even when in their particular matter letter or the recommendations that they just released, they acknowledged that and said, "Well, we only are basing this off of this draft document and we haven't seen any responses or edits based on our review. But you know, given that, I guess this is what we would say." So they're going to be in the same position now for ozone, where they don't have that time for that thorough review.

Laura: So because EPA isn't taking the time to answer these questions, it sounds like they're hamstringing CASAC in another way by making them come out with these new drafts or conclusions without actually giving them any of the help that they need to do their job.

Gretchen: They're really stuck between a rock and a hard place. They're just in a very tough spot because they're just being asked to do this even though they don't have any help and I mean this would be an accelerated timeline even if you had the panel and a CASAC that was comprised of people that have done this for decades. It's very accelerated. At the October meeting I told them in my public comments that they should just not do it. They should at the very least demand to get a second draft of the science assessment before being asked to deliberate on the policy because even if they wanted to do a good job, they're not really given the tools to do that.

Laura: I'm sure I know the answer to this, but just to confirm, is this unprecedented? Has something like this happened before?

Gretchen: It has not happened before. This is lightning speed compared to how quickly this usually goes and they're doing it with less people and those people are less experienced.

Laura: And so that leaves us with what's next. It sounds like what we should be looking for is this final letter to the administration from CASAC on the particulate matter recommendations and the December meeting for ozone, but are there other big events that we should keep an eye out for it towards the end of the year?

Gretchen: Those are the things that are up and coming directly related to NAAQS. There's other ongoing things at the EPA that might affect this work of course, but those are the next steps and we'll see what they can do. They've said they want to get this completed by the end of 2020, that leaves them not too much time to go through the rest of the process of having a draft rule, taking comments on that rule, responding to all the comments on the draft rule and issuing a final rule. So we'll see how far they're able to get on both particulate matter and ozone

Laura: Speaking of the other things the agency is doing, this week was also big for a leaked document of EPA's supplemental proposal for its transparency and regulatory science proposed rule that it put out last summer, or I guess summer 2018. Do you want to take a stab at telling us what this proposal is and what its impacts would be? I know that's a pretty big question.

Gretchen: Yeah, absolutely. So the EPA proposed this rule, this strengthening transparency rule, and it seems very innocuous. It purports to be about transparency and what it says is that if EPA wants to use any scientific study in its rulemaking, all of the underlying data must be public. And it sounds intuitive, it sounds like, "Sure, we'd want that." The problem is with doing that, you ignore many concerns and reasons that you cannot make data public. And so this includes health data, of course, where there's of ethical and legal reasons you cannot release health data simply because the EPA wants to see it. It runs into intellectual property concerns, confidential business information. And so there's lots of concerns about how that would play out and people express that. On the proposed rule there were 600,000 comments, the vast majority of which were opposed to the rule. Nearly any scientific authority you can think of has come out against it. The National Academies, many scientific societies and many individual scientists also commented as well. And so there's a lot of concerns about this rule.

Gretchen: To go back a little on the history of this concept, so it first was offered in the tobacco industry documents from the '90s where a tobacco industry lobbyist said, "In order to stave off regulation from secondhand smoke, let's focus on the process rather than the scientific substance because we can't possibly win on scientific substance." So they came up with this idea that they would demand that all of the underlying data be public, and that would be their strategy. And we saw it resurface again as a bill in the House a couple of years ago, led by representative Lamar Smith. So he had the HONEST Act and the Secret Science Reform Act, so he tried for several years to get a version of this passed in Congress and failed to do so. He then gave it to the EPA when the Trump administration came in and said, "You should try to do this as a rule because I couldn't get it through Congress." And we saw they did pick up that torch and made it a draft rule.

And so I say that all just to acknowledge that this was never about transparency, it was always about delaying inconvenient regulations. And we know that Lamar Smith in particular was very focused on the Harvard Six Cities study and wanting to get the underlying data from that study because he refers to this as secret EPA science, but we of course know that this is a peer-reviewed study, it has gone through the necessary checks within the scientific community to ensure it is a legitimate scientific study. It was re-analyzed in 2001 by the Health Effects Institute and this issue has been put to rest in the scientific realm, but certainly not in the political realm as it keeps resurfacing as it does in this rule.

Laura: And just in case, why is the Harvard Six Cities study so important? Why does Lamar Smith care so much about it?

Gretchen: So the Harvard Six Cities study was a landmark study that showed connection between particulate matter and early death, people dying prematurely from chronic exposure to particulate matter. It looked at six cities as the study's named and it followed people for years to look at what the impact of particulate matter exposure was on mortality. And

so this was an important study, it was not one that could be easily or quickly repeated because of the time and efforts involved to do that. And it was a very damning study if you are someone who does not want particulate matter to be controlled. And so it became this focal point of many opponents to air pollution protections just because of the findings were just so clear and it was very clear that we needed to strengthen particulate matter protections in order to protect people from early death.

Gretchen: That study has since been confirmed by many other studies that have also found similar things. It's been repeated on different populations, different parts of the world and so it's very clear that these results are real, yet the focus continues to be on this single study. You of course cannot release health data from this study and many other studies because of concerns about confidentiality, personally identifying information, as well as legal reasons, for when scientists choose to do studies, they sign agreements about if and how they will share that data and so this doesn't make sense in many ways.

One important fundamental thing when we are talking about studying environmental pollutants is that you inherently have to study two important things: you need health information about health effects that people are experiencing and you need location because you need to know where those people are in time and space in order to get some sort of estimate of what pollutants they're exposed to. And so many study designs rely on those two key parameters, which is great in that it allows us to observe what people are exposed to and what health effects are of that exposure, but it means that there are inherent challenges to releasing that data because that is personally identifying if we know people's health effects and we know their location.

And so that's one fundamental challenge that makes this rule incompatible with looking at environmental pollutants, we have to just look at what is happening in the real world and try to determine from that what health effects we see from pollutants. And so this is the inherent challenge of doing that work and it is the reason that you cannot in many cases release all of the underlying raw data that goes into these studies.

But for purposes of scientific review and making sure that we do have a high quality of science that is getting published from these studies, scientists are able to look at studies and review them adequately without seeing that underlying sensitive data. Scientists in peer review will typically look at methodology, they'll look at the results data found, they know about the methods that were used to perform that scientific analysis, and that is often sufficient for scientists to judge the merit of scientific papers. And so there really isn't a reason for this rule, it's not needed within the scientific community where we already have systems in place that ensure a high quality of science gets published in peer-reviewed literature. And so this is clearly not needed from a scientific perspective, it is of interest by the people advocating for this role. It's of interest from a political perspective because it would allow outside groups to reanalyze work and that seems to be where the motivation for this is coming from.

Laura: So it sounds like, for the NAAQS specifically, this rule really would have a big impact based on how many epidemiological studies are important to that standard setting.

Gretchen: Yeah, it seems like it would, I mean there's many, many studies of course that go into NAAQS reviews, but many of the important studies that help us understand where to set the standard do rely on sensitive health data.

Laura: And I know there's been some debate about whether what was leaked this week will actually be the proposed supplemental rule that EPA puts out. But if it were, can you tell us a little bit about what the big differences are? How this new proposal is adding to the original one from last summer?

Gretchen: We got a lot more information from this new supplemental notice and as you said, if it is true, which they are claiming it's not the final, so it's hard to know. But if it is, it does shed a lot more light on what this proposal is and what it would do. The original proposal is fairly vague and it's not as clear what it does and doesn't do, but we got a lot more details out of the supplemental notice that suggested it'd be very problematic for a lot of ways. One of the key differences is that they've now clarified that this doesn't refer only to dose response models, but in fact all models, all data that underlies studies. So that's a huge expansion of the original rule.

Another new thing we learned in that the supplemental proposal is that it is really focused on re-analysis instead of on reproducibility and replicability. So in the original proposal and a lot of the discussion around it, it was claimed to be about ensuring science is reproducible and replicable. And so they were very concerned about this reproducibility crisis, so-called in science community, and this was to address that. That was one of the arguments they were making about this.

Laura: And reproducibility, that means using the same data or it means going back into the field for a different cohort of people or what have you and reproducing the results?

Gretchen: So reproducibility is if you started with the same data and redid it, would you get a similar result? And replicability is can it be repeated? So, different data, different other things. So, different location, different group, different methods, but can you repeat the same finding? And so these are bigger issues in science and we think about that in the scientific community of how do you make sure that we are doing science that can be reproduced and replicated by other scientists. And this is something the National Academies recently issued a report talking about this. And it is something that the scientific community works on. It is not, however, something that is going to be solved with a narrow EPA rule. There are conversations and issues that could be tackled in that space, we'd start with looking at funding sources, looking at incentives in academia, how do you encourage scientists to try to replicate results of others? And you could talk to scientific journals and work with them about what you could do. The National Academies had some suggestions in their recent report.

Gretchen: So there's lots of things you could do if that was the problem you wanted to tackle. That's not what this is doing at all. Instead, in the supplemental notice, what we're seeing or now understand from the supplemental is that it's not even worried about those things at all, it's only worried about re-analysis, where you use the exact same data, the exact same models and methods and see if you get the same result. So that's not looking at whether the science can be repeated and whether the findings are truly what we're observing in the environment, those broader scientific challenges, that's just checking to see if the authors made any math errors or there was any minor flaw with the original study. And so it's a very odd focus scientifically because no one is suggesting there's a crisis of math errors in scientific studies and that's not something that the EPA should be focused on. And so it just is telling about where the priorities are.

Because what this would do is then it would just allow anyone who wants to pick apart a study, they could just go in and try to nitpick the methods of it. And I don't think that's really solving a major problem that we see with scientific studies. And then I'll just add to that, EPA already does, to a very high degree, make sure they have the relevant data to inform their decision making. So one example of that is on the 2015 Ozone Standard, my scientific work from academia was used in the integrated science assessment for ozone, and EPA staff contacted me and asked me for the data that was behind a figure that was in a published paper I wrote. And so they asked me for the results data to make sure they had the data that they were looking for. So, they're already doing a very robust process to ensure they have the science behind what they're using for decisions, so this would just add an unnecessary layer. They didn't ask me for my raw data, they asked me for the results data, which is something that is reasonable and already EPA does.

Laura: Well, sounds like we have another thing to look forward to, to see what EPA ends up doing with the censored science rule. And I know we're close to wrapping up, but I'd be remiss if I didn't ask you one final question. I purposely saved the most important question in my mind for last and that is with all of these changes, with everything you've described to us in this podcast, how will this matter for communities and for people out there breathing our air and going about their everyday lives?

Gretchen: I think this stands to have a tremendous impact on people. EPA has for decades followed this robust science-based process to ensure that the public is protected from air pollution and we're seeing the administration dismantle that in every way they can think of and I think that's going to have consequences on people's health. If standards get weakened, if the standards fail to be tightened, when the science say that they should be, the air's certainly not going to get cleaner and it might get dirtier. And that's especially true under climate change where we know that increased heat and other factors increase some kinds of pollution like ozone. So I think this will have negative consequences on people's health.

Gretchen: I think this is especially true for environmental justice communities and those who are disproportionately exposed to certain air pollutants. The broader population is mostly protected by the NAAQS and as long as those don't get significantly walked back, hopefully we would see at least maintained levels of air pollution and health effects. But environmental justice communities are often reliant on EPA ability to do risk assessments and protect them from hazardous air pollutants and others where EPA needs to be able to do risk assessments that rely on confidential health data. And if EPA isn't able to do those assessments or they aren't able to do them the way that scientists judge that they should do them, as opposed to decision makers, non-scientists, interfering in what models scientists choose to use to estimate what the health harms are of pollutants, then we're going to see consequences for those communities. They're not going to necessarily even know whether or not they're exposed to a harmful pollutant.

And that means if EPA can't even detect that and do the analysis that would find those things, then we can't have a hope of protecting them because it won't kick in all of the policy processes that would help ensure that there's mechanisms for them to be protected by them for industry emissions to be cinched down. So I'm most concerned for how this will affect those fenceline communities.

Laura: Well, thank you so much, Gretchen, for all of the work that you're doing to help continue protecting those communities and for taking the time to talk with us today. Really, really appreciate it.

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