Exhibit 618

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
NO. 7:23-CV-897

IN RE:)
)
CAMP LEJEUNE WATER LITIGATION)
)
)
This Document Relates to:)
ALL CASES)
_____)

VIDEOTAPED DEPOSITION OF
LISA A. BAILEY, PH.D.,

a witness herein, called by the Plaintiffs for examination, taken by and before Ann Medis, RPR, CLR, CSR-WA, and Notary Public in and for the Commonwealth of Pennsylvania, via Zoom Videoconference, at Keller Postman, 1101 Connecticut Avenue, NW, Suite 1100, Washington, DC 20036, on Wednesday, July 9, 2025, commencing at 9:31 a.m.

A P P E A R A N C E S

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Also present

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P R O C E E D I N G S

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THE VIDEOGRAPHER: We are now on the record. My name is David Campbell. I'm a videographer for Golkow, a Veritex Division. Today's date is July 9, 2025, and the time on the video monitor is 9:31 a.m. This deposition is being held at 1101 Connecticut Avenue, Northwest, Suite 1100, Washington, D.C. 20036. This is in the matter of in-house enhanced re Camp Lejeune water litigation this is in the United States District Court for the District of North Carolina Southern Division. The deponent today is Lisa Bailey.

The court reporter is Ann Medis, also with Golkow. Counsel, will you please identify yourselves for the record after which the reporter will please swear in the witness.

MR. SNIDOW: J.J. Snidow on behalf of the PLG.

MR. MICELI: David Miceli appearing by Zoom on behalf of PLG.

MR. MANDELL: Zac Mandell for PLG.

MR. SHERMAN: Dean Sherman. I'm a summer associate with Keller Postman.

MS. GRAVES: Raleigh Graves, litigation assistant.

MS. ELLISON: Anna Ellison on behalf of the United States.

MS. SILVERSTEIN: Kailey Silverstein on behalf of the United States.

MS. PLATT: Elizabeth Platt on behalf of the United States.

LISA A. BAILEY, PH.D.,

having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. SNIDOW:

Q. Good morning, Dr. Bailey. Like I said, I'm J.J. Snidow. I think you understand that I represent the plaintiffs in this case.

A. Yes.

Q. Now, I'm not going to mark them all, but for the record am I correct you prepared 25 different reports in this case?

A. Correct.

Q. And that's five for each of the diseases; true?

A. Correct.

Q. So bladder cancer, kidney cancer,

leukemia, non-Hodgkin's lymphoma and Parkinson's disease?

A. Yes.

Q. And five each?

A. Right.

Q. Am I correct that all the opinions that you intend to offer in each of those cases is contained in those reports?

A. Yes.

Q. Am I correct those reports contain all the literature that you relied on?

A. Correct.

Q. So if I look at the materials considered list, I'll see every piece of scientific evidence that you relied on; is that true?

A. Correct.

Q. If I look in your report, I'll see the full scope of the opinions; true?

A. Correct.

Q. Am I correct that in those reports, you try to give an accurate account of the methodology that you used?

A. Yes.

Q. No steps that you took that are not in those reports; true?

A. Correct.

MS. ELLISON: Objection. Form.

BY MR. SNIDOW:

Q. Having reviewed all the evidence, the science and the plaintiff-specific materials, is there any Camp Lejeune plaintiff who you believe experienced an increased risk of getting any disease?

A. Based on my evaluation of the exposure information for each of the plaintiffs and the methodology in my report, I don't believe the exposures were high enough for any of the plaintiffs to be of concern for health effects.

Q. You say of concern. Was there any increased risk for any of the plaintiffs?

MS. ELLISON: Objection. Form.

THE WITNESS: In terms of the calculation, I calculated risks based on exposure, individual exposure information. And the risks fell within EPA's acceptable risk range or below for each of the plaintiffs.

BY MR. SNIDOW:

Q. You did those risk assessments individually; correct?

A. Correct.

Q. Have you ever seen a published risk assessment done on an individual?

A. So site risk assessments and risk assessments that are done for communities are done on the community. They're done on a population.

You can use similar methodology for individuals. It's commonly done, particularly in specific causation analyses. You would want to use a similar approach using similar regulatory toxicity values, but with individual exposure information, which is what I did in my report.

Q. Let me break that down. It sounds like you have seen in the published literature that people use risk assessments to evaluate the risk to a population; true?

MS. ELLISON: Objection. Form.

THE WITNESS: Can you repeat the question?

BY MR. SNIDOW:

Q. Sure. In the published literature, people sometimes do a risk assessment for a population; correct?

MS. ELLISON: Same objection.

THE WITNESS: I have seen in published literature risk assessments for populations, yes.

BY MR. SNIDOW:

Q. In particular, even for Camp Lejeune, there's a published risk assessment for Camp Lejeune; true?

A. There is, yes.

Q. Sometimes they do it for particular communities; is that fair?

A. Yes.

Q. You've seen that published in the literature; correct?

A. I have.

Q. I understand you're saying that you've seen risk assessments done for an individual in litigation; true?

A. Correct.

Q. Have you ever seen a risk assessment done for an individual in the published scientific literature?

MS. ELLISON: Objection. Form.

THE WITNESS: I don't recall seeing it in published literature. That doesn't mean it's not a reasonable approach for a specific causation.

BY MR. SNIDOW:

Q. I understand. Sitting here today, in no

way in your report do you cite any literature where a scientist has conducted a risk assessment for an individual; true?

MS. ELLISON: Same objection.

THE WITNESS: I am not aware of something in the published literature. It's possible that there is. But, again, it doesn't mean it's not appropriate for a specific causation.

BY MR. SNIDOW:

Q. Have you ever read the text of the Camp Lejeune Justice Act?

A. I have not read the text.

Q. In preparing your report, were you ever instructed to use the standard from that text?

MS. ELLISON: Objection. Foundation.

THE WITNESS: I was asked to do a risk evaluation, evaluate the exposure information for each of the plaintiffs. That's what I did.

BY MR. SNIDOW:

Q. Were you ever asked to determine whether it was at least as likely as not that the chemicals contributed to the plaintiffs' injuries?

MS. ELLISON: Same objection.

THE WITNESS: I was not asked to do that

specifically. I was asked to evaluate potential exposures and potential risks for plaintiffs.

BY MR. SNIDOW:

Q. Excuse me, Dr. Bailey. I'm not trying to cut you off.

In your reports, am I correct you do not apply the as likely as not standard?

MS. ELLISON: Same objection.

THE WITNESS: That's not a term that I use in my reports.

BY MR. SNIDOW:

Q. Do you agree that the Camp Lejeune site has been remediated?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: That is not something that I evaluated for my report.

BY MR. SNIDOW:

Q. I understand. But you've seen reference to the cleanup at Camp Lejeune; correct?

A. That's not something that I looked at for my report. It wasn't relevant to my report, so I did not look at that.

Q. Do you agree that remediation was appropriate given the concentration of chemicals

present at Camp Lejeune?

MS. ELLISON: Objection. Foundation.

THE WITNESS: I didn't specifically look at the site as a whole in the context of remediation. I was looking at individual exposures to the contamination at the time. So I didn't look at the site in terms of whether it should be cleaned up or not.

BY MR. SNIDOW:

Q. You know one purpose of risk assessment is to determine when remediation is appropriate?

A. Yes. That is one use of risk assessment.

Q. You calculated that the risks to the Camp Lejeune population were below acceptable levels; true?

A. They were within the acceptable range or below for cancer risk, yes.

Q. So in your view, remediation was not necessary given the risks involved?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: Again, that's not something that I looked at for my report. I looked at individual exposure information and

potential risks that would be calculated using EPA's standard methodology for individual exposures. I was not looking at it as a population. That's something that you would want to consider at a population level for cleanup. It was not what I did.

BY MR. SNIDOW:

Q. What is the background risk rate for kidney cancer?

A. I have that in my report, but I have to look at my report to tell you what it is. I don't have it, off the top of my head.

(Bailey Exhibit 1 was marked.)

BY MR. SNIDOW:

Q. I'm going to mark as Exhibit 1 your report for Terry Dyer. Here's your report for Terry Dyer.

MR. SNIDOW: By agreement, one of these for counsel.

MS. ELLISON: Thank you.

MR. SNIDOW: You're welcome.

BY MR. SNIDOW:

Q. Am I correct that this is a report that you prepared for one of the plaintiffs in the Camp Lejeune litigation?

A. Correct.
Q. And this is for bladder cancer?
A. This is for bladder cancer.
Q. Do you know what the background risk rate for bladder cancer is?
A. It's in my report, and I will find it. Slightly less than one in two for men, slightly more than one in three for women.
Q. Your testimony is that the risk of getting bladder cancer --
A. Sorry. I correct myself there. That is on total cancer.
Q. Yes.
A. Let me see. For bladder cancer, it's 3.6 percent for men, 1.1 percent for women.
Q. What page is that on?
A. Page 16.
Q. Then you go on to report the background cancer risk for all individuals at 40 percent; correct?
A. Correct. That is the average background cancer risk for all cancers combined.
Q. Just to be clear, that's not the risk of developing one of the particular cancers at issue. It's the risk of developing cancer generally;

correct?

A. Correct.

Q. Did you review any human epidemiology yourself?

A. Yes, I did.

Q. Let me distinguish a couple of things. You're aware there were a series of studies done looking at Camp Lejeune in particular?

A. Yes.

Q. The Bove series?

A. Yes.

Q. Then there are studies that underpin some of the risk assessments; is that fair?

A. That's correct.

Q. The Charbotel study, for example?

A. Correct.

Q. I understand in your report you discuss the Charbotel study; true?

A. Not in this report.

Q. In the kidney cancer.

A. Yeah, in the kidney cancer report.

Q. But you don't discuss the series of studies done on Camp Lejeune; true?

A. I do not discuss those in my report, correct, only in the context of what Dr. Goodman

says in general about those studies.
Q. That was going to be my question.
In your report, you don't have any opinions on the Camp Lejeune epidemiology; true?
A. I don't have opinions written in my report about the Camp Lejeune epidemiology.
Q. For that you're relying entirely on Dr. Goodman?
A. I'm relying on Dr. Goodman's methodology, yes. I'm relying on her conclusions for those studies.
Q. You're also aware that there is epidemiology not underpinning the risk assessment, not Camp Lejeune, but looking at water contamination events at different parts of the country; correct?
A. I'm aware of those, yes.
Q. You don't have any opinions on those types of studies, do you?
A. Only in the context of some of my discussions about some of those studies and the rebuttals of the plaintiffs' experts.
Q. In your rebuttal, I think you again rely on Dr. Goodman; correct?
A. I generally rely on Dr. Goodman;

correct. If there is something more specific about the study that is important for exposure and risk, I do -- I have looked at it in that context.

Q. Did you review the Camp Lejeune water modeling?

A. I reviewed the expert reports of the Camp Lejeune water modeling experts.

Q. Such as Dr. Maslia?

A. I looked at the expert reports of Spilotopoulos and Dr. Hennet.

Q. Did you review the underlying water modeling done by ATSDR?

A. I did not review the details of the modeling. I'm aware of the modeling, but I did not review the details of the modeling. It was not what I was asked to do.

Q. Understood. That's what I'm trying to get at. When you say you reviewed the details, did you actually look at the ATSDR water modeling?

A. I looked at the water modeling results, yes.

Q. You did? You're not offering any opinions on the integrity of that water modeling; true?

A. I did not do an evaluation of that

modeling, but I did review the opinions of Dr. Spilotopoulos and Hennet who did review based on that modeling.

Q. Of course. My only point is you, yourself, are not offering any independent opinions about the integrity of that water modeling?

A. I did not review the water modeling, so I'm not offering that opinion. That was not what I was asked to do.

Q. To be fair, you're not an expert in water modeling?

A. Correct.

Q. Do you agree that risk assessment is ultimately based on results from either human epidemiology or animal studies?

A. The toxicity values that EPA uses are typically, yes, based on human or animal studies.

Q. In general, it's preferable to use the human epidemiology when you have it; true?

A. I would not say that that's true. It depends on the quality of the studies. EPA does a lot of evaluation of those animal and epidemiology studies and based on that information determines whether the animal study is the best to derive a

toxicity value or a human study. And there are a number of factors that go into that decision.

Q. All else equal in terms of study quality, agree you should use human epidemiology?

A. That's a hypothetical question. So I can't answer that just generally. And I think it would be very difficult to say they're equal in quality. They're very different studies. So I don't think that is ever something that comes up. I think all of the information needs to be integrated.

Q. So you think there are times when you should rely on the animal studies rather than the human subjects?

MS. ELLISON: Objection. Form. Foundation.

THE WITNESS: I'm saying that that's what EPA has done. They sometimes rely on the animal studies if -- based on a number of factors and interpreting epidemiology data with the animal data.

BY MR. SNIDOW:

Q. Do you agree that risk assessment is not an exact science?

A. Risk assessment is an estimate of -- a

conservative estimate of potential adverse health effects based on exposure information. So it's not an exact science, but it is -- because of that, it's very conservative.

Q. You say it's very conservative. Do you agree that risk assessments can sometimes underestimate the risk?

A. In general, EPA risk assessments do not underestimate risk. They typically overestimate risk based on conservative exposure assumptions and conservative assumptions about the toxicity chemical.

Q. I hear you on "in general." But you agree it is possible for risk assessments to underestimate the risk; true?

A. Again, that's a hypothetical. I would need to look at the specific risk assessment, the specific chemical and say whether I think this might be underestimating risk. I have not seen a situation where I thought the risk result was underestimating risk.

Q. How do you know what the real risk is?

MS. ELLISON: Objection. Form.

THE WITNESS: Well, what I do know is that the exposure information is often estimated

to be a very high estimate of possible exposure information. The exposure parameters are typically conservative. So you're assuming people are spending a lifetime at the site, drinking a large amount of water daily, maybe spending the entire time in their home, things that would be overly protective so that you're not missing a possible risk.

BY MR. SNIDOW:

Q. You agree epidemiology studies the distribution and occurrence of diseases across populations?

A. Yes. That's typically what epidemiology is.

Q. Risk assessment is distinct from epidemiology; correct?

A. Risk assessment is different from epidemiology, but it uses epidemiology.

Q. Of course. But it's a different discipline?

A. They're related.

Q. In your report, you discuss various reference values, like cancer slopes and inhalation risks; correct?

A. Correct.

Q. Do you agree that those reference values cannot give you an estimate of causation?

MS. ELLISON: Objection. Form. Foundation.

THE WITNESS: So those risk values can provide a good sense of whether the exposures are high or low relative to what EPA considers acceptable. So in that sense, they can be very helpful for a specific causation.

BY MR. SNIDOW:

Q. Let me give a statement. You can tell me if you agree or disagree.

Do you agree reference values have no place in the estimate of causation?

MS. ELLISON: Objection to the form.

THE WITNESS: I don't agree with that.

BY MR. SNIDOW:

Q. Do you agree that risk assessment is not a causation analysis at all?

MS. ELLISON: Object to the form.

THE WITNESS: I agree that there is a place for risk assessment in specific causation because it provides perspective about potential exposures for individuals.

BY MR. SNIDOW:

Q. Do you agree that risk assessment is not a causation analysis?

MS. ELLISON: Object to the form.

THE WITNESS: Risk assessments, risk calculations by themselves are not a causation analysis, but that's not what I did. That was one part of my evaluation.

BY MR. SNIDOW:

Q. Besides doing a risk assessment, what did you do to evaluate causation?

A. I looked at the margin of exposure, which is looking at the point of departure that is the basis of the toxicity values. So it's looking at -- essentially looking at epidemiology as the basis of the toxicity value.

If the toxicity value was not based on the health endpoint of concern, I also looked at epidemiology specific to that endpoint and compared those exposure estimates from those studies to the exposure estimate to the plaintiffs. So you need to do all of those things.

Q. Do you think that reference values can be used as estimators of risk?

A. Reference values can be used to provide -- to demonstrate whether exposures may be low or high relative to what EPA considers health protective.

Q. Let me ask it again. Do you agree that reference values -- well, strike that.

I'll ask it this way. Agree or disagree, reference values cannot be used as estimators of risk?

A. So EPA has risk values for cancer and they have reference values for noncancer. Noncancer is not typically described -- noncancer risks are technically not described as risks because they're not calculated that way. So it's a threshold. So it's a comparison value for reference values. But they can be used to determine whether potential exposures are high or low relative to that value, which is what EPA considers health protective.

Q. Agree or disagree, reference values cannot be used as estimators of causation?

MS. ELLISON: Objection. Form.

THE WITNESS: Reference values can be used as part of a causation analysis.

BY MR. SNIDOW:

Q. It sounds like you disagree with the statement I read.

MS. ELLISON: Objection. Form.

THE WITNESS: Can you read the statement again?

BY MR. SNIDOW:

Q. Sure. Reference values cannot be used as estimators of causation.

MS. ELLISON: Same objection.

THE WITNESS: Reference values can be used to provide perspective on causation.

BY MR. SNIDOW:

Q. Do you agree that EPA and ATSDR have stated that risk assessments can't be used to quantify the risk of cancer?

A. I need more context for that.

Q. Correct me if I'm wrong. I read your report to be using risk assessment to quantify the risk of cancer; true?

A. So I used risk assessment to provide perspective on the exposures for the individual plaintiffs and did a risk calculation based on individual exposure information and EPA's toxicity values. So in that context, they can be used.

Q. Right. But my question was: Is it your belief that risk assessment values can be used to quantify the risk of cancer?

A. So at a population level, those cancer risk values are used to estimate the probability that individuals in that population -- so if they're all exposed in the same way that you're -- whatever the exposure assumptions are for that calculation -- sorry.

Can you ask that question again?

Q. Can risk assessment values be used to quantify the risk of cancer?

A. So it can be used to provide a risk estimate. It's a theoretical estimation for a population based on everyone being exposed the same way, is what I was trying to say. So it's theoretical in the sense that it's based on very conservative exposure assumptions, considering sensitive individuals within the population.

So it can provide perspective within the population about whether that population may be at risk if it's above ten to the minus four or below ten to the minus six or within range. It's helpful.

Q. Do you consider yourself to be an expert

on cancer?

MS. ELLISON: Objection. Form.

THE WITNESS: My expertise is in human health risk assessment and toxicology where I do have to think about cancer studies and carcinogenic chemicals.

BY MR. SNIDOW:

Q. When you're speaking to scientists, do you hold yourself out as an expert in cancer?

A. In cancer risk assessment.

Q. You do?

A. Yes. In risk assessment, yes.

Q. And you've done that before. You've described yourself as an expert in cancer to other scientists?

A. In human health risk -- in the context of toxicology and human health risk assessment. So understanding potential mechanisms of carcinogenesis and evaluating risk.

Q. I truly understand that you do risk assessment. I'm just saying: Do you hold yourself out as an expert in cancer?

A. I think that's very general, so I can't really answer that.

Q. How about kidney cancer?

A. Again, that's very general. I can't answer that. There are lots of different areas that should be considered in terms of being an expert in cancer in general or kidney cancer in general.

Q. Have you ever told another expert that you're an expert in kidney cancer?

MS. ELLISON: Objection. Form.

THE WITNESS: I have not said that I'm an expert in kidney cancer, but I have said that I'm an expert in evaluating risk and exposure. And those risk assessments often consider chemicals that are carcinogenic and are -- some of them have been shown to cause kidney cancer. So in that context, yes.

BY MR. SNIDOW:

Q. You know what a nephrologist is; right?

A. Yes.

Q. It's a medical doctor which you're not; correct?

A. Correct.

Q. They specialize in kidney cancer; correct?

A. Correct.

Q. They are, of course, experts in kidney

cancer; correct?
A. Correct.
Q. That's not you; correct?
A. That's why I did not say that I was.
Q. The same for bladder cancer, have you ever described yourself as an expert in bladder cancer?
A. I'm not a medical doctor, so no.
Q. Leukemia?
A. I'm not a medical doctor, so I would not generally say that I'm an expert in leukemia. But in evaluating risk for chemicals that might cause leukemia, yes.
Q. And the same for NHL, right, you've never described yourself as an expert in non-Hodgkin's lymphoma?
A. That's correct. But I have done risk evaluations for chemicals that cause that.
Q. Of course. Have you ever described yourself as an expert in neurodevelopmental disorders?
A. I'm not a medical doctor, so, no, I'm not an expert in that field.
Q. Same for Parkinson's specifically; true?
A. Correct, but again, risk evaluations

where I'm looking at chemicals and exposure to those chemicals.

Q. Have you ever published any cancer epidemiology studies?

A. I have not published a cancer epidemiology study, no.

Q. Have you ever published any studies on biologic mechanisms underlying cancer?

A. I have authored some weight-of-evidence evaluations that consider mechanisms of cancer, yes.

Q. I understand. But you've never published, for example, an animal study on cancer?

A. I have not published an animal study, no.

Q. Have you ever been a primary investigator for an epi study?

A. I have not.

Q. How about for a clinical trial?

A. I have not.

Q. Ever served on an IARC advisory panel for a carcinogen?

A. I have not.

Q. EPA?

A. I have spoken with EPA about carcinogens

when they're evaluating -- deriving toxicity values. But I'm not on EPA panels.

Q. And never have been; correct?

A. I have not.

Q. Has any regulatory body asked you to evaluate a carcinogen on their behalf?

A. No.

MS. ELLISON: Object to the form.

THE WITNESS: I correct that. I have been. I did an evaluation for Health Canada on naphthalene in indoor air.

BY MR. SNIDOW:

Q. Have you ever published a paper on kidney cancer?

A. I don't believe I have.

Q. Bladder cancer?

A. I have not published a paper on bladder cancer.

Q. Leukemia?

A. I am an author on a formaldehyde paper that involves leukemia.

Q. Am I correct, in that paper, you determined that formaldehyde likely does not cause leukemia?

A. I would have look at the paper, but I

believe that the mechanisms -- I would have to look at the paper. It was a while ago.

Q. We might look at it later.

Have you published on NHL?

A. I have not.

Q. You have published on trichloroethylene; true?

A. I would have to look at my CV, but I don't believe I have a published paper on trichloroethylene.

Q. I thought it was produced to us, but it's okay.

Have you ever published on perchloroethylene?

A. As I sit here today, I don't recall that.

Q. Benzene?

A. I don't recall a publication on benzene.

Q. Vinyl chloride?

A. No, I have not.

Q. Have you ever published a Bradford Hill analysis?

MS. ELLISON: Object to the form.

THE WITNESS: I have considered Bradford Hill criteria in my evaluations, but I have not

published on Bradford Hill, no.
BY MR. SNIDOW:
Q. Have you ever employed the equipoise standard in one of your publications?
MS. ELLISON: Objection. Foundation.
THE WITNESS: As I sit here today, it's not something that I recall.
BY MR. SNIDOW:
Q. The government is, of course, compensating you for your expert work?
A. Correct.
Q. Have you totaled up the invoices that you sent?
A. I haven't added them up, no, but I have a sense of them.
Q. Maybe we can shortcut this. As far as I can tell, Gradient has billed the government about $1.7 million so far. Is that approximately correct?
A. That sounds correct.
Q. That's great. I'll just mark the invoices as Exhibit 2. For the record, this is a composite exhibit bearing a leading Bates-stamp of BAILEY_USA_SUBPOENA_1, and it is a collection of the invoices and government forms documenting the

contract agreement.

(Bailey Exhibit 2 was marked.)

BY MR. SNIDOW:

Q. Dr. Bailey, I'm not asking you to look at every single page. Can you just verify that this appears to be a collection in the back half of the invoices that Gradient sent to the government and the front half documentation produced by the government for Gradient's contracts?

A. Yes. This looks like our invoices.

Q. You can put that aside for now.

Did you discuss this case with any other experts or the government?

A. Yes. Yes, I did.

Q. Who?

A. I have talked to Dr. Judy LaKind.

Q. Was counsel present for those conversations?

A. Yes.

Q. Anyone else that you spoke to?

A. Not that I recall.

Q. Did you ever speak to Dr. Goodman?

A. I think early on for like logistics, but no, I did not talk to Dr. Goodman.

Q. Dr. Goodman works for your company; am I correct?

A. Correct.

Q. You're relying on her evaluation of the epidemiology; correct?

A. Yes.

Q. But you did not speak to her about it?

A. I did not.

Q. How many times did you speak to Dr. LaKind?

A. I don't know the exact number, but it was a handful of times.

Q. You're relying on Dr. LaKind's opinions about exposure for individual plaintiffs; true?

A. Correct.

Q. Did you take that from her reports, or is there anything in conversations that you relied upon?

MS. ELLISON: Just objection. Really quick, Dr. Bailey, don't discuss anything that was said between you and Dr. LaKind. That's privileged. So to the extent that your answer requires you to say anything about the substance of your discussions, I'll instruct you not to answer.

THE WITNESS: The question again, please?
BY MR. SNIDOW:
Q. In your report you're relying on exposure assessments performed by Dr. LaKind?
A. Correct.
Q. Did you get those exposure assessments from her reports or from conversations with Dr. LaKind or both?
MS. ELLISON: Same objection. I won't do it while you're in the middle of a question.
THE WITNESS: It was mostly about information about exposure transmitted to me from -- through DOJ that would be in her report so that we had that information early on to do a risk evaluation.
BY MR. SNIDOW:
Q. Understood. So fair to say it's not necessarily the numbers that are in her final report, but DOJ transmitted to you the numbers that eventually appeared there?
A. They are -- and if there was any updates, of course, they would. We made sure that everything was consistent in the final report.
Q. Were you asked to assume that

Dr. Goodman's analysis of the epidemiology is correct?

MS. ELLISON: Again, objection.

Dr. Bailey, to the extent that answering that question involves anything that you discussed with the attorneys, I'll instruct you not to answer.

MR. SNIDOW: I'll note just for the record I am allowed to ask her if she was directed to assume anything.

MS. ELLISON: Yes. If there are any assumptions that you relied on that we provided to you, you can answer, but limited to assumptions.

THE WITNESS: I was asked to rely on Dr. Goodman's report, but I did also review her methodology. And I agree with her methodology. I was comfortable relying on her report.

BY MR. SNIDOW:

Q. Who asked you to rely on her report?

A. DOJ in the process of doing my evaluation.

Q. What did you do to verify that her methodology was correct?

A. Well, I generally know what the methodology -- what one does in terms of doing

systematic review to determine whether the evidence supports a potential association between a certain chemical and a disease. I've been involved in those evaluations myself. So I'm familiar with the methodology, and it's consistent with what I would do.

Q. When you say "the methodology," are you talking about the weight-of-the-evidence methodology?

A. Yes.

Q. You agree that's a pretty broad methodology without a lot of rules to it; correct?

MS. ELLISON: Object to the form.

THE WITNESS: EPA does have a systematic review guidance, yes.

BY MR. SNIDOW:

Q. You didn't do a systematic review of the literature that Dr. Goodman reviewed, did you?

A. I did not do the systematic review, no. Dr. Goodman did.

Q. And you agree when doing a weight-of-the-evidence analysis, you definitely need to review all the evidence; true?

A. Correct.

Q. So how do you know that she got the

weight of the evidence correct?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: So I agree with her methodology. I don't have any reason to doubt that she looked at all of the available literature. Her reports were quite large and extensive and considered a lot of data, a lot of epidemiology, animal data, mechanistic data and the Camp Lejeune studies.

BY MR. SNIDOW:

Q. But in terms of the weight of the evidence, you did not, I assume, review all the evidence that Dr. Goodman reviewed?

A. Not to the extent that she did.

Q. I'll represent to you she has reports for each of the diseases.

Did you read every page of those reports?

A. I looked very carefully at those reports, particularly at the tables at the end.

Q. Not really my question. She's got five reports, hundreds of pages. Did you review every page?

MS. ELLISON: Object to the form.

THE WITNESS: I did not review every page, but I reviewed the key sections, the sections that I know were relevant to my analysis.

BY MR. SNIDOW:

Q. You agree when doing a weight-of-the-evidence analysis, you have to weigh evidence, some more strongly and some less strongly?

A. Correct.

Q. Do you agree you can't do that without actually reviewing evidence?

A. That's right. And that's what Dr. Goodman did. She reviewed the evidence.

Q. I understand. But how do you know that she weighed it correctly without reviewing it yourself?

A. Because I agree with Dr. Goodman's methodology, and I relied on her evaluation of those data. I don't have any reason to doubt her evaluation considering that she -- her methodology is consistent with what I would do and what I have done in other evaluations.

Q. Which is employ the weight-of-the-evidence approach?

A. Yes.

Q. Which involves some degree of scientific judgment. Wouldn't you agree?

A. Based on the evidence.

Q. Yes. And did you independently verify that you agreed with Dr. Goodman's judgment?

A. I did not independently verify. But again, I agree with her methodology. It was not what I was asked to do.

Q. How many times have you testified in depositions?

A. I believe seven.

Q. Have you ever testified at trial?

A. I have not.

Q. Obviously, this count -- well, there shouldn't be for deposition. What depositions have you given testimony in?

A. It's on my list of testimony, my testimony list, which I believe you have. So I'd have to look at that to list them all.

Q. Do you remember what the last one was, the most recent one?

A. The most recent one, can you give me the date for that one?

Q. Do you know approximately how many reports you've written for litigation?

A. I have been involved in many reports for litigation, some as the expert and some as support for other experts in my 25 years of my career.

Q. Do you think it's more than a hundred?

A. As I sit here today, I don't know, but it's possible.

Q. I was looking for a ballpark. Is a hundred a reasonable estimate?

A. I would say between 50 and a hundred, maybe not quite a hundred.

Q. How many times have you published an article on behalf of Gradient?

A. I would have to look at my CV to tell you how many publications I have while I was at Gradient.

Q. You've published with Dr. Goodman; correct?

A. I have, yes.

Q. That was done under the auspices of Gradient?

A. That was while I was at Gradient, yes.

Q. Let me put it a different way. You haven't published with Dr. Goodman in a situation where you were both academics, for example?

MS. ELLISON: Object to the form.

THE WITNESS: Correct.
BY MR. SNIDOW:
Q. Have you ever been -- has Gradient ever been paid for an article that you published?
A. Gradient has been compensated for my time to evaluate any of the science that's part of a publication.
Q. I think you've published that chrysotile asbestos doesn't cause mesothelioma or lung cancer; is that true?
A. I'd need to look at the publication that you're talking about.
(Bailey Exhibit 3 was marked.)
BY MR. SNIDOW:
Q. I'll show you a document we'll mark as Bailey Exhibit 3, which is a publication called "Electricians' Chrysotile Asbestos Exposure From Electrical Products and Risks of Mesothelioma and Lung Cancer."
Dr. Bailey, do you see this is a publication that you are one of the co-authors of?
A. Yes.
Q. So is Dr. Goodman?
A. Yes.
Q. And this was published in 2014?

A. Yes.
Q. That's when you were working -- one of the years when you were working at Gradient; true?
A. Yes.
Q. And if you go to page 13, and in the Conclusion section, last paragraph, it says, "We conclude that epidemiology studies reporting an increased risk of mesothelioma or lung cancer among electricians, the most likely cause of lung cancer is smoking, and the most likely cause of mesothelioma is exposure to amphibole asbestos as a result of renovation, demolition work or working in close proximity to other skilled craft." True?
A. That is what it says.
Q. Did you produce this paper as a result of compensation from an asbestos manufacturer?
A. I don't recall, so I'm going to read the conflict of interest here.
It looks like we did not. We were not compensated for this work. This was our own time, but some of the work was done in the context of litigation matters.
Q. By Dr. Goodman?
A. Dr. Goodman, yeah, that's what it says here.

Q. The work you're referring to, it appears Dr. Goodman was serving as an expert witness?
A. Yes.
Q. Do you know if that was in asbestos litigation?
A. I would imagine it is. I'm assuming it is just because this paper is about asbestos, and that's what it's talking about, but I don't know exactly what the litigation is that she's referring to here.
Q. You are aware that Dr. Goodman has served as an expert witness on behalf of asbestos manufacturers?
A. I don't know the clients that Dr. Goodman has testified on behalf of.
Q. You can put that to the side.
During your time at Gradient, you've done work on a manganese?
A. Yes.
Q. That work was done on behalf of the Manganese Interest Group?
A. Yes.
Q. Which I assume is a trade group for folks who mine manganese?
A. They have interest in the use of

manganese.

Q. Some of your work was regarding whether the manganese industry should be more regulated; true?

A. That's not how I would characterize it, no.

(Bailey Exhibit 4 was marked.)

BY MR. SNIDOW:

Q. I'm showing you Bailey Exhibit 4, which is an article called "Potential Implications of New Information Concerning Manganese Ohio Community Health Effects Studies."

That's your name at the top?

A. Yes.

Q. You're the author on this paper?

A. Yes.

Q. This was published in 2021?

A. Yep.

Q. This was when you were working at Gradient?

A. Correct.

Q. This paper Gradient was compensated for; true?

A. I believe this is with the manganese industry, yes.

Q. So you're publishing in the peer-reviewed literature, but the Manganese Interest Group is financing it; correct?

A. They are financing it, but, of course, it's still based on science.

Q. Of course. Then at the bottom of the abstract, do you see where it says, "These results are important, particularly in determining whether the study should influence regulatory reference values related to manganese." Correct?

A. Yes. For this particular paper that is what we did because there was concern that this study might be considered for derivation of a revised manganese reference value.

Q. The Manganese Interest Group didn't want that to be revised; correct?

A. The Manganese Interest Group wanted us to look at the science to see what the science supported for a manganese value.

Q. You in this paper actually gave the Manganese Interest Group the ability to comment on your manuscript.

A. That's what it says here, yes.

Q. Is that appropriate, do you think, to let an industry group comment on a peer-reviewed

publication?

MS. ELLISON: Object to the form.

THE WITNESS: I don't think it's inappropriate as long as my evaluation is consistent with the science, and that is always what I do. So as long as the comments are editorial in nature and not -- and don't conflict with my opinion based on the science, then I don't think it's inappropriate.

BY MR. SNIDOW:

Q. When you say "editorial in nature," do you mean you didn't receive substantive comments from the Manganese Interest Group?

A. Correct.

Q. You didn't?

A. Correct.

Q. Do you remember, what did they comment?

A. I don't remember, but I know that my evaluation is based on the science, and they did not influence my opinion based on the science.

Q. You've done work on naphthalene?

A. I have.

Q. And you argue that there's a threshold for naphthalene?

A. Yes. We have a paper on that.

Q. You argued it should not be considered a mutagenic carcinogen.

A. Naphthalene as a primary chemical is not mutagenetic. So that's correct.

Q. And you argued that it should not be considered a carcinogen in humans at all; true?

A. I would have to look at my paper, but I don't believe that that was our conclusion.

Q. You don't believe that was your conclusion?

A. I believe that we were looking at the data to determine what exposure information was available for naphthalene and what concentrations may result in cancer in animals based on naphthalene exposure and whether those concentrations were high compared to what occupational exposures are to naphthalene.

Q. You did this work on behalf of the Naphthalene Research Committee?

A. Correct.

Q. Which I assume is a trade group for the folks who deal with naphthalene?

A. Yes.

Q. They compensated Gradient for your work on that; right?

A. Yes.

(Bailey Exhibit 5 was marked.)

BY MR. SNIDOW:

Q. I'll show you Bailey Exhibit 5, an article called "Hypothesis-Based Weight-of-Evidence Evaluation and Risk Assessment for Naphthalene Carcinogenesis."

You're the first author on this; true?

A. Yes.

Q. Published in 2016; right?

A. Yes.

Q. This is when you were at Gradient; correct?

A. Yes.

MS. ELLISON: Can we get copies?

MR. SNIDOW: I'm sorry.

BY MR. SNIDOW:

Q. If you to page 37, there's a section called Discussion.

Do you see that?

A. Yes.

Q. And then do you see where the sentence begins, "Our evaluation of human relevance" -- I'm sorry. I said that so wrong.

Do you see where it says, "Our

evaluation of human relevance"?

A. On page 37?

Q. Yes.

A. Yes.

Q. It says, "Our evaluation of human relevance suggests that low naphthalene metabolism in human respiratory tissue is most consistent with little to no toxicity or carcinogenic risk at typical naphthalene environmental exposures."

Did I read that correctly?

A. You did. And "exposure" is important in that sentence.

Q. So let me understand. You're not disputing that naphthalene can cause cancer humans; correct?

A. The evidence is that it can cause cancer in animals. And so you would want to think about that in the context of potential cancer in humans.

Q. Maybe I'm asking this the wrong way. I read this sentence as you suggesting that naphthalene probably doesn't cause cancer in humans.

Is that the way you read it?

A. Let me read this again.

So at typical naphthalene environmental

exposures, the evidence suggests naphthalene is not metabolized in human respiratory tissue to the extent that it would cause toxicity and carcinogenic risk at typical naphthalene environmental exposures. At very high concentrations, that's a different question.

Q. Understood. So you're saying at typical levels of naphthalene exposure, it probably doesn't cause cancer in humans?

A. Correct, based on my analysis.

Q. If you look at page 42 at the top right-hand side, it says, "This paper was prepared with financial support to Gradient from the Naphthalene Research Committee." Correct?

A. Correct.

Q. It confirms that they're indeed a trade group for naphthalene; correct?

A. Correct.

Q. It says that that group was given the opportunity to comment on this manuscript as well; right?

A. Correct, but not on the science. They relied on our interpretation of the data.

Q. When you say "not on the science," I mean, this is a paper that's published in a

scientific journal; right?

A. Correct.

Q. This is Critical Reviews of Toxicology?

A. Correct.

Q. Why does a trade group need to comment on the manuscript?

A. For editorial, editorial comments they had to make sure that we are sort of talking about the chemicals in a way that makes sense in the context of potential exposures to humans.

So we will look at the data and look hard at the science and evaluate potential risks to animals, how it might extrapolate to the humans, and then we think about how that exposure compares to typical exposures in the environment.

So they're funders of the manuscript. They can look at the language and make sure that it's -- editorial comments on the manuscript is reasonable, but they did not comment on our interpretation of the science.

Q. How do you define editorial? How are you defining it here?

A. We have punctuation, grammar.

Q. So it's your testimony that the only thing that the Naphthalene Trade Group did was

correct grammar and punctuation?

A. I don't remember all of it. I don't remember the comments. I'd have to look back. They might not even have done that. I don't recall. I just know that they did not comment on the science. They relied on our evaluation of the science, which is the most important part of this evaluation.

Q. You can put that one aside.

You've done work for Gradient on the relationship between formaldehyde and leukemia?

A. Yes.

Q. And you dispute --

MS. ELLISON: Hold on a second.

(There was a pause in the proceedings.)

BY MR. SNIDOW:

Q. And you argued formaldehyde is not causally associated with leukemia; correct?

MS. ELLISON: Sorry. I missed the beginning of the question. Can you just ask it again, please?

MR. SNIDOW: Sure.

BY MR. SNIDOW:

Q. You've done work for Gradient on formaldehyde and leukemia?

A. Yes.
Q. And you published a paper on that?
A. Yes.
Q. In that paper you argued that formaldehyde is not causally associated with leukemia; correct?
A. I believe that was the conclusion, but that was a long time ago.
Q. You did that work on behalf of the Formaldehyde Council?
A. Yes.
Q. You agree that's an organization that probably doesn't want a determination that formaldehyde causes leukemia?
MS. ELLISON: Object to the form. Foundation.
THE WITNESS: That organization wanted our opinion about what the science says about potential for formaldehyde to cause leukemia, which is what we did.
BY MR. SNIDOW:
Q. They were paying for you; right?
A. They did support us, but our evaluation was based on the science.
Q. Do you think they would have been

pleased if you determined their product caused leukemia?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: I'm not sure whether they would have been pleased or not. That was not -- that had no bearing on the evaluation.

BY MR. SNIDOW:

Q. You again allowed them to review the manuscript and provide comments?

A. I would have to look at the paper to see what we did there.

(Bailey Exhibit 6 was marked.)

BY MR. SNIDOW:

Q. I marked as Bailey Exhibit 6 a paper called Exposure to Formaldehyde -- a paper called "Is Exposure in Air Causally Associated with Leukemia?" You'll see at the top you are the second author on the paper.

A. Yes.

Q. And Julie Goodman is the third author on the paper?

A. Dr. Goodman is on the paper as well.

Q. If you will turn to page 616, if you see the last paragraph there, you'll agree that your

conclusion was that formaldehyde does not cause leukemia in humans; correct?

A. Where are you looking on 616?

Q. Bottom right, the last sentence right before the Acknowledgments.

A. The conclusion is that it was weak in comparison to more substantial weight of evidence supporting the lack of causal association. So the evidence is weak. That was our conclusion.

Q. The evidence for causation was weak?

A. Yes.

Q. You thought the evidence against causation was stronger?

A. Correct.

Q. If you turn to the page 617, middle of that paragraph on the left, it says, "The preparation of this review was sponsored by the Formaldehyde Council." Correct?

A. It does, yes.

Q. I guess I didn't ask this, but I assume that is a trade group for people who deal with formaldehyde; true?

A. Correct.

Q. It confirms that you provided them the opportunity to review a draft of the paper;

correct?
A. Yes.
Q. I assume you don't remember the comments they provided?
A. I don't remember the comments.
Q. Your testimony is it was entirely editorial; right?
A. I know that their comments did not change our opinions about the science.
Q. You've published an article stating that the pesticide chlorpyrifos -- do you know how to say that?
A. Chlorpyrifos.
Q. -- does not cause neurodevelopmental harm; right?
A. I was an author on that paper.
Q. That was done on behalf of Dow Chemical?
A. I don't recall. It was a long time ago.
(Bailey Exhibit 7 was marked.)
BY MR. SNIDOW:
Q. I'll show you a document that I'll mark as Bailey Exhibit 8 -- Bailey Exhibit 7. If you look at the top, you'll see you're the third author on this paper.
A. Yes.

Q. Dr. Goodman is again a co-author on this paper; correct?

A. Yes.

Q. If you will look at the page ending in 899, it says that the paper was prepared with financial support to Gradient by Dow AgroSciences; right?

A. Yes.

Q. I assume that they are the manufacturer of this pesticide?

A. I don't recall if they are, but I am going to assume they are since they -- yes.

Q. At this time, this paper was done because the EPA was considering putting in place new ECELs?

A. I actually don't recall. I was very peripherally involved in this paper. So I don't recall the details of this, how this work came about.

Q. Do you know whether Dow AgroSciences was permitted to comment on this paper?

A. I don't know.

Q. You've done work for the national petroleum institute?

A. I don't recall the national petroleum

institute.

MS. ELLISON: J.J., I don't know how many more of these you have. We've been going about an hour.

MR. SNIDOW: Do you mind like giving me five minutes?

MS. ELLISON: Yes.

BY MR. SNIDOW:

Q. I'm sorry. Have you done work for the American Petroleum Institute?

A. Yes.

Q. That's no fair.

MS. ELLISON: You were close.

BY MR. SNIDOW:

Q. Any other industry groups besides the ones that we've gone through that I haven't mentioned that you've done work for?

A. The only other group that I recall is the American Chemical Council.

Q. They're a trade group for chemical companies?

A. Correct.

Q. Have you ever published a paper funded by industry where you determined that there was strong evidence in favor of causation?

A. I don't recall that that was a conclusion, but it's always based on the science.

Q. Of course. But as far as you can recall, every time an industry group has asked you to look at their chemical, your conclusion was that it does not cause the disease in question?

MS. ELLISON: Object to the form.

THE WITNESS: That is not correct. It's in the context of exposure information typically. Some may cause a health effect at a high exposure concentration, but then it's important to compare that to what's a typical environmental exposure or occupational exposure. So that part is very important.

BY MR. SNIDOW:

Q. That's fair. But every time you've been asked to evaluate whether a typical exposure causes a particular disease, you've been asked by an industry group who makes that chemical, your conclusion has been not enough evidence of causation; right?

MS. ELLISON: Object to the form.

THE WITNESS: Off the top of my head, I have not -- I don't know that we have talked about all of my evaluations today. But most

importantly, they're all based on the science. And some of them may have concluded that high exposures could cause a health effect, but at more typical exposures, it's unlikely.

But that's sort of a broad answer. I would need to look specifically at all of my papers to see.

BY MR. SNIDOW:

Q. I understand. I'm asking you based on your memory. Can you recall a time when you've been asked by an industry group that makes a certain chemical, hi, Dr. Bailey, please take a look at the evidence and tell us whether our chemical causes a certain disease at typical exposures, that you've published a paper that saying yes, it does?

MS. ELLISON: Object to the form.

BY MR. SNIDOW:

Q. Can you recall ever doing that?

A. Again, I feel like I would need to look at everything. I've done evaluations where we may have talked about chemicals at certain exposure concentrations being potentially problematic in terms of publishing.

Particularly talking about the papers

that you showed me today, I don't think I can answer that because some of these are occupational exposures where I didn't look at typical exposure concentrations for the general population. So it's a difficult question to answer without the specifics.

Q. So, first, of all, I'm asking you based on your memory. I understand you'd like to review every single one of the papers.

Based on your memory, can you ever recall publishing a paper about a chemical that an industry group is involved with where you said, yes, this is likely to cause a certain disease at typical levels of exposure? Can you recall ever doing that?

MS. ELLISON: Object to the form.

THE WITNESS: I can't recall that specific conclusion as I sit here today, but whatever the evaluation was, it's based on science.

BY MR. SNIDOW:

Q. I understand. Have you ever been asked by an industry group to look at the relationship between their product and a particular disease and published a paper determining that there's a

serious risk to human health from what that industry was doing?

MS. ELLISON: Object to the form.

THE WITNESS: Can you repeat that question?

BY MR. SNIDOW:

Q. Yeah. Let's take an example. The formaldehyde people asked you to look at formaldehyde and leukemia; right?

A. Correct.

Q. The asbestos people asked Dr. Goodman and you to look at chrysotile asbestos and mesothelioma and lung cancer; right?

A. Correct.

Q. Dow Chemical, it looks like, asked you to look at the pesticide and neurodevelopmental effects; right?

A. Um-hum.

Q. Each time you came out and said, in my view of the science, I don't think that there's a risk to human health at typical exposures; true?

MS. ELLISON: Object to the form.

THE WITNESS: Again, the conclusions in these papers are -- that's what I would stand by. Some of them are occupational. Some of them are

typical.
BY MR. SNIDOW:
Q. Let me ask a different way. Have you ever been approached by a group like one of these who produces a chemical that people are out there saying might be linked to this disease at typical levels and said, bad news for you, guys; absolutely this is a huge public health problem? Ever published anything like that?
MS. ELLISON: Object to the form.
THE WITNESS: So we're asked to look at the science and to determine whether the science supports an association between chemical exposures and health effects. And sometimes at high concentrations, there is an association. And then we need to look at what more typical exposures are.
So I would not start out with any conclusion one way or the other. It's always based on the science.
BY MR. SNIDOW:
Q. I get that, Dr. Bailey. But do you remember my question.
My question was: Can you ever remember publishing a paper like I described?

MS. ELLISON: Object to the form.

THE WITNESS: I think you asked me that already, and I said that I have not published anything where I stated that conclusion because that was not what the science supported.

MR. SNIDOW: Break.

THE VIDEOGRAPHER: Off the record at 10:38.

(Recess from 10:38 a.m. to 10:52 a.m.)

THE VIDEOGRAPHER: Back on the record at 10:52.

BY MR. SNIDOW:

Q. I'm going to my switch topics, but just a couple of follow-up questions to some of the stuff we talked about, Dr. Bailey.

Have you worked with Dr. Goodman on other projects for Gradient?

A. I have.

Q. When you worked on those other projects, had you discussed your work with Dr. Goodman?

A. Yes.

Q. Gradient has billed, it looks like so far, $1.7 million to the government for this work.

MS. ELLISON: Object to form.

THE WITNESS: For my project, yes.

BY MR. SNIDOW:

Q. Are you aware that for Dr. Goodman's project, it's about $4 million?

A. I'm not aware of what her project billed.

Q. Your testimony is that you and Dr. Goodman have never once discussed Camp Lejeune?

A. That's correct.

Q. Have you ever seen a publication that uses a risk assessment to assess causation in a population, in a population level?

A. Risk assessments are often used to evaluate causation not typically in published literature because we don't publish typically on the individual.

Q. I'm asking about population.

A. Oh, population. Sorry.

Q. I understand that you've seen it done in litigation. I'm asking about peer-reviewed literature.

Have you ever seen a peer-reviewed publication that uses risk assessment to assess causation in a population?

MS. ELLISON: Object to the form.

THE WITNESS: As I sit here today, I can't recall of a publication that assesses causation in a population.

BY MR. SNIDOW:

Q. Using risk assessment?

A. Using risk assessment; right.

Q. Do you think that risk assessments for an individual can be used to disprove causation?

MS. ELLISON: Objection to the form.

THE WITNESS: Sorry. Can you repeat that?

BY MR. SNIDOW:

Q. Do you believe that risk assessments for an individual can be used to disprove causation?

A. I think they are an important part of a causation analysis for individuals. And so, yes, they can be used to support causation or to suggest that there is not a causal relationship.

Q. So let's make it concrete. So if you have a person who is exposed to a certain chemical, if the risk assessment shows a low enough hypothetical increased risk, do you think you can rule out the possibility that chemical caused the disease?

MS. ELLISON: Object to the form.

THE WITNESS: I think that's one part of the evaluation. You need to also consider the epidemiology and compare the concentrations in the epidemiology to the estimated exposures for the individual.

BY MR. SNIDOW:

Q. Are you aware that Gradient is owned by Blackstone?

A. Gradient is part of Geosyntec, and Blackstone is, yeah, an investor.

Q. Do you know if Blackstone owns any entities that manufacture any of the chemicals at issue in this case?

A. I don't know.

Q. Are you a principal at Gradient?

A. Yes.

Q. Does that mean you have an equity stake in the company?

A. Yes.

Q. Have you done work for a company called Westlake?

A. I don't recall.

Q. Do you know if Gradient has?

A. I don't recall.

Q. Do you know if Gradient has to do any

monthly, quarterly or yearly reporting to Blackstone?

A. I'm not familiar with the reporting that goes on.

Q. Do you do revenue projections for matters that you work on?

A. Yes.

Q. Have you done one for this case?

A. I typically do revenue projections for all my projects combined.

Q. But do you think you -- do you split out how much money -- excuse me -- how much Gradient is going to probably bill for the Camp Lejeune case?

A. That's typically not how we report it. We report a lump sum of what we think our revenue might be going forward.

Q. For all the matters you work on?

A. Yes.

Q. Do you have a target billing that you are tasked to try to hit?

A. I think in general, yes, we do have a target billing.

Q. What's your target?

A. I'm saying this off the top of my head

because I don't have the information in front of me, but for principal level, it's around 750,000.

Q. Per year?

A. Yes.

Q. So roughly maybe half, maybe 40 percent of what Gradient has billed the government so far for your work?

A. 750,000 is half of the 1.5 roughly million, yes.

Q. Let's look at your Dyer report, which I think I marked as Exhibit 2. If you could turn to page 8.

MS. ELLISON: I think it's my Exhibit 1, just for the record.

MR. SNIDOW: Thank you.

BY MR. SNIDOW:

Q. If you go to page 8, you'll see that you have a Conclusion section, and you say, "Based on the results of my analysis described above, it's my opinion to a reasonable degree of scientific certainty that there's insufficient evidence to conclude that Ms. Dyer's exposure to, TCE, PCE, benzene, vinyl chloride and 1,2-tDCE from tap water during the 14.5 years that she lived and spent time at Camp Lejeune are causally associated

with her bladder cancer."

Did I read that approximately correctly?

A. Yes.

Q. Am I correct that you -- aside from swapping out the years of time on Camp Lejeune and the relevant disease, that is the exact same conclusion that you reach for all 25 of the plaintiffs that you evaluated?

A. I used similar language, but, of course, it's based on the individual exposure evaluations and risk evaluations.

Q. That's what I mean. It says Ms. Dyer's exposure was 14.5 years; right?

A. Yes.

Q. So for other plaintiffs, you put in different years; correct?

A. The years differ, but other things differed as well, whether they were potentially exposed during swimming, whether they worked at a mess hall.

Q. I'm just talking about this conclusion. My question is about your reports. I've read them.

Am I correct that you have essentially this paragraph, with the exception of the years,

the name and the disease, for every single one of the plaintiffs that you looked at?

MS. ELLISON: Object to the form.

THE WITNESS: That paragraph is similar, but the exposure evaluation and the evaluation for each plaintiff is different.

BY MR. SNIDOW:

Q. If you go to page 21 of your report, if you go down, do you see the paragraph right below Margin of Exposure Estimate that begins "In some cases"?

A. Yes.

Q. It says, "In some cases, it is also helpful to compare plaintiff-specific exposure information to exposure information from reliable epidemiology studies." Correct?

A. Correct.

Q. That's helpful to do in support of a causation analysis. I think you already told me that; right?

A. Yes.

Q. So one thing you want to do is you want to look at how much the plaintiff was exposed to and see how much people in epidemiology studies were exposure to; correct?

A. Also animal studies.
Q. Also animal studies. What you want to see is are people in the epidemiology studies who have similar exposures, do they have an increased risk of disease; right?
A. Well, you want to look at epidemiology studies that may or may not have reported an association. You want to understand the exposure in those studies and then compare that to the exposure estimate for the plaintiff and see how it compares.
Q. That's what I'm getting at. Let's say a study reports an increased risk for a certain disease, a certain exposure. You want to compare that result to the exposure that the individual has; correct?
A. Well, you want to look at the study. The study may report something, but you'd want to look at the study to see -- you want to look at the results of the study. You may interpret the study differently from what the study reports.
Q. Of course. But if you looked at the study, you interpreted that this is a reliable study, you'd want to look at the risk ratio for the exposure category in the study and then

compare that to the individual exposure; correct?

A. That's generally what we do, yes.

Q. And if the individual had exposure that corresponded to an exposure category in the study that showed an increased risk, that would increase the likelihood that you find a causal association; right?

MS. ELLISON: Object to the form.

THE WITNESS: I would want to look at the results of the study to see how I interpret whether there's an increased risk or not. So I don't take the conclusions of the authors at face value. It's my interpretation of the studies.

BY MR. SNIDOW:

Q. So I assume that you did what I just described in this case; right?

A. I looked at the -- I did what I described.

Q. But you didn't actually read the Aschengrau study; correct?

A. I did.

Q. It's not in your report.

A. The Aschengrau study is on my MCL.

Q. You read that?

A. I did.

Q. You compared the exposure levels of the Aschengrau study to the exposure levels of the people at Camp Lejeune?

A. I considered how the authors evaluated exposure in that study. And I don't agree that those exposures are comparable to exposures of individuals in Camp Lejeune.

Q. Where do you say that in your reports?

A. There is -- actually, I think I do cite it in my report because I think I --

Q. What you just said. Your testimony is you went through the Aschengrau exposures and compared that to the exposures of the people at Camp Lejeune.

MS. ELLISON: Object to the form.

THE WITNESS: I did consider the Aschengrau studies and the exposure information that was reported in those studies. And I talk about that in some of my rebuttals if the plaintiff expert talked about Aschengrau.

So I don't know if that's the case for Dyer. But I have talked about the Aschengrau studies in my rebuttals in Section 9 of some of the bladder cancer plaintiff reports.

BY MR. SNIDOW:

Q. Maybe I'm just asking this wrong. Let's look at page 21 of your report again. You say, "In some cases, it is also helpful to compare plaintiff-specific exposure information to exposure information from reliable epidemiology studies." Correct?

A. Correct.

Q. Your testimony is you did that; right?

A. I did.

Q. For all of the epidemiology studies?

A. For all of the reliable epidemiology studies.

Q. Which ones are reliable?

A. Aschengrau is not.

Q. How do you know that?

MS. ELLISON: Object to the form.

THE WITNESS: I have looked at the Aschengrau study, and I understand how the exposure information is reported in that study. And it's not reliable for individual exposure information.

BY MR. SNIDOW:

Q. I think maybe I'm asking this the wrong way.

Do you see the sentence begins, "In some cases"?

A. Yes.

Q. Will you please show me in your report where you did the comparison that's described in that sentence?

A. Sure. Section 8. Section 8 describes epidemiology in animal studies relevant to bladder cancer, and I looked at studies in -- for that section, I looked at epidemiology studies and animal studies that had exposure information and compared those to the plaintiffs' exposure.

Q. So where is Aschengrau?

A. Aschengrau was not a study that I consider reliable. So I did not consider it here.

Q. Where do you say that? Where do you say I read Aschengrau; it's not reliable, so I didn't cite it here?

A. For this section I relied on Dr. Goodman's evaluation of all of the data. Dr. Goodman does not consider Aschengrau in her evaluation. But I did look at Aschengrau in the context of my rebuttals, my rebuttal section, and also in the context of some of the rebuttals that I reviewed from other plaintiff experts.

Q. Did you review Moore 2010?
A. I did review Moore 2010.
Q. Did you review all the studies from Woburn, Massachusetts?
A. I have looked at those.
Q. You don't discuss any of those here, do you?
A. Well, I was not asked to discuss the individual epidemiology studies that Dr. Goodman considered in her report. So I relied on her evaluation of those studies. I agree with her methodology. I looked at some of the studies that had specific exposure information, epidemiology studies with specific exposure information, and then compared that to the plaintiffs' exposures, the reliable epidemiology studies.
Q. Did you defer to Dr. Goodman's interpretation of what studies were reliable?
A. I used Dr. Goodman's report for a summary of reliable studies, yes. But I agree with her methodology.
Q. I understand you agree with her methodology. Just to be clear, her methodology is employing the weight-of-the-evidence approach; right?

MS. ELLISON: Object to the form.
THE WITNESS: She did a systematic review of the available information.
BY MR. SNIDOW:
Q. That absolutely requires scientific judgment to determine what studies are reliable or not; right?
A. Yes.
Q. And my question is this: Did you defer to Dr. Goodman's determination about what's reliable, or did you individually read each of these EPA studies and assess whether you thought they were reliable?
MS. ELLISON: Object to the form.
BY MR. SNIDOW:
Q. Which one?
A. In general, in terms of an overall evaluation of potential causation for a chemical exposure and health effects, I relied on Dr. Goodman's systematic review. There were individual studies within her evaluation that also had exposure information. I considered those studies more carefully for my Section 8 and other studies that were not reliable in the context of my rebuttal in Section 9.

BY MR. SNIDOW:

Q. Do you agree that epidemiology studies provide the primary methodology for demonstrating a causal relationship?

A. Epidemiology studies are one set of data that you'd want to consider.

Q. But do you agree they're the primary method?

A. I don't. I think that you need to look at epidemiology, animal studies and mechanistic data and integrate all of that information.

Q. So you disagree?

MS. ELLISON: Object to the form.

THE WITNESS: I agree that epidemiology needs to be considered certainly in the context of animal data and mechanistic data.

BY MR. SNIDOW:

Q. Did you do your own independent literature search to find the epidemiology literature?

A. I did not.

Q. So the universe of epidemiology literature you considered was limited to Dr. Goodman's review?

A. Yes, it was. And again, I agree with

her methodology.

Q. Well, you know what a literature review is; right?

A. Of course.

Q. That's where you go on PubMed or something similar and try to collect all the literature on a certain topic; right?

A. Yes.

Q. You didn't do that?

A. That's not what I was asked to do for my evaluation.

Q. Did you copy and paste any sections of your report for one plaintiff into another?

A. Some of the general sections I did, yes.

Q. Do you agree that an individual's risk varies based on different factors including age, sex, race, lifestyle, family history?

A. Yes. That is part of what is important for whether someone may have a health effect or not.

Q. Your risk assessments that you performed here do not take into account the plaintiff's age; correct?

A. They do.

Q. They do?

A. Yes.
Q. How does it take into account the plaintiff's age?
A. Well, for example, Amsler, child, the risk assessment for Amsler considers age-dependent adjustment factors that EPA recommends, and I used those.
Q. That's fair. That's specifically for children; correct?
A. Yes.
Q. But for the plaintiffs here who are exposed as adults, your risk assessment does not consider their age; correct?
A. Well, I didn't apply those adjustment factors for the adults, so it does consider their age.
Q. I think we're talking past each other. Whether the plaintiff was 20 when exposed, 50 when they got the disease, or whether the plaintiff was 35 when exposed, 70 when they got the disease, your risk assessment would come out the same way; correct?
MS. ELLISON: Object to the form.
THE WITNESS: So I followed EPA's standard methodology for evaluating risk. And

there are risks that you -- risk calculations that you conduct for adults and risk calculations that you conduct for children. So I conducted the risk evaluations for the adults as adults.

BY MR. SNIDOW:

Q. Again, do you remember my question though? The risk calculation that you do you for adults doesn't depend on their age; correct?

MS. ELLISON: Object to the form.

THE WITNESS: EPA does not consider a specific age for individuals other than children versus adults.

BY MR. SNIDOW:

Q. That was my only question. Your risk assessment that you did did not depend on the person's adult age; correct?

MS. ELLISON: Object to the form.

THE WITNESS: EPA's standard risk approach for adults is to consider -- actually, I take that back, because we did consider body weight that may vary for different ages. So we considered I believe -- if the body weight was slightly different for a younger adult versus an older adult, that might have gone into the calculation.

BY MR. SNIDOW:

Q. How about gender, did you take that into account in your risk assessment?

A. Specifically for the calculations, we would consider the gender. For a default exposure assumption, it's typically based on the more conservative sex, either male or female, in terms of body weight -- in terms of body weight specifically.

Q. So it doesn't vary based on the person's sex? You used one for everyone?

A. I would have to look at Dr. LaKind's report to see what we used for some of the plaintiffs. But I know that body weight was something that was considered based on the age of the individual.

Q. I'm not asking about body weight. Age and body weight are different; correct? Sex and body weight are different.

You understand those are different concepts; right?

MS. ELLISON: Object to the form.

THE WITNESS: I think you asked me about sex. I was answering body weight, with body weight based on different concepts.

BY MR. SNIDOW:

Q. Maybe I'm not asking this concretely enough. Let's take two plaintiffs. They have the exact same facts except one is a female and one is male. Your risk assessment would come out identically for both of them?

MS. ELLISON: Object to the form.

THE WITNESS: The risk calculation would come out to be -- it depends on whether the male -- the woman or the man. There are other factors that are important for that calculation. How were they each individually exposed?

BY MR. SNIDOW:

Q. Assume for me all of that is the same. They were on base the same amount of time. They did the exact same activities. Every single thing that you considered about their experience was the same, except one is a male, one is a female.

Your risk assessments is going to come out to be the exact same for both of them; correct.

MS. ELLISON: Object to the form.

THE WITNESS: It may not depending on the body weight. So I would have to actually run a calculation to see how different it might be.

BY MR. SNIDOW:

Q. Assume that they weigh exactly the same. The only difference is their gender. Your risk assessment would come out exactly the same for them; true?

A. If they weighed exactly the same and they had the same activities, same time period. We are assuming that they're living in the same location, that they were both healthy Marines at the time, ingested similar amounts of water. You'd have to consider all those things.

Q. Correct. If you did and the only variation was gender, the risk assessment would come out exactly the same; correct?

A. The risk calculation would be similar, yes.

Q. Same answer for race; true?

MS. ELLISON: Object to the form.

THE WITNESS: It would, but you have to remember that the toxicity values applied in those calculations do consider potentially sensitive subpopulations. So the calculation may be conservative -- is generally conservative because those subpopulations were considered.

BY MR. SNIDOW:

Q. I understand. But again, I think it's easier if we just make it concrete.

You've got two individuals. Assume one is Caucasian. One is African-American. They have the exact same body weight, the same exposures, the same all the facts that you describe your report. Your risk assessment will come out exactly the same for both of them; correct?

A. The risk calculation -- if everything is exactly the same, that would be the risk calculation, and it would be a conservative estimate.

Q. Same answer for family history; correct?

A. The risk calculations could be -- could come out to be the same. Again, you'd have to make sure everything is exactly the same, the assumptions you're making, the conservative assumptions you're making. But again, this is only one part of the risk evaluation, of the specific causation evaluation I should say.

Q. I get it. I'll make it concrete. You've got two plaintiffs. One has got no family history of cancer. One has got a ton of family history of cancer. Assuming they had the same

weight, exposure, all the things I ticked through, all else equal except family history, your risk assessment will still come out the same for both of them; right?

A. The risk calculation portion of the specific causation analysis might come out to be the same, but that's not the only thing that you would think about.

Q. I know. But you agree that the cancer risk for someone with a substantial family history is not at all the same as someone who doesn't have a family history; correct?

MS. ELLISON: Object to the form.

BY MR. SNIDOW:

Q. Sorry. Dr. Bailey, listen to my question. I know you're not trying to be difficult. But you certainly agree --

MS. ELLISON: J.J., she was just answering your question. She began answering. So I'd ask that you let her finish. Then you can ask whatever follow-up questions you have.

BY MR. SNIDOW:

Q. Do you agree that the cancer risk for someone with a family history of cancer is not the same for someone who doesn't have a family history

of cancer?

A. In general, if there's a family history of cancer, there's a possibility that there's increased risk for an individual -- for an individual whose family has a history of cancer. But that doesn't mean that the -- that has nothing to do with the exposure evaluation piece of it. That's a separate analysis.

So, yes, familial connection is an important part of the specific causation analysis. And the exposure evaluation is also an important part of the exposure analysis.

Q. Did you do any assessment of smoking exposure for each plaintiff?

A. I did not.

Q. Did you do any assessment of exposures to any other risk factors for each plaintiff?

A. I did not.

Q. Did you do any assessment of the cancer risk any of the plaintiffs would have experienced from smoking?

A. I have not.

Q. Did you do any assessment of the cancer risk that any of the plaintiffs would have experienced from any other risk factors?

A. I did not. That was not what I was asked to do.

Q. Did you do any assessment of any protective traits that any of the plaintiffs might have had?

A. What do you mean by protective traits?

Q. Whether they're in good shape, whether they had no family history, anything like that.

A. I did consider in the context of uncertainty factors for variability within the human population. I did consider that some of the plaintiffs were healthy Marines at the time of exposure. That was something that I did consider.

Q. But you made that assumption across the board; correct?

A. That's an assumption that's important for the noncancer population. So that would have been the Parkinson's disease patients, plaintiffs.

Q. Again, I think we're talking past each other.

Did your assumption about whether they're healthy or not vary between plaintiffs?

A. For plaintiffs that were civilians, I did not do that adjustment for the Parkinson's disease patients -- plaintiffs. Excuse me.

Q. You, yourself, did not create any exposure measurements for the individual plaintiffs; Dr. LaKind did that?

A. That's correct. Dr. LaKind did the exposure calculations.

Q. She provided you the daily exposure doses; true?

A. Correct.

Q. That takes into account -- sorry. And she provided you the daily exposure concentrations; correct?

A. Yes.

Q. And just to clarify, the daily exposure doses, that's for the oral and dermal exposures; true?

A. Correct.

Q. The daily exposure concentration, that's for inhalation; true?

A. Correct.

Q. From that, she provided you with an ultimate measure of average daily dose; correct?

A. Yes.

Q. So just in concrete terms, the number that Dr. LaKind provided to you is the average daily dose of the chemicals that each of the

plaintiffs was exposed to; right?

A. Yes.

Q. Dr. LaKind did not provide you a measure of the cumulative amount of the chemicals that the plaintiffs were exposed to; correct?

A. That's correct. That was the part I did.

Q. And her metric that she provided to you does not account for intensity of exposure; true?

A. The metric that she provided is an estimate of the exposure concentrations from the water that the plaintiffs may have been exposed to at that time.

Q. Let me ask a different way. If someone had two years of exposure at a thousand micrograms and two years at zero, that would get treated the same way as someone who had a thousand micrograms for four years; correct?

MS. ELLISON: Object to the form.

THE WITNESS: Can you say those numbers again?

BY MR. SNIDOW:

Q. Someone had two years of a thousand micrograms and two years of zero, you treat that the same as someone who had a thousand micrograms

for four years?

A. That is the way the EPA does the risk calculations, yes.

Q. That's the number that Dr. LaKind provided to you?

A. Well, I would say that's a hypothetical. So in terms of the amount that you're providing to me, I don't know how that compares to any of the plaintiffs. In terms of micrograms, that's not how we report doses. It's milligram per kilogram day or microgram per meter cubed. So I don't know what the 1000 is. But EPA does have that assumption that it's exposure times time.

Q. Average exposure?

A. Yes.

Q. Dr. LaKind provided to you -- you said this, but I'll say it again -- with daily exposure concentrations; right?

A. Yes.

Q. That's expressed in what unit?

A. Microgram per meter cubed.

Q. And that unit does not depend on the weight of the person; correct?

A. Correct. That is how EPA does that calculation.

Q. So regardless if someone weighs 80 pounds or 250 pounds, their daily exposure concentration, all else equal, will be the same; true?

A. That's correct, but it is based on -- EPA did consider that, and it is based on assumptions that the inhalation rates that they assume for those toxicity values are comparable for construction workers and children, so the people in the population that you think might have a higher exposure, sort of a higher inhalation rate.

So EPA does consider that, and that's why microgram per meter cubed is justified.

Q. Let me just break this down. Daily exposure doses is one measure of exposure Dr. LaKind provided you; right?

A. Daily exposure concentrations.

Q. I'm actually talking about daily exposure doses for the oral and dermal. That's one measure that she provided?

A. Daily exposure dose does not sound like the right...

Q. Turn to page 3 in your report. Go down to the last bullet.

A. Yes, yeah. That is what -- sometimes we say average daily dose. That is how she reported it.

Q. That's one measure of exposure that she provided to you; right?

A. Yes.

Q. You think that's a valid measure of exposure; correct?

A. Correct, for the day, yes.

Q. The other measure that she provided you is daily exposure concentrations; right?

A. Correct.

Q. That's for the inhalational?

A. Yeah.

Q. The first one, DED, that one does explicitly take into account the individual's weight; true?

A. Correct.

Q. Because it's a per kilogram basis; correct? The other one, daily exposure concentration, does not explicitly take into account a person's weight; correct?

A. Correct. And that's consistent with EPA's approach.

Q. I get it.

A. And they just have provided good justification for why that is reasonable.
Q. My question is just if someone said an exposure calculation must vary based on someone's weight, you'd disagree with that; right?
A. For the oral dose, it would.
Q. But not for the inhaled dose?
A. Not for inhalation because the toxicity values are very conservative, and EPA has discussed how they're protective of a number of age ranges and inhalation rates within the population.
Q. Based on Dr. LaKind's exposure metrics, you then made certain assumptions to calculate the lifetime average daily dose; correct?
A. Yes.
Q. You assume an exposure frequency; right?
A. Yes.
Q. And an exposure duration; correct?
A. Yes.
Q. And an averaging time?
A. Right.
Q. And for exposure frequency, you assume 365 days a year; right?
A. For exposure pathways where it would be

everyday. So for drinking water, yes.

Q. That's what we're talking about here; right?

A. We're talking about other pathways, too, inhalation from showering.

Q. Is it your testimony that you varied the exposure frequency by plaintiff?

A. For certain pathways, yes, depending on what their exposures were. For drinking water, no, that's daily.

Q. You also made an assumption about averaging time?

A. The averaging time for cancer risk calculations are 70 years. That's standard.

Q. That's what you said, 25,550 days?

A. Yes.

Q. Then for exposure duration, you used the number of years the plaintiffs spent on base; true?

A. Correct. Depending the exposure pathway, some of those did vary. Swimming was not every day. Working in the mess hall was not every day. Those exposure durations were slightly different.

Q. Then based on that, you ultimately

calculated what you term LADDs, which means lifetime average daily doses; true?

A. Correct.

Q. That's for oral and dermal exposure; correct?

A. Yes.

Q. And for inhalational exposure, you calculated lifetime average daily exposures; true?

A. Correct.

Q. You did not calculate total micrograms of exposure?

A. I did not.

Q. You did not calculate, say, other mass units, right; no total milligrams, no total nanograms, no cumulative exposure expressed in terms of the mass of the chemicals; true?

A. Correct.

Q. You also did not calculate total microgram per liter months of exposure?

A. I calculated cumulative exposures, so this would be a concentration in air over time. So I did do similar calculations for my Section 8 comparisons to epidemiology.

Q. Your testimony is you calculated microgram per liter months of exposure?

A. No. Micrograms per meter cubed years or PPM years of inhalation exposure. So cumulative for the epidemiology inhalation studies for Section 8, not microgram per liter month for water.

Q. Let's do the ingestion first. For ingestion, you did not calculate microgram per liter months of exposure?

A. I didn't calculate that specifically, but I did look at the concentration over time.

Q. You know what an area under the curve calculation is; right?

A. Yes.

Q. And you agree that the unit microgram per liter months is an area under the curve metric; true?

A. Yes.

Q. For the ingestion exposure, you did not calculate an area under the curve metric for any of the plaintiffs; true?

A. I did a calculation described in my report here where it's microgram -- milligram per kilogram day is the concentration that Dr. LaKind calculated based on microgram per liter. And then I take that. So it's based on microgram per liter

of water, how much water was ingested, and then divided by the body weight for a day.

Then I take that, which has the microgram per liter in it, and multiply by the exposure frequency and exposure duration, and that's where the months come in. So it's in my calculation, but I don't specifically report microgram per liter months. But I do consider the number of months or years.

Q. Understood. You don't specifically report microgram per liter months of exposure for the plaintiffs; true?

A. I don't report that, but it's in my calculation.

Q. Or micrograms per liter years; correct?

A. Again, I don't report that, but it's in my calculation. You can back that out of my risk calculation.

Q. But you didn't do that, did you?

MS. ELLISON: Object to the form.

THE WITNESS: It was not something I needed to do for my risk evaluation because I wanted to compare to toxicity values from EPA that are reported in milligram per kilogram day or risk per milligram per kilogram day.

BY MR. SNIDOW:

Q. Are you capable of doing those calculations?

A. Yes.

Q. You're capable of expressing an area under the curve pretty easily; true?

A. Yes. I'm capable of calculating the microgram per liter month concentration.

Q. You calculated average daily exposure; true?

A. Yes.

Q. Did you do any calculation of total cumulative exposure for ingestion?

A. Are we talking ingestion or inhalation?

Q. Ingestion.

A. I did -- the cumulative part of the calculation is in my risk calculation. It's part of my risk calculation. So the days, years are in there. So I don't report the cumulative values the same way that you're asking, the microgram per liter month, but it's part of my calculation.

Q. But you don't report the total cumulative exposure for ingestion, do you?

A. I didn't report that because I didn't need that for my risk calculations. But again,

it's within my calculation. But that's not an endpoint for my calculation because that's not useful for comparison to toxicity values that EPA provides.

Q. You're aware that ATSDR says that there's sufficient evidence that TCE at Camp Lejeune causes bladder cancer; true?

A. That is what they conclude in their public health assessment.

Q. And you disagree with that?

A. I relied on Dr. Goodman's report in addition to EPA's reports, IARC for conclusions on PCE.

Q. You know that IARC classifies PCE as a possible carcinogen; right?

A. Yes.

Q. You know that's based on bladder cancer epidemiology; right?

A. I would want to look at the IARC monograph for PCE, but I believe that there is some uncertainties with the bladder cancer studies, the epidemiology bladder cancer studies that EPA and IARC both talk about in their evaluations.

Q. But ATSDR says there's sufficient

evidence for causation for PCE and bladder cancer; right?

MS. ELLISON: Object to the form.

THE WITNESS: ATSDR does make that conclusion in their public health assessment.

BY MR. SNIDOW:

Q. Dr. Goodman disagrees; right?

A. Dr. Goodman's conclusions are that there's not enough evidence for an association.

Q. And you went with Dr. Goodman over ATSDR; right?

MS. ELLISON: Object to the form.

THE WITNESS: I looked at Dr. Goodman's report. I looked at EPA's report and IARC. So I considered all of that information.

BY MR. SNIDOW:

Q. So just out of curiosity what did you do to determine Dr. Goodman was correct about this over ATSDR?

MS. ELLISON: Object to the form.

THE WITNESS: Well, again, I am confident in Dr. Goodman's methodology. She considers many epidemiology studies, animal studies, the reliability of those studies. So I don't have any reason to disagree with her

conclusion.

But then I also looked at EPA's conclusion for PCE and bladder cancer and IARC's conclusion for PCE and bladder cancer, and they are not conclusive that there is a causal association for PCE and bladder cancer.

BY MR. SNIDOW:

Q. Did you review the PCE and bladder cancer literature yourself?

A. That was not what I was asked to do for my evaluation. But I needed to understand Dr. Goodman's conclusion based on methodology I agree with and Agency conclusions.

Q. So that's a no, you didn't consider the PCE and bladder cancer epidemiology?

MR. SNIDOW: Object to the form.

THE WITNESS: I looked at the PCE epidemiology studies that are relevant to my Section 8.

BY MR. SNIDOW:

Q. Okay. So let's do that. Let's look at Section 8. Am I correct in Section 8.2 on page 43 you cite precisely one study looking at PCE and bladder cancer?

A. It is one study that reported inhalation

concentrations of PCE, an occupational study, and also looked at incidence of bladder cancer in that population.

Q. So I assume that's the only study that that's ever looked at PCE and bladder cancer?

A. I looked at any study that had exposure information, and this is the one epidemiology study that had exposure information and looked specifically at bladder cancer in humans.

Q. Did you review any other studies looking at PCE and bladder cancer?

A. If I had, I would have cited it here.

Q. And there aren't any others; correct?

A. That's correct. This was the one study that had exposure information. If there were more than one, I would have considered it.

Q. So before deciding to agree with Dr. Goodman over ATSDR, you reviewed one study on the relationship between PCE and bladder cancer?

MS. ELLISON: Object to the form.

THE WITNESS: So again, I rely on Dr. Goodman's report because I agree with her methodology. I don't have any reason to believe that her conclusions are incorrect. And it's not inconsistent with EPA's conclusions and IARC's

conclusions.
BY MR. SNIDOW:
Q. The only reason I entered this, I asked you if you did any independent evaluation of this, and you said you did.
I'm just asking: Did you do anything besides read the Hadkhale 2017 study to independently verify that Dr. Goodman's conclusion was correct?
MS. ELLISON: Object to the form.
THE WITNESS: I specifically said that I reviewed the studies in Section 8, which is what I did and what I confirmed with your later questions.
BY MR. SNIDOW:
Q. You agree there's one study cited there?
A. There's one study that looked at exposure information, and that's why I looked at it. If there were more, I would have cited it here.
Q. I assume when we look at Hadkhale 2017, it's going to show evidence that PCE does not cause bladder cancer?
A. I'm would want to look at that study to see exactly what the conclusion was, although I

can probably read it here.

Hadkhale reported no significant associations and no trends between bladder cancer and PCE occupational exposure to PCE inhalation exposure at concentrations as high as 87.55 PPM years. So that's what Hadkhale -- that summarizes the information from Hadkhale for PCE.

Q. You are an epidemiologist, yes?

A. I review epidemiology studies often for my human health risk assessments.

Q. You do not hold yourself out as an epidemiologist?

A. Epidemiology is something I have to look at all the time. I don't have a degree in epidemiology, but I look at epidemiology often in my work.

Q. When you are speaking to other scientists, do you describe yourself as an epidemiologist?

A. I describe myself as a toxicologist, human health risk assessor.

Q. So no, not an epidemiologist?

A. I don't use the word epidemiologist, but I certainly need to consider epidemiology in my evaluations.

Q. Do you consider yourself an expert in epidemiology?

A. I have to review epidemiology for many of the evaluations that I do.

Q. So you know how to read it. You know the basic principles; true?

A. Correct.

Q. So to be a confounder, you agree that a variable needs to be correlated both with the relevant exposure and the outcome of interest?

A. So confounding is not something that I talk about in my report. But I generally understand what confounding is because I have to consider it for my evaluations.

Q. So is what I said correct?

A. Can you repeat it?

Q. Yeah. To be a confounder, a variable needs to be correlated both with the relevant exposure and the outcome of interest.

A. That's generally how we talk about confounding.

Q. It's not enough for it just to be correlated with the outcome of interest; true?

A. This is not something that I talked about in my report. I would want to look at

Dr. Goodman's general discussion of epidemiology before I -- and discussion of confounders before I agree to that.

(Bailey Exhibit 8 was marked.)

BY MR. SNIDOW:

Q. I'll mark this as Exhibit 8. I'm going to draw a diagram for you here. Exposure. Other variable.

I'm showing you Exhibit 8. What I'm trying to describe here is in a situation where the exposure is correlated with another variable, that in turn is correlated with the outcome, that's a confounding situation; correct?

A. Yes.

(Bailey Exhibit 9 was marked.)

BY MR. SNIDOW:

Q. I'll mark this as Exhibit 9. What I'm trying to describe here is a situation where the exposure is not correlated with the other variable or the other variable is correlated with the outcome of interest, that is not a confounding situation; true?

A. In the general sense, yes. I would probably need specific...

Q. Of course. But that's generally

correct?

A. Yeah. I mean, that's very simple, but yes.

Q. So do you know what the risk factors are for Parkinson's disease?

A. That's not something that I discussed in my report, so it's not something that I can opine on.

Q. Do you agree that knowing what the risk factors are for a certain disease would be helpful in determining if there's potential for confounding?

A. What I was asked to do was to look at whether the exposures to the individual chemicals at the site were potentially related to the plaintiffs' health effect. That's what I did.

I did not consider risk factors, potential confounding. That is something that you'd want to think about in a specific causation analysis. But my part of the specific causation analysis was just the risk calculations and whether the exposure information could have led to health effects.

Q. Do you know what nondifferential exposure misclassification is?

A. I have heard of that. It's not something that I had to think about for my report.
Q. Do you agree that it will bias results in a study toward the null?
A. My understanding is that depending on how the results are reported, it can bias toward or away from the null. That's true.
Q. How about for a dichotomous exposure and dichotomous outcome, do you agree that nondifferential exposure misclassification will produce bias toward the null in that situation?
A. When there's individual exposure groups, it can -- it may bias toward or away from the null.
Q. You know what the term dichotomous is; right?
A. So that would be like an ever versus never.
Q. Yep.
A. Often that is considered -- well, I'm not going to answer that because that's not something that I am familiar enough about to answer, to opine on here. It was not part of my evaluation.
Q. You do know though what bias toward the

null is; true?
A. Yes.
Q. That means that the result will be dampened?
A. There's a potential that the result is, yes, lower.
Q. Moving lower, yes. It will make an epi result appear weaker than it is in reality; true?
MS. ELLISON: Object to the form.
THE WITNESS: That's generally what bias towards the null means, that term, yes.
BY MR. SNIDOW:
Q. In doing a risk assessment, do you agree the ultimate output is increased probability of a certain disease?
A. The output is what the risk might be, the calculated theoretical risk might be for a population exposed, everyone exposed the same way. And the risk calculation is what the risk calculation is based on exposure information. And then you determine whether that's potentially a problem.
Q. I'm just asking about units. It's expressed in units such as a theoretical one extra cancer in a population of a million; true?

MS. ELLISON: Object to the form.

THE WITNESS: Yes. It can be reported that way.

BY MR. SNIDOW:

Q. Or one in a thousand, whatever it is; correct?

A. Right.

Q. My question is though: It's not a -- you know what relative risk is; right?

A. Yes.

MS. ELLISON: Object to the form.

BY MR. SNIDOW:

Q. Risk assessments don't produce relative risks?

A. Correct. It's a different type of risk calculation.

Q. Epidemiology sometimes produces relative risks; true?

A. Correct.

Q. But the risk assessment is going to produce theoretical risk in absolute terms; correct?

A. It's the calculation that's based on exposure information for the plaintiff, and it's based on epidemiology studies that do report

relative risks. So they are connected.

Q. I get they're connected. I'm just talking the ultimate output.

The ultimate output is going to be in absolute terms; correct?

MS. ELLISON: Object to the form.

THE WITNESS: I don't know what you mean by absolute terms.

BY MR. SNIDOW:

Q. Like one in a thousand, one in a million.

A. That is what the calculation comes out to be, yes, but you have to interpret that number with other information.

Q. So how big does that number need be for you to look at it and say that's big enough to say that there's causation in this individual case?

A. Well, you wouldn't look at just the risk calculation by itself, but if the risk calculation comes out to be something well above ten to the minus four, you would -- you would want to understand the exposure information better. And you'd want to understand whether you made conservative assumptions about the exposure information. And often that is the case. And

then you'd want to potentially think about whether that's a realistic exposure.

So if something is within ten to the minus six, ten to the minus four, that's considered a target risk range for EPA, not very much of a concern. Above that, you would want to think about the very conservative exposure estimates that went into the calculation and think about whether you might want to adjust some of those.

Q. Maybe I'll try to make this concrete. In your report, for all 25 plaintiffs you conclude that your risk assessments make you confident that there's not causation; right?

A. So my risk calculations provide perspective on the exposure information estimated for a plaintiff.

Q. What ten to the minus would make you find causation or be concerned about causation?

MS. ELLISON: Object to the form.

THE WITNESS: It would not be just that calculation.

BY MR. SNIDOW:

Q. I understand it wouldn't be.

MS. ELLISON: One second. Sorry. The

court reporter -- can we all just slow down a little bit.

MR. SNIDOW: Sorry.

BY MR. SNIDOW:

Q. Let me say I get it that you did a risk assessment; correct? You did a margin of exposure analysis; correct?

A. Um-hum.

Q. Did I miss anything else?

A. Comparison of epidemiology.

Q. Right. That's kind of baked into your margin of exposure, isn't it?

A. No, because the margin of exposure is specific to the toxicity value point of departure. The epidemiology section considers the endpoint of concern and compares the exposure in those studies that are for the endpoint that we're talking about.

Q. Did I miss anything besides those three things?

A. Those are the three things that I considered for my exposure evaluation, which is only part of a specific causation analysis.

Q. For your exposure evaluation, the calculated risk was ten to the minus one, so

10 percent.

Would that raise concerns for you?

A. Well, that's a hypothetical question. That's not a risk I calculated for any of the plaintiffs. So the plaintiffs' risks were well below that. So in your hypothetical example, that would be something that could be considered high.

Q. How about ten to the minus two?

A. That's well above ten to the minus four, so again hypothetical. Not something I calculated for any of these plaintiffs. But in the hypothetical example, that would be considered high. But you'd also want to consider other information because it's a conservative estimate of risk.

Q. Ten to the minus three, would that be concerning?

A. It's getting closer to the ten to the minus four. Again, you have to think about -- at that point, you'd probably not need to be careful and think about the exposure assumptions that you're considering and whether they're very conservative or not.

Q. Then at ten to minus four, no concern?

A. At ten to the minus four, I don't think

there's a concern because that's a conservative estimate of risk based on EPA's exposure assumptions and very conservative toxicity values, particularly if you're using a linear no threshold approach, which is what we do for risk calculations. And that's a very conservative approach.

So my opinion is it is not. It's very low compared to 40 percent in cancer risk in the population. A ten to the minus four is .01 percent. So it's very low.

Q. Have you ever seen a published risk assessment performed to calculate an individual person's chance of getting a disease?

A. I believe you asked me that earlier, and I said I've not seen publications that reports that. It's not typically in the published literature. But I have seen those evaluations.

Q. Done by Gradient?

A. Some of them done by Gradient, yes.

Q. Anyone else?

A. I don't usually look at expert reports for other companies.

Q. So sitting here today, can you think of anyone other than Gradient who's ever done a risk

assessment to calculate an individual person's risk of getting a disease?

A. As I sit here today, I can't recall one, but it's certainly something that is done often in specific causation evaluations where you want to get a sense of what the exposure is. It's very useful.

Q. Where have you seen it done?

MS. ELLISON: Object to the form.

THE WITNESS: It doesn't matter whether I've seen it done or not.

BY MR. SNIDOW:

Q. That's what I'm asking you.

A. I know that it's an evaluation that's useful because it provides information. It provides perspective on what the exposure estimates are for an individual and how that compares to what considers EPA considers safe. So I don't need to see it anywhere else. I know from my experience that it's useful.

Q. That's fair. I'm just asking. You said you know it's not in place.

Have you ever seen it done by anyone except Gradient?

MS. ELLISON: Object to the form.

THE WITNESS: I don't think it's relevant to my evaluation because I know it's an important part of the question --

BY MR. SNIDOW:

Q. Is that a "no"?

A. -- regarding exposure.

Q. Is that no, you've never seen it done?

MS. ELLISON: Object to the form.

THE WITNESS: I know it's an important part of my evaluation. I have not seen other expert reports outside of Gradient, but that doesn't mean it's not a useful evaluation.

BY MR. SNIDOW:

Q. Dr. Bailey, I appreciate you're trying to answer my question. I do think I'm asking it pretty concretely.

My question is: Besides Gradient, have you ever anywhere, anywhere seen a risk assessment performed to calculate the individual person's risk of getting a disease?

MS. ELLISON: Same objection.

THE WITNESS: I have not seen a specific evaluation, but that doesn't mean it's not a useful evaluation. I don't know where I would have the opportunity to.

BY MR. SNIDOW:

Q. Have you ever seen anyone other than Gradient use a risk assessment to disprove causation?

A. Again, I've only worked on Gradient expert reports where we have done that kind of evaluation, and these are reasonable approaches for expert reports. So I have not seen other reports, but that doesn't mean they don't exist. It just means I haven't seen them. I don't know how I would have an opportunity to see them.

Q. So the answer is no, sitting here today, you can't point to anyone other than Gradient who's ever done a risk assessment to disprove causation?

MS. ELLISON: Object to the form.

THE WITNESS: Again, doing a risk assessment -- doing a risk assessment for causation is a very reasonable approach to providing perspective on exposure. I would not have an opportunity to see whether other experts did that type of evaluation. So I can't answer that question.

But I know from my experience and my expertise that it is reasonable, provides

perspective on what the exposures are.

MR. SNIDOW: Move to strike. Nonresponsive.

BY MR. SNIDOW:

Q. My question is: Have you ever seen it done? Have you seen it, or have you not seen it?

MS. ELLISON: Object to the form.

THE WITNESS: I've seen it done in Gradient expert reports. I have not seen it done in other expert reports because I have not seen those reports.

BY MR. SNIDOW:

Q. Or anywhere else. You've just never seen it anywhere in the world, peer-reviewed literature, expert reports, website, anyone other than Gradient ever done an individual risk assessment to calculate an individual's risk of getting a disease, have you?

MS. ELLISON: Object to the form.

THE WITNESS: Individual risk assessments are not published typically. They're typically done for litigation, and the reports that I've looked at at Gradient, I have seen it. I have not seen other reports.

So I have not seen it, but it doesn't

mean it doesn't exist. I just haven't seen it in other expert reports, and it wouldn't be something published in the literature. So the answer is no, but there's a good reason why.

BY MR. SNIDOW:

Q. The answer is no, never seen it done outside of Gradient; correct?

MS. ELLISON: Object to the form.

THE WITNESS: Correct, but there's a good reason why. I think I explained it.

BY MR. SNIDOW:

Q. Did you calculate the relative risk ratios for exposure to any of the chemicals in any of the diseases?

A. That's not how you view a risk evaluation for an individual. You would want to look at the individual exposure information and calculate a risk based on that exposure information and EPA's toxicity values. Relative risks are done for populations in epidemiology studies, not for an individual.

Q. You say that's now you do it. How did you learn to do an individual risk assessment to determine an individual's risk of getting a disease?

A. I've been doing risk assessments for 25 years. So I know how to do risk assessments.

Q. For an individual, like where do I go? You said that's not how it's done. Where do I go to see how it's done?

A. I think it's fairly straightforward. The risk assessments that are done for population, you use exposure information based on what might be the most sensitive individual in that population. When you do something for an individual, you look specifically at exposure information for that individual, when they were exposed and the specific timeframe and activities.

So it's logical that you would want to use exposure parameters specific to an individual to do an individual risk calculation.

Q. Did you calculate relative risk ratios for any of the disease and chemical combinations at issue here?

A. I did not do relative risk. I did risk calculations based on EPA's approach.

Q. Dr. Bailey, your view, correct me if I'm wrong, is that there is a threshold dose for carcinogens?

A. I think that there is likely a threshold

for many carcinogens because of repair mechanisms and detoxification mechanisms that we have in our bodies to deal with chemicals.

Q. So is that, yeah, you think there's a threshold dose for carcinogens?

A. I think that it is possible, yes, that there is a threshold dose for carcinogens because of the mechanisms that we have in our bodies to deal with toxic exposures.

Q. What's the threshold dose for TCE and kidney cancer?

A. So in my report, I talk about how a threshold is very likely. It's biologically plausible because we have these mechanisms in our bodies to deal with chemical exposures, detoxification, DNA repair mechanisms.

It's very difficult to determine what that level is. And so EPA, because it's very difficult to determine those thresholds, uses the linear no threshold approach. But what my point is is that because it's very likely that there is a threshold, as you get down to very low concentrations, that linear no threshold approach is a conservative estimate because you're now -- you're drawing a line below what the threshold --

it's very difficult to know what that threshold is, which is why EPA use the linear no threshold extrapolation, and I agree with that.

But it doesn't mean that that threshold doesn't exist. It likely does. It's biologically plausible, and that's my point in my report.

Q. So what's the threshold dose for TCE and kidney cancer?

A. I don't know.

Q. How about TCE and NHL?

A. I don't know, but I didn't use a threshold for my calculations.

Q. Fair enough. How about TCE and leukemia?

A. As I said, it's difficult to determine what those thresholds are, but they likely exist. It just makes sense. Biologically plausible that you're going to have some level of repair or detoxification that happens.

And then once those systems are overwhelmed, then you start to see an increase. But that's where the threshold is. And what that is for each chemical is not easy to determine, but they're biologically plausible.

Q. Well, in your report, you're actually a

little stronger; right? You say that it's not biologically plausible for there to be a threshold; right?

A. I'm saying it's not biologically plausible for their -- get the language here.

Q. Page 20. Because before you were telling me you think it's biologically plausible that there is a threshold; right?

A. Yes.

Q. But in your report, you actually say it the other way. You see in the middle of the paragraph, page 20, "And, therefore"?

A. Yes.

Q. You say, "It's not biologically plausible that there's no threshold."

A. Let me read this. I'm saying that the concept that there's no threshold below which increased cancer risk is unlikely is not biologically plausible. So the concept that there's no threshold is not biologically plausible. In other words, the concept that there is a threshold is biologically plausible.

Q. I know. But you're saying because that there's not one, it's not even biologically plausible; right?

A. Yes, because of DNA repair mechanisms and detoxification mechanisms that exist in the body.

Q. So what authority says it's not even biologically plausible to believe that carcinogens don't have a threshold dose?

A. So I'm not basing it on an authority. I'm basing it on my understanding of the science. I have a lot of years of experience before I even started in consulting understanding the mechanisms of DNA damage repair, mutagenesis. And it's just not biologically plausible from my understanding of the science to not have -- to not have a threshold.

(Bailey Exhibit 10 was marked.)

BY MR. SNIDOW:

Q. I'm going to show you a document that I'll mark Exhibit 10. So this is the Federal Reference Manual on Scientific Evidence, Third Edition.

Have you ever seen this before?

A. I might have. I don't recall.

Q. If you could go to page 670.

MS. ELLISON: I'll just note for the record that pages 651 through 656 are missing, so

it's not the complete chapter.

MR. SNIDOW: I'm going to do excerpts for stuff. If there is -- actually, I should say this.

BY MR. SNIDOW:

Q. Dr. Bailey, I'm showing you an excerpt here. If there's material from this or basically any other large document that we've excerpted that you want to read, let me know. I'll have Raleigh print it and you can take a look on a break. We've been killing a lot of trees. I'm trying to cut down on that a little bit. I think though on this one, you might not, but --

MS. ELLISON: And, J.J., for the record, can you note when one of the reports or papers is incomplete just so that Dr. Bailey and I are both aware that it's an incomplete document for the record?

MR. SNIDOW: Of course.

MS. ELLISON: Thank you.

BY MR. SNIDOW:

Q. Do you see at the top of page 670 it's talking about NOEL levels?

A. I see that.

Q. You know what that is; right?

A. Yes.
Q. No effect level?
A. Yes.
Q. It says, "This analysis does not apply to substances that exert toxicity by causing mutations leading to cancer. Theoretically, any exposure at all to mutagens may increase the risk of cancer, although the risk may be very slight and not achieve medical probability." Correct?
A. That's what it says, yes.
Q. I assume that you disagree with that?
A. I don't have the rest of the paragraph here.
Q. Go to the previous page.
A. The previous page is 657.
Q. Do you want to see it?
A. Sure.
Q. Put this one aside.
MR. SNIDOW: Raleigh, if you wouldn't mind printing -- just print this entire chapter from the reference manual.
MS. GRAVES: What chapter is that?
MR. SNIDOW: It begins on page 633.
BY MR. SNIDOW:
Q. We'll take a look at this in a second.

But suffice it to say you don't agree that any exposure at all to mutagens may increase the risk of cancer, do you?

A. So from a public health perspective, EPA does calculate a risk all the way down to zero using their linear no threshold approach. What is the year of this report?

Q. Dr. Bailey, I'll give you the full copy. In your report, you say that the concept of the no threshold dose for carcinogens is not even biologically plausible; correct?

A. Correct.

Q. This is saying the opposite; right?

MS. ELLISON: Objection. She's asked to see the full document. Until she has time to review it, I don't think these questions are appropriate.

(Bailey Exhibit 11 was marked.)

BY MR. SNIDOW:

Q. Let's do another one. I'll show you a document that I'll mark as Exhibit 11. This is from ATSDR. You see this is from their -- this is from the Public Health Guidance Manual.

If you could turn to page 8, do you see in the middle of the paragraph it says, "ATSDR

does not have an acceptable cancer risk range"?

A. That's what it says.

Q. Do you see where it says, "Health assessors should avoid using phrases such as within the acceptable cancer risk range"?

A. It does say that. This is in the context of a public health assessment where you're talking about health of the community. So it's not a general guideline for individual risk assessments. It's a guideline for public assessments.

Q. Remember earlier when I asked how you figured out how to do individual risk assessments and you said, well, just look at how you do it for populations?

MS. ELLISON: Object to the form.

BY MR. SNIDOW:

Q. That was your testimony, wasn't it?

A. It is a similar calculation, yes.

Q. Do you agree this is about how to do it for populations; right?

A. This is about populations, yes, conservative estimates for individuals in those populations.

Q. It says, "Avoid using phrases such as

within the acceptable cancer risk range." Right?

A. It does say that for a population because you need to understand individuals, all the individuals in that population. Although it is a conservative estimate, I think you would want to be careful to have that type of conclusion in a public health assessment for a community. That's different. That's a health decision.

For individual risk assessments where you're looking at individual exposure information, that's a different type of evaluation where you're a looking specifically at an individual, what their exposures might have been, how much water they might have ingested, based on their own discussions about that. So that's different.

The public health assessment looks at a community where everyone is exposed similarly for sensitive individuals in the population and where the exposure assumptions are very conservative. It might not apply to an individual. I think this statement is because the risks that come out of these calculations for a community are overly conservative. So you wouldn't want to make that general statement for a community.

Q. You're going to have to break that down

for me. You said these estimates are conservative; true?

A. Yes. They are typically conservative.

Q. Let's just be clear what that means. That means when you're doing risk assessments for a population, it's going to give you, if anything, an overly high estimate of the risk; correct?

A. Yes.

Q. ATSDR says don't call any of these numbers the acceptable cancer risk range when you're doing it for a population; correct?

A. That's what they're saying for a public health assessment, yes.

Q. Why does it matter -- why does that change if you're doing a risk assessment for an individual?

A. I think you want to -- for an individual you're looking specifically at the exposure information for that individual. And so you're sort of looking at a more refined risk calculation for that individual. So that's how it's different.

Q. Can you point me to any peer-reviewed publication that says that when you're talking about an individual risk assessment, it's okay to

talk about acceptable cancer risk?

A. It doesn't have to be in peer-reviewed literature for me to from my own background and expertise know that that's reasonable. This is a range that EPA considers acceptable and often will regulate to ten to the minus four.

So in my mind, because EPA -- in my expertise and from my experience, EPA has determined that that's a cancer risk that's considered within their target range and acceptable, that that would provide perspective about an individual exposure if that risk falls below ten to the minus four or at ten to the minus four for an individual and you have exposure information for that individual, specific to that individual that provides perspective and can demonstrate that exposures for that individual are low.

MR. SNIDOW: Move to strike. Nonresponsive. Let me ask it again.

BY MR. SNIDOW:

Q. Is there any peer-reviewed literature that says when you're doing individual risk assessments, you're allowed to talk about acceptable cancer risk ranges?

A. There's no peer-reviewed literature that says that, but it's logical.

Q. Can you point to me any document outside of Gradient that says that you should use that kind of language when doing an individual risk assessment?

A. Well, as an expert in the field and as an expert in health risk assessment and toxicology, I know that it's a reasonable approach. I don't need to find an article that says that it is. It's logical scientifically, my perspective.

Q. Any authority you can point to?

MS. ELLISON: Object to the form.

THE WITNESS: I don't think an authority on my evaluation is relevant. I think my expertise in human health risk assessment is what's relevant.

BY MR. SNIDOW:

Q. Let's to go Tab --

MS. ELLISON: J.J., I don't know if you're in the middle of a topic, but just flagging that it's been about ten over the hour.

MR. SNIDOW: Yeah. Break now is good.

THE VIDEOGRAPHER: Off the record at

12:11.

(Recess from 12:11 p.m. to 12:33 p.m.)

THE VIDEOGRAPHER: Back on the record at 12:33.

(Bailey Exhibit 12 was marked.)

BY MR. SNIDOW:

Q. Dr. Bailey, I'm going to show you a document that I'll mark as Exhibit 12. These are EPA's Guidelines for Carcinogen Risk Assessment. It's an excerpt. You've seen this document before?

A. I have.

Q. If you look on the back page, which is 3-24, do you see where it says, "For effects other than cancer, reference values have been described as being based on the assumption of biological thresholds"?

A. I see that.

Q. That's referring to the fact that for cancer, the reference values are based on the assumption that there is a threshold?

A. For cancer, there's an assumption threshold that there's not a threshold.

Q. For cancer, there's the assumption that there's not a threshold?

A. Yes.
Q. You think that assumption is biologically not plausible?
A. I think it's biologically not plausible; correct?
MS. ELLISON: J.J., just to confirm, this is actually 3.3.4. I'll just note for the record the entirety of Section 3.3.4 is not here.
MR. SNIDOW: Yep.
BY MR. SNIDOW:
Q. Then it says, "The agency's more current guidelines for these effects...do not use the assumption, citing difficulty of empirically distinguishing a true threshold from a dose-response curve that's nonlinear at low doses."
Did I read that correctly?
A. That's correct.
Q. What that is saying is even for noncancer, the EPA is moving away from assuming a threshold; correct?
A. Let me read this. I don't think that's what it says. I think it just says that it's difficult to empirically distinguish a true threshold dose-response curve nonlinear at low

doses.

Q. Do you see where it says, "The more current guidelines do not use this assumption"?

A. The current guidelines for non -- for other effects other than cancer do use reference values.

Q. Let's read it again. "For effects other than cancer, reference values have been described as being based on the assumption of biological thresholds." Correct?

A. Right.

Q. So that's saying for noncancer effects, we assume that there is a threshold; correct?

A. Correct.

Q. For those effects; correct?

A. Correct.

Q. Then it goes on to say the more current guidelines for those effects do not use this assumption; correct?

A. I would want to look at those guidelines because they still use thresholds. They use reference values for noncancer. So I don't know what that means without looking at the reference documents in that sentence.

Q. You can put that one aside. While he's

getting that, you testified earlier that it's difficult to determine what the threshold is; correct?

A. For carcinogens, yes.

Q. Why is that?

A. Because there are mechanisms that are important for determining or sort of defining what that threshold might be. And for some chemicals we're still trying to understand those mechanisms. And then we're often looking at that information in animals and then extrapolating that to humans. So there's a lot of information that goes into understanding what the threshold might be. And so they're difficult to determine empirically.

(Bailey Exhibit 13 was marked.)

BY MR. SNIDOW:

Q. Let me show you a document that I will mark as Exhibit 13. This is from the National Academy of Sciences, 1977. You agree the National Academy of Medicine is a reputable organization?

A. Yes.

Q. Can you turn to page 54 in this excerpt.

MS. ELLISON: Just for the record, this not a complete excerpt.

MR. SNIDOW: You're welcome to a standing objection.

MS. ELLISON: Thank you.

MR. SNIDOW: You're welcome to note it.

MS. ELLISON: Appreciate it. I'll take it.

BY MR. SNIDOW:

Q. Do you see in the middle of page it says, "With respect to carcinogenesis, it seems plausible at first thought it has often been argued that threshold must exist below which even the most toxic substance would be harmless"?

A. Yes.

Q. Then about three lines later, it says, "There is no scientific basis for such estimations of safe doses in connection with carcinogenesis."

A. That is what it says. It also says, "Unfortunately, a threshold cannot be established experimentally that is applicable to the total population." And that's what I'm saying.

Q. Well, you're saying there is a threshold or just that you can't estimate it?

A. That there is a threshold that's difficult to estimate.

Q. You think -- do you have any authority that says that, that there's a threshold for genotoxic carcinogens?

A. I mean, in my expert opinion, so I am -- with my 25 years of experience, beyond that actually, meaning grad school, I did a lot of work on DNA damage repair mutagenesis. So there is mechanisms that our bodies use to deal with exposures at low concentrations and, that information is clear in the science.

So just understanding what types of mechanisms are involved in dealing with sort of detoxification and DNA repair, that you would have to be above those concentrations. The concentrations sort of overwhelm those mechanisms. That's where the threshold would be, and that makes biological sense based on the science.

Q. Any peer-reviewed publications that you can point to that says that genotoxic carcinogens have a threshold?

A. Well, I do cite several articles in my report that talk about the biological plausibility of a threshold for carcinogens.

Q. It's one thing to say it's biologically plausible that there is a threshold. It's another

thing to say, as you do, that it's not biologically plausible to have a no threshold theory; right? Those are different.

MS. ELLISON: Object to the form.

THE WITNESS: Can you repeat that? Because I'm not sure that they're different.

BY MR. SNIDOW:

Q. In your report, you say -- you know what the non-threshold model is; correct?

A. Yes.

Q. It's what the EPA uses.

A. A linear extrapolation.

Q. Yes. You think that that's not even biologically plausible to do; correct?

A. I understand why EPA does it. It's a public health decision that they have made. It's not consistent with what's biologically plausible in terms of science.

Q. I'm asking you: What peer-reviewed publication says that?

MS. ELLISON: Object to the form.

THE WITNESS: I don't think I need a peer-reviewed publication that specifically says that. I know from my own expertise in the field that it makes sense. It's biologically plausible

that there would be. And this -- what you just put in front of me here says it seems plausible that a threshold must exist below which even the most toxic substances would be harmless.

Unfortunately, a threshold cannot be established experimentally that is applicable to a total population. So I feel like that sentence -- those two sentences sort of acknowledge that there is one, but we just can't determine what it is, which is exactly what I'm saying.

BY MR. SNIDOW:

Q. I'm just saying it sounds like no peer-reviewed literature. Any other document that I could point to that says, look, the idea that there's not a threshold for genotoxic carcinogens, that's just not biologically plausible?

MR. SNIDOW: Object to the form.

BY MR. SNIDOW:

Q. Anything, any authority.

A. I think that you can interpret some discussions about thresholds and non-thresholds as it being possible or that it is biologically plausible that there isn't one, but we can't determine what it is. So because of that, the linear no threshold is the approach for public

health decisions.

Q. Any specific authority you can give me?

A. I think I answered the question that it doesn't need to be specifically stated. I think my understanding of the science and the way the science is discussed in reports, Agency reports, including the one you just put in front of me, suggests that there is a threshold, but we just can't determine what it is.

It's biologically -- of course, it's biologically plausible that there would be. We have ways to deal with chemicals in our body. And once those mechanisms are saturated and no longer functional, then that's where the threshold would be. But it's not easy empirically to determine what that is. It doesn't mean it doesn't exist.

(Bailey Exhibit 14 was marked.)

BY MR. SNIDOW:

Q. Let's do another one. Marking Exhibit Bailey 14, which is an excerpt.

You're familiar with NIOSH?

A. Yes.

Q. Are they a pretty reputable organization?

A. Yes.

Q. Can you go to the page that's marked 19. Do you see where it says, "For carcinogen risk assessment, NIOSH generally treats exposure response as low-dose linear unless a nonlinear mode of action is clearly established"?

Did I read that correctly?

A. Where is that?

Q. Second paragraph down. It begins, "For carcinogen risk assessment..."

A. Yes. I see say that.

Q. You see the last sentence there, "In general, whether the model forms are linear or nonlinear, any nonzero exposure to a carcinogen is expected to yield some excess risk of cancer." Correct?

A. In that calculation, we're using a linear low-dose extrapolation. You would calculate a risk, but that didn't mean that there's a risk of health effect. You then have to look to see what that number is compared to what EPA considers de minimis.

Q. It says whether it's linear or nonlinear; correct?

A. It does say whether it's linear or nonlinear.

Q. It says, "Any nonzero exposure to carcinogens is expected to yield some excess risk of cancer." Correct?

A. In the application of the nonlinear threshold, that is how the calculation comes out. I don't think that's saying that there's no threshold. It's just saying that when you use a linear no threshold approach, you're calculating a risk even at very low concentrations. You could be below the threshold. I think the two are not -- the two are different.

So is it biologically plausible to not have a threshold? I don't think it's biologically plausible to not have a threshold. Does EPA use a linear extrapolation and calculate risk above zero? Yes, but that's a health decision because we don't understand what's going on at very low concentrations. So they're using a conservative approach.

Q. You keep saying when you're doing a linear model. Do you see where it says whether it's linear or nonlinear?

A. Yes.

Q. So it's not just when you're doing a linear model; correct?

MS. ELLISON: Object to the form.

THE WITNESS: I think there are other shapes of the curve that can happen below a threshold. So it may be super linear. So it may be not a straight line. But the assumption is that it's there in the straight line.

BY MR. SNIDOW:

Q. You think that there's a threshold dose for TCE in cancer?

A. I have looked at the mechanisms of TCE, and I believe that there is likely a threshold for TCE carcinogenesis, but I don't know what it is.

Q. Put aside what it is. I know you can't tell me that.

What's the best evidence you have that there is a threshold for TCE?

A. I understand how TCE is metabolized. And there are likely downstream metabolites that are responsible for the carcinogenesis of TCE. And I have an understanding of when those metabolites are likely generated, and they're not until higher exposure concentrations.

Q. So what are the metabolites of TCE?

A. I could not name them, off the top of my head, but I do know that TCE is metabolized to

different -- many different types of metabolites, particularly at higher exposure concentrations when the detoxification mechanisms are not active.

Q. So like can you name one of these metabolites that have convinced you that there is a threshold for TCE?

A. Not off the top of my head. I'd have to look at some of my evaluations on that.

Q. How about in your report?

A. I don't talk about that in my report.

Q. Walk me through it again. How does it work? So you know that TCE has some unknown metabolites; right? That's the first step.

A. There are known metabolites.

Q. It's got metabolites?

A. Yes.

Q. You don't know what they are?

A. I have written about them, and I've looked at them. I just can't name them as I sit here right now.

Q. Walk me through -- it's got metabolites. How do I get from that to, well, there might be some safe level of TCE?

MS. ELLISON: Object to the form.

THE WITNESS: So this is not something

that I talked about in my report, so I don't want -- I'm not going to opine on the details of my understanding of the threshold. But I do know from looking at the science for TCE that there is likely a threshold, and it's based on metabolism. That's all I can say about that for now as I sit here without looking in my analysis.

BY MR. SNIDOW:

Q. Well, can you give me any authority saying that there is a threshold for TCE?

A. I don't know if there's an authority that says that, but based on my review of the science, I believe there is.

Q. So no authority saying TCE probably has a threshold?

MS. ELLISON: Object to the form.

THE WITNESS: I consider myself an authority on or an expert in the area of evaluating TCE toxicity and mechanistic information and risk assessment. So based on my expertise.

(Bailey Exhibit 15 was marked.)

BY MR. SNIDOW:

Q. I'm going to show you a document that I will mark as Exhibit 15. This is another excerpt.

This is from the European Chemicals Agency.

MS. ELLISON: I think you said this, but just to make sure that the court reporter got it, this is another excerpt, so not the entire document that J.J. just handed the witness.

MR. SNIDOW: That's correct.

BY MR. SNIDOW:

Q. Could you turn to page 2. Do you see in the kind of middle of the page there's a sentence that begins "Trichloroethylene"?

A. Okay.

Q. Do you see where it says, "Trichloroethylene is a non-threshold carcinogen"?

A. Yes.

Q. Do you disagree with that; right?

A. I do.

Q. Could you go to page 4. It says Characterization of Risk.

A. Yes.

Q. It says, "Trichloroethylene is considered to be a genotoxic carcinogen."

I think you agreed with that so far; right?

A. Trichloroethylene is a carcinogen, and its metabolites have been shown to be genotoxic.

Q. Then it says, "No threshold can be determined below which exposure would be safe." Right?

A. That is what this says. That's not what I agree with.

Q. I know. You can put this one aside.

Did you review -- you're aware that the EPA has banned TCE; right?

A. Under Tosca, it has banned TCE for certain uses of TCE. Well, based on uses of TCE I should say.

Q. I don't know what that means. You know that EPA has banned TCE; correct?

MS. ELLISON: Object to the form.

THE WITNESS: In the Tosca rule, it's banning TCE based on certain uses of the chemical, and many of them are occupational uses.

BY MR. SNIDOW:

Q. Put aside what evidence was compiled in support of the ban. I'm asking: The EPA banned trichloroethylene entirely; true?

A. They banned the uses of TCE in occupational settings. That's what they did.

(Bailey Exhibit 16 was marked.)

BY MR. SNIDOW:

Q. I'm going to show you a portion of their -- an excerpt of their risk assessment, which I'll mark as Exhibit 16.

Have you reviewed their risk evaluation for TCE?

A. Yes.

Q. If you could turn to the bottom of page 237.

A. Okay.

Q. Do you see where it says Human Studies?

A. Yes.

Q. And it's talking TCE exposure and neurogenerative disorders?

A. Yes.

Q. It cites the Bove 2014a, 2014b and Goldman 2012?

A. Yes.

Q. You don't cite those in your report; right?

A. They are likely on my MCL, but I did not talk about them in -- I may have talked about -- I may have referenced them in the context of some of my rebuttals.

Q. So you think that you did reference the

Goldman 2012 study?

A. I'd have to look at my Parkinson's disease reports to see if I did, but I have looked at it for the rebuttals of the plaintiffs' experts.

Q. You can put this one aside for now.

Do you have Exhibit 1 in front of you?

A. I can get it in front of me. I do.

Q. If you go to page 4, you quote the background lifetime cancer risk for all cancers combined at 40 percent.

A. Yes.

Q. And then do you see you state that one times ten to the negative four is .0001 percent probability?

A. Right.

Q. Then you add that to the 40 percent?

A. That is the way to think about it, yes.

Q. You are not taking into account the specific background risk from for bladder cancer; right?

A. Not in this calculation, but you could do that.

Q. You did not?

A. I did not, but you could easily add that

low percent to whatever the risk is for bladder cancer.

Q. Well, you'd also have to figure out what the risk is for bladder cancer specifically; right?

A. I think I have some discussion of that in my report.

Q. You do. Am I correct that for each of the diseases, you simply added one times ten to the negative six to the overall background risk for cancer in the general population?

A. Just to provide some perspective on how low these numbers are. It was not part of my calculation. It was just illustrative.

Q. In your risk assessment, you used cancer slope factors and inhalation risk units to calculate risk; right?

A. Yes. Those are the values that I used for the risk calculations.

Q. Those are based on a single disease endpoint; true?

A. They're often based on the most sensitive endpoint based on all the data that EPA has evaluated, yes.

Q. So for a certain chemical, the cancer

slope factor and inhalation risk unit could be based on kidney cancer; right?

A. Yeah.

Q. Or leukemia?

A. Yes.

Q. Or some random cancer like liver cancer; right?

A. That is one cancer that it has been based on after EPA looks at all cancers.

Q. Then you took the cancer slope factor and applied it to other cancers?

A. I applied it to a cancer risk calculation because it's the most sensitive and it's protective of all the other cancers that EPA looked at. So it's a general cancer risk value that EPA uses to determine cancer risk in general. So it includes everything that they looked at.

Q. But, for example, I think you know the cancer slope factor for kidney cancer -- strike that.

The cancer slope factor for trichloroethylene is based on kidney cancer; correct?

A. One of them is based on kidney cancer.

Q. The cancer slope factor is based on

kidney cancer?

A. There are three cancer slope factors for TCE.

Q. There are plaintiffs that you reviewed who were exposed to TCE and developed, say, leukemia; correct?

MS. ELLISON: Object to the form.

THE WITNESS: There are several plaintiffs who have leukemia, and I looked at exposures for all of the chemicals to see where the risks came out.

BY MR. SNIDOW:

Q. And to determine the cancer risk for leukemia plaintiffs, you used the cancer slope factor for TCE that was based on kidney cancer; right?

A. So I used the cancer slope factor that EPA derives based on looking at all of the information for TCE, including studies that looked at the potential for leukemia risk following exposure to TCE. So those studies have been considered by the Agency.

But the Agency determined that kidney cancer was the most sensitive endpoint. And non-Hodgkin's lymphoma was another endpoint that

they used to calculate a TCE risk value.

Q. I may have missed asking this wrong. So you've got two plaintiffs. One has got bladder cancer and one's got leukemia; right? And they've got exactly the same everything except for that.

Your cancer slope calculation for them will come out exactly the same?

MS. ELLISON: Object to the form.

THE WITNESS: I use the cancer slope factor that EPA uses that considers leukemia as a potential endpoint for TCE. So the leukemia studies are within their evaluation, their systematic review. And they don't calculate a leukemia slope factor because there's not enough information to suggest that there's an association. So the calculation -- the number that they derive is based on where they see -- from reliable epidemiology studies and animal studies where they see an association. And that's what they use to calculate their cancer values.

BY MR. SNIDOW:

Q. I'm not trying to be difficult, Dr. Bailey. You remember my question; right?

My question was: Assume you've got two plaintiffs. They've got different cancers.

Everything else is equal. Your cancer slope calculation is going to come out the same for them; correct?

MS. ELLISON: Object to the form.

THE WITNESS: It would. And for the leukemia plaintiff, it would be a very conservative estimate because there's no evidence to support an association between TCE exposure and leukemia. So it would be a very conservative risk for cancer in general for that plaintiff.

BY MR. SNIDOW:

Q. So that's a yes, it's going to come out the same; correct?

A. It will come out the same, but you have to interpret it differently.

Q. Same answer for if you had a bladder cancer patient and a kidney cancer patient. With respect to TCE, your analysis is going to come out exactly the same for them; right?

MS. ELLISON: Object to the form.

THE WITNESS: So this is a hypothetical question. I would have to consider -- of course, in my evaluation I considered lots of other things, the exposure, different exposure information for the plaintiffs, the areas where

they lived, the exposure frequency, duration, the activities. All of that would be part of my calculation.

BY MR. SNIDOW:

Q. I understand. I'm asking you -- I'm basically asking how your formula works. And your formula does not change based on the specific cancer type; is that correct?

A. For TCE, it would because there are three cancer values for TCE. So NHL would be different from kidney cancer, or if liver cancer was one that we're evaluating, it would be different.

But if there is no toxicity value that EPA derived for a certain endpoint, I don't use it because there isn't one. But it doesn't mean that they didn't look at it. It means that they looked at it, and the endpoint that they -- the value that they derived is based on the most sensitive endpoint protective of all cancers.

Q. You agree that individual tumor types should be considered separately; right?

A. Well, you'd want to consider that in the epidemiology studies, which is what I do in my Section 8.

Q. Because different tumor types are -- involve different cell types; right?

A. In terms of -- I mean, that is something that you'd want to consider in interpreting the data for when you're doing a weight-of-evidence evaluation and looking at all of the data. Certainly that would be something that would be important. I would imagine medical experts look at that as well.

Q. And also because different tumors often have different mechanisms of action?

A. That I can't answer because that's a hypothetical. I'm not looking at a particular chemical. I don't know the specifics of what you're asking me.

Q. You don't know the different mechanisms of action between PCE and TCE seen between kidney cancer and bladder cancer?

MS. ELLISON: Object to the form.

THE WITNESS: That's a very general question. There are proposed mechanisms for different chemicals that may be associated with certain diseases. There are different proposed mechanisms. And I can't answer that here without doing an evaluation of the data.

BY MR. SNIDOW:

Q. Do you agree leukemia and kidney cancer have different risk factors?

A. I don't know. I would have to look at the risk factors for each of them to see what they are and compare them.

Q. You didn't do that before writing your report?

A. That was not something that was part of my evaluation.

Q. Same answer for bladder cancer, NHL, kidney cancer, Parkinson's, you're not aware of the different risk factors for them?

A. That's not something that I did in my report. My report was focused on the exposure piece of the specific causation analysis.

Q. Do you agree that kidney cancer and leukemia have different causes?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: That's not something that I wrote -- that my report discusses. So I'd have to look at the different causes of the different cancers to tell you if they're different.

BY MR. SNIDOW:

Q. Before writing your report, you didn't look into what does cause kidney cancer, did you?

A. That was not something that I was asked to do for this report because my report is based on the exposure piece of the specific causation analysis, not the risk factors.

Q. Same answer, you didn't look into different causes for bladder cancer, NHL, leukemia, Parkinson's disease?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: I did not look at those because they're not -- that was not part of my evaluation. That was not what I was asked to do.

BY MR. SNIDOW:

Q. In your report, you estimate various margins of exposure; correct?

A. Correct.

Q. I just want to be clear on that methodology. So first you define a POD; is that right?

A. Yes.

Q. And that means point of departure; correct?

A. Correct.
Q. And that's the exposure level at which there is either no risk or a very, very, very, very, very low risk; right?
A. Yes, based on the toxicity values.
Q. Well, I think it's actually based on the animals and human epi; right?
A. That's what I mean, the studies that are the basis of the toxicity values, yes.
Q. That's what I wanted to clarify.
So the point of departure, correct me if I'm wrong, is you look at either the animal literature or the human epidemiology, and you determine the point at which there's no risk or extraordinary de minimus risk; right?
A. No. That is not the point of departure for my margin of exposure section. It's based specifically on the study that EPA used to derive the toxicity value.
Q. Let's look at page 41 of Exhibit 1. Do you see where it says Plaintiff-Specific Margins of Exposure?
A. Yes.
Q. It says, "As discussed in Section 3, the exposure levels at which health effects are

predicted to be associated with no or a very low response from animal or human studies are the starting point, (i.e., points of departure) used to derive regulatory toxicity criteria."

Did I read that correctly?

A. Yes.

Q. Sometimes that's derived from animal studies; true?

A. The point of departure that EPA used to derive the regulatory toxicity criteria specific number, sometimes it's from animal studies, and sometimes it's from epidemiology.

Q. And you agree that human data are the preferred point of departure?

A. I think I answered this earlier. It's something that you would want to look at in combination with animal data, with mechanistic data. And then based on all of that information, integrating all of that information, you determine and EPA has determined whether the animal data or the human data are best for derivation of the toxicity value.

(Bailey Exhibit 17 was marked.)

BY MR. SNIDOW:

Q. Showing you Exhibit 17, not an excerpt

this time. That's your name on the top right, right, Lisa Bailey?

A. Yes.

Q. This is an evaluation of methyl methacrylate that you did?

A. Okay.

Q. Yes?

A. Yes.

Q. I believe again just in the study, you also determined that there was not human risk at low levels of exposure?

A. This one was very a long time ago. I would have to review this study again to tell you what the conclusion was.

Q. Turn to page 9 -- Section 9, page 231. Do you see the last paragraph there beginning "Human data"?

A. Yes.

Q. It says, "Human data are often recommended as the preferred point of departure when setting occupational exposure standards." Right?

A. Often recommended, yes.

Q. I think I asked you in general if that was true before, and you said, well, not

necessarily.

Do you agree it's often recommended?

MS. ELLISON: Object to the form.

THE WITNESS: I think it is often recommended, but it has to be -- it still has to be in the context of a systematic review of all of the information. Sometimes it comes out to be an epidemiology study, and sometimes it doesn't. If the data integration suggested an epidemiology study is reliable and sufficient for a calculation, then it will be used. If it isn't, then the animal data will be used.

BY MR. SNIDOW:

Q. Do you agree that using animal data creates some uncertainty about whether the results are applicable to humans?

A. There is some uncertainty, yes, and it's usually dealt with by doing conservative extrapolations, using conservative assumptions for the extrapolation from animals to humans.

Q. First you have to extrapolate from animals to humans; correct?

MS. ELLISON: Object to the form.

THE WITNESS: I don't know if that's the first step. I'd have to look at the evaluation.

Sometimes there's something else you need to do first with the animal data before extrapolating to humans.

BY MR. SNIDOW:

Q. It's certainly one of the things you do; right?

A. Yes.

Q. Put this one aside. If you go back to the report, in your report, I believe you define the point of departure as the exposure level that's associated with a 1 percent increased risk.

A. It depends on the chemical. And you'd have to get that from the EPA toxicological profile. And they report what the risk is for the point of departure. So that's what I start with. If it's 1 percent, I start with that. If it's something else, I'll start with that.

Q. For TCE you agree you started with 1 percent?

A. I'd have to look at the appendix.

Q. Do you have E-1 there?

A. Yes. That is what I started with.

Q. 1 percent?

A. Yes.

Q. And I think it's your testimony that 1

percent is a de minimus risk?

A. No.

Q. No?

A. This is the risk that was reported in the study that's associated with this particular dose, milligram per kilogram data. This is the highest level of exposure from the study. It's where they started.

Q. I know, but you say you have this equation. You have a POD.

A. Yes.

Q. It ultimately is going to give you the exposure that leads to a 1 percent increased risk; right?

A. That's the -- that is the number that comes out of EPA's dose-response evaluation. It's a conservative estimate. It's based on modeling and looking at confidence intervals around that modeling and estimating where the 1 percent risk would fall using conservative assumptions.

Q. My only question though is: The POD that you're modeling is 1 percent increased risk; correct?

MS. ELLISON: Object to the form.

THE WITNESS: It is because that's the

starting point for the point of departure for the toxicity value.
BY MR. SNIDOW:
Q. And that's one in a hundred; right?
A. 1 percent is one in a hundred.
Q. If you go back to page 41 of your report, at the top you define the point of departure as the levels at which health effects are predicted to be associated with no or a very low response for animal or human studies?
A. Yes. That's how they're defined by EPA. That's their starting point.
Q. So 1 percent is no or very low response?
MS. ELLISON: Object to the form.
THE WITNESS: That is a low starting point for a point of departure.
BY MR. SNIDOW:
Q. A cancer risk of one in a hundred?
MS. ELLISON: Object to the form.
THE WITNESS: So that is a number that comes out of EPA's derivation of the toxicity value. And again, it's based on conservative modeling, conservative confidence intervals around that model. And it's estimating where on that model a 1 percent risk would be. And then that's

the starting point. Then that's where they then -- they do the linear extrapolation from that point.

BY MR. SNIDOW:

Q. I'm just saying 1 percent increased risk is in no way a de minimus risk; correct?

MS. ELLISON: Object to the form.

THE WITNESS: Well, the de minimus risks that EPA uses for a population is ten to the minus six or lower.

BY MR. SNIDOW:

Q. So 1 percent is, what, 5,000 times above that?

A. But that's not what they use for evaluating risks. They use a linear extrapolation from that point, which is why I did both. I looked at the comparison to the point of departure and I calculated risks.

Q. You keep -- I don't think you're doing it intentionally. My only question is: Do you consider a 1 percent absolute increased risk of cancer to be de minimus?

MS. ELLISON: Object to the form.

THE WITNESS: Mathematically it's not equal to the ten to the minus six, but I'm using

it in a different way here. And I'm comparing that point of departure, which is a conservative estimate, to the exposures for the plaintiff, and they're well below that starting point, which is one part of my analysis.

BY MR. SNIDOW:

Q. This is in absolute terms, not relative terms; right?

MS. ELLISON: Object to the form.

THE WITNESS: It is a direct comparison of the exposure for the plaintiff estimated based on conservative estimates of the exposure in comparison to the estimated point of departure for the toxicity value that EPA used, yes.

BY MR. SNIDOW:

Q. You don't know what the relative risk for a certain cancer that will correspond to this 1 percent increased risk is, do you?

A. I would have to look at the study to see -- I think there's a way you can do that. I don't know, off the top of my head, how it compares to the exposure information from the study where the relative risk was X.

Q. We're going to look at that, I promise.

My only question is: You didn't

calculate it; right?

A. I calculated risks based on EPA's method to provide some perspective on the exposure. I did not do relative risk calculations for a population. That's an epidemiology study calculation. It wouldn't make sense to do that here.

Q. Once you calculated the POD, you then created what you call a margin of exposure; right?

A. Yes.

Q. As I understand it, if the individual experienced exposure to amounts associated with 1 percent, then their margin of exposure would equal 1.0; correct?

A. Yes.

Q. If they were exposed to amounts that were below 1 percent, then their margin of exposure would be greater than one; correct?

A. Yes. If you're comparing it to the concentration that's the basis of the 1 percent, yes, it would be lower than -- greater than nine.

Q. Conversely, if they were exposed to concentrations that were greater than the risk associated with 1 percent, their margin of exposure would be less than one?

A. If their exposure was greater than the point of departure that I looked at -- again, this is a hypothetical question. None of my margins of exposure came out to be less than one. They were all well above one. If it was greater than the point of departure, then it would come out to be less than one.

Q. And then if you look at page 22 of your report, you say that, "If the margin of exposure is greater than one, that provides support that adverse health effects would not be expected for the individual."

A. That provides some additional support, yes. You wouldn't want to do it -- only do this calculation. You'd want to look at other things as well, as I did.

Q. So if it was -- let's say it's .9. Why does having an increased risk of cancer on the order of 0.9 percent, why does that provide support there's no adverse health effects?

MS. ELLISON: Object to the form.

BY MR. SNIDOW:

Q. That's a huge increased risk, isn't it?

MS. ELLISON: Same objection.

THE WITNESS: So again, that's

hypothetical. Nothing came out to be .9. Everything was well above one for the plaintiffs here. But as I said, you want to look at the risk calculation that's plaintiff specific, see where that falls relative to the EPA's acceptable range of ten to the minus six, ten to the minus four, and also look at a margin of exposure. That's one part of the evaluation. Nothing came out to be .9.

BY MR. SNIDOW:

Q. I understand. But in your report, you don't provide any other ratios besides MoE greater than one; right? You don't say it needs to be ten times. It needs to be hundred times. You say if the margin of exposure is greater than one, that provides support that adverse health effects would not be expected; right?

A. You also have to look at the other parts of my evaluation. So you'd want to look at the risk calculation and also look at the epidemiology comparison I did in Section --

Q. Let's stay focused on the MoE.

MS. ELLISON: Just the talking over, please.

MR. SNIDOW: I'm not trying to.

MS. ELLISON: I know.

BY MR. SNIDOW:

Q. We've talked about the risk assessment. I promise we'll talk about the epidemiology. Right now I want to talk about the margin of exposure. Okay?

A. That's what we're talking about.

Q. You did this analysis because you thought it informed your causation opinion; correct?

A. Yes, in the context of the other information, not by itself.

Q. I want to talk about why it's in here at all. How does it follow that if the MoE is greater than one, that means adverse health effects would not be expected?

A. I didn't say that they are not expected. I said it provides support that adverse health effects would not be expected meaning that it's additional support in combination with the risk calculation and with the Section 8.

Q. Why does that provide support at all? Why does it provide any support at all for the proposition there's no adverse health effects if

you've got an MoE of 1.0 if .9 percent absolute increased risk of cancer?

A. I'm confused about the hypothetical. My margins of exposure are higher than that. So if you calculate something that's well above one, that provides support that the exposure for the plaintiffs is well below EPA's starting point for the toxicity value, the level that EPA considers a no effect level or a very low effect level. That's the point of margins of exposure.

Q. You're really not suggesting that a 1 percent absolute risk is a no effect level, are you?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: It's the point of departure that EPA starts with.

BY MR. SNIDOW:

Q. A risk of one in a hundred?

A. Again, you need to look at that in combination with the risk calculation which do not come out to be one in a hundred. They come out to be much lower than that.

Q. Let's look at page -- just down a little bit, you say, "If the plaintiffs' exposures are

well below exposures where effects have been observed in epidemiology or toxicology studies, even if there is a risk calculation greater than U.S. EPA's targets, these results provide support the individual exposures are not likely to be associated with the health effect of concern."

You wrote that; right?

A. Let me read it. Yes. That's why you want to look at both of the results from the margin of exposure calculation and the cancer calculation, the cancer risk calculation. But again, that's not what happens with the plaintiffs. All of the risks are within EPA's targets. So that's not something that I think about.

Q. I'm asking about your methodology now. You chose to say if MoE is greater than one; right? You wrote that sentence?

MS. ELLISON: Object to the form.

THE WITNESS: That sentence I wrote, yes.

BY MR. SNIDOW:

Q. I'm asking you: Why does that follow?

MS. ELLISON: Object to the form.

THE WITNESS: I think I explain it in my

report. It means that the exposure for the individual is lower than the starting point for the cancer toxicity value, the conservative starting point that EPA uses to derive the toxicity value. So if you're lower than that, it provides support that the exposures are lower than what's been observed in the literature.

BY MR. SNIDOW:

Q. You then did plaintiff-specific margins of exposure for all 25 plaintiffs; right?

A. Yes.

Q. Have you ever seen that done in the scientific literature?

A. Yeah.

Q. For individuals?

A. No, not for individuals. I mean, it's commonly done. EPA did margins of exposure for -- in the Tosca risk evaluations.

Q. So you've seen it done for populations; right?

A. Yes.

Q. Have you ever seen a peer-reviewed publication that calculates the margins of exposure for an individual?

A. There are not typically publications for

individuals. But I have seen it done in the context of expert reports that are looking at individual causation analysis.

Q. Were those expert reports written by Gradient?

A. The ones that I've looked at, yes, because I work at Gradient.

Q. Well, you say that, but how many litigations have you been involved?

A. Many.

Q. During those litigations, do you sometimes review expert reports from other people?

A. Sometimes.

Q. You did here; right?

A. Yes.

Q. And you often, I'm sure, review expert reports from people who are on the same side of litigation as you do?

A. Not often.

Q. You did here; right?

A. Not an evaluation that was similar to mine.

Q. I know. But you review other expert reports; correct?

A. I do review other expert reports.

Q. In the course of your entire career, have you ever seen anything in the published literature or an expert report where someone does a margin of exposure calculation for an individual person?

A. Yes. I've seen expert reports where that's done.

Q. Oh, really? Outside of Gradient. Sorry.

MS. ELLISON: Object to the form.

THE WITNESS: I have not looked at reports -- I can't recall looking at a report outside of Gradient where -- I may have. I've been doing this for a very long time. It's certainly a very reasonable approach.

BY MR. SNIDOW:

Q. You apply this analysis to noncancer and cancer endpoints; correct?

A. I do.

Q. And have you seen it done for cancer endpoints even with respect to a population?

A. As I sit here right now, I can't recall when that has been done. But again, it's certainly a reasonable approach to consider where the starting point is for derivation of the

toxicity value and compare that to what the exposure is for an individual.

It gets at the question that I'm asking, is this exposure something that is of concern for human health. You have to look at it.

Q. But just to clarify, whether we're talking about an individual or even a population, you can't recall ever seeing a margin of exposure analysis done for cancer; correct?

MS. ELLISON: Object to the form.

THE WITNESS: I have seen it done for individuals or populations.

BY MR. SNIDOW:

Q. In a Gradient expert report?

A. Yes.

Q. Any other place?

A. I can't recall right now, but again, it's a reasonable approach. It's something that you should look at as a risk assessor, someone who is trying to answer the question about whether exposures are elevated or not. It's an important part of the analysis.

Q. Let's walk through exactly how you derived the margin of exposure for TCE and bladder cancer. So look at Exhibit 1, page 22.

A. Yes.
Q. You say, "If the plaintiffs' exposures are well below exposures where effects have been observed in epidemiology or toxicology studies, even if there's a risk calculation greater than USA EPA's targets..."
Then I think we've discussed the rest of the sentence; right?
A. Yes.
Q. Let me just focus on the first part. What if the relevant exposure simply has not been evaluated in an epidemiology study? Would you still say that the fact that the plaintiffs' exposures are below the levels that have shown results indicates no causation?
MS. ELLISON: Object to the form.
THE WITNESS: I don't know what you mean by relevant exposure.
BY MR. SNIDOW:
Q. You know what a dose-response is; right?
A. Yes.
(Bailey Exhibit 18 was marked.)
BY MR. SNIDOW:
Q. Let me just draw it and I'll show you. The dots, I'm going to use this to mean the levels

of exposure that have been shown to increase risk in the epi. Okay?

A. Risk for what endpoint?

Q. For whatever you want.

A. The endpoint is important.

Q. Cancer.

A. Okay.

Q. My star down there is what you're calling here the plaintiffs' exposure, which is less than demonstrated in the epidemiology; right?

A. There are no numbers on here.

Q. I'm just trying to figure out what you're saying.

A. I'm not sure what you're asking me. I'm sorry.

Q. You say -- it's in the second half of the sentence. You're referring to where effects -- exposures where effects have been observed in epidemiology or toxicity studies; right?

A. So this is specific to the study related to the toxicity value that EPA had derived. That's what this margin of exposure calculation is based on. It's based on the toxicity value that EPA derives and the endpoint associated with that

toxicity value. Those are the effects.

Q. You see you refer to exposures where effects have been observed in epidemiology studies; right? Do you see that?

A. Yes.

Q. I'm telling you this is what I'm trying to represent with the dots. Those are exposures that have been demonstrated in the epidemiology studies.

A. Yes.

Q. You say, "If the plaintiffs' exposures are well below those levels, that means that there's not likely to be a health concern."

I'm asking you, can you explain to me why that is true?

A. Because that is -- those are the points where effects have been observed in studies. So if exposures for the plaintiffs is well below effects that have been or concentrations or doses where effects have been identified, then you can say that the exposures are well blown what we know and what we have seen causes this health effect for this particular chemical.

Q. How do you know it doesn't also cause this health effect at the lower exposures that

weren't examined in the epi?

A. So the study was used to derive a point of departure, and then EPA does a linear extrapolation from that point all the way down. It does calculate a risk down here, but these are very low exposure estimates. So EPA does the best that they can with the information that's available.

Most of the studies that we have are at doses that are well above exposures in a population. So then they use that information and apply conservative estimates to determine a way to provide some perspective on whether there might be a risk at this very low concentration.

(Bailey Exhibit 19 was marked.)

BY MR. SNIDOW:

Q. Let's look at Tab J, which I'll mark as Exhibit 19. This is the high risk toxicological review for TCE from the EPA, which I think you reviewed this.

A. Yes.

Q. If you could go to page 5-140.

MS. ELLISON: I can't recall if you said, but for the record, this is not a complete copy.

MR. SNIDOW: It's not a complete copy. I think we got the full chapter this time.

MS. ELLISON: Thank you.

MR. SNIDOW: You're welcome.

BY MR. SNIDOW:

Q. If you will go to actually first on page 5-139, it's talking about Dose-Response Analyses: Human Epidemiologic Data; right?

A. Yes.

Q. In the middle of the page, it says, "The Charbotel 2006 study was selected as the sole basis for the derivation of inhalation unit risk estimate for kidney cancer." Correct?

A. Yes.

Q. Did you read the Charbotel study?

A. I have looked at the Charbotel study for a number of projects, yes.

MS. ELLISON: Also, just for the record, what was handed to Dr. Bailey is not a complete copy of the chapter. I believe there is a complete copy if you want to enter it as an exhibit. I don't know if it matters for your purposes.

MR. SNIDOW: No.

BY MR. SNIDOW:

Q. We're on page 5-140. So TCE and kidney cancer, you agree that the Charbotel study forms the sole basis for the inhalation unit risk; right?

A. For kidney cancer.

Q. For kidney cancer. And the inhalation unit risk then gets transformed into the cancer slope; correct?

A. Inhalation unit risk is the cancer -- yes. Then that is used to derive the OR kidney slope factor.

Q. For kidney cancer there's not any other epidemiology that all of that is based on other than Charbotel; correct?

A. Charbotel is the basis of the toxicity value, yes.

Q. If you see on page 5-140, it shows the results for Charbotel 2006; right?

A. Yes.

Q. And the exposure categories are nonexposed, low, medium and high; true?

A. Um-hum.

Q. The odds ratios are 1.62, 1.15 and 2.16; right?

A. Yes.
Q. This is based on factory workers in France; correct?
A. Yes.
Q. This is renal cell carcinoma and not any of the other cancers at issue in this case; correct?
A. I would have to look at the study. Yes, RCC is what it says here, yes.
Q. In the Charbotel, the dose-response wasn't totally linear; correct?
A. I would have to look at the model data to tell you whether it's linear.
Q. Well, you can just see from it; right? It's 1.62, 1.5, 2.16.
A. Yes.
MS. ELLISON: Object to the form.
THE WITNESS: I mean, those numbers go down, but there's also some variability. I mean, the important number is the top number where the risk is significant.
BY MR. SNIDOW:
Q. Well, you need all the results to model the dose-response curve; do you not?
A. Yes.

Q. EPA did that here; right?
A. Yes.
Q. Even though the 1.62 and 1.5 are not statistically significant; correct?
A. They did. You have to look at all the data for a dose-response curve.
Q. That's right. And even though this dose-response curve not monoatomic; true?
A. That is true.
Q. Then EPA based on those three results extrapolates the linear regression model down to zero; true?
A. Correct, based on the modeling of that data.
Q. And you have reviewed the Charbotel study, so you know that the PPM years in the low, medium and high categories are higher than they were at Camp Lejeune; correct?
MS. ELLISON: Objection. Foundation.
THE WITNESS: I would have to compare the PPM years. I did that in my -- by looking at the margins of exposure for the kidney cancer plaintiffs. So that would be the comparison.
BY MR. SNIDOW:
Q. So these are higher than are at Camp

Lejeune?

A. Yes.

Q. Nowhere in the Charbotel study were people exposed to the levels of TCE that the people at Camp Lejeune were exposed to; right?

MS. ELLISON: Objection to the form. Foundation.

THE WITNESS: The inhalation exposure concentrations are higher than those at Camp Lejeune just based on my margins of exposure, which are high.

BY MR. SNIDOW:

Q. I'm asking something else. It's not as if in Charbotel they looked at low levels and found no effect; right?

MS. ELLISON: Object to the form.

THE WITNESS: EPA typically relies on worker studies of higher exposure concentrations because often they're more reliable in terms of exposure information for the chemical of concern and the health effects of concern. So sometimes that's what EPA needs to do and often, does that often with occupational studies for derivation of toxicity values. The exposures are higher than what people are exposed to in the population.

BY MR. SNIDOW:

Q. So how does it follow from Charbotel that people exposed to lower exposures are not at increased risk?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: Because, I mean, even if the 253 and 62 PPM year, that's not a significant risk.

BY MR. SNIDOW:

Q. We just talked about this. The EPA treats these numbers as real. They're using this to model everything you did in your report with respect to RCC and TCE; right?

A. Yeah. Exposures lower than those would be less likely to have health effects.

Q. Sure, less likely. But why is below this no risk?

MS. ELLISON: Object to the form.

BY MR. SNIDOW:

Q. How do you know that in cumulative exposure categories below the ones in Charbotel there's not an increased risk?

A. It's based on all of the information that EPA looks at, including the animal data,

mechanistic data and this Charbotel study. It uses the exposure information from the Charbotel study and assumes that there is some risk higher than zero all the way down to zero. So anything above zero you do calculate something.

And then that number, and this is a conservative derivation of the toxicity value because it's based on conservative modeling of that data, and then that is compared to what EPA considers a safe level of exposure.

Q. Two more.

A. Go for it.

Q. Your POD, the level at which there's no or de minimus risk; right?

A. The POD is not equivalent to de minimus risk. EPA considers the POD -- that's the starting point. It is what it is. It's the starting point of derivation of the toxicity value. Then you use that to calculate risk. And if the risks are -- based on the linear extrapolation from that point, if the risks are ten to the minus six, then it's de minimus based on the toxicity value. It's conservative, a conservative estimate based on Charbotel's study.

Q. Even though there's increased risk of

every exposure category in Charbotel?

MS. ELLISON: Object to the form.

THE WITNESS: There's increased risk at the highest exposure, which is a significant exposure, and it's well above the exposures in the -- for the plaintiffs.

MR. SNIDOW: Take a break.

THE VIDEOGRAPHER: Off the record at 1:40.

(Recess from 1:40 p.m. to 2:33 p.m.)

THE VIDEOGRAPHER: Back on the record at 2:33.

BY MR. SNIDOW:

Q. Dr. Bailey, did you calculate what Ms. Dyer's exposure was in terms of micrograms per liter month of TCE?

A. I took Dr. LaKind's exposure estimates, which were milligram per kilogram day. I did start with a microgram per liter concentration. I then took that and multiplied by months or years or the exposure duration. So that calculation is within my risk calculation. So I don't report microgram per liter months, but it's part of the calculation that I do.

Q. If I changed Dyer to any of the other 24

plaintiffs, you do not report microgram per liter month of TCE for any of them; true?

A. I don't report that, but again, I didn't because it's not comparable to EPA's toxicity values, but it is -- I considered all of those parameters in my calculations.

Q. If I changed TCE to any of the other chemicals, same answer; you considered it, but you don't report those values, do you?

A. I don't report microgram per liter month, right, but it's part of my calculation.

Q. Now, you mentioned that for TCE, there is no cancer slope for bladder cancer specifically.

A. EPA does not have the cancer slope factor for bladder cancer; correct.

Q. For that reason, you used the kidney cancer slope factor?

A. I used all of them combined. So I used some of kidney cancer, liver cancer and non-Hodgkin's lymphoma, so a very conservative estimate.

Q. That's what I was going to say. You said that's conservative. Given that there is no cancer slope for bladder cancer, how do you know

that it isn't steeper than for the other cancers?

A. Because EPA considered any study that looked at TCE exposure in bladder cancer. And if they thought that the studies were reliable enough to derive a toxicity value, they would have. And then if that was less sensitive or resulted in a higher risk than NHL or kidney cancer, they would have used it. But they didn't because it was not the most sensitive endpoint, that or the data were not -- did not suggest that there's an association.

Q. But you don't actually know what the slope of the TCE dose response curve looks like for bladder cancer, do you?

MS. ELLISON: Object to the form.

THE WITNESS: Well, it's not something that EPA calculated because the data are not reliable enough to do that type of calculation. The data don't support -- EPA did not conclude that TCE is a bladder carcinogen.

BY MR. SNIDOW:

Q. If you were trying to calculate the risk of melanoma, do you think it would be appropriate to use the kidney cancer slope?

A. From what chemical?

Q. TCE, PCE.
A. Yes. What I'm looking at specifically is whether there's a cancer risk for exposure to TCE for all cancers that EPA considered. And if melanoma was something that was found to be associated with TCE, then would be considered.
Q. Even though the causes are just so very different; right?
MS. ELLISON: Object to the form.
THE WITNESS: You would look at that as one part of the evaluation, and you would also look at are there any epidemiology studies that specifically looked at melanoma and TCE. And you look at that and you look to see what those exposures might be. And if they're available, then you can do that comparison. And I did that in my Section 8.
BY MR. SNIDOW:
Q. How many people did you have helping you with this report?
A. So I have one person who is my main risk person who sets up the spreadsheets and essentially works through the risk calculations. So that's one key person.
I have another person who's more -- her

focus is more on the hazard piece, so the toxicology, the epidemiology. So she provides support. And they each have people that provide support to them.

Q. Do you know how many people total?

A. The main people would be those two plus a few more that I know have looked at the risks and looked at plaintiff-specific information, and then maybe three or four that also looked at the hazard information, that section.

Q. So maybe six or seven total?

A. Roughly, yeah. I don't recall the exact number.

Q. Do you have Exhibit 2 in front of you?

A. Yes.

Q. If you could turn to the page with Bates-stamp ending 149.

MR. SNIDOW: I think you guys have a copy of this somewhere.

MS. ELLISON: Yeah. Thank you.

BY MR. SNIDOW:

Q. Are you there?

A. Yep.

Q. So that's you at the top there, Elizabeth Bailey. That's one.

A. Yes.
Q. Then Mary Hixon.
A. Yes.
Q. Anna Engle?
A. Yep.
Q. So that's three. Then six copy editors.
A. Yes. They were not involved in the evaluation. They were copy editors. So they were looking for grammatical errors, sentence structures, spelling fix. They were the copy editors.
Q. So up to nine total?
A. I would not count the copy editors as individuals who worked on my report in terms of any part of the evaluation.
Q. I'm just trying to get a sense of who's touched this report. So that's nine people so far?
A. For the copy editors, I had 25 reports, so I had a lot of copy editors.
Q. Then if you go down, it looks like there's Jiayang Chien.
A. Yes.
Q. So ten so far?
A. Five or six are the main people. Then

the copy editors if you want to add them would be around ten.

Q. And then three associates, what were they doing?

A. So Dan is a library person. So he would be looking for literature that we asked him to look for. Same for Rebekah. Catalina helps with the risk piece.

Q. So 13 so far. Then the next page, it looks like we've got five more with one repeat.

A. Yeah. Again, copy editors mostly. Sarah is the library person again looking for literature for us. Copy editing and library staff, whoever is available will be used for that. But they're not at all involved in the analysis. Janet was one of the people that helped Jiayang with the risk spreadsheets.

Q. So 17 people listed on this one invoice; right?

A. If you're counting all of the copy editor or library people.

Q. What are the library people doing exactly?

A. So if we have a study that we need to look at, they will get it for us. Sometimes they

need to be purchased, and they will purchase them for us and get them to us.

Q. Do they read it?

A. No.

Q. They just pull it?

A. Yes.

Q. And it takes them this many hours to do that?

A. So it depends on how many we're asking them to look at or to find. Sometimes there's a very long list of articles that we need them to get.

Q. Do you read all the articles yourself?

A. I read all of the key articles for my analysis, yes.

Q. Well, you said all the key articles. Are you a hundred percent sure that you read every article that's listed in your report?

A. I can't say I read every single article on my MCL from cover to end, but the documents that I cite in my report -- I cited some very large like Agency documents. I would not have read those from cover to cover because they're not -- the sections are not all relevant.

But I look at -- I look at the entirety

of the report. I look at -- and for publications I would look at tables. I look at the key information. Sometimes I don't look at the background information because it's not as relevant. But, yes, I do look at all of the studies.

Q. I understand you haven't read them cover to cover. Is it your testimony that you looked at every single study in your materials considered list, or did you delegate some of it?

A. No. I put eyes on all of the documents.

Q. You did?

A. Yes.

Q. Every single one?

A. Yes.

Q. Do you agree that risk assessment does not produce an estimate of risk for a specific cancer type?

A. Risk assessment can be used to provide perspective on certain cancer types if the cancer of concern is also the basis of the toxicity value that's used for the risk calculation. So it can be. It depends.

Q. Well, you don't in your report produce any specific risk estimates for a specific type of

cancer, do you? It's cancer generally.

A. That's the first part of the calculation. But then I look at studies that also look at the specific cancer and the exposures in those studies.

Q. Epi studies?

A. Yeah, and some of the animal studies.

Q. You agree that human epidemiology can tell you what the risk is for a particular type of cancer; correct?

MS. ELLISON: Object to form.

THE WITNESS: Human epidemiology studies are useful in providing perspective on whether -- on what exposures might -- what exposures are reported in the literature to be associated with certain health effects. So you'd want to look at that in the context of the other information.

BY MR. SNIDOW:

Q. Do you agree that the Bove series of studies produced relative risk ratios for all of these diseases?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: The Bove study did report relative risks.

BY MR. SNIDOW:

Q. How many Bove studies were there?

A. I don't recall, off the top of my head. I'd have to look at my MCL to see how many.

Q. And you think you read them all?

A. I have looked at them, and I mostly looked at the tables, yes.

Q. All the Camp Lejeune epi you read?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: Like I said, I look at --

MS. ELLISON: Sorry. Just let me say the objection.

Sorry. Could you repeat your question, J.J.?

BY MR. SNIDOW:

Q. You think you read all the Camp Lejeune epidemiology?

A. I have looked at the Camp Lejeune studies.

Q. If you go to page 42 of your report, you see there's a paragraph that begins "Although Dr. Goodman..."

A. Um-hum.

Q. It ends with Goodman 2025?

A. Yes.

Q. Do you disagree with me that this is the only thing in all of your 25 reports that you say about the Camp Lejeune epidemiology?

MS. ELLISON: Object to the form.

THE WITNESS: I am citing Dr. Goodman for her evaluation of the Camp Lejeune studies because she did an extensive evaluation of those studies in her report, and I agree with her methodology. So that is how I talk about those studies.

BY MR. SNIDOW:

Q. My question though is: This is it; right? This is the only statements that you make about the Camp Lejeune epidemiology in all 25 of your reports?

A. I might have discussed some of the Camp Lejeune epidemiology studies in the rebuttal sections, but that would be report specific, and I don't recall.

Q. Do you want to take a look?

A. For this one, I guess I could take a look. It only speaks to one of the plaintiffs. So I do talk about in Section 9 the one bullet where Dr. Hatten, Longo and Bird refer to Camp

Lejeune studies. And I'm generally providing the same statement that I did early on based on Dr. Goodman's review of those studies.

Q. So that's it; right? That's all you did on that?

A. That is what I did for my report, yes, because that is...

Q. You said before all of the literature that you reviewed is in your materials considered list; right?

A. Yes.

Q. So let's look at page 51. Do you see where it says Bove?

A. Yes.

Q. And you've got one Bove study; correct?

A. I do. This is my reference list. This is not the MCL.

Q. These are the references. These are ones we discussed; right?

A. In my report, but that's not my MCL.

Q. In your report, you say, "I did not" -- excuse me -- page 42. You say, "I did consider exposure estimates from those studies because of the methodological limitations of the studies, e.g., high likelihood of exposure

misclassifications as discussed by Dr. Goodman." Right?

A. Correct.

Q. Besides high likelihood of exposure misclassification, what are the other methodological limitations in the six Camp Lejeune studies?

A. Well, I think that is by itself a major uncertainty, which is why I highlighted it here, particularly in the context of what I'm doing because it's very important to understand how individuals were exposed. And we don't have that information for the individuals in the Bove studies.

Q. Any others besides that that you can tell me?

A. Off the top of my head, no, because that's what Dr. Goodman described. But that is a very key limitation to interpretation of those studies, is the -- we don't have the exposure information for each of the individuals. But I did rely on Dr. Goodman's evaluation of the other limitations.

Q. And it's your testimony we don't have exposure information for individuals in any of the

Camp Lejeune epidemiology?

MS. ELLISON: Object to the form.

THE WITNESS: So in epidemiology studies, for the people with the various diseases, we don't have individual exposure information for those people and for those study participants.

BY MR. SNIDOW:

Q. That's your testimony, that's your understanding, is that there's no individual exposure information in any of the Camp Lejeune epidemiology?

A. Correct.

Q. And you verified that by reading the studies, I assume?

A. Yes. I have a general understanding of the studies, and I know that there's not individual exposure information for the study participants.

Q. You know that?

A. Those studies were not done with individual exposure information for each of the plaintiffs -- sorry -- each of the study participants.

Q. Am I correct that if we look through all 25 of your reports, I'm going to find this exact

same boilerplate language about the Camp Lejeune epidemiology?

MS. ELLISON: Object to the form.

THE WITNESS: So it's not boilerplate language. It's a discussion of Dr. Goodman's conclusions based on her evaluation of the Camp Lejeune studies. It's different depending on the endpoint. And as I mentioned before, I do agree with her methodology for evaluating those studies, but it's not boilerplate language.

BY MR. SNIDOW:

Q. It's not identical in every single one your reports?

A. No.

Q. It's not?

A. No, because there's a different discussion about the conclusions for each endpoint.

Q. You mean it changes like bladder cancer to kidney cancer?

A. Well, that's one thing, but also the context of whether the risks were -- this one says statistically null and close to one. Some of them say something different depending on the endpoint. They don't all say statistically null and close to

one.

Q. Am I correct sitting here today, besides exposure misclassification, you can't identify any limitations of the Camp Lejeune epidemiology?

MS. ELLISON: Object to the form.

THE WITNESS: I know there are other limitations, but I'm not going to guess what they are. Dr. Goodman talks about them. But certainly, as I already indicated, exposure misclassification is key. We need to understand how much people were exposed to.

BY MR. SNIDOW:

Q. Can you get Exhibit 10.

A. Okay.

Q. If you could turn to page 657.

MS. ELLISON: And just stating again for the record I don't believe this is a complete copy of the document.

MR. SNIDOW: I thought we had.

MS. ELLISON: No. We gave her a complete version of the toxicological review.

BY MR. SNIDOW:

Q. You can go down to footnote 67, Dr. Bailey. Do you see where it says, "In terms of general causation, accurate exposure assessment

is important because its true effect can be missed because of the confounding caused by cohorts that often include workers with little exposure to the putative offending agents thereby diluting the actual effect."

A. I do see that sentence.

Q. Any reason to disagree with that?

A. I would need to look at this example here. I want to read this again.

Yes. I think that's saying essentially what I was saying, that accurate exposure assessment is important.

Q. Right. It gives the reason why accurate exposure assessment is important; right?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: That's an example of one reason why you would want to make sure you have correct exposure information, for missing things or for just estimating something wrong.

BY MR. SNIDOW:

Q. It doesn't say that part though; right? It says --

A. It doesn't need to. I think that's --

Q. I'm just asking what it says. It

doesn't say anything except because you can miss a true effect; correct?

A. You can miss a true effect, but you can also incorrectly say that there is an effect because of confounding.

Q. It's talking about exposure misclassification there; right?

A. It's talking about accurate exposure assessment being important.

Q. What it's saying is you've got a cohort and it's got workers with little exposure. That's going to dilute the effect that you'll observe for the workers that had higher exposure; correct?

MS. ELLISON: Object to the form.

THE WITNESS: I mean, that is one reason that you would want to make sure you have exposure information, but the opposite is also true. You could be assuming that people are exposed to much higher concentrations than they actually were. It's just important -- it's an uncertainty. You need to have exposure information for study participants in order to have a good analysis of whether the exposures are related to the health effects that are being reported.

(Bailey Exhibit 20 was marked.)

BY MR. SNIDOW:

Q. Let's look at -- give me Tab 2, which I will mark as Exhibit 20.

Dr. Bailey, this is your expert report that you prepared in the Mousser case. I'll give this to you. And this is a kidney cancer case; correct?

A. Yes.

Q. And if you will turn to page 38, if you look at the bottom of the -- do you see the paragraph that says "Trichloroethylene"?

A. Yes.

Q. And it says, "Dr. Goodman concluded that the epidemiology evidence provides support for an association between kidney cancer and very high occupational TCE exposures, more than 335 parts per million years based on Charbotel."

Did I read that correctly?

A. Yes.

Q. So you're deferring to Dr. Goodman's opinion that TCE can cause kidney cancer at high exposures; correct?

A. Correct.

Q. Based on the Charbotel study; correct?

A. Right.

Q. Then it says, "Mr. Mousser's exposure estimates are well below 335 parts per million years." Correct?

A. Yes.

Q. Tell me, how does it follow that just because Mr. Mousser's exposure was less than the exposures in Charbotel, that that means Mr. Mousser was not at an increased risk?

A. So I would need to look at the other parts of my evaluation. So I also -- so I actually compared the exposure concentrations for Mr. Mousser to the 335 PPM years. That's my margin of exposure calculation, which is in Section 7. And so he was 200fold below the exposure information -- the exposure estimates for -- for TCE I have a separate margin of exposure range. It was 200 to 506,000fold lower than that 335 PPM year estimate that's considered to be a concentration where there may be health effects. So that's one thing.

I also did a risk calculation for Mr. Mousser.

Q. Just before you do that, that's ultimately going to bottom out in Charbotel; right?

MS. ELLISON: Object to the form.
THE WITNESS: Excuse me?
BY MR. SNIDOW:
Q. For TCE and kidney cancer you did a risk assessment; right?
A. I did a risk calculation.
Q. That's going to rely on cancer slope factors and the IERs; right?
A. Right.
Q. All of that is ultimately based on three endpoints in Charbotel; correct?
A. It's based on the dose-response evaluation of the Charbotel study that EPA -- yes, that EPA used.
Q. Three endpoints; right?
A. It's based on -- no. For kidney cancer it's just based on kidney cancer, kidney cancer endpoint, not the other -- you mean concentration.
Q. I mean three actual results, low exposure, medium exposure, high exposure in Charbotel. That's it. Everything you did with respect to Mr. Mousser and kidney cancer is based on that?
MS. ELLISON: Object to the form.
THE WITNESS: No, because at the end,

that's what I used to calculate his risk, but that's based on EPA and Dr. Goodman and the other agencies doing a full evaluation of all of the available data for kidney cancer and determining that the Charbotel study is the best study to use to evaluate risk.

So it's a study that's used -- in the end, it's the study that's used, but it's used in the context of a lot of other available information that was looked at to come to the decision that the Charbotel was the best, most representative study for risk evaluation.

BY MR. SNIDOW:

Q. Did you do an independent review of other studies looking at TCE and kidney cancer?

A. I did not do that for my report. Dr. Goodman did.

Q. She told you the other ones weren't very good; right?

MS. ELLISON: Object to form. She was still answering the question. So I'd just ask that you let her finish it. Thank you.

THE WITNESS: I agree with Dr. Goodman's methodology. She did look at a lot of studies related to TCE and kidney, cancer including animal

studies and mechanistic studies.

(Bailey Exhibit 21 was marked.)

BY MR. SNIDOW:

Q. Let's do Tab K. Mark as -- put this one to the side. Mark as Exhibit 21 the Charbotel study.

You recognize this as Charbotel; right?

A. Yes.

Q. You've reviewed this in doing your report; right?

A. I have looked at this study, yes.

Q. Let us start with -- if you will go to page 778. If you look at the bottom right-hand column, do you see where it says, "An expert performed"?

A. Um-hum.

Q. It says, "An expert performed the exposure assessment by using information from the occupational questionnaires (a questionnaire devoted to the screw-cutting industry and a general one for any other jobs) and the task exposure matrix for the screw-cutting tasks." Right?

A. Yes.

Q. So that's how they evaluated TCE

exposure in Charbotel; correct?

A. They used a job matrix, yes, job exposure matrix.

Q. All based on a questionnaire about where people worked? Yes?

A. It does look like a questionnaire, an occupational questionnaire was used, but the idea that they have information about the different tasks that people did or do and what the exposures are for those types of tasks.

Q. And in your view, that is a high quality exposure metric?

A. It is based on -- I mean, sometimes there are epidemiology studies, occupational studies that look at exposures with personal monitoring, and those are good estimates of exposure.

But job matrix is a very common way to look at exposure information in occupational studies. And ultimately the exposure information that goes into the job matrix is based on monitoring of workers in those tasks. So it is something that's commonly used in epidemiology.

Q. You agree that's going to lead to some exposure misclassification?

A. I can't say that for sure for this report. I don't know. I mean, I would have to look at -- Dr. Goodman would be the one to opine on that. That's not something that I talked about in my report.

Q. Let's walk it through. What the authors are trying to figure out is how much TCE these employees were exposed to; true?

A. Yes. The authors yes.

Q. You want number to be as accurate as possible; correct?

A. Correct.

Q. In an ideal world, you can have like a little badge or something and you would monitor exactly how much TCE people are exposed to; right?

A. Right.

Q. They don't have that in Charbotel, do they?

A. That's right.

Q. Instead, they went and sent out a questionnaire and said, where did you work in the factories and how long did you work there; right?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: I don't know the exact

questions that were asked, but it was developed from a questionnaire. But it's also common to gather exposure information in that way for epidemiology studies, and EPA considered that when they chose this study as a reliable study.

BY MR. SNIDOW:

Q. You have an independent opinion that Charbotel provides the best exposure estimates for the risk of kidney cancer from TCE; right?

MS. ELLISON: Object to the form.

BY MR. SNIDOW:

Q. You're not just relying on EPA. That's your opinion?

MS. ELLISON: Object to form.

THE WITNESS: So I am relying on EPA's evaluation of the studies to determine which of the studies best reflect what exposures might be associated with TCE. I'm relying on EPA's evaluation and Dr. Goodman's evaluation.

BY MR. SNIDOW:

Q. To state the obvious, using a questionnaire is not going to give you a perfectly accurate estimate of the exact amount of TCE that workers were exposed to; correct?

MS. ELLISON: Object to the form.

THE WITNESS: Using a questionnaire will give you an estimate of the exposure. But it's not a personal monitor, so it's not exact, no. But it is the way that they did the evaluation here. And a lot of times the epidemiology studies that we have, we do what we can with the information that is available and EPA has determined. And this is a very common way to look at exposure in epidemiology studies.

BY MR. SNIDOW:

Q. Yep. Another way would be a questionnaire about where people live; correct?

MS. ELLISON: Object to form.

THE WITNESS: Another way to do what?

BY MR. SNIDOW:

Q. Another valid way of trying to get an exposure when you don't have personal monitoring, you can ask people where they live?

A. So that's different. I think for occupational studies, it's common to use an exposure matrix when you know that people are exposed to a certain chemical, but you're not sure what it is. Where people lived is very different because there's a lot of additional other things that you'd want to consider for where someone

lives.

Q. If you go to page 781 at the bottom, it defines the dose tertiles that's used in Charbotel, right, and it says, "The cumulative dose tertiles defined on controls' exposure were 1 to 150 parts per million years." Correct?

A. Correct.

Q. That is an area under the curve measurement; correct?

A. PPM years is cumulative, yes.

Q. That does not take into account someone's weight; right?

A. No. This is just inhalation concentration.

Q. Correct. That's a perfectly valid way of doing exposure estimates for inhalation; true?

A. For inhalation, yes.

Q. Just to be clear, the cancer slope is ultimately going to be based on the IUR; correct?

A. The cancer slope factor does based on off of the IUR using a PBPK model that does that extrapolation and accounts for body weight.

Q. Then it looks like they've classified these workers into low, medium and high cumulative doses; true?

A. Right.
Q. Then if we go over and look at the results, it says the table that was reprinted in IRIS EPA that we were looking in the bottom right, Table 6?
MS. ELLISON: What page are you on?
MR. SNIDOW: 782 at the top, Table 6, bottom right.
THE WITNESS: Yes, I see that.
BY MR. SNIDOW:
Q. If we look at low, that's 1 to 150 parts per million years?
A. Yes.
Q. And the adjusted odds ratio there is above 1.0; true?
A. The first number is, but the confidence interval includes one, so it's not statistically significant.
Q. That doesn't mean you just ignore it; right?
A. It means that it's not significant, so you don't know whether there is an association or not. It suggests that there may not be an association. It's not statistically significantly elevated.

Q. If you look in the bottom, it says, "A significant trend was also identified between cumulative dose and RCC risk." Right? Bottom left of 782.

A. Yes. That's what it says.

Q. And that is statistically significant?

A. Just barely, below .05, yes.

Q. Just barely. This is the paper that the EPA uses to calculate -- to create the dose-response curve for TCE?

A. Yes.

MS. ELLISON: Object to the form. Just let me object.

BY MR. SNIDOW:

Q. So what that means is in a statistically significantly way, the higher the TCE, the higher the kidney cancer risk; true?

MS. ELLISON: Object to form.

THE WITNESS: So the higher the TCE exposure concentration, the higher the risk calculation will be. That doesn't necessarily mean that there's a concern for health effects.

BY MR. SNIDOW:

Q. I don't follow. You have to explain that one.

A. Can you ask your question again? I'm not sure I understand your question.

Q. The statistically significant dose-response trend means the higher the TCE exposure, the higher the risk of kidney cancer?

A. It means that there is an increase of risk with increasing doses, yes.

Q. Now, where in Charbotel does it suggest that exposures below 335 parts per million don't increase the risk of kidney cancer?

A. So that is something that I relied on from Dr. Goodman's report and her interpretation of this study. So I'm not going to say where it says 335 PPM year in this study. But her evaluation of the study and those exposure estimates are the basis of that cutoff point.

Q. You don't have any independent opinion on whether there's a risk of kidney cancer from TCE below 335 parts per million years?

A. Well, based on my report, there is likely to be -- that's the threshold. That's the concentration where you're likely -- where it's possible to see kidney cancer following that TCE exposure.

Q. That's the threshold?

A. That's the high concentration. Based on the Charbotel study, that's what comes out of that study. Based on Dr. Goodman's review of that study, that high concentrations of TCE, 335 PPM, greater than 335 PPM year in the occupational studies will -- can result in kidney cancer.

Q. You understand that a threshold means the exposure below which there's not an increased risk; right?

A. Yes.

Q. So your testimony is 334 parts per million years of TCE, no increased risk of kidney cancer?

A. The Charbotel study supports that levels between 335 PPM year as Dr. Goodman describes in her report are not expected to result in an increased risk of kidney cancer.

Q. Show me that in Charbotel. That was my question.

MS. ELLISON: Object to form.

BY MR. SNIDOW:

Q. I know what you say in your report. I know what Dr. Goodman says in her report. I'm asking you. You guys say that, but where is that in Charbotel?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: So that is something that Dr. Goodman would be able to answer. That's not something that I did, that I evaluated for my report. I rely on Dr. Goodman's analysis. I rely on her methodology. I know that she looked at that exposure information and came to her conclusion.

BY MR. SNIDOW:

Q. Go to page 777 of Charbotel, the front page. Do you see at the bottom, in the abstract, there's a sentence that says, "This study suggests"?

A. Yes.

Q. It says, "This study suggests an association between exposures to high levels of TCE and increased risk of RCC." Correct?

A. Correct.

Q. That's the 336 parts per million years result?

A. I think that this is referring to the high dose of the three.

Q. I do, too. So 336; right?

MS. ELLISON: Object to form.

Foundation.
BY MR. SNIDOW:
Q. Or 335, I guess.
A. Yes. That actually is here, that 335 PPM years. I see that now.
Q. Then turn to the front again, 777. The next sentence says, "Further epidemiological studies are necessary to analyze the effect of lower levels of exposure." Correct?
A. That is what it says.
Q. Dr. Goodman has interpreted Charbotel to establish a threshold at below 335 parts per million; correct?
MS. ELLISON: Object to form. Foundation.
THE WITNESS: So the 335 PPM year does come from the high dose where it's statistically significant. The epidemiology study reports the results of the study. It's often a conclusion in epidemiology studies or other studies that additional studies are necessary to analyze effects or other exposure concentrations or other types of studies could be done.
That doesn't mean that there are effects at lower concentrations. That just means that it

would be helpful to be able to look at a study that looks that low. But that's not what we have.

What we have and what we often have for epidemiology studies are high exposure concentrations where there is an effect. Then EPA does what they can with that information and extrapolates using very conservative exposure estimates down to much lower concentrations.

BY MR. SNIDOW:

Q. So you agree though, like you said, it would be helpful to look at studies that looked at lower levels of TCE exposure and then see whether they showed an increased risk of kidney cancer?

A. It's always helpful to have more information.

Q. Especially when the study authors are saying you need further studies to analyze the data; right?

MS. ELLISON: Object to form.

THE WITNESS: The authors of these types of publications will often say additional information would be helpful.

BY MR. SNIDOW:

Q. So did you do that? Did you look at studies looking at lower levels of TCE to see if

there's a link with kidney cancer?
MS. ELLISON: Object to form.
THE WITNESS: There are no studies that are this reliable that look at levels that low.
BY MR. SNIDOW:
Q. My question was: Did you read any?
MS. ELLISON: Object to form. Foundation.
THE WITNESS: So Dr. Goodman would have reviewed those studies and considered those studies in her report. If that was a study that had exposure information and I thought it was relevant for me to look at, which I would have if that study existed, then I would have looked at it. But that study doesn't exist.
BY MR. SNIDOW:
Q. Can you tell me any studies that you looked at to see if they were reliable?
MS. ELLISON: Objection. Form.
THE WITNESS: I looked at the studies that Dr. Goodman cites in her report. I looked at the studies that she cited and talked about in her report. I looked specifically at ones that have exposure information. And that's what I looked at.

BY MR. SNIDOW:

Q. Did you review the Andrew 2022 study? Sorry if I asked this earlier. Forgive me if I already did. Did you review Andrew 2022?

A. I don't recall Andrew 2022.

Q. So I'm going to mark as Exhibit 23 --

MS. ELLISON: 22 maybe?

MR. SNIDOW: Isn't Charbotel 22?

MS. ELLISON: I have it as 21.

MR. SNIDOW: You guys are right. I'm marking as Exhibit 22 Andrew.

(Bailey Exhibit 22 was marked.)

BY MR. SNIDOW:

Q. Here's Andrew 2022. And just put it next to Charbotel for a second and confirm that it came out 16 years after Charbotel.

A. 2022 is, yes, 16 years later.

Q. Have you read this study?

A. This is not a study I'm familiar with.

Q. Do you want to take a second to read it?

A. I can look at the abstract. I think it would take me a while to read it all and interpret the study. I can read the abstract to start.

Q. Start by reading the abstract. If you want to go off the record and read it, that's

totally fine.

MS. ELLISON: If she reviews it, we'll be on the record. We're not going to have her review anything off the record. That's what you all have been doing in all depositions.

MR. SNIDOW: That's my policy. Your policy is my policy.

MS. ELLISON: We're on the same page.

THE WITNESS: Am I reading the whole?

BY MR. SNIDOW:

Q. Start with the abstract. If you need a second, I will let you read it. There's only a few portions I want to go through.

A. Okay.

Q. So if you will look at page 4, you'll see Section 3.3 says Trichloroethylene in New Hampshire?

A. Yes.

Q. It reports the mean median -- mean and median groundwater TCE levels; right?

A. Yes.

Q. And the median TCE levels was 135 micrograms per liter?

A. Yes.

Q. And you agree that's within the range of

Camp Lejeune contamination levels?

A. The median concentration is, but the range that is being shown here is much higher.

Q. And you agree this is orders of magnitude less concentration than the folks in Charbotel were exposed to; correct?

A. So this is drinking water versus inhalation. So it's a different -- that's why I can't do a direct comparison.

Q. Just in terms of straight concentration, a microgram per liter is a part per billion; correct?

A. Microgram per liter is a part per billion in water. It's a very different analysis for air. And it's a different route. You're ingesting versus inhaling. So it's different.

Q. If you go to page 5, do you see it reports increased risk in the 50th to 75th percentile?

A. Yes, but I also see that there's a decreased risk in a greater than 75th percentile, which is interesting.

Q. Dr. Bailey, you haven't read this at all; right?

A. I'm looking at the table. I'm looking

at the results.

Q. In considering -- doing your analysis of any of the 25 people, you never read this report; right?

A. I did not read this report. I'm looking at it now for the first time.

Q. If you turn to the Conclusions, page 9, it says, "In summary, we observed an increased risk of kidney cancer associated with estimated TCE exposure." And then the last thing, it says, "A study of heightened cancer surveillance for members of the public with a history of TCE exposure is warranted." Right?

A. That's what it says.

Q. I assume you agree that is entirely under the threshold at 335 parts per million years for TCE; right?

A. 335 parts per million years is an inhalation concentration. This is a drinking water concentration. I would say that this study does not conclusively say that there's an increased risk considering that a higher dose showed a decreased risk. So I don't think this is a reliable study.

Q. I want to make a record on this. You

read the abstract; correct?

A. I did. And I'm also looking at the data.

Q. Hold on. You read the abstract. I showed you the table and the conclusion; correct?

A. I can go read the study if you would like.

Q. Hold on. I want to actually get to a process point with you, which is you are willing to testify that this is an unreliable study without having read it?

MS. ELLISON: So if you want her to read the study --

MR. SNIDOW: No. She didn't have to offer that. She could have asked to read it.

MS. ELLISON: You're asking her questions about the study, J.J. So either ask her questions and give her time to review or don't ask questions. But don't ask questions and then say you have no idea what's in that study.

MR. SNIDOW: Okay.

BY MR. SNIDOW:

Q. You can put that one aside.

Did you read the Moore 2010 study?

A. I have looked at the Moore 2010 study.

Q. Is that a reliable study?
A. That is a study that EPA did consider in its evaluation for TCE but ultimately decided that the Charbotel study was a more reliable study for quantitative estimates of risk for TCE.
(Bailey Exhibit 23 was marked.)
BY MR. SNIDOW:
Q. I'll mark this as Exhibit 23. This is the Moore 2010 study.
If you will look at page 2, the end of the abstract, it says, "These findings provide the strongest evidence to date that TCE exposure is associated with increased renal cancer risk."
A. That's what the authors of the study concluded.
Q. And where in your kidney cancer report do you discuss this study?
A. So I do not discuss this study because I relied on the toxicity value that EPA calculated that's based on the Charbotel study. So that's the study that I briefly talk about in my report. Dr. Goodman did talk about this study in her report.
Q. Break this down. Before we were talking, you said you did a risk assessment. You

looked at the MoEs and then you compared the plaintiffs' exposure to reliable epidemiology; correct?

A. Yes.

Q. Is Moore 2010 one of the pieces of epidemiology that you compared the plaintiffs' exposure to?

A. So I did not compare the exposure information from Moore because of EPA's interpretation of the Moore study in the context of the Charbotel study where they concluded that the Charbotel study was more reliable quantitatively. So I used that study for comparison.

Q. So is that a no, you didn't do any comparisons with Moore?

MS. ELLISON: Object to form.

THE WITNESS: I did a comparison for the Charbotel study because that's the one that EPA relied on after reviewing both of them.

BY MR. SNIDOW:

Q. Let's go to the results on page 6, middle of the page. Do you see where it says "For TCE exposure"?

A. Yes.

Q. It says, "For TCE exposure, ORs" -- you know that means odds ratio; right?
A. Um-hum.
Q. -- "were significantly elevated for all exposure indices and was strengthened after analyses were restricted to a high confidence assessment." Correct?
A. That's what it says. I don't see confidence intervals there.
Q. Go to page 13. You see that they do cumulative PPM years?
A. Yes.
Q. It looks like they've broken it into less than 1.58 PPM years and more than 1.58 PPM years; right?
A. Yes.
Q. And both odds ratios are above 1.0?
A. Yes.
Q. And the result for more than 1.58 parts per million years is statistically significant; correct?
A. It is.
Q. This is, what, two orders of magnitude less than the exposures in Charbotel?
A. If you're comparing to the 335,

mathematically it is lower. But I would have to look to see how that compares to the plaintiffs' exposures. I did calculate -- let's see. I could see how that compares. But the bottom line is that EPA did look at this study, and with the information from the study in addition to the Charbotel study decided that the Charbotel study was a better study to derive a quantitative toxicity value.

So EPA did not think that this exposure estimate was reliable enough to derive a risk value. So that's the basis of my comparison to Charbotel.

Q. So that's a no, you didn't look to see if any of the plaintiffs at Camp Lejeune had exposures of more than 1.58 parts per million years?

MS. ELLISON: Object to form.

THE WITNESS: I did not. I relied on the Charbotel study, which is the study that EPA determined was more reliable for a quantitative estimate of exposure and risk and dose-response evaluation.

BY MR. SNIDOW:

Q. Now, the EPA didn't say Moore is an

unreliable study. You're not testifying to that?
A. EPA said that the Charbotel study was more reliable for deriving a quantitative risk value.
Q. To do risk assessments; correct?
A. For risk assessments.
Q. That's why I keep going back to this. You did risk assessments. You did the MoEs. Then you did the comparison to epidemiology that was deemed reliable by you or Dr. Goodman; right?
MS. ELLISON: Object to form.
BY MR. SNIDOW:
Q. Correct?
A. I did that comparison, yes.
Q. I'm not talking about the first one. I'm talking about the last one where you said you compared to epidemiology.
Why didn't you compare the exposures of the plaintiffs to the results of Moore 2010?
A. Because I was comparing to -- I already have a comparison to a reliable epidemiology study that EPA determined to be more reliable than the Moore study based on the exposure information, and ultimately that is what I'm doing.
I'm comparing exposure information in

the study to exposure information for the plaintiffs. And it makes sense to me to use what the Agency is considering to be a more reliable study for exposure, and that's Charbotel.

Q. You can put this one to the side for a moment.

Did you review the Parker and Rosen study looking at people in Woburn, Massachusetts?

A. I don't recall looking at that specific study for my report.

Q. So you didn't do any comparisons with the results from Woburn, Massachusetts?

A. I did not do any comparison to Woburn, Massachusetts drinking water. I believe it was a drinking water study.

Q. Let us -- can you go to your report for Mousser, which I think is marked as Exhibit 20.

MS. ELLISON: 20, yeah.

BY MR. SNIDOW:

Q. Go to page 39.

A. Okay.

Q. And this is the section where you're evaluating the link between PCE and kidney cancer; right?

A. This is where I look at -- let me read

this. I'm pointing to studies that looked at possible associations between PCE exposure and kidney cancer, yes.

Q. And you don't cite any?

MS. ELLISON: Object to form.

THE WITNESS: So I looked for reliable studies in Dr. Goodman's report, and there are no epidemiology studies, reliable epidemiology studies that report exposure information for PCE, and also looked at kidney cancer. But I do point to the animal studies that do look at that.

BY MR. SNIDOW:

Q. So did you do an independent review of the literature to look for links between PCE and kidney cancer?

MS. ELLISON: Object to form.

THE WITNESS: I did not do an independent review. That's not what I was asked to do. I relied on Dr. Goodman's review. And again, I agree with her methodology and her systematic review approach.

BY MR. SNIDOW:

Q. You say that Mr. Mousser's PCE exposure estimates are well below those reported in the animal bioassays; right?

A. Yes.
Q. Then you point out that his exposure is less than the animals got; right?
A. Yes.
Q. Now, it's quite common in animal studies to give them much higher doses than humans would realistically be exposed to; true?
A. That is true.
Q. The reason for that is because -- well, one reason is because you are ethically allowed to experiment on animals, but you can't do that on humans; true?
A. Yes. You can give animals. You can't do experiments with humans in a laboratory.
Q. So how does it follow that just because the animals had higher doses, that means humans at lower doses aren't at an increased risk?
A. So for the PCE studies, Dr. Goodman's report on those studies indicates -- this is what I'm reading from my report -- that there are no significant increases or trends in kidney tumors in two-year chronic animal bioassays at concentrations as high as 1,072 milligram per kilogram day or 600 PPM inhalation. So there were no effects in the animals even at those high

exposure concentrations.

So I think that that suggests that in humans at doses well below where you're not seeing effects in animals, you're not likely to see effects in humans.

Q. Did you read those animal studies?

A. I have looked at the results of the animal studies as Dr. Goodman reported them in her report.

Q. So is that a no, you didn't review them yourself?

A. I reviewed -- for the animal studies, I relied on Dr. Goodman's summary of the exposure information for the animal studies.

I don't have any reason to disagree with her tabulating of the exposure information from those studies. And I actually did have some people in my group check to make sure that that exposure information was tabulated correctly in her report.

Q. I'm not trying to be cute. But like this is an expert report. This is a paper. I'm asking you the animal studies.

Did you review this, like Dr. Goodman's version of this, or did you review the animal

studies? You, yourself.

MS. ELLISON: Object to form.

THE WITNESS: So I reviewed the results from Dr. Goodman's report. I don't have any reason to believe that she entered the information, the exposure information from the animal studies incorrectly, but we did check to make sure that that information was entered correctly and that those exposure concentrations did result in no significant increase.

BY MR. SNIDOW:

Q. But did you read the animal studies? Did you read them?

MS. ELLISON: Object to form.

THE WITNESS: I have looked at those studies in the past. I did not look at -- I didn't read those studies recently, but I have looked at them, and I have looked at the results of those studies.

BY MR. SNIDOW:

Q. Can you name me any of them?

MS. ELLISON: Object to form.

THE WITNESS: I can't name them, off the top of my head, but if I looked at Dr. Goodman's report, I can tell you who the authors are.

BY MR. SNIDOW:

Q. Do you have the Terry Dyer report?

MR. SNIDOW: Break? How long have we been on?

THE VIDEOGRAPHER: Off the record at 3:38.

We've gone 4 hours, 37 minutes.

(Recess from 3:38 p.m. to 3:53 p.m.)

THE VIDEOGRAPHER: Back on the record at 3:53.

BY MR. SNIDOW:

Q. Dr. Bailey, I asked you if you talked to Dr. Goodman. You said no.

Do you know if your team spoke to Dr. Goodman's team?

A. I don't believe that the teams were allowed to talk to each other.

Q. So did you and Dr. Goodman pull the same articles in the literature review with your librarians?

A. Dr. Goodman pulled the studies that she thought were important. And then that information was transmitted to DOJ, and then that list of studies and those studies were transmitted to me.

Q. And then your team pulled them again?

A. Yeah. We pulled them from the file that came from DOJ in the studies.

Q. But remember on the invoice for the librarians. Were they actually pulling material from publicly-available sources, or were they just opening a packet from DOJ with Dr. Goodman materials, do you know?

A. They were not involved in that. So they would have been pulling maybe risk specific studies that I was interested in looking at or -- yeah, I think that's what they were pulling. They were pulling different studies. I don't recall the exact studies that they pulled, but...

Q. Now, if I understood correctly, you were relying pretty heavily on the EPA in choosing to rely on Charbotel; right?

A. Yes. I was relying on EPA's evaluation of all of the data and Dr. Goodman's.

Q. You're aware that the EPA has banned TCE at levels lower than 335 parts per million; correct?

A. So they have banned TCE based on worker exposures, based on occupational exposures. And in terms of the exposure concentration, I don't know exactly what the exposure concentrations are

for those workers, but they did risk calculations based on exposure estimates for the workers and then determined that there should be a ban on TCE based on how the risk calculations came out for the workers.

Q. So I want to quickly go through for bladder cancer. If you could turn to the Dyer report, which I think was Tab 1.

A. Yep.

Q. Go to page 30. I want to talk about how the PODs were calculated for PCE.

A. Okay. I'm on page 30.

Q. You cite a source there, US EPA 2012b and c.

A. Yes.

Q. And that's the IRIS assessment?

A. That's the IRIS assessment.

Q. Did you review the IRIS assessment when putting together your report?

A. Yes.

Q. You're aware that the PCE cancer slope is derived from animal studies?

A. It is derived from animal studies and liver cancer at the endpoint.

Q. So the cancer slope and IUR that you

used ultimately are not based on human epidemiology; true?

A. They are in the sense that EPA reviewed any available epidemiology for PCE and health effects associated with exposure to PCE in those studies and determined that the animal data for liver cancer is the most reliable for deriving a toxicity value in consideration of the epidemiology on the animals.

Q. The cancer slope is not based on human epidemiology, is it?

MS. ELLISON: Object to the form.

THE WITNESS: The cancer slope factor is based -- is calculated based on an animal study, but that animal study was chosen in the context of reviewing a lot of other information, not just that one animal study.

BY MR. SNIDOW:

Q. Right. I understand they considered a lot of other information. But they eventually created the cancer slope factor in the IUR using the results from a study on rats in liver cancer; correct?

A. Yes, as protective of all cancers for humans.

Q. Then you ultimately used that IUR and that cancer slope factor derived from the liver cancer rat study to calculate the risk of bladder cancer in humans?

A. I calculated a cancer risk from the exposures in humans. You can apply that to bladder cancer because EPA considered that data in deriving its toxicity value and landed on liver cancer in animals as being the most conservative, most protected.

Q. You think that that is a better methodology, for example, than looking at the epidemiology linking PCE to bladder cancer?

A. So it's one part of my evaluation. It's a conservative estimate of cancer risk for PCE, but then I also looked at the epidemiology in Section 8 where there is a study that looked at PCE exposure and bladder cancer. So I did both.

Q. What's the study that looked at -- no. I understand. We'll get there in a moment. I want to go through the steps you have to go through to do that.

First you have to use the liver cancer rat study in order to create a dose response model for the rats; correct?

A. That is what EPA did, yes.
Q. Then the EPA has to extrapolate that from rats to humans; correct?
A. They do extrapolate that from rats to humans.
Q. Then when you're doing the IUR, you have to create a slope that lets you extrapolate from high to low exposures; correct?
A. The IUR is typically a straight down line from the point of departure down to the point of origin.
Q. Then to get the ingestion risk, you have to turn the IUR into a cancer slope; correct?
A. Correct. And they used the PBPK model to do that extrapolation.
Q. Those steps that I just described were how you calculated the increased risk from PCE; right?
A. So those steps are what EPA used to derive the toxicity values for PCE. Then I used those toxicity values to calculate risk.
Q. You did say that you looked at some epidemiology for bladder and PCE; correct?
A. Yes.
Q. That's the Hadkhale study?

A. Correct.
Q. Then if you turn to page 43 of your report.
A. Yes.
Q. You say, "I relied on Hadkhale 2017, which is the only bladder cancer epidemiology study that Dr. Goodman evaluated that reported exposure estimates for PCE."
Then you say, "Hadkhale reported no significant associations and no trends between bladder cancer and PCE inhalation exposures at concentrations as high as 87.55 PPM years." Right?
A. Yes.
Q. Did you verify whether that is true?
A. Yes. I looked at the Hadkhale study.
Q. So when we look at it, we're not going to find any significant associations or trends between bladder cancer and PCE all the way up to 87.55 PPM years; right?
A. So I looked at significant associations and trends. So there might have been a significant association, but if there's no trend, then it's not considered significant. So it would be like a non-monotonic dose response or

something. So I looked at both of those, significant and trend.

Q. That's what you're trying to say here, is that you only -- this says reported no significant associations and no trends; right?

A. Yes. I'm saying I looked at both of those things. They're both important.

Q. That's what you meant by putting and "no trends" in parentheses?

A. Yes.

MS. ELLISON: Object to form.

BY MR. SNIDOW:

Q. That's what you meant?

A. This particular study -- they don't always report trends, but this particular study reported associations, confidence intervals so you can get an idea whether it's significant or not and also trends. So I wanted to make it clear that I looked at the trends in addition to whether the association was significant or not.

Q. So you, it sounds like, agree that Hadkhale did report significant associations between PCE and bladder cancer; right?

A. I'd like to look at Hadkhale to tell you what they concluded.

(Bailey Exhibit 24 was marked.)
BY MR. SNIDOW:
Q. Let me show you Exhibit 24. Here you go. And this is the Hadkhale article that you were referencing in your report; right?
A. This is not -- this is the Hartwig.
MR. SNIDOW: Sorry. We'll leave this as 24 though.
MS. ELLISON: Okay.
(Bailey Exhibit 25 was marked.)
BY MR. SNIDOW:
Q. This we'll mark as 25. So this is the Hadkhale study that you're referencing in your report?
A. Yes.
Q. This is the only PCE epidemiology bladder cancer study you discuss in your report; right?
A. It's the only one I had exposure information, so yes.
Q. We'll come back to that. If you go on page 1739 at the bottom.
A. Yes.
Q. It's talking about an American study that observed an increased risk of bladder cancer

among those exposed to the trichloroethylene at the highest exposure level. Then it goes on to say, "The study observed a dose-response relationship with exposures to trichloroethylene."

And if you look at footnote 12, you'll see that's the Zhao study.

A. Yes.

Q. Did you review that one?

A. I don't recall reviewing that study.

Q. If you go to page 1745, at the conclusion at the end, it says, "The study provides evidence of an association between occupational exposure to," and then it mentions perchloroethylene and bladder cancer risk; right?

A. I'm sorry. Where again are you?

Q. 1745, last paragraph, right at the end. The study provides evidence of an association between occupational exposure to trichloroethylene, some other chemicals that aren't relevant here, and bladder cancer risk. Right?

A. That's what the authors concluded, yes.

Q. Right. And you and Dr. Goodman interpreted this study to show no bladder cancer risk up to 87.55 PPM years; right?

A. For perchlorethylene, I believe.
Q. That's one of the chemicals we just went through; right?
A. Yes. But you weren't specific about that for 87.5. So that would be specific to perchlorethylene. Let me just look and see if that's correct. Yes.
Q. So you have interpreted the study to find no association between PCE and bladder cancer even though the study authors said they got one?
MS. ELLISON: Object to form.
THE WITNESS: So I don't rely on the author's interpretation. I look immediately at the results of the analysis. And what I'm seeing is for perchlorethylene, the trend is there's no significant trend. And that's because although there's a significant reported risk in the middle range, there is not -- it actually significantly decreased at the higher range.
So it doesn't reliably suggest that there's an increased risk if you consider the trends and the fact that it's -- the risk goes up and then goes down.
BY MR. SNIDOW:
Q. You agree that bladder cancer is more

common in males than females?
A. I don't recall if that's true.
Q. Go to page 1744. Do you know where the PCE results are there?
A. I see the PCE results.
Q. Statistically significant trend for the males?
A. There is not a statistically significant trend for the males at the highest dose.
Q. Do you see P for trend?
A. I do see a trend, but there is not -- it's not statistically significant. So you need to look at both of those things, is it statistically significant and a trend. It goes up and then goes down in terms of significance.
Q. In terms of significance, but not in terms of the risk ratios.
A. Right, but you have to interpret the ratios in the context of the confidence intervals. And if the confidence interval includes one, then you can't say whether there's an association or not because it's not statistically significant.
So I interpreted that that data to suggest that at 87.55 PPM, there's not an increased -- plus .05 is borderline. I don't even

know if it's considered statistically significant. That's borderline for the trend.

Q. So you interpreted the study as no association at any level between PCE and bladder cancer?

A. Up to 87.55.

Q. Yes, even though the authors say they found an association between PCE and bladder cancer?

MS. ELLISON: Object to form.

THE WITNESS: The authors made that conclusion, but I made my conclusion based on my review of the data, which is reasonable.

BY MR. SNIDOW:

Q. Again, you didn't write this study; right?

A. I did not author the study.

Q. For TCE and bladder cancer, if you go to page 25 of your report, it looks like you again relied on the Hadkhale study.

A. On page 25 of my report, I don't believe I'm talking about Hadkhale there. 25 of my report? Which report are we looking at?

Q. Dyer, Tab 1.

A. Page 25?

Q. Sorry. I wrote this down wrong. In your assessment of TCE and bladder cancer, you did not mention the Hadkhale study at all, did you?

A. Where are we talking about in my report?

Q. 5.1.1.

A. I'm referring to Dr. Goodman's review of all of the epidemiology, which would include Hadkhale. And then I'm relying on the ATSDR, EPA and IARC for that. But Hadkhale -- what's the date for Hadkhale? 2017. So it wouldn't have been discussed in IARC, and it wouldn't have been discussed in 2012 for EPA.

Dr. Goodman did consider it, and ATSDR might have considered it. I don't know what the cutoff was for studies for ATSDR in 2019.

Q. One of the things you did is you said you compared the plaintiffs' exposure to exposure in the relevant epidemiology; right?

A. Yes.

Q. The reliable epidemiology. It looks like you guys agree that Hadkhale is reliable; right?

MS. ELLISON: Object to form.

THE WITNESS: So it is a study. It was one study that looked at exposure information.

It's an occupational study. Dr. Goodman includes in it her report as a reliable study to be considered for all -- in the context of all of the other information.

BY MR. SNIDOW:

Q. Did you do any comparison of any of the plaintiffs' TCE exposure and the bladder cancer results in the Hadkhale study?

A. Yes.

Q. You did. Show me.

A. In Section 8. 3.1.

Q. I think maybe this is where I wanted to go. If you look at the Hadkhale study on Tab -- excuse me -- on page 1740 at the top.

A. Yes.

Q. You've got a statistically significant result at 129.5 parts per million?

A. Yes.

Q. You've got borderline --

A. At greater at 129.5.

Q. Borderline statistically significant result at 32.8 parts per million?

A. Yes.

Q. The authors interpret the study as finding association between TCE and bladder

cancer?

A. That's the author's interpretation, yes.

Q. And you interpreted it as not finding an association?

A. Let me read what I said here. So I described the Hadkhale study as reporting statistically significant associations between TCE exposure and bladder cancer. Then I talk about the limitations in the study.

Further, there are limitations in the study including self-reported occupational history to estimated exposures and also lack of adjustment for smoking. But even so, I did look at the lowest concentration in that range and compared the lowest concentration in that range to the plaintiffs just to provide some perspective about how much lower -- even if you look at this study and the exposure information in the study, how does it compare to the exposure estimates for the plaintiffs. So that's what I did.

Q. You did that even though this is relying upon self-reported occupational history; right?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: I did do that comparison

because it was the only study that looked at exposures, occupational exposures to these chemicals and bladder cancer. And it still provides some perspective on this study in the context of how it compares to the plaintiffs.

If we were talking about exposures that were much higher, then you'd want to look more carefully at this. But what I'm saying here is the exposures are below even the lowest exposure in this study, and there's uncertainty for the study because of the smoking.

BY MR. SNIDOW:

Q. Because of what?

A. Of the smoking, potentially confounded by smoking.

Q. Can you cite to me any scientific evidence suggesting that TCE exposure is correlated with smoking?

A. I can't cite scientific evidence specifically, but in general, it's my understanding that bladder cancer is a risk factor for -- smoking is a risk factor for bladder cancer. But I don't have any of the studies at the tip of my tongue.

Q. Do you know whether 12 to 86 part per

million years is a realistic exposure for Marines at Camp Lejeune?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: I can't answer that question. I need more information about what do you mean by realistic.

BY MR. SNIDOW:

Q. Could Marines have gotten to that level of exposure?

MS. ELLISON: Object to form.

THE WITNESS: I don't know. I would need to understand where that number comes from.

BY MR. SNIDOW:

Q. Well, it comes from what we were just looking, at Hadkhale at 1740 for PCE.

A. We're talking about PCE then.

Q. No. Sorry. For TCE. Do you see in the middle -- oh, for PCE. Sorry. See in the middle 13.6 to 87.55?

A. Yes.

Q. Did you do any calculations of whether any of the Marines would have fallen into that exposure category?

A. Well, I did compare the exposure

estimates for the Marines, and they were all below that. So they would have been below, any of the Marines that had bladder cancer.

Q. I think you compared it to 87. Did you compare it to 13?

A. So I compared it to -- I actually did an adjustment. I took the 87.55 PPM, which is an occupational exposure, and adjusted it for something that would be more continuous. So it's the lower number, 21 PPM years. And none of the plaintiffs were above that.

Q. I think I still don't understand. You did something with the 87.55 result. Did you do any comparisons with the 13.6 to 87.55 result?

A. I did not because looking at that data as a whole, I conclude that the 87 -- that there's -- that the study did not find -- does not support an increased risk of bladder cancer for PCE exposures up to 87.55 PPM years.

So based on my interpretation of the data, based on the fact that there's not a significant trend and the higher exposure group, there's not a significant confidence interval, I used the highest exposure estimate from that range.

Q. You said before you did review the Aschengrau study.
A. Yes.
Q. Did you compare any exposures from the Camp Lejeune plaintiffs to the exposures that the Aschengrau subjects experienced?
A. I did not because the Aschengrau study does not provide individual exposure information.
MS. ELLISON: Is there another copy, by any chance?
MR. SNIDOW: Yeah.
MS. ELLISON: Thank you.
BY MR. SNIDOW:
Q. If you go to page 291, in the bottom right, the conclusion is, "We found evidence for an association between PCE-contaminated public drinking water and leukemia and bladder cancer." Right?
A. That's what it says.
Q. And then it said, "Thus, its carcinogenic potential is a matter of public health concern." Right?
A. That is what the study -- that's what's written there.
Q. You disagree with that. You don't think

that PCE at the levels here are a public health concern?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: So this study looked at different areas of PCE contamination and sort of ranked them based on higher or lower concentrations and reported what they reported. But there's no discussion in this paper about the specific exposure concentrations, the specific levels of PCE in drinking water that people were exposed to or for the individuals who had bladder cancer.

BY MR. SNIDOW:

Q. If you look at page 289, do you see in the middle where they're talking about relative to liver dose?

A. 289. First column, second column?

Q. Left-hand column.

A. Yes.

Q. Second to last paragraph, relative to liver dose estimates?

A. Yep.

Q. That's a measure of exposure; right?

A. It's a relative measure of exposure.

You're looking at different areas and saying this is higher, this is the next. It's a method that you can use to rank areas in terms of which might be higher than the other. But it's not an actual concentration that they're estimating.

Q. Well, they actually do give a cumulative dose in absolute numbers; right? The 90th percentile among exposed controls were 27.1 and 44.1 milligrams?

MS. ELLISON: Object to form.

THE WITNESS: So that's 90th percentile among exposed controls. This was, I believe, the amount that is going into the home. Again, it's not a concentration. It's a mass amount.

And they calculate that and then sort of rank each of the areas based on that total mass that's going into the house. That's not a water concentration. It's not something that you can use to calculate a dose for individual people. It's not something that you can use to say even what the water concentration was. It's just total mass. It's best used for sort of ranking different areas.

(Bailey Exhibit 26 was marked.)

BY MR. SNIDOW:

Q. I'll show you Exhibit 26. Did you review what ATSDR said about the Aschengrau study?

A. I probably did, but I would like to look at what they said.

Q. I assume you've reviewed the ATSDR summary of the evidence. This one is an excerpt.

You said you have seen this before?

A. I have looked at the ATSDR report, yes.

Q. If you look at page 89, do you see they're talking about Aschengrau?

MS. ELLISON: Just for the record, I will just say that this excerpt only contains pages 1, 89 and 96 and nothing else.

BY MR. SNIDOW:

Q. If you need other parts of it, Dr. Bailey, I'm happy to print one for you.

Do you see where it says Exposure Duration Information in that column?

A. Yes.

Q. It says, "Note: High exposure (greater than 90th percentile) was in range of Camp Lejeune drinking water levels." Right?

A. That is what it says here.

Q. Yes. ATSDR seems to think that you can

use this to get a sense of exposure; right?

MS. ELLISON: Object to form.

THE WITNESS: I'm would like to see where they determine that based on my read on Aschengrau. I'm not seeing water concentrations or water levels in this study or certainly not directly related to the individuals who had health effects in this study.

BY MR. SNIDOW:

Q. So if you go to page 285, look at the top.

MS. ELLISON: Of Aschengrau?

MR. SNIDOW: Um-hum.

THE WITNESS: Yep.

BY MR. SNIDOW:

Q. Do you see where it says, "A large proportion had been installed in the five towns of the upper Cape Cod area"?

A. Yes.

Q. It says, "Typical concentrations in affected lines in one town, Falmouth, range from 1600 to 7750 micrograms per liter"?

A. I do see that. That's a large range, and it's much higher than levels at Camp Lejeune.

Q. Well, you were just saying that they

don't report them at all; right? You were wrong on that.

A. Well, what they don't do is -- what you don't know is what specifically is going into each of the homes where these people are living. What you only have from the study is the total mass. This is just generally talking about typical concentrations in affected lines.

There's nothing in this study that directly connects the exposure in the concentration of water to the individual who might have been ingesting that water and the amounts they were ingesting. So you can't connect, directly connect the exposure concentration, the level in the water, to the people who had bladder cancer.

Q. Any idea why ATSDR might have used it to compare directly to the Camp Lejeune levels?

MS. ELLISON: Objection. Foundation. Form.

THE WITNESS: I don't know why they did that.

BY MR. SNIDOW:

Q. You can put this one aside.

(Bailey Exhibit 27 was marked.)

BY MR. SNIDOW:

Q. I need to mark an exhibit. I will mark as Exhibit 27 the report for Richard Sparks. This is a report that you did for one of the Parkinson's disease plaintiffs; correct?

A. Yes.

Q. And when you were reviewing the epidemiology for Parkinson's and TCE, if you go to page 39, it looks like you reviewed one study.

A. I considered all studies that reported exposure information of the chemical that I was looking at and the disease of concern. And Solomon was the only one that had an inhalation -- an epidemiology study that also had inhalation exposure information.

Q. Did you read any other studies looking at TCE and PD?

A. I have looked at other studies related to -- I looked at some of the animal studies related to TCE and PD.

Q. How about human epidemiology?

A. If there was no exposure information specifically described in the study, I didn't review it carefully. I didn't review it in the context of my report. So I reviewed sort of the

overall -- Dr. Goodman's overall review of those studies that did not include exposure information. Again, I agree with her methodology and her conclusions about whether the chemical exposures are related to Parkinson's disease.

But I specifically reviewed the studies that looked at the exposure information because that's what I did here in my Section 8.

Q. For one study; right?

A. If there were more than one, I would have looked at all of them.

Q. You would have?

A. Yes.

Q. So you reviewed Goldman 2012?

A. Goldman 2012 is a study that I did look at in the context of some of the rebuttals for the Parkinson's disease experts, plaintiffs' experts.

Q. Do you want to show me that?

A. I don't believe it is in this report.

Q. This is a Parkinson's report; right?

A. If the plaintiff expert didn't talk about the Goldman study, I did not talk about it because the Goldman study is a drinking water study. I would like to look at the Goldman study if you have it. I have looked at it. But just to

refresh my memory.

Q. I do. And just so you know, it's not a drinking water study. I really am curious as to whether you have ever seen it.

A. Yeah.

MS. ELLISON: Objection to form.

(Bailey Exhibit 28 was marked.)

BY MR. SNIDOW:

Q. I'll mark it as Exhibit 28. This is Goldman 2012. So you think you read this one?

A. So there were several Goldman studies. I'm not sure if this is the one that I'm thinking of or a different one. I believe there's a different one that I may be thinking of.

Q. So did you review this one or not sure?

A. This one I don't recall looking at. I did review a Goldman study, but this is not the one that I'm thinking of.

Q. This is an occupational study; correct?

A. I would have to review it.

Q. Can you just confirm for me that in your Parkinson's report, either in Section 8 or your rebuttals to plaintiff experts, that you don't discuss this study?

MS. ELLISON: Just to be clear, the only

report that's in front of her is the Sparks report for Parkinson's, not the other four reports.

THE WITNESS: So I did not look at this specific study. And I would have to look to see whether Dr. Goodman reviewed this study. But it's possible that she included this in her evaluation. And EPA certainly would have considered this study in its evaluation for TCE -- are we talking about TCE? Yes, TCE -- and perc, particularly in the most recent Tosca risk evaluation.

BY MR. SNIDOW:

Q. My question is just: Do you discuss this paper?

A. I'd have to look at my references, but I don't believe that I did because it was not something that came up as a reliable study that should be considered here.

Q. When you say "came up," you mean on Dr. Goodman's analysis?

A. Based on Dr. Goodman's analysis of all of the available information, yes.

(Bailey Exhibit 29 was marked.)

BY MR. SNIDOW:

Q. I'll mark as Exhibit 29 Goldman 2023. Do you know whether you reviewed this study?

A. I did review this study.

Q. You did. Okay. You don't discuss it anywhere in your report though; is that correct?

A. I don't discuss this in my report because it sort of falls under the category of Camp Lejeune studies that Dr. Goodman talks about in her report. And there are limitation to those studies as I summarize in my report.

Q. So this one is not Bove; right? This is a different author?

A. Correct.

Q. What are the limitations of this one?

A. Let me look. So Dr. Goodman looked at this study in the context of other Camp Lejeune studies that looked at -- she looked at this study that looked at Parkinson's disease. I don't recall if there were other ones that looked at Parkinson's disease.

But her conclusion was there's no consistent associations reported between either working or living at Camp Lejeune and TCE, PCE, benzene or vinyl chloride exposures at Camp Lejeune and Parkinson's disease. And that study was included in her evaluation.

Q. Do you see the conclusions of Goldman

2023 here on the front?

A. Yes.

Q. It says, "The study's findings suggest that the risk of PD is higher in persons exposed to TCE and other VOCs in water four decades ago." Right?

A. That's what the study concludes. That's what the authors of the study conclude. That's not what Dr. Goodman concludes about the Camp Lejeune studies.

Q. So you'd go with Dr. Goodman over the actual authors of Goldman 2023?

MS. ELLISON: Object to the form.

THE WITNESS: I rely on Dr. Goodman's evaluation of all of the available information. She doesn't rely on just one study. She looks at all of the available information and integrates all of that information, including study quality, and reaches the conclusion that there is no association -- the best available science does not suggest that there's an association between TCE and Parkinson's disease.

So that's what I rely on. And I agree with her methodology.

MR. SNIDOW: Take a quick break.

THE VIDEOGRAPHER: Off the record at 4:35.

(Recess from 4:35 p.m. to 4:50 p.m.)

THE VIDEOGRAPHER: Back on the record at 4:50.

(Bailey Exhibit 30 was marked.)

BY MR. SNIDOW:

Q. Dr. Bailey, I'm going to show you a document that I'll mark as Exhibit 30. This is your report in the Connard case. If you'll look, just confirm this is a leukemia plaintiff.

A. Yes.

Q. If you'll go to page 37 in Section 8, do you see the section -- and it's on 36 as well -- you discuss the Talibov study?

A. Yes.

Q. Am I correct that's the only epidemiology study that you mention looking at the link between TCE or PCE and leukemia?

A. So that is one of the studies, and I believe it may have been the only one of TCE and the PCE that looks at specifically at -- there were a number of leukemias. I can't remember if it was leukemia in general or AML, acute myeloid leukemia, that we looked at in this study. I

think it's just leukemia in general. This is what it says in my report.

Q. This is the only epidemiology study you cite?

A. Yes, in this section. And so it must have been the only epidemiology study that had exposure information for TCE and PCE and also looked at leukemia specifically.

Q. And in Talibov, what was their measure of exposure based on?

A. I don't recall. I'd have to look at the study.

Q. But you chose that one to discuss because it had the best measurement of exposure?

A. It was -- based on my report, it looks like it was the only one that had inhalation exposure information for these chemicals and also looked at that endpoint.

Q. Did you review the Cohn 1994 study? Have you?

A. I'm familiar with that study.

Q. You don't talk about it even though it looked at the link between trichloroethylene and leukemia; correct?

MS. ELLISON: Object to form.

Foundation.

THE WITNESS: I have talked about that study in the context of the rebuttals, I believe. And let me check my Section 9.

So I do talk about Dr. Gondek's reference to that study. And then I talk about Dr. Goodman's conclusion about the study. So I relied on her evaluation of the Cohn study and where she also says that EPA concluded that the evidence for that study was not robust or conclusive for an association between TCE exposure and childhood leukemia.

BY MR. SNIDOW:

Q. Did you do any comparison of any plaintiff exposures to the exposure in the Cohn study?

A. I did not.

Q. Do you know what the exposure levels were in the Cohn study?

A. Since EPA considered this to not be a very robust or conclusive study, I did not consider the exposure information in the Cohn study.

Q. So it's a no, you don't know what the exposure was?

A. Off the top of my head, I don't. But it's also not considered a robust study. So it's not really relevant.

Q. In your report, you don't describe any of the strengths and limitation of the Cohn study, do you?

A. I don't specifically describe the strength or limitations, but Dr. Goodman does in her report, and EPA does as well, and concluded that the evidence was not robust or conclusive based on that study.

Q. I don't mean to be rude.

Do you know whether the EPA is actually talking about the Cohn study in that sentence?

A. Dr. Goodman is talking about how the Cohn study was considered in EPA's toxicological profile within which EPA concluded that the evidence was not robust or conclusive.

Q. Right. But you made it seem that the EPA said that the Cohn study was not robust and conclusive. You have no evidence of that, do you?

MS. ELLISON: Object to form.

THE WITNESS: So if I could look at the EPA toxicological profile and find its discussion of the Cohn study, I could point to where EPA

concludes that the evidence was not robust or conclusive. But I don't have any reason to believe that that's not true if I wrote that in my report and Dr. Goodman states it in her report.

BY MR. SNIDOW:

Q. You think that you independently reviewed the Cohn study?

A. I likely looked at whether that was -- before I wrote that in my report, I'm quite certain that I would have checked to make sure the EPA said that.

Q. I understand that you reviewed the EPA writeup. Did you review the Cohn study itself and do your own evaluation about whether it was a reliable study?

MS. ELLISON: Object to form.

THE WITNESS: I have looked at the Cohn study but mostly in the context of how Dr. Goodman describes the study and also EPA's conclusion about the study.

BY MR. SNIDOW:

Q. Put that aside. I'm going to mark as Exhibit 30 the Connard report.

If you'll turn to 37, do you see that you discuss -- I'm sorry -- the two Rinsky

studies, 1981 and 1987?
A. Yes.
Q. Those are benzene studies?
A. Yes.
Q. And in your report, you compare exposure of the plaintiffs to the exposures in the Rinsky study?
A. Yes, I do, in the context of my margin of exposure because the toxicity value for benzene is based on those studies.
Q. Do you know what the exposure in those two studies was based on?
A. I'm not sure what you mean by what the exposure was based on.
Q. Do you remember Charbotel used an occupational survey; right?
A. Yes.
Q. Do you know how they measured exposure in the two Rinsky studies?
A. I don't recall how they measured exposure, but it is an epidemiology study that EPA relied on for its evaluation for benzene.
MR. SNIDOW: Give me Tab 4.
(Bailey Exhibit 31 was marked.)

BY MR. SNIDOW:

Q. I will mark this as Exhibit 31. This is a report that you did for plaintiff Fiolek. If you'll look and confirm this is a report on NHL.

A. Yes.

Q. If you go to page 4 -- 40, you state there that ATSDR concluded there's sufficient evidence for causation for TCE exposure in NHL; correct?

A. ATSDR did reach that conclusion.

Q. And Dr. Goodman said that she thought that the scientific evidence did not support a causal association; right?

A. Yes. That's what Dr. Goodman concluded.

Q. And you relied on Dr. Goodman on that; correct?

A. Yes. I relied on her systematic review of the available information for that possible relationship.

Q. Am I correct you reviewed only one epidemiology study looking at the link between TCE and NHL, and that's the Raaschou-Nielsen study?

A. So what this is talking about here is the Raaschou-Neilsen study is the basis of the toxicity -- the NHL toxicity value for TCE. So by

comparing -- by doing a margin of exposure for TCE for the NHL toxicity value, I'm doing a comparison to that study, yes. So I'm relying on the study that EPA relied on.

Q. And you're aware that that study did find an association between TCE and NHL?

MS. ELLISON: Object to the form. Foundation.

THE WITNESS: So it is the basis of EPA's toxicity value for NHL. So at some level, EPA is saying there's an exposure to TCE that can result in non-Hodgkin's lymphoma. That's based on EPA's evaluation. But then you used that information to do a risk calculation.

And then if you're well below the concentration in the study or particularly if you calculate a risk that's within EPA's or below EPA's acceptable risk range, then it provides support that those exposures are not of concern for this health effect.

BY MR. SNIDOW:

Q. So just to break that down, EPA does rely on Raaschou-Nielsen; correct?

A. To derive its NHL toxicity value for TCE.

Q. For TCE. You though don't think TCE is causally linked with NHL; correct?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: So EPA based on their evaluation of the data concludes that -- let me see where they have the conclusion, specifically what they say.

BY MR. SNIDOW:

Q. Go in the middle of page 40 under TCE. It's the sentence following ATSDR.

A. EPA, ATSDR, IARC concluded that epidemiology studies suggest a causal relationship between TCE exposure and NHL, yes.

Q. So to recap, ATSDR says there's sufficient evidence; right?

A. Yes.

Q. EPA says that the study suggests a causal relationship; right?

A. EPA says that.

Q. So does ATSDR; right?

A. ATSDR says that.

Q. So does IARC; right?

A. IARC does say that.

Q. Dr. Goodman says no; right?

A. Yes. And that's based on her review of the information, and it's also based on a review of more current information.

Q. You decided to accept her view over that of ATSDR, EPA and IARC; right?

MS. ELLISON: Object to form.

THE WITNESS: So I'm not -- in my calculation or evaluation of potential risk for the plaintiffs here that have NHL, I'm not -- that particular conclusion from Dr. Goodman's report does not factor into my analysis because I still used EPA's toxicity value that's based on NHL to calculate a risk. And I still compare the studies that look at NHL and TCE. And I compare the exposure information.

So I'm still looking at those studies in the context of the exposure information from those studies to the exposure information for the plaintiffs regardless of Dr. Goodman's conclusion or the Agency's conclusion. I'm still considering that exposure information and EPA's toxicity value.

BY MR. SNIDOW:

Q. If you go to page -- if you could pull out the Mousser report, which is Exhibit 20. Go

to page 42. On page 42, you have some criticisms of Dr. Smith, Dr. Cooper and Dr. Del Pizzo.

A. Yes.

Q. And then in the second paragraph you say, All three experts make these conclusions without providing a robust analysis of the best available scientific information relevant to potential specific causation -- specific causal association to exposure to these chemicals and kidney cancer. Right?

A. That is what I wrote.

Q. What's the best scientific available information on that topic?

A. So for this particular part of my report, I think I am talking about their reference to -- sort of this general reference to increased levels of exposure, substantial levels of exposure without providing a basis for why they consider it substantial. There's no comparison to what EPA considers an elevated concentration of exposure, an elevated dose or an elevated inhalation concentration. There's no comparison.

It's just based on Dr. Reynolds' total mass and then a conclusion that this is significant and substantial without really saying

anything about why they think it's significant and substantial.

Q. So when you say the best available scientific information there, what are you referring to?

A. I'm referring to EPA's toxicity values that provide a perspective on what the exposure concentrations are that are associated with a risk of ten to minus four, ten to minus six. I'm talking about all of the studies that Dr. Goodman looked at in her report. That's what I'm talking about. So a systematic review of the available information that EPA did and that Dr. Goodman did.

Q. On page 43 you criticize three of the plaintiffs' experts for relying on the Camp Lejeune studies.

MS. ELLISON: Object to form.

THE WITNESS: Yes. I point out that there are methodological limitations in those studies, particularly the exposure information.

BY MR. SNIDOW:

Q. Again, you're just repeating the criticisms of Dr. Goodman there?

MS. ELLISON: Object to form.

THE WITNESS: I'm relying on

Dr. Goodman's interpretation or conclusions about those studies, but particularly pointing out the exposure piece, which is uncertain. And it's an important part of my evaluation, the exposure for the individuals.

BY MR. SNIDOW:

Q. Do you know how exposure was done in the Camp Lejeune studies, how it was measured?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: I would have to look at those studies, but I believe it's based on the concentrations in the water.

BY MR. SNIDOW:

Q. And how should they have done it?

MS. ELLISON: Object to form. Foundation.

THE WITNESS: So those studies are not the best available science for evaluating potential associations between the chemicals and the health effect. So what they should have done is looked at a more systematic review of all of the information and used the best available science similar to what EPA did.

They could have used EPA's toxicity

values that are more reflective of the best available science.

BY MR. SNIDOW:

Q. I'm talking about the Camp Lejeune epidemiology in particular. The one criticism that you've given me is there's exposure misclassification; right?

MS. ELLISON: Object to form and foundation.

THE WITNESS: For those studies, yes.

BY MR. SNIDOW:

Q. I'm asking: How should they have done their exposure classification that would have done it better?

MS. ELLISON: Object to form and foundation.

THE WITNESS: I think that those types of studies are -- drinking water studies are -- they're sort of difficult studies to get reliable exposure information, particularly for one chemical for individuals. So in terms of what they should have done, I think it's difficult to say for drinking water studies.

Again, Dr. Goodman would be the one to answer that kind of question for that particular

epidemiology study, but there are many other studies they could have considered.

MR. SNIDOW: No further questions.

MS. ELLISON: We don't have any questions either.

THE VIDEOGRAPHER: Anybody on Zoom have questions? Off the record July 9, 2025 at 5:09 p.m.

(Whereupon, at 5:09 p.m., the taking of the instant deposition ceased.)

COMMONWEALTH OF PENNSYLVANIA)
COUNTY OF ALLEGHENY) SS:

C E R T I F I C A T E

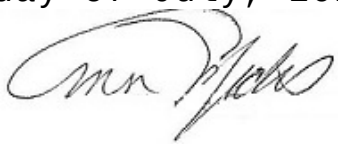
I, Ann Medis, RPR, CLR, CSR-WA and Notary Public within and for the Commonwealth of Pennsylvania, do hereby certify:

That LISA A. BAILEY, PH.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify the inspection, reading and signing of said deposition were not waived by counsel for the respective parties and by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 22nd day of July, 2025.



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Notary Public

COMMONWEALTH OF PENNSYLVANIA) E R R A T A
COUNTY OF ALLEGHENY) S H E E T

I, LISA A. BAILEY, PH.D., have read the foregoing pages of my deposition given on July 9 , 2025, and wish to make the following, if any, amendments, additions, deletions or corrections:

Page	Line	Change and reason for change:
____	____	_____
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In all other respects, the transcript is true and correct.

_____
LISA A. BAILEY, PH.D.

_____ day of _____, 2025.

_____
Notary Public

GOLKOW, a Veritext Division
One Liberty Place
1650 Market Street, Suite 5150
Philadelphia, Pennsylvania 19103
877.370.3377

July 22, 2025

Anna Ellison, Esquire
U.S. Department of Justice
1100 L Street, NW
Washington, DC 20005
Re: Deposition of LISA A. BAILEY, PH.D.
Notice of Non-Waiver of Signature

Dear Ms. Ellison:

Please have the deponent read her deposition transcript. All corrections are to be noted on the Errata Sheet.

Upon completion of the above, the Deponent must affix her signature on the Errata Sheet, and it is to then be notarized.

Please forward the signed original of the Errata Sheet to John J. Snidow, Esquire for attachment to the original transcript, which is in his possession.
Please return the completed Errata Sheet within 30 days of receipt hereof.

Sincerely,

Ann Medis, RPR, CLR, CSR-WA

cc:

John J. Snidow, Esquire

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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