Exhibit 154

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA

CAMP LEJEUNE WATER LITIGATION,	)	
Plaintiff,	)	Civil Action No. 7:23-cv-00897
Vs.	)	
UNITED STATES OF AMERICA,	)	
Defendant.	)	

VIDEO DEPOSITION OF: DAVID A. SAVITZ, PH.D.

BEFORE: Angella D. Clukey, Notary Public, at the United States Attorney's Office, John Joseph Moakley United States Federal Courthouse, 1 Courthouse Way, Boston, Massachusetts, on Friday, May 16, 2025, beginning at 9:04 a.m.

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Also Present:
Alex Jaundro, Videographer

DEPONENT: DAVID A. SAVITZ, PH.D.

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(This deposition was taken before Angella D. Clukey, Notary Public, at United States Attorney's Office, John Joseph Moakley United States Federal Courthouse, 1 Courthouse Way, Boston, Massachusetts, on Friday, May 16, 2025, beginning at 9:04 a.m.)

* * * * *

VIDEOGRAPHER: We are now going on the record. My name is Alex Jandrow and I'm a videographer for Golkow a Veritext Division.

Today's date is May 16, 2025, and the time on the monitor is 9:04 a.m.

This deposition is being held at 1 Courthouse Way, Boston, Massachusetts, in the matter of Camp Lejeune Water Litigation versus United States of America.

This is for the United States District Court for the Eastern District of North Carolina.

The deponent today is Dr. David Savitz.

Counsel will introduce themselves for the record and the witness will be sworn.

The court reporter today is Angella Clukey.

MR. BAIN: Adam Bain for the United States.

MS. ADAMS: Jennifer Adams for the United States.

MR. McGOWAN: Chad McGowan for the plaintiffs.

MS. GREENWALD: Robin Greenwald for the

plaintiffs.

(The deponent was administered the oath by the Videographer.)

DAVID A. SAVITZ, PH.D., called, after having been duly sworn, on his oath deposes and says as follows:

* * * * *

EXAMINATION

BY MR. BAIN:

Q Good morning. Could you please state your full name for the record?

A My name is David Allen Savitz.

Q And what is your current address?

A I live at 127 -- I'm sorry, I moved recently -- 252 Whiteface Road in North Sandwich, New Hampshire.

Q Dr. Savitz, my name is Adam Bain, I represent the United States.

You understand this is a court proceeding even though we are not in a courtroom?

A Yes, I do.

Q And you're under -- you understand you're under oath and obligated to tell the truth?

A Yes, I do.

Q And you have been deposed previously in this case; is that correct?

A That's correct.

Q You were a fact witness in that instance.
Do you recall that?
A Yes, I do.
Q And today you're here retained as an expert witness for the plaintiffs; is that right?
A That's correct.
Q As you know, and you've been in depositions before, that a court reporter is taking down everything that we say today. So it's important to answer your questions verbally with a yes or a no rather than shaking your head.
Do you understand that?
A Yes, I understand.
Q We should also try to avoid interrupting each other so that the court reporter can get down a clean transcript.
Do you understand that?
A Yes, I do.
Q Once the deposition is complete you will be given an opportunity to read the transcript of your testimony and make any corrections and you would then be asked to sign it.
Do you understand that?
A Yes, I do.
Q If you don't understand a question, please let me

know and I will try to clarify the question.

If you don't ask for clarification, I will assume that you understood the question; is that fair?

A That's reasonable, yes.

Q Is there any reason today why you would be unable to give your most truthful and accurate testimony?

A No, there's not.

Q You may ask for a break at any time. I only ask that you wait until you finish answering my questions before you ask for a break; is that fair?

A Yes.

Q Dr. Savitz, I'll show you what has been marked as Exhibit 1.

(Deposition Exhibit No. 1, Deposition Notice and Subpoena, was marked for identification.)

BY MR. BAIN:

Q Do you recognize this as the subpoena and notice of your deposition here today?

A Yes, I do.

Q Have you reviewed the request for production of documents as part of this exhibit?

A Yes, I have.

Q Do you have any responsive materials to produce?

A I did not bring the materials that I cited in my report. All in the open literature I have -- again,

I don't have any other materials that were used other than what's listed there.

Q So if you look at the first page of Attachment A, do you recall having any communications with any individuals listed on the first page?

A The only -- I've had no contact with Morris Maslia at any time as best I can recall.

In the other list in Item 2, I had worked some years ago on a National Academies Committee, which Susan Martel was the project director, so I had quite a few communications with her.

The other people that I've ever even had any contact with, and again it would have been through their comments to the committee, would have been Frank Bove and Jerry Ensminger.

I don't recall any of the other names of having any contact.

Q So those communications you just referenced would have been in connection with your work with the National Academy of Sciences?

A That's correct. There's been no communication actually with any of them since.

(Deposition Exhibit No. 2, Rebuttal Report on Methodological Considerations and Epidemiological Studies Evaluating Random Error and Statistical

Significance Testing, was marked for identification.)

BY MR. BAIN:

Q Dr. Savitz, I've shown you what has been marked as Exhibit 2.

This is entitled Rebuttal Report on Methodological Considerations and Epidemiological Studies Evaluating Random Error and Statistical Significance Testing prepared by David A. Savitz, Ph.D. on March 17, 2025; is that correct?

A Yes, it is.

Q And is that your report in this case?

A Yes, it is.

Q Can you turn to Page 1? And if you look at the last sentence on Page 1, it states, In this rebuttal report, I have been asked to address two topics, random error and statistical testing, and my opinions in this case are limited to those -- these two topics.

Is that correct?

A Yes, it is.

Q Prior to the preparation of this report, did you review the reports of any of plaintiff's general causation experts in this case?

A I did not.

Q Prior to the preparation of this report, did you

review the reports of any of the government's general causation experts?

A I did not.

Q If you can turn to Page 2. You state in the first sentence that, Epidemiological studies are often focused on assessing causal relationships between exposures and health outcomes; is that correct?

A Yes, that's correct.

Q And you further state that, The way this is done is by collecting data to assess the statistical association between exposures and health outcomes, correct?

A That's right, yes.

Q So looking at statistical associations and considering factors such as confounding, selection bias, exposure or disease measurement error and random error, you can see whether the association supports an inference of causal effect between the exposure and the health outcome, right?

A Again, I -- I would say that you can evaluate the extent to which it supports that. I don't -- my only -- it's really kind of a narrow point, but it -- there's not a verdict delivered, yes, no. It's interpreting the association based on all those factors that you indicated.

Q So the magnitude of the association is a factor in making an inference of causal effect; is that true?
A It's one of the considerations, yes.
Q And another consideration is the potential for random error in making the inference of causal effect, right?
A Yes, that's correct.
Q And the other concepts potential for confounding selection bias and exposure or disease measurement error are also factors in making the inference of causal effect?
A Yes. Again, the only thing I would sort of say that -- that -- again, I don't know whether we're talking just about a single study or the body of research because the -- the principles stay the same, but the application is somewhat different in trying to judge a single study in isolation versus putting an array of other relevant studies together.
Q And can you elaborate a little bit how the considerations are different in looking at a single study versus an array of studies?
A They're -- there are a number of factors that can be addressed when you have a body of research. You can of course look at the consistency of findings across studies, but also there's this concept of

triangulation where -- this is just an example, but let's say in a given study, you're not certain whether a potential confounding factor has introduced bias. But if you have other studies of the same topic that have looked at it and put that issue to rest, you may be more confident in assuming that the study that couldn't address it, that it may not be so important.

So it's the way that the research across studies can to a degree inform judgments about the methodology by looking at the array of results and not just the single study in isolation.

Q In an epidemiological study the magnitude of the association can be reflected in various ways; is that correct?

A Yes, there are a number of statistical measures that can be used. Generally either ratio measures, like odds ratios or other forms of relative risk, or sometimes difference measures where you subtract the rate of disease in the -- unexposed from the rate of disease among the exposed people.

Q So one of the ways you just mentioned was the odds ratio, correct?

A That's correct, yes.

Q And another measure you mentioned was the relative

risk; is that right?

A Yes. I mean, that -- that sometimes is used -- it's often used generically as any ratio measure or it can be referring to when you actually calculate the risk and look at the ratios. There are other related terms, hazard ratio.

I think that they reflect different statistical approaches, but they're all getting at the same thing.

Q I want to ask about another measurement which is called the standard incidence ratio or SIR.

My understanding is that compares the incidence of disease in a group to the general population controlling for demographic factors such as age, race and sex; is that correct?

A That is -- yes, it can either -- you know, standardized incidence ratio or standardized mortality ratio. It's not conceptually different than the others other than, as you said, the referent group is not generally from within the study, the referent group is an outside population, like the United States population or the population of North Carolina, or whatever the general population group might be.

Q Okay. That's helpful. So the standard incidence

ratio looks at an incident of disease, correct?
A Yes. I mean, there are different ways -- in some cases, it's an observed versus expected ratio.
So that in the population you're studying you observe a certain number of cases or deaths and then you calculate what you would have found -- how many you would have found if that group experienced the same rate as the general population.
And so that is a -- again, standardized for age and calendar year, perhaps other factors, but it's that comparison of the experience of a study population to a referent population.
Q And the difference between the standard incidence rate and the standard mortality rate is the incident rate looks at the incidence of disease and the mortality rate looks at the cause of death from that disease; is that right?
A That's -- that's right, that's the way that's used.
Q Do your opinions regarding random error and statistical significance apply to all those ways of measuring an association, the odds ratio, the risk ratio, the standard incidence ratio and the standard mortality ratio?
A Certainly the -- the general principles would apply to really any statistical measure. The other factors

may differ in terms of, you know, potential for confounding and measurement error and so on. But the -- the impact of random error, the efforts to quantify the precision would apply regardless of which measures used.

Q Okay. So it will apply to all those different types of measures I mentioned?

A Yes, it would.

Q And the potential for random error in the results of an epidemiological study can be reflected by the confidence interval, correct?

A That's right. And again it's -- not to quibble over the fine-tuning of the words, but maybe potential is not a bad way to think of it. There's an inherent statistical uncertainty. And that is a way to try to quantify the magnitude of that uncertainty.

So it isn't that you declare it, you know, random error is or is not present. It's assumed it's always present, and this is an attempt to convey some idea of the magnitude of that effect.

Q If you look at Page 2 of your report, the first sentence in the last paragraph you state, We can quantify the potential random error through statistical calculations determining a range that is likely contained -- to contain the true value

referred to as a confidence interval discussed in more detail below. Correct?

A That's correct, yes.

Q And the confidence interval is often shown after the magnitude of association in a review article or an expert report and depicted by the acronym CI; is that correct?

A That's right. The general way that would be described or presented is the point estimate with this interval -- confidence interval around it.

Q And the confidence interval is usually reflected by a parenthetical after the point estimate that includes a percentage and a range of numbers; is that right?

A Yes, that's -- that's right.

Q And the percentage given is typically 95 percent, correct?

A That is the traditional and certainly most commonly used basis for confidence intervals.

Q If you turn to Page 4 of your report, you have a section D called Confidence Intervals, correct?

A That's correct, yes.

Q And about halfway into that paragraph you say, By tradition confidence intervals are usually designed to provide a range of possibilities such that 95 percent of such intervals would, paren, if truth

were known, close paren, contain the true value; is that correct?

A That's correct, yes.

Q Is it fair to say that means that statistically 95 percent of the results will fall within the range that is represented by the confidence interval?

A This is where the -- the -- the technical versus sort of a, you know, intuitive approach, I'm not sure I have it precisely correct, but it is designed to reflect uncertainty. And there's a certain arbitrariness in the way it does that. But it -- as I said, I think that is the correct wording that 95 percent of such intervals would be found to contain the true value which again technically is slightly different than saying, we're 95 percent certain that the true value lies within the interval. I think we're getting into the -- the nuances of the process.

And the -- I think maybe I didn't say it as clearly as I could have. These are guidelines. They shouldn't be taken too literally. They're based on assumptions and shorthand ways of trying to convey the sense of precision. And as you pin it down to exactly the formal statistical -- sort of statistical underpinnings it at least in my interpretation, is

almost taking it too literally or overinterpreting it a bit to give it that much precision and credibility in what it means.

Q I want to ask you some questions using the term "relative risk," which is what you use in your report. A relative risk of 1 in epidemiology is called the null, right?

A That's correct, yes.

Q And when you have a relative risk or a point estimate of 1, it means the results of the statistical analysis show that there's no greater or lesser effect in the exposed group in comparison to the control group, right?

A It's saying that -- again, the point estimate is -- is -- if it's 1, you would say that it's indicating null association or the absence of association. It's a separate issue from addressing how certain are you that it's 1, and that's where again the -- we're just talking about precision now and random error but obviously there will be some range of possibilities around 1.

Q But that point estimate of 1 given the uncertainty you just described, reflects no greater or lesser effect in the exposed group versus the control group, right?

A That is right. That's what the point estimate would reflect.
Q If the relative risk or point estimate is above 1, that means that there is a greater effect in the exposed group than in the control group, right?
A Again the -- algebraically that means that the -- let's say the rate of disease or the risk of disease is at least somewhat, you know, to an extent greater among those with exposure than those without. That's what the relative risk above 1 would mean.
Q If the relative risk is less than 1, it means that there is a lesser effect in the exposed group than in the control group, right?
A Again, I would say yes, I guess that -- again it's -- maybe I'm overly worried about exactly the terms. It's saying that in this given study or -- or, you know, source the calculation, the rate of disease is lower among the exposed than the unexposed.

Sometimes we use "effect" to mean in a causal sense. That's a different sort of interpretation than just sort of the simple algebra what that means.
Q Thanks, that's helpful. And I was -- wanted to get to that now.

That number alone doesn't give you all the information you need to make the inference of whether

the exposure causes the effect or the exposure prevents the effect, right?

A Right, or the same if you observe a 1, it doesn't mean that you've exonerated the exposure and shown it's not a causal factor. It depends on the other considerations, the quality of the study, the accuracy and so on.

Q So as you mention in your report, the other factors that the epidemiologist needs to consider include the potential for confounding selection bias, measurement error and exposure and effect in random error, correct?

A That's right. Again, it's a secondary issue. It's just another form of exposure measurement error, but you can get into more complex issues if the confounder is not measured well, you may not have adjusted for it effectively and so there are other sort of twists and turns in there. But that's basically -- there's an array of considerations that bear on the validity of the study and the extent to which it is informative regarding a potential causal effect.

Q The confidence interval representing the 95 percent statistical range of results helps the epidemiologist assess random error; is that right?

A That's right. It's -- it's a -- it's a marker, is the way I think of it, of the study's precision. I think as I indicated in the report, we need some way to say that whatever random error is and, you know, philosophically or conceptually, bigger studies have less of it than smaller studies.

And it's a -- as I said, it's -- it's a formal way of trying to quantify a concept. And I think it's -- by its familiarity, it's become a pretty standard way of doing it, and it is a sort of an indicator solely of the random error. It doesn't address these other methodologic features.

Q So the wider the confidence interval is, the less precision there is in the result, right?

A That's right. There's more uncertainty around whatever that point estimate is. There's -- right, the range of possibilities is wider.

Q So when you use the term "precision," you're referring to uncertainty you have in the point estimate; is that right?

A Based -- right, based solely on the statistical -- again, this concept of random error.

Q And I think you also mentioned that the -- the magnitude of the association of the confidence interval doesn't tell you about confounding selection

bias or measurement error and exposure effect, right?
A That's correct.
Q And to assess those factors you have to look at the methodology of the study.
A That's right.
Q If any of those factors are present, then there is less confidence that the magnitude of the association, the risk ratio is showing a true association between the exposure and effect; is that correct?
A There's -- I would again put it more on a continuum of the extent to which the study was susceptible to confounding. That's a -- that's something that we scrutinize and, you know, they provide data to help inform that.

Again, we don't deliver a verdict and declare it's free of it or it's a problem; it's a matter of degree. And the same with all those other factors including random error. And so it's -- but the interpretation back to the sort of the concept, we generate the statistical measure and we're -- we're looking to see whether there's reason to believe it is an accurate reflection of the causal effect or lack thereof, whatever the measure is -- is the statistical measure of association indicative of what

the causal effect is.
Q Is it good practice in epidemiology to include the confidence interval when -- when reporting a risk ratio or an odds ratio or a standard incidence rate or standard mortality rate?
A It's -- it's generally done, and I think it's a useful thing to do, yes.
Q Is that a good practice?
A Well, good in the sense that it's sort of consistent with the conventions in the field, yes. And I think it's also informative.
Q And what is the issue in failing to report the confidence interval when referencing a risk ratio or an odds ratio or standard incidence rate or standard mortality rate?
A Again, the purpose of it is to give a sense of the really the volume of data that the estimate is based on. And so I don't know -- if you don't give me that additional information, I don't know whether it's coming from a study with five people in it or 5 million. And that -- the size of the study does matter because it -- it affects the -- just again the precision of the estimate in random error.
Q Okay.
(Deposition Exhibit No. 3, Camp Lejeune Bladder

Cancer Expert Report of Benjamin Patten dated December 9, 2024, was marked for identification.)

BY MR. BAIN:

Q Dr. Savitz, I handed you what has been marked as Exhibit 3. This is the Camp Lejeune Bladder Cancer Expert Report of Benjamin Patten, dated December 9, 2024.

Do you see that?

A I see that, yes.

Q And I take it from your prior testimony that you've not reviewed this report before; is that correct?

A That's right.

Q Take a look at Page 23. This is an excerpt, I should say and so page 23 isn't the 23rd page of exhibit; it's earlier in the exhibit. Take a look at the bottom pages of the report.

A 23 you said?

Q Yes.

A Okay.

Q And if you look at the middle of the page, do you see where the subheading is Mayo Bladder Cancers Northern Italy?

A Yes.

Q And do you see halfway in that paragraph it states, an elevated measure of association odds ratio 1.21

with ever exposed -- ever exposure to TC was identified.

Do you see that?

A Yes.

Q Does that provide you sufficient evidence to infer causation?

A Again, not having -- well, not having seen the rest of the report, not having -- not being familiar with the studies it's based on, it's hard to give any sort of an overall assessment of how that isolated finding bears on the question of a causal inference. It -- the sort of -- that has to be looked at in context and with an array of information.

Q And part of that context is the confidence interval, correct?

A Well, one of the features of the study that, if I were trying to judge the contribution of the study to the overall weight of evidence, and that's what I'm assuming was -- was the goal of making -- whenever you're talking about a causal -- evaluating whether a causal effect is present, that's going to be based on some weighting of the evidence and there would be a number of features of the study that would need to be taken into account as well as, of course, all the other studies.

So that's a long way of saying, yes, random error in each study is of importance. All the other methodologic features are as well.

Q And here where the odds ratio is reported without the confidence interval, you have no way -- from looking at this particular sentence -- of knowing how precise that is or what the potential for random error is in that particular result, right?

A I mean, as I've indicated generally, the -- unless I know something either about the -- the numbers it's based on or some quantification of precision, it's hard for me to make inferences specifically. Again, I'm narrowing this to saying something about the potential impact of random error in the study.

Q And you can't tell that from what is given in this particular sentence here, correct?

A As I've said, you know, again for addressing random error in that study, yes, I would need more information.

Q Turn to Page 26, just a few pages later.

At the bottom do you see a subheading for Camp Lejeune?

A Yes, I do.

Q And here again, do you see where it says, No overall association 1.07 with bladder cancer deaths was

identified in a 10-year lagged analysis of military personnel stationed at Camp Lejeune compared to Camp Pendleton with at least low exposure to benzene, citing Bove 2014 A; however, elevated measures of association with medium hazard -- with medium hazard ratio 4.04 and high hazard ration, 2.26, were identified.

Do you see that?

A I see where it says that, yes.

Q And again, with respect to the numbers of a hazard ratio of 4.04 and 2.26, you're unable to tell without the confidence interval how precise those point estimates are; is that correct?

A Again, I -- obviously, I don't know if -- you know if -- you know, it's an important issue. I don't know how it all weighs in on the overall body of research, but as I've indicated, that in order to make any sort of a -- even a qualitative assessment of the role of precision, one does need to know something about the size of the study or some other statistical measure.

Q Okay. And if you take a look at the appendix, which is the tables at the back of the exhibit...

Are you at the appendix?

A Yes, I am.

Q And do you see the tables there have a measure of association indicated a column, I think it's the third column.

Do you see that?

A Yes, I do.

Q And, again, do you see that hazard ratio point estimate numbers are given in that column for each of the studies?

A Yes.

Q But there's not a confidence interval indicated along with the point estimate, is there?

A Again, that -- that's correct and what the report says, I -- I'm not speaking to the importance of it or the -- the impact of that, but only to agree that that is what is -- you know, the only -- the point estimates are provided but not with confidence intervals.

Q Would you agree that having a point estimate without having other information is insufficient to make an inference regarding causation?

A Well, again, it -- as I said, an inference regarding causation is a weighting of evidence across studies that ideally takes all of the different considerations into account. And so one could say any one isolated piece is not going to tell the whole

story. And so I agree with that as a general principle. But as I said, in this case I'm just not familiar with what the overall story is that's being addressed and so it's hard to comment on -- it's like having, you know, an isolated piece of a puzzle without knowing what the puzzle looks like or what the puzzle should look like at the end.

So that's a way of saying that -- that there's a lot of items that would go into that assessment including precision.

Q So you can't just have one piece of a puzzle in order to make an inference of causation; you need to look at all the different factors that you discussed, the potential for random error, the potential for confounding, looking at an array of studies; is that right?

A That's right. Again, it needs to -- in my view, and I think it's a pretty conventional view, it's identifying and considering all of the relevant studies, their methods, their results, the -- just array of factors that bear on that judgment about whether there's likely to be a causal effect present.

Q Okay. You can put that exhibit aside.

A Okay.

Q And I think you referred to this previously, but

confidence intervals generally will be wider with a smaller sample than with larger sample sizes; is that right?

A That's true, yes.

Q And that's, I believe, consistent with the statement in your report on Page 2, bottom of the next-to-last sentence.

Do you see where it says, The impact of random errors decreased as the study size increases; is that correct?

A Sorry, this is on Page 2 the last paragraph?

Q The last full paragraph.

A Okay. I'm sorry.

Q The last sentence.

A That's correct, yes.

Q Now much of your report is focused on the concept of statistical significance, correct?

A That's correct.

Q And you state that statical tests have historically been used to dichotomize results declaring that an association is or is not present based on a calculated probability of less than .05 or 0.05 or greater, correct?

A That's correct, yes.

Q And that has been the historic test of statistical

significance, correct?
A That is the way that the -- right, the terminology is the statistical significance has come to be defined.
Q It is also sometimes represented as a P value; is that correct?
A Well, there's a little bit of a difference in that P values, of course, can take on any value between 0 and 1, and there -- this is referring to the calculation of a P value and then making a dichotomous judgment based on what that P value is.

And so yes, it's a step that enables the -- the determination of statistical significance, but it's not automatic. You can calculate a P value and not make a declaration or dichotomize the results.
Q So it's the dichotomization of results that you're essentially taking issue with; is that right?
A That's correct. I mean, again, I'm talking here about statistical significance, but I could probably say more generally, there's no litmus test of, is this a convincing positive study or not?

It's certainly not that and I don't think -- conceptually, I mean, it's -- you can't avoid grappling with the details. And unfortunately statistical significance testing has been used as a way to not come to grips with all the other important

aspects of the study.

Q And when you talk about statistical significance in your report are you talking about confidence intervals, P values or both?

A Well, the -- the classic way of calculate -- or determining whether a given association is statistically significant is simply to do the calculation, see what the P value is, and if it's less than .05, declare it significant; if it's .05 or greater, declare that it's not.

Confidence intervals -- 95 percent confidence intervals can be -- and I -- again, maybe it's -- it's -- can be basically degraded into a statistical test. So you can say -- it's a different presentation, but it gets at exactly the same issue where the dichotomy here is, does the interval contain the null value or not? And that's identical to simply saying it's statistically significant or not.

The only benefit, I suppose, is that for those of us who want to -- who find the confidence interval useful in other ways, we -- we at least have the confidence interval presented. They may not make what I consider to be -- the authors may not make what I would say is the best use of that information,

but I can do so independently.
Q So with respect to the confidence interval, if it contains the null value, then is that the same as the effect not being statistically significant?
A That's correct.
Q The P value still appear in epidemiological papers, don't they?
A All of the variants we're talking about appear, but certainly P values -- again, with or without statistical tests, P values are encouraged rather than statistical tests. They at least give more information than a -- simply the dichotomy of significant or not significant.
Q And those values still generally appear in epidemiological papers that appear in epidemiological journals today, right?
A I'm sorry, what --
Q P values for statistical significance?
A Well, there are two issues there.
Q Mm-hmm.
A There are those who continue to use statistical significance testing as the sort of litmus test that I've -- that has come to -- is not considered the most informative approach, but that doesn't mean it's not done.

In other words, you know, change happens slowly and it evolves. And I've been doing this for a long time. It's evolved quite a bit in the last 10 or 20 years. It's very different than it was in the past.

It continues to be done and every variant thereof; so there can be statistical significant tests, there are those who -- again, I think unfortunately calculate confidence intervals because maybe the journal editor required them to and they still make it into a statistical test.

And then I think increasingly there's momentum towards the way I'm describing it as a useful marker of precision without a declaration of, you know, based on a -- on either the confidence interval containing the null or the P being less than .05.

And, again, that I think is increasingly recognized by statisticians and epidemiologists and journal editors and so on.

Q What is your understanding of the history or evolution of using statistical significance to dichotomize results in the field of epidemiology?

A You know, again, I -- there's -- there's others who know the detailed history of how this sort of reasoning evolved.

It -- the -- again it's hard for me to -- again I can't speak to it with authority as sort of historical evolution, but it was borrowed from experimental sciences. Originally I think it was looking at crops and using different fertilizers on different fields and so on. I think there's long been a recognition that it is particularly unsuitable, the formalities of it, when we don't -- we don't randomly allocate our exposure.

So if you're doing, let's say, a study with rats in a laboratory, you can interpret the P value as a -- as an estimate of how likely it is that despite doing a perfect random allocation through random error alone, all the healthy rats ended up getting the drug and all the sick rats didn't, that's theoretically possible.

And it -- it gives it a little bit more of a literal interpretation, How likely is it that this random allocation has gone awry. Well, in epidemiologic study we don't do any random allocation; we observe.

And so it -- whatever -- you know, it may be problematic, even in laboratory studies, but it really -- it's a growing recognition that we're just pretending that exposure is randomly allocated. It's

not. And what that does is it makes random error less of a dominant concern.

In the rat studies, everything else is tightly controlled, so the only way they go wrong more or less is through random error. Epidemiologic studies have a lot of other factors, and so it's that extrapolation from experiments and the rigid interpretation where I think it's taken a while to acknowledge that that's not the most appropriate way to interpret epidemiologic data.

Q Is statistical significance still used by epidemiologists today to dichotomize results?

A It is used by some. I think the numbers -- again, I haven't done a formal survey. I think the -- the numbers and the rigidity are declining fortunately with time.

Q Would you agree that if an epidemiologist has a result that is statistically significant, the epidemiologist will almost always note that the result is statistically significant?

A I wouldn't say that. I mean, that's again getting into the almost always note.

The -- yeah, I don't have any basis for -- for trying to quantify that. I'm just thinking of it as I cited, there's now some of the leading journals

explicitly say don't do that, and it sort of is almost as an editorial point. Present the results, interpret them as you wish, but highlighting that point is strongly discouraged.

And so whether people comply, whether they enforce it, I have -- have no idea. But it's a -- I think there's a -- a direction.

I think, again, there's practice and then there's what -- what is recommended in the textbooks by the journal editors, there's sort of these authoritative voices. Obviously not everybody complies.

Q You would agree, wouldn't you, though that noting that results are statistically significant continues to the present day in papers and leading epidemiological journals?

A Again if you're asking if it is in any journals, any papers, absolutely. The prevalence of it I don't know. The -- the time trends I can't speak to. But, you know, I was going to say there -- there are a lot of -- there are a lot of things individual researchers do that I would take exception with and that I think are out of line with good epidemiologic practice, but it's not a -- there's -- there's more freedom than that in what you publish and what you say.

Q What would you consider to be the -- the leading journals in your field?
A I would say that it includes the American Journal of Epidemiology, Epidemiology just the one word, International Journal of Epidemiology. I think those -- in the pure epidemiology journals, that would be -- those would be at the -- I think at the top of the list. There are certainly other respected journals.

Epidemiology appears in a wide range of medical journals. But as far as specific to the field of epidemiology, I put those three at the top.

Q Are you aware whether any of those three have any type of guidelines that say, don't reference statistical significance in your papers?
A Well, as I indicated in the report, two of them do now. Epidemiology and the International Journal of Epidemiology. The American Journal of Epidemiology, as far as I could tell, has not weighed in on that issue.
Q Are you aware of whether journals that publish epidemiological studies include statistical significance as a criterion for publication?
A That's -- again, that depends on individual reviewers and editors. Again, it's been discouraged as a basis

but it -- I -- I recognize it -- it is not -- it still is on occasion used by the authors to promote their findings or by reviewers or editors to highlight those findings.

There's -- yeah, I mean, I think that there's all those variants of -- of what is sometimes done, but it doesn't -- again, the fact that it's done on occasion is -- is in part just a reflection of the independence that authors have, reviewers, editors. There's not a -- there's a reluctance, I think, to be overly rigid, to be honest. To impose rules is -- is something that I think researchers resist.

Q Have you ever served as a peer reviewer on a journal that had statistical significance as a criterion for publication?

A You know, I honestly don't know whether it was -- I've reviewed an awful lot of journals. And I don't know whether it's an official policy. Certainly as a reviewer it's something that -- well, I've been critical of articles that -- that choose to dichotomize results in that way. Whatever -- I can't say what the editors do with my opinion; that's up to them.

So I think that -- it's -- it's really it's thought of as one of the challenges in being

entrusting that what's published accurately reflects the state of knowledge. If it's a -- there's a concern always with the selective publication, and if the journal demands statistical significance, people may find a way to make things, you know, look statistically significant, but it's not necessarily the most accurate portrayal of the results.

Q But going back to what I think my question was, which was, have you ever served as a peer reviewer on a journal that used statistical significance as a criterion for evaluation of papers?

A I guess I'd have to say I don't know whether they did or not.

Q In your report you state using statistical significance as a benchmark doesn't reflect certain other considerations that are important, such as how noisy the measured association may be as a result of random error; is that right?

A Well, there's -- there's -- right. It -- statistical testing conflates the size of the study with the magnitude of association. And so it doesn't tell you exactly about either one.

And so at least on that level even if it's just on those two issues -- and there's many other issues that are important. It doesn't tell you about

response gradients or let alone confounding and so on. But on the simple issue of how big is the study and what is the estimate of the association, that -- it -- it doesn't tell you either of those. It -- it mixes those together.

And so that's why I say that it doesn't -- well, again, it's -- it doesn't provide clear information for interpreting the study's precision because it could be -- you could measure an association with an odds ratio of 10 that goes from 1.1 to 50. You'd say, oh, it's statistically significant. Well, it's highly elevated and imprecise.

That's the way I would describe it. Or a relative risk of 1.1 that goes from 1.05 to 1.15, and that's statistically significant, and I would say it's a very small increased risk but measured very precisely.

So it's -- it's just trying to -- it's not -- it's just trying to make it more transparent in terms of what it's saying.

Q You would agree, wouldn't you, that all data needs to have some testing for chance of randomness?

A I would not say testing. It needs to -- if you're going to interpret an association, you would want to consider information on the role of random error. It

doesn't need to be that idea. It needs to be tested as though you make a declaration. That is -- that's not a -- a good strategy.

Q Would you agree that it needs to have a statistical analysis done?

A Certainly for epidemiologic studies that are looking at potential, you know, cause and effect relationships, yes, we need some indication of the association or other measure that indicates statistically just whether the exposure is related to the health outcome.

Q So it's still standard epidemiological and clinical practice to do statistical analysis to assess chance?

A Certainly -- well, I was going to say, we do statistical analysis to -- to understand what -- what the study results say. And a component of that is trying to address random error and precision.

But it can also be to better understand whether confounding is present or not or to look at the effect -- I mean, statistical analysis covers a lot of territory, and -- and -- and it can be used for a variety of purposes. You can use statistical analysis to look for dose response gradients. You can use it to see if confounding is a major problem and so on.

Q So epidemiological journals still require statistical analysis to be done in papers that are submitted; is that true?
A Again, define "broadly." I can't imagine how you would -- how you would get information on the study's results without statistical analysis.
Q And without information like that on the study's results, a journal will not publish a paper; is that true?
A Right. Well, you can't just make a declaration without showing the data. And in general certainly any higher quality journal is -- is going to expect and demand that you describe the methods clearly and that you describe the results clearly. And that describing the results means some appropriate statistical analysis, yes.
Q Okay. I'm about ready to change subjects a little.
Do you want to take a break or should we keep going?
A Keep going for a bit.
Q Okay.
A Just need a little water.
(Deposition Exhibit No. 4, Excerpts from Epidemiology and the Law, was marked for identification.)

BY MR. BAIN:

Q Dr. Savitz, I've shown -- showing you what's been marked as Exhibit 4, and I believe you're familiar with this. This is excerpts from your book excerpts from Epidemiology and the Law.

Do you see that?

A Yes, I do.

Q And starting on Page 75, you have a section entitled Commonly Used Argument in Support of Judgment of Causality.

A Yes. 75 you said?

Q Yes. Are you there?

A Yes, I am.

Q Again, the title of that section is Commonly Used Arguments in Support of a Judgment of Causality, correct?

A That's correct.

Q And the first section is entitled Statistical Evidence of an Association, correct?

A Yes.

Q And it states, The first criterion that needs to be met is evidence that a statistical association is present, a necessary but not sufficient basis for inferring causal effect. Correct?

A That's correct, yes.

Q And why is having statistical association necessary to infer causal effect?
A Well, the -- again from the point of view of epidemiology, there -- in order to make an inference that exposures caused an increase in risk, you need to demonstrate that those who are exposed have a higher risk than those who are not. And that's what I mean by a statistical association.
Q And why is having a statistical association not sufficient to infer causal effect?
A Well, there could be a variety of noncausal reasons that there is a -- an association is present. It could be due to confounding or a particular pattern of measurement error or a -- due to random error among other -- I mean, that's not the only list, but there's a -- there's a judgment to be made about whether that is likely to be a -- a result of a causal effect versus some artifact of a methodologic problem.
Q In the next sentence you point out that, Statistical evidence of association is often in the form of a relative risk comparing the frequency of disease among those who are exposed, open paren, or more exposed, close paren, to those who are not exposed, open paren, or less exposed, closed paren; is that

correct?
A Yes, it is.
Q And then in the next sentence you state, in presenting that relative risk, there is an interest both in how big it is in absolute terms and how precise it is; is that correct?
A Yes, it is.
Q Why is there an interest in how big it is?
A Well, the -- ultimately, when you're trying to infer a -- whether or not there's a causal effect present, this does go all the way back to the Bradford Hill considerations; if it's a large association, there may be less plausibility that it's a product of artifacts.

That's the general statement. Not always true. It's a concept that I think is reasonable, but in order to interpret it -- and again, in this weighting of evidence, you would be interested in both of those factors, how big and how precise as well as, of course, all the other -- all the other methodologic considerations.
Q You mention the Bradford Hill criteria and one of those is strength of association, right?
A That's right. Again, considerations. It's a -- again, quibbling over the point that it's another

area where the original intent was to, having observed an association, to help evaluate how likely it is to be causal and that's one of the considerations he raised with the idea that that makes all other things equal, a large association is less likely to be a product of some artifact.

Q So all other things being equal, the stronger the association is, the more confident that you can be that the association reflects a real relationship, right?

A Well, there's -- again, the -- again, I would be careful about the word "real." You can -- the statistical evidence of an association is greater if the -- you know, the relative risk is bigger and the precision is better.

So the question, is there even a statistical association present, our confidence in that goes up as those factors are taken into account. I would separate that from the inference, is it causal or not? That -- that's more complicated.

Q So you're distinguishing between a statistical association and the ability to infer causation?

A That's correct, yes.

Q In your book on the same page below where we just read, you note that, 1.0 indicates no association,

correct?
A That's correct.
Q And you state, At 1.2 there may be a modest increase, correct?
A That's -- again, illustratively, yes.
Q And also illustratively you say, A relative risk of 1.5 to 2.0 is a more substantial increase, right?
A Yes. Again, I -- those are -- I hope it's clear at least in the writing that those are illustrative numbers and they're not -- there's no magic to them. There's no binning that would say -- that those are criteria to be met.

It's just trying to be clear that an association -- you know, that the magnitude is something to pay attention to.
Q And you say that larger associations are those beyond 2.0, correct?
A Again, increase or a larger association.

As I said, it's -- I hope the writing is clear, at least I intended it to state, not that these are bins but that there's a spectrum of elevated risk from lower -- you know, lesser increases to greater increases.
Q And in the last sentence of that paragraph you state, It's harder to make a convincing case for a causal

effect of small associations as compared to larger ones, correct?

A That's correct, yes.

Q And I think as you already mentioned, in addition to how big the statistical association is, there's a consideration of precision of the point estimate and that's reflected by the statistical testing that we've discussed earlier, right?

A Again, I would reflect it in the confidence interval, but, yes, statistical analysis, I would say, is used to help characterize the precision and the -- that's -- with any association there's an interpretation involved. And with small associations there is a -- you know, a greater focus on the potential that -- that it's really null and just -- that the small elevations are not meaningful.

But with enough -- with the right research and the right context and so on, there's certainly a real but small causal associations. I mean, a dramatic example is air pollution where we have these tiny increments in risk from particulates but are quite confident in -- and regulatory agencies are confident, others, that it's a causal effect. It's just a small increment.

Q And usually because that's based on a study that is

surveying very large groups, right?
A They've done studies of, you know, 60 million people and so they get very precise results but it's also -- you know, this business I mentioned of triangulation, you can replicate it using different designs. It's consistent with more sort of biologic effects on the lung.

There's a variety of ways to address it that can build that confidence. It's easier, I would say, when the associations are larger to make a convincing case.

Q Would you say that when the association is -- is smaller, it's more important to have those other considerations of Bradford Hill pointing toward causation?
A Again, I -- I think -- the way I think of the Hill considerations is that they're trying to distinguish causal and noncausal effects and I think that the scrutiny that's required often is greater for -- you know, to make that judgment regarding smaller magnitudes of association.

You know, and we discovered that the human papillomavirus is related to cervical cancer with a relative risk of 30. Of course it made biologic sense, it meets all the criteria.

There is sort of less inherent plausibility of a -- of an artifact with air pollution and respiratory disease there's more possibilities because it's small.

So it -- it's really back to that issue of distinguishing between associations that are causal and those that are due to artifacts.

Q So as we discussed in addition to how big the relative risk is, there's the consideration of the precision of the relative risk, which is indicated, you said, by confidence intervals, correct?

A Yes.

Q And as you state at the bottom of this page, I'm looking at Page 75 of your book, Evaluation of precision is an attempt to distinguish between signal and noise with small studies less able to do so with confidence and larger studies more discerning, correct?

A That's correct.

Q And then you go on to state, A small and imprecise indication of an elevated relative risk may be unpersuasive, right?

A Yes.

Q And that's unpersuasive with respect to causal inference, right?

A Again, I -- I would -- we're still, I think, on that first step. Are we -- are we confident there's an association present?
Q Okay.
A And so it's -- it's a -- it's a step towards the causal inference but it's not the causal inference itself.
Q So confidence that it's in a real -- a real association?
A Yes. That there's a statistical association present. That -- that is, I think, what I meant by that.
Q And then you state, A large and precise indication of relative risk makes the argument that an association is present more convincing, correct?
A It's an easier argument to make when you have those attributes.

And, again, these are obviously -- it's written in a way that it's pretty clear these are sort of generic guidelines that in any given case, you know, of course the usual answer, it depends. But these are general principles that I think are worth keeping in mind.

Q Written with the lawyer audience in mind to make it easy to understand?
A I tried, but again -- well, whether I succeeded or

not, others -- others can judge, but to not have this division between -- which is troubling to me of the way these things are viewed in the scientific arena and in the legal arena.

And there are those times where I feel like we've not maybe communicated well, it hasn't penetrated. I can't speak to the legal arena other than I'm trying to do what I -- you know, I was trying to do what I could to make it accessible and intuitively reasonable, but again, that's up to the reader.

Q So you mention here, A small and imprecise indication of elevated relative risk and a large and precise indication of elevated relative risk.

What would you say about -- or how would you characterize a large but imprecise --

A Mm-hmm.

Q -- indication of relative risk?

A Mixed. I mean, it's a -- you know, there -- as I said with any example we come up with, there are times where these -- that kind of evidence is proven to be important indicators of a causal effect.

And so it -- it's a matter -- you know -- you know, it depends on what decision you're trying to make from it. I think that -- that the -- all other things equal, the larger the effect size and the

greater the precision, the more weight it carries in not just the causal inference but in whether it's going to lead to future research and improved studies. In some ways when it's just -- when the problem is study size if it's feasible that's actually a more tractable problem than some of the other things we run into.

If the solution is a bigger study, then that is, you know, to a degree that may be an attainable goal, so...

Anyway, I think that there's not a dividing point; it's the -- as I said, this is back to the -- these are all relevant considerations.

Q Are you familiar with the term "confidence interval ratios"?

A Yes, I am.

Q What is your understanding of confidence interval ratios?

A It's, I think, a useful way to try to give a sense of precision of the study -- note, it's interesting, it doesn't relate to what the point estimate is, we're putting that aside from now. It's separating those issues. But it's trying to convey a sense of the study's precision.

And so I think in this -- well, book or I -- but

anyway, it was in my report, but there's a -- you know, when you get to a certain magnitude, it's saying, this is a very imprecise study. You know, you get ratios like 10.

That means, like, a -- you know, let's say the confidence interval is, you know, .2 to 2, you've got a -- you know, you've got a challenge there to try to -- it just says it's potentially very noisy. It doesn't mean you throw it out, but it's saying that's pretty noisy; whereas if it's, you know, 1.1 to 2, well, okay, we're okay there, there we can work with that.

Q So the confidence interval ratio is the upper end of the confidence interval divided by the lower end, right?

A That's correct, yes.

Q And the smaller that number is the more precise the point estimate is?

A That's right.

Q And you believe that's a useful measure of precision?

A It's a simple benchmark that can be used to -- to try to -- again, it's sort of a way of -- even though it's a number, I would say it's a way qualitatively of saying is this a, you know, is this a reasonably precise study, has it got a lot of problems with

imprecision; and it's a -- it's sort of a shorthand indicator, I would say.

Q You've reviewed some of the ATSDR's public health studies on Camp Lejeune, haven't you?

I saw you commented on some of them in the press.

A I had seen some -- boy, this is going back a ways timewise.

I had seen some initial results. It may have -- I'm not sure. I think it went beyond the press release, but I'm not sure about that. You know, I haven't examined those in detail or -- or wouldn't be in a position now to sort of offer any sort of a detailed assessment. I'm certainly aware of them. Let's put it that way.

Q Were you aware that the -- some of the ATSDR Camp Lejeune studies used the concept of confidence interval ratios to identify noteworthy findings?

A That I -- I don't -- I was not aware of or am not aware of.

Q Okay.

MR. BAIN: Do you want to take a break now?

THE WITNESS: Sure. Thank you.

VIDEOGRAPHER: All right. We're going off record at 10:19.

(Whereupon a recess was held at 10:19 a.m., and

the deposition was resumed at 10:34 a.m.)

(Deposition Exhibit No. 5, Cancer Incidence Among Marines and Navy Personnel and Civilian Workers Exposed to Industrial Solvents in Drinking Water at US Marine Corps Base Camp Lejeune: A Cohort Study, was marked for identification.)

VIDEOGRAPHER: We're going back on record. The time is 10:33.

BY MR. BAIN:

Q Dr. Savitz, I've handed you what has been marked as Exhibit 5. This is a Cancer Incidence Among Marines and Navy Personnel and Civilian Workers Exposed to Industrial Solvents in Drinking Water at US Marine Corps Base Camp Lejeune: A Cohort Study.

Do you see that?

A Yes, I do.

Q And have you read this study before?

A I do not think that I have.

Q If you look at the abstract, and do you see the section titled Results?

A Yes, I do.

Q And if you look at that section, do you see that results are identified that had a hazard ratio of greater than or equal to 1.20 with CIR, which I take it stands for confidence interval ratio, of less than

or equal to 3?
A Yes, I see where it says that.
Q What does that benchmark that was used tell you about the size of effect in the precision of the finding?
A Well, again the -- without having read the paper, and I can't speak to it in detail, but when they set up those criteria, presumably they were looking for the most I would say credible or convincing associations that are based on the point estimate and based on the confidence interval ratio.

And they made those a joint criteria for what they're highlighting there.
Q Do you agree with that methodology for identifying significant results?
A Well, that's not -- again, as I said, I -- it -- it -- I think that -- that it's reasonable to consider both of those factors. I am always wary of dichotomies that, you know, if the confidence interval ratio was 3.1, well, would you not be talking about it, and wherever you draw the line that's going to be an issue.

I think that it's very reasonable though to -- to have some joint consideration of the magnitude and precision those -- that that would be reasonable. As I said, it's the -- and I don't know what their

purpose was without having read the paper in terms of screening the results.

I assume it's just to decide what to highlight and that somewhere in the paper they would present the full array of results.

Q In your opinion is that benchmark better than applying statistical significance?

A I think -- it's -- it's certainly -- I mean, first of all it's conceptually clearer. They're not smashing together both of those factors. They're looking at them separately.

When you say better, I think it's a -- I want to say it's going to sort of be more inclusive. It's -- it's to me at least a bit less arbitrary, other than the extent to which any cutpoint is going to be arbitrary.

This -- this seems -- again, without having read the paper, going into detail, it seems like a reasonable benchmark for what they choose to highlight.

Q So I think you said you believe this is more inclusive than the benchmark of statistical significance; is that correct?

A I think that -- I can't off the top of my head tell you the degree to which they would correspond. In

other words, whether every -- every association that -- that is statistically significant would be captured that way.

But intuitively I would think that it's -- it's capturing a number of those that would not have been flagged based on statistical significance alone. I have to look at the -- again, I'm just glancing through the abstract. And it -- and there are certainly some that are highlighted presumably based on -- as I said, I should probably be careful.

I'm trying to do an accounting of their results without having read the paper. So I -- I would need to look at that specifically. But, again, I was -- that was a guess that it would be more inclusive.

Q Well, if you look at the bottom it includes at least one where the lower end of the confidence interval ratio was below one which would be for myeloid cancers.

Do you see that one?

A Let me read through here.

Polycythemia vera. There are several -- right. It's interesting that -- and again I have -- most of them are -- are, you know, conventionally statistically significant. A few of them the boundary is a little bit below one, but -- but no

less credible.

Q So going back to my original question, would you say that this in your view of how you view point estimates and confidence intervals a better benchmark than using statistical significance?

A Again, I -- I -- I can't give you a generic answer better for what purpose.

Q For identifying significant results from a study.

A I -- as I said, I'm not trying to be evasive, but, you know, significant in the sense of worth paying attention to. You know, I would be wary of any method that highlights some and dismisses others because again it's -- it's an arbitrary sort of benchmark.

I think that for any one of the outcomes of interest, the results would be interesting and relevant without making a declaration, these are positive, these are not. They would be adding information outcome by outcome.

Q So you can't say in your opinion whether this would be better than statistical significance as used as a benchmark for identifying significant results?

A Without -- again without a clear understanding of the purpose, I can't.

Q Are you familiar with confidence interval ratios

being used in other epidemiological studies?
A Oh, that -- I mean, as a general statement, yes. I mean, they're commented on. I don't know -- again, I don't -- I can't off the top of my head tell you where it's been used -- said to decide what to highlight the way it -- at least from the abstract appears to be used here.

But I have seen it -- the calculation is -- is -- is not infrequently done to try to put the results into -- into some context with regard to precision.
Q So you -- you have seen that in other papers outside the ATSDR's work?
A I believe so. Again, I can't give you citations of that, but I've -- I've seen it used. I probably at one time or another have used it myself.

(Deposition Exhibit No. 6, Excerpts of the ATSDR Assessment of the Evidence for the Drinking Water Contaminants at Camp Lejeune and Specific Cancers and Other Diseases dated January 13th, 2017, was marked for identification.)
BY MR. BAIN:
Q Dr. Savitz, I've shown you what has been marked as Exhibit 6. And this is excerpts of the ATSDR Assessment of the Evidence for the Drinking Water Contaminants at Camp Lejeune and Specific Cancers and

Other Diseases dated January 13th, 2017.

Do you see that?

A Yes, I do.

Q And if you turn to Page 8.

A Okay.

Q And if you see the -- the last full paragraph, it's the next-to-the-last paragraph on that page, do you see where it says, In the disease-specific tables, 95 percent confidence intervals were provided in order solely to indicate the level of precision or uncertainty in the effect estimates. An effect estimate, open paren, e.g., risk ratio, odds ratio or standardized mortality ratio, closed paren, was considered to have good precision, open paren, or less uncertainty. If the ratio of the upper limit to the lower limit of its 95 percent confidence interval was less than or equal to 2.

Do you see that?

A Yes, I do.

Q Do you agree that that is a good indication of precision where the ratio of the upper limit to the lower limit of the 95 percent confidence interval is less than or equal to 2?

A It seems to me like a -- again, a reasonable approach with the caveat that any -- any dividing line is

arbitrary, and if it's close to that value, you know, as I said whenever you're, you know, distinguishing something that's 1.9 as a ratio versus 2.1, there is that issue.

But overall I think that that statement suggests to me that they're thinking about this and approaching it in a reasonable way.

Q I think you said that you may have used confidence interval ratios yourself; is that correct?

A I may have. I -- I don't -- I can't tell you -- again, I've written a lot of papers over the years, and I just honestly don't remember.

Q Do you recall whether you used any particular confidence interval ratio as indicating a certain level of precision?

A You know, I -- I -- I think if I used it, it would have been only to note, you know, what it was either -- and as I said, this is speculative.

At least maybe I should just say that I think that ideally the way I would want to use it would be to make the calculation and have it be just without a declaration, like without a cutpoint just as part of the consideration. If I looked at a confidence limit ratio and it was 10, I might say, well, you know, we're really not very sure about that at all.

But I don't think I would have -- I tend to avoid these, you know, sort of arbitrary cutpoints, if I can.

Q So is your whole perspective to kind of do a holistic view rather than use any type of benchmark or litmus test to separate significant from insignificant findings?

A I think that when I'm -- again usually I'm in -- trying to assess the -- sort of the integration of the evidence, waiting studies, and that waiting is inherently got a lot of dimensions to it. So it's -- it's again the combination of the methods and the results.

But I would say that I do use multiple considerations for a given study and in assembling the evidence across studies.

Q Okay. You can put that aside.

(Deposition Exhibit No. 7, Dr. Steven B. Bird General Causation Expert Report, was marked for identification.)

BY MR. BAIN:

Q Dr. Savitz, I'm showing you what has been marked as Exhibit 7. This is the General Causation Expert Report of Steven B. Bird, M.D., Hematopoietic Cancers, Leukemia, Non-Hodgkins Lymphoma.

Do you see that?
A Yes, I do.
Q And I take it from your prior testimony you've never -- you've not reviewed this report?
A I have not.
Q Turn to Page 42. And, again, this is an excerpt of his report.
A Okay.
Q Do you see under Leukemia Findings there is the statement that, Civilians exposed to medium levels of TC and PCE combined. And in parentheses it says, 10,868 to 50,563 part per billion months for TCE or 457 to 2,118 PP months for PCP, close paren, had an odds ratio of 1.41, 95 percent confidence interval range of 0.38 to 5.28 reflecting a 41 percent increase of the leukemia compared to Camp Pendleton civilians.
Do you see that?
A Yes, I do.
Q Under a traditional understanding of statistical significance, that result is not statistically significant because the lower end of the confidence interval is less than 1, right?
A That is true, yes.
Q Would you agree that the confidence interval is very

wide?

A Again, you know, we get into adjectives describing it, but yes, I would say that that is a wide confidence interval.

Q And would you have any hesitation about using that result to make an inference of causal relationship?

A I think that in an overall assessment, the way I would describe it is results like that weigh weakly in a positive direction.

In other words, it -- if you're saying, is it pointing toward -- more positive than negative? Well, it's imprecise, it's not adding a lot of weight, but it -- it hints at a direction, and I would not overinterpret or put -- as I said, put a lot of stock in this as an isolated finding.

Q Okay. If you look at the next paragraph, do you see where it says, When comparing civilians at Camp Lejeune to their counterparts at Camp Pendleton, the overall odds ratio was 1.10, 95 percent confidence interval, 0.36 to 3.38, providing evidence that exposure to the contaminated water and to the chemicals it contained during the time of the study period was sufficient to increase the risk of leukemia.

Do you see that?

A I see that, yes.
Q And under a traditional understanding of statistical significance, that result is not statistically significant because the lower end of the confidence interval is less than 1, correct?
A That is correct.
Q The confidence interval is also wide with a ratio of almost 10; is that right?
A That would be correct, yes.
Q Would you have any hesitation in using that result to make an inference of causation?
A Again, it -- it depends whether you're saying in isolation that alone would be providing strong evidence. I would actually focus back on sort of the -- it adds a tiny bit of statistical support to the body of evidence pointing in a positive direction, but very weakly and to a very limited extent.

I think that -- that, again, it's -- it's -- as I said, it's -- you know, in making a causal inference, I don't want to do -- I never would want to do that on any one study, this one or any other one.

It's just a matter of how does this puzzle piece or this brick or whatever metaphor you want to use

weigh in. And it -- given the imprecision, it's a very modest -- you know, very, very little contribution.

Q The statement is that, This provides evidence that exposure to contaminated water and the chemicals it contained during the time period of the study was sufficient to increase the risk of leukemia.

Would you consider that to be an overstatement?

A Again, I don't know what all that was based on. I think that -- as I said, I think this result alone is quite fragile and quite limited regarding a statistical association or -- or a causal effect.

Q Okay. If you turn back to Page 32.

Do you see there's a section entitled TCE there?

A Yes, I do.

Q And do you see in the second paragraph there's a statement, Talibov, et al, investigated elevated risk of AML with solvent exposures including TCE in a case-control study from Scandinavia. And the citation of the study is provided in brackets.

And then it states, They found an elevated HR of 1.12, 95 percent confidence interval .83 to 1.49 in medium and high exposure groups.

Do you see that?

A Yes, I do.

Q Are you familiar with that study?
A I am not.
Q And again under traditional understanding of statistical significance, that result is not statistically significant because the lower end of the confidence interval is less than 1, right?
A Again, as a -- right, as you said, couching it in the formalities in -- and traditions of statistical significance testing, that would not be statistically significant.
Q Would you have any hesitation inferring a causal relationship based on that result?
A Again, I -- I would put aside for the moment a causal relationship because that -- that is a question more broadly about -- in this case, apparently, TCE and whatever -- you know, at least in that case, we're dealing with acute myeloid leukemia.

I would say that in looking at that, that it provides some, but modest, support for a small elevation in risk, that it's -- in contrast to some of the other ones we've talked about, the confidence interval suggests it's a reasonably large study, it's a modest increase. And so I would take that into account in weighing the overall body of evidence.

Q And this -- this study came out in 2014 which was

after the NRC work that you did on TCE and PCE in Camp Lejeune, right?

A That's -- again, correct. Again, referring back to the -- I'm hesitant to say my work, the National Academies Committee that took this on and addressed it and wrote that report.

Q If you had had the benefit of this particular study, do you think that would have changed in any way that the academy classified the relationship between TCE and leukemia?

A That -- that really is impossible to speculate given, you know, it's obviously in the context of a -- not just a large body of research but a whole team on the committee that would have been looking at it, so I can't really say.

Q Okay. If you can turn to Page 35?

And looking at the first full paragraph, do you see where it says -- and this is in relationship to the Aschengrau, et al, 1993 study.

If you look on the prior page, it says, The authors define the risk of leukemia and other cancers for the Cape Cod cohort people exposed to any amount of PCE had a relative risk of leukemia of 1.72, 95 percent confidence interval 0.5 to 4.71, which demonstrates a 72 percent increased risk.

Do you see that?
A Yes, I do.
Q And again, under the traditional understanding of statistical significance, that result is not statistically significant, correct?
A That's correct.
Q And this study by Aschengrau was done in 1993 so the National Academy of Sciences Committee which you chaired would have had the benefit of that study, right?
A I assume so. I'd need to just look at the reference list just to make sure, but I believe it did.
Q Do you recall that study at all?
A Again, it's been quite a long time and in very general terms, I do remember we had a section on community studies separate from occupational studies, and I believe it would have been included in that.
Q And the confidence interval ratio for that particular result is close to 10, correct?
A That's correct, yes.
Q And you would consider that to be a wide confidence interval, wouldn't you?
A Yes. Again, as we talked about, it's a -- you know, potentially a meaningful elevation in risk that is -- suffers from imprecision.

MR. BAIN: Okay. I'm done with that particular exhibit.

(Deposition Exhibit No. 8, General Causation Expert Report of Steven B. Bird, MD, Parkinson's Disease, was marked for identification.)

BY MR. BAIN:

Q Dr. Savitz, I've shown you what has been marked as Exhibit 8, General Causation Expert Report of Steven B. Bird, MD, Parkinson's Disease.

Do you see that?

A Yes, I do.

Q And based on your prior testimony you haven't reviewed this report before, have you?

A That's correct, I have not.

Q I would like you to turn to Page 28.

If you look at the first full paragraph, do you see where it states, When comparing Camp Lejeune civilians to those at Camp Pendleton, the study found a hazard ratio of 3.13, 95 percent confidence interval, 0.76 to 12.86, indicating that civilians at Camp Lejeune had a 213 percent higher risk of PD, Parkinson's disease, than those at Camp Pendleton, more than a doubling of the risk. These findings reinforce the idea that the chemicals at Camp Lejeune were present in sufficient quantities to cause

Parkinson's disease.

Do you see that?

A Yes, I do.

Q And just to make sure you know what that particular paragraph is referring to, if you turn to the prior page, this section deals with the Bove 2014B study, cancer mortality study of civilian employees exposed to contaminated drinking water at Camp Lejeune, North Carolina.

Do you see that?

A Yes.

Q So going back to that result, 3.13 with a confidence interval of 0.76 to 12.86, again, under traditional statistical significance, that result is not statistically significant, is it?

A Right, that's correct.

Q And the confidence interval ratio is over 10, right?

A I -- I don't know exactly what it is, but it's -- it's substantial. So, again, the idea of presenting both is that it suggests a rather sizeable increase in risk.

It -- there's a lot of uncertainty around it, but that -- I wouldn't -- I would certainly not consider that a -- just, again, just based on the numbers alone. No -- I can't give you any context, I can't

tell you more about the report, but I would say that that provides, you know, meaningful evidence supportive of an association.

Now, whether it's 3.1 or 2.5 or 7, I can't -- you know, the -- there's a lot of variability around it, but it's -- it's substantial enough that even with the wide confidence interval, I think it does provide some meaningful support.

Q And I think you said in your answer support for an association, right?

A Yes, that's a separate then that isn't going to be evaluated based on that study alone. Looking at the totality of evidence is what you would need to do to make a judgment about a potential causal effect.

Q And the author says, These findings reinforce the idea that the chemicals at Camp Lejeune were present in sufficient quantities to cause Parkinson's disease.

Do you see that?

A Yes, I do.

Q So the author uses the term, "cause," correct?

A That is correct, yes, in that phrase.

Q Do you know how many persons died at -- of Parkinson's disease at Camp Lejeune versus Camp Pendleton which formed the basis for that statement?

A I do not.

(Deposition Exhibit No. 9, Mortality Study of Civilian Employees Exposed to Contaminated Drinking Water At US Marine Corps Base Camp Lejeune: A Retrospective Cohort Study, was marked for identification.)

BY MR. BAIN:

Q Dr. Savitz, I've shown you what has been marked as Exhibit No. 9. That is entitled Mortality Study of Civilian Employees Exposed to Contaminated Drinking Water At US Marine Corps Base Camp Lejeune: A Retrospective Cohort Study.

Do you see that?

A Yes, I do.

Q And do you see the date is 2014?

A Yes.

Q And does that correspond to the study we were just discussing, which was commented on in Exhibit No. 8?

A Again, I -- I really don't know. I'd have to --

Q Okay.

A -- track back and see which population, what comparison and so on.

Q So we'll take a look at that.

If you'd turn to Page 8 of that study.

A Okay.

Q And do you see at the bottom of the list of Diseases of Secondary Interest Parkinson's disease is noted?
A Yes.
Q And do you see the hazard ratio there of 3.13 with a confidence interval ratio of .76 to 12.86?
A Yes, I do.
Q And does that correspond to the estimate -- or the figure that was referenced in Exhibit 8 that we just looked at?
A Yes, it does.
Q And do you see that there is listed a -- numbers in the -- the final columns of that particular table?
A Yes.
Q And do you see for Camp Lejeune the number is -- is 5?
A Yes.
Q And for Camp Pendleton the number is 4?
A Yes.
Q So the fact that this statistic is based on five deaths from Parkinson's disease at Camp Lejeune versus 4 deaths from Parkinson's disease at Camp Pendleton, does that give you any less confidence that that number is helpful for making any type of inference on causation?
A Again, I would focus first on -- on what it can say

about the -- my confidence that there is a statistical association present putting causality aside. It's interesting I think those are all -- across the whole set of columns those are informative numbers; the point estimate, the confidence interval, the P value and the number of cases.

And I think they reinforce the notion that there appears to be an elevated risk that is limited by the -- the rarity of the disease and the -- the resulting precision. But it -- remember the rarity of the disease and the size of the populations are sort of, in a sense, what you're stuck with.

And then it's saying excepting that, what does this study tell us. And it -- to me at least it says there really may well be a signal out there. There is evidence supportive of an association.

And I wouldn't say -- you know, if you told me the numbers were 1 and 2, I would say, well, this is negligible. This is just -- you know, again it's -- it's modest, but it's -- it's not negligible. If the P value were .8, I would say, oh, this is really, really fragile. It's -- it's limited but it's not negligible in my view.

Q Okay. Turn back to -- put that exhibit aside for a bit --

A Okay.
Q -- and go back to Exhibit No. 8.
A Okay.
Q And go to Page 28, which is the same page we were on before. So it's referring to the same study.
A Okay.
Q And do you see in the middle of the page there is a paragraph that starts with this study?
Do you see that?
A Yes, I do.
Q And it states, This study also compared civilians at Camp Lejeune with below median exposure to those with above median exposure for TCE the hazard ratio is 2.51, suggesting a 151 percent increased risk of PD, Parkinson's disease.
For PCE the hazard ratio was 2.68, suggesting a 168 percent increased risk of Parkinson's.
For TVOC, a combination of all the chemicals, the hazard ratio was 2.52, suggesting a 152 percent increased risk of PD.
Do you see that?
A Yes, I do.
Q And those particular hazard ratios are provided without providing the corresponding confidence intervals, correct?

A At least again in the text that's provided there, that's correct.
Q And I think as we discussed earlier -- and correct me if I'm wrong but it's standard practice to include the confidence intervals when including a hazard ratio in epidemiology, right?
A Again, I think that -- that it is traditional not -- you know, it's -- it's commonly done to quantify the precision.
Q Okay. If you can look back at Exhibit No. 9. And -- and keep that open because it will help you refer to what we were just discussing. And go to Page 10 -- I mean, sorry -- yeah, Page 10.
A Okay.
Q And do you see a table that it provides Hazard Ratios for Categorized Maximum Cumulative Exposure for Continuous Cumulative Exposure for Certain Conditions?
A Yes.
Q Table 6.
A Okay.
Q And so for the -- the TC hazard ratio number that was in the report we just looked at, 2.51, do you see that the confidence interval was from .21 to 30.76?
A I do, yes.

Q Given that confidence interval, do you believe that the 2.51 is a reliable hazard ratio to consider in making a statement that there was 151 percent increase in Parkinson's disease?

A I would probably avoid any -- anything that sounds that precise. I mean, if I -- again just looking at the table without the context, I think the exercise of asking the question, even with only four cases, where they tend to concentrate in the subset with higher exposure, reasonable question to ask. And I would -- you know, subject to the very limited numbers, there was a tendency for those with higher exposure -- the risk -- the elevation tended to be concentrated in the subset with the higher exposure.

I'd be very careful about quantifying it or conveying a sense of any precision given that -- given that confidence interval and given the just -- even without the confidence interval, with only four cases you're getting into a range where it's problematic to make calculations like that.

Q And we saw previously that there were only five cases overall, correct?

A I don't -- I recall there was five in one group and four in the other. I don't recall which was which.

Yes, five cases, right, in -- I'm looking now at

Table 4 where it indicates five cases in the Camp Lejeune population and four cases of Parkinson's in the Camp Pendleton population.

Q So you wouldn't make a representation as precise as you saw in that report that there was a 151 percent increase in Parkinson's disease?

A As I said, again, based on the numbers I'm seeing there, I would say the ability to examine dose response relationships was limited by the numbers, but within those bounds they tended to -- the cases tend to be concentrated in the higher exposure subgroup and kind of leave it at that.

Q And if you look back at Table 6, do you see the PCE number that was reported at 2.68 has a confidence interval of 0.2 to -- to 33.28?

A I do see that, yes.

Q And for the TVOC number that was reported 2.52, the confidence interval ratio was 0.21 to 30.83.

Do you see that?

A I do, yes.

Q Those are also very wide confidence intervals, aren't they?

A Yes. Extremely.

Q And so that would give you less confidence in the precision of that increase, correct?

A That's -- right. I mean, the quantitative estimate of the -- of the hazard ratio should be interpreted with the imprecision in mind.

You know, again, there's different ways to look at it, but it's -- as I said, I think the effort made sense and they did the best they could with the data they had. They just can't go very far given the small numbers.

Q And do you see there where the size of the cohort is indicated at the bottom of the table?

A Yes, I do.

Q And what is that number?

A 4,647.

Q So what -- what does that indicate to you when they're indicating what the size of the Camp Lejeune cohort is?

A Well, that -- again, that's the source population. I mean, I think for these purposes the main -- the limiting factor is the number of cases that even after all those years, the, you know, Parkinson's disease, of course, is more common in older individuals, and the Camp Lejeune population even I -- you know, I'd have to look at the details of that, but presumably is still a relatively young population.

And so that -- I can't say whether that observing, you know, whatever five cases in a total population like that is high or low, but it's -- you know, which is a function, as I said, of the number of people and the duration of follow-up and the age.

Q And there -- there were four cases at Camp Pendleton which was considered to be a comparable cohort for comparison, correct?

A Right. The intention of making a comparison between the two military groups is with the idea that, you know, that they would be more comparable in other respects.

Q Okay. You can put both those exhibits aside.

(Deposition Exhibit No. 10, Excerpts of General Causation Expert Report of Steven B. Bird Bladder Cancer, was marked for identification.)

BY MR. BAIN:

Q I'm showing you what has been marked as Exhibit No. 10. This is identified as General Causation Expert Report of Steven B. Bird Bladder Cancer. This is excerpts of that particular report.

Do you see that?

A Yes, I do.

Q If you turn to Page 40.

A Okay.

Q And just to turn back to Page 39, I'm going to read a statement that's in reference to the Bove 2024B study Cancer Incidence Among Individuals Exposed to Contaminated Drinking Water at Camp Lejeune.

Do you see that?

A Yes, I do.

Q If you look at Page 40, the last paragraph of that section states, Again, results found that individuals stationed at Camp Lejeune had a higher incidence of bladder cancer. Overall marines and navy personnel showed a relative risk of 1.09, 95 percent confidence interval and 0.95 to 1.24. And civilians showed a relative risk of 1.10, 95 percent confidence interval of 0.91 to 1.50. These findings suggest exposure to the water at Camp Lejeune, particularly during the years 1975 to 1985, increases the risk of bladder cancer.

Do you see that?

A Yes, I do.

Q And those results under the traditional understanding of statistical significance are not statistically significant, are they?

A Right. That's correct.

Q But those confidence intervals are much more narrow than the ones we saw previously, right?

A Yes, that is correct. I mean, these I would -- again, the wording of, what does this mean, just based again on this paragraph alone, I would make note of the fact that it was strikingly similar in what I believe are two independent populations, the civilians and the military personnel. It's a very modest magnitude of increase, but with, you know, very good precision.

I don't know how much more you can glean other than, you know, without getting into the -- the details, that this is very different. The confidence intervals to me are quite narrow.

Q But the strength of association is also very, as you said, modest, right?

A That's right. Again, that's all part of what goes into the -- the weighting or the weighing of evidence of how strongly supportive of a positive association is this? And again, it suggests a modest increase in risk but with some reasonable precision.

Q And in your book you -- you indicated 1.2 is a modest increase and these are even lower than that, right?

A Again, I really tried to avoid these sort of benchmarks or cutpoints, just in absolute terms independent of any sort of effort to dichotomize or benchmark them by -- these are modest associations.

1.1 is a very modest association.

Q And you recall we discussed the 2024 Cancer Incidence Study which used the benchmark of a relative risk of greater than 1.2 and a confidence interval ratio of less than or equal to 3.

Do you recall that?

A I recall that algorithm, yes.

Q And neither of these findings would meet that benchmark because the relative risks are each below 1.2, correct?

A Again, quantitatively, that's true. I don't know about what the applicability of that sort of benchmark was and so on, but just in terms of the sheer numbers, these numbers would not be -- would not qualify under that decision ruling.

Q Okay. Put that aside.

(Deposition Exhibit No. 11, General Causation Expert of Steven B. Bird, M.D., Kidney Cancer, was marked for identification.)

BY MR. BAIN:

Q Dr. Savitz, I'll show you what has been marked as Exhibit No. 11, General Causation Expert of Steven B. Bird, M.D., Kidney Cancer.

Do you see that?

A Yes, I do.

Q And if you can turn to Page 15.
A Okay.
Q And do you see there's a section on benzene there?
A Yes, I do.
Q And if you look about halfway down that section, do you see the paragraph that starts, In 2014?
A Yes, I do.
Q And that paragraph states, In 2014, Bove 2014A reported on a cohort study of United States Marines and Navy personnel who served during the 1975 to 1985 and were stationed at either Camp Lejeune with its contaminated water and Camp Pendleton, which did not have contaminated water, and the citation to the Bove studies in brackets follows that.

Then it says, benzene was present at concentrations above the U.S. maximum contaminant levels, MCL. Military personnel in the Camp Lejeune cohort had an elevated mortality for kidney cancer, HR 1.35, 95 percent confidence interval, 0.84 to 2.16. Furthermore, a monotonic cumulative exposure trend was observed for kidney cancer and total contaminants. In the supplemental data benzene was associated with increased rates of kidney cancer at low, hazard ratio 1.31, 95 percent confidence interval 0.52 to 3.29 medium. Hazard ratio 1.38,

95 percent confidence interval, 0.58 to 3.28, and high hazard ratio 1.36, 95 percent confidence interval 0.57 to 3.25 exposure levels.

Do you see that?

A Yes, I do.

Q Would you agree that none of those increases in mortality from kidney cancer are statistically significant?

A That's correct.

Q And with respect to the -- the statement, A monotonic cumulative exposure trend was observed for kidney cancer and total contaminates.

What is the purpose of referencing, in your understanding, a monotonic cumulative exposure trend?

A The -- the interest is in -- when you're examining the -- the exposure response relationship in general, a graded response with higher risk with higher exposure supports -- is more supportive -- well, let's just say is supportive of potential causal effect.

MR. BAIN: Okay.

(Deposition Exhibit No. 12, Exposure Response Analysis, was marked for identification.)

BY MR. BAIN:

Q And you can keep that exhibit open. I want to show

you Exhibit No. 12.

Exhibit No. 12 is the exposure response analysis from the 2014 mortality study that is being referenced in the report that we were looking at.

Do you see that it's a supplemental file with the exposure response analyses?

A Again, I -- I'm -- I'm accepting your statement that this is the data that he is referring to.

Obviously I haven't independently gone --

Q Mm-hmm.

A -- back and forth to verify that.

Q Well, if you look at the kidney cancer, do you see hazard ratio goes from 1.42 in the low exposure column to 1.44 in the medium exposure column and 1.54 in the high exposure column?

A Yes, I do.

Q And does that, in your view, show a monotonic exposure or response trend?

A Technically it does in the sense that, you know, the numbers get bigger as you go across. The magnitude of that increase is very little. But as I said, technically and formally, it does.

Q And each of those hazard ratios are not statistically significant under a traditional concept of statistical significance, correct?

A Again, that is true. It's not necessarily what I would be focusing on, but that it is factually correct.

Q In addition to the possibility of random error with each of these separate hazard ratios that are indicated in this table, would you agree that there's a possibility that a monotonic exposure response trend itself is a result of random chance?

A Again, there are statistical tools for asking about -- for quantifying the degree of support for a linear trend or for a gradient in risk. And so in principle, random error can -- you know, can mask or create apparent patterns, including dose response trends.

Q So that it can show a dose response trend that might not really be there because of random chance and it could also mask such a trend; is that true?

A That's right. There may be a true underlying dose response gradient and the study was, you know, had too much imprecision to see that clearly.

And so it's -- it's another -- again, random error is just that, it can have -- make random effects on the -- the point estimates and the patterns.

Q Given what you see with the apparent dose response

trend here with respect to kidney cancer and total volatile organic compounds, would you put much weight on that?

A Again, it's technically a monotonic trend, but it's suggesting there's very little -- the key distinction is between no exposure and any exposure more so than between low to medium and medium to high. They're all elevated to -- to some degree.

Q Okay. If you turn to Page 3 of the table.

And do you see that this is in reference to benzene, the exposure to benzene?

Do you see that?

A Yes, I do.

Q Just a moment. And do you see that these numbers correspond to the numbers that are in Exhibit 11 on Page 15?

A Give me a moment. I'm going to have to look. Yes, I see those numbers.

Q And you see the confidence intervals that are provided for each of those numbers?

A I do.

Q And none of those hazard rations are statistically significant, correct?

A That's correct.

Q In fact, the lower end of the confidence interval as

well, under 1, for each of the hazard ratios, right?
A Again, the -- as I've said, I think, in the report, that is true, but it's also true that the upper bound is well over 3 for each of them and there are no -- there's -- those values are comparable.
In other words, the -- again, within the range that's described there, the plausibility that the true relative risk is .52 is no different than the possibility that it's 3.2.
Q Would you consider this to be a monotonic exposure response trend?
A Again, technically it's not and it's similar to what I would have said for the other one, that there is -- they're all elevated to some degree -- a similar degree, but that there is not a -- a clear gradient of increasing risk across the -- the levels.
Q So while the prior one we showed technically was a monotonic exposure response trend because the number was higher for each increment, it was -- the numbers were very close, right, so that made it hard to say that there was something significant there?
A I was -- I would probably give the same response on both of those, the one that happened to be just slightly in a positive trend and this one is flat but it's clear that the main -- the most meaningful

difference is between no exposure and any exposure across these groups.

Q So that would be just reflected by the .31, which is 31 percent higher than 1; is that what you're saying?

A Right, or if you integrated them together, which I guess is probably done -- maybe done somewhere else --

Q Mm-hmm.

A -- it would be much more precise and it would zero in on this, you know, around 1.3, 3, 1.35 would be the overall aggregate, but the confidence interval would be much tighter.

And so again, I think it's reasonable to look at the possibility of a dose response gradient, it's a reasonable question to ask, but I think that this is showing a pattern of generally-elevated risk in each of the groups of a similar magnitude.

Q And those numbers comparing, you know, the unexposed group to the exposed group would be presented in a different place in the report usually, right?

A Again, it's not in the tables that you pointed me to. I don't know -- obviously I have not looked at the report, so I -- I don't know -- you know, I would expect it would appear elsewhere but I haven't -- I can't verify that.

Q And where you see the column that has an N, what -- how do you interpret that?
A Again, this is back in the table?
Q Yes.
A Yeah, that's presumably the number of cases.
Q Do you have any familiarity with how the dose response analyses were done by the ATSDR for the 2014 studies?
A I don't know that.
Q You don't know the methodology?
A No, I don't know how they defined high, medium and low, what the basis was. I'd have to look at the report, obviously, to get that in detail.
Q You're familiar with the fact that ATSDR did a water model that produced monthly mean concentrations for different chemicals?
A I'm familiar with that -- that effort, yes.
Q Do you know if or how that model was used for any dose response analysis that ATSDR did?
A I don't know that, no.
Q Do you know what the referent group was for either the 2014 dose response analysis or the 2024 dose response analysis that the ATSDR did?
A No. Again, I'd have to look at the report to know who the -- the presumably unexposed referent was.

Q Would it be appropriate to pick one of these values in this table out in isolation and use it to make an inference on causation?
A Well, as I've said, I think the inference about causation comes from looking at the totality of the evidence and so that, you know, with a single study or with a single number, it can contribute and add, you know, support but it -- it would not be something that would in and of itself without any other information support, you know, it -- by -- as I said support on its own a causal inference.
Q For example, if a statement were made based on this benzene table that, a medium exposure to benzene between 45 and 110 micrograms per liter months results in a 38 percent increased risk in kidney cancer; would that be a statement you'd make based on this table?
A Again, it's a matter of how it's worded. I would say predicts a risk of rather than necessarily results in a risk which at least implicitly suggests it causes it.

That's a -- I would try to separate out those inferences, yeah, describing the results and the numbers and what they say and separating that from an assessment of what the numbers mean largely because

the latter is going to have to be done in -- in context in a broader way.

In other words, the individual studies do not I would say ever, but almost ever stand by themselves as the sole basis for making a causal assessment.

Q Your view is that it has to be a holistic analysis of some of the Bradford Hill considerations and others that you deem in your judgment to be appropriate to making that decision?

A It's -- it's really the -- each study contributes based -- you know, to the extent that it has -- based on the quality of its methods, and then in looking across the studies, there is a -- a judgment to be made that considers whether -- you know, if there's an observed association, the -- all the evidence that helps you figure out if that association is likely to be causal or not.

And that includes the Bradford Hill considerations. But I think there's different ways of answering the same question.

Q Okay. You can put those exhibits aside.

(Deposition Exhibit No. 13, General Causation Expert Report of Howard Hu, MD, was marked for identification.)

BY MR. BAIN:
Q I'll show you what has been marked as Exhibit 14 -- excuse me -- Exhibit 13, General Causation Expert Report of Howard Hu, MD.
Do you see that?
A Yes, I do.
Q And this is not a report you've reviewed before, is it?
A That's correct.
Q Turn to Page 28. You see at the bottom of -- of that page in the text above the footnotes the sentence starts, Using multivariable Cox models, they found that the association between exposure to PCE and NHO had a hazard ratio of 2.32 among males, 95 percent confidence interval 0.75 to 7.15, comma, five cases, and 2.35, 95 percent confidence interval 0.52 to 10.71, two cases.
Do you see that?
A I -- I do but I'm not clear. I assume that the contrast between males and females but I don't see the referring to what the other -- the 2.35 is -- is referring to.
Q Yeah. I think that's left out. That was my thought, as well.
A Okay. That would be -- again I can't verify that,

but that seems like the way it's written that would be the expectation.

Q And this is referring to -- if you turn back to the prior page, the Radican, et al. study of 14,455 workers at an aircraft maintenance facility?

A Okay. Yes.

Q Do you recall that study?

A No. I mean, I -- I -- no. I may have seen it. I -- I honestly don't recall though.

Q Can you recall as you sit here today whether it was one of the studies that the National Academy of Sciences considered in its work?

A You know, I don't know that -- that's getting close to our cutpoint, and I would have to look at the report to see the reference list to know for sure whether it's something we were able to incorporate or not.

Q Do you recall how the National Academy of Sciences committee that you chaired classified non-Hodgkin's lymphoma with relationship to TCE or PCE?

A No, I don't.

Q You do recall, don't you, that in -- in that particular work that the National Academy of Sciences did, they didn't put in any diseases in the category of sufficient evidence of causation or sufficient

evidence of association?

A Again we -- obviously we're basing that on evidence of whatever, 15-plus years ago. And also again everybody who assesses causality has a different sort of benchmark in mind. It was not obviously for any legal purposes.

And so at the time, and I -- I don't have any reason to think that it wasn't the right thing to do at the time -- that was the committee's collective judgment about where the evidence stood.

I think we did define though and we use standard terminology for what we mean by, you know, sufficient cause -- sufficient evidence, I should say, which means not just an established association, but that random error and bias have been excluded as potential reasons for it. There's a whole -- there's a whole terminology there.

And so, again, using that criteria at that time as a collective judgment, that's what that reflects.

Q And I think as you just said, the National Academy of Sciences' work wasn't done for any legal purpose?

A No. And I think it uses, from my experience at least, a more stringent benchmark in the sense that it's not a more probable than not; it's sufficient and conclusive in a way that again we don't quantify

what that number is, but from my experience it's a higher bar.

Q And things like more probable or not or as likely as not are typically not used by epidemiologists in -- in their written conclusions; is that true?

A Yeah, again, I can't say ever; you know, people do different things. But that is not typically done. It's sort of -- again, there's different -- you know, sometimes they make judgments as whether it's sufficient for regulating a chemical or for -- oh, for -- for some of the veterans' work related to compensation.

And they use -- usually they're explicit about what the criteria are, but I am not familiar with the -- that sort of a more -- more probable than not outside of legal settings. It may be used somewhere else, but that's where I'm most familiar with it from.

Q Are you aware of when scientists do that type of regulatory work to determine, for example, presumptive diseases for veterans that sometimes the standards are less stringent than are used in other contexts?

A Again, I'm aware that they vary for -- for various purposes, and I don't -- I don't have a detailed

knowledge of the -- the standard, but, you know, when -- when groups making the evaluation are given an assignment, we do take the wording very seriously and we often return to it, committees I've been on and I would expect that others do the same in looking at -- you know, in comparing what's available from the evidence to the benchmark that's been given to us to work with.

(Deposition Exhibit No. 14, General Causation Expert Report of Timothy M. Mallon, was marked for identification.)

BY MR. BAIN:

Q Before we close that, if we can go back to --

A Okay.

Q -- Page 28, 29.

Those -- those point estimates under Traditional Statistical Significance were not statistically significant, were they?

A Which ones are you referring to there; the ones at the top of the page?

Q Yeah. 2.32 and 2.35.

A That is correct.

Q And the confidence intervals are -- are quite wide, correct?

A Yes. They -- again, fairly substantial elevation in

the point estimate with a great deal of imprecision.
Q Yeah. That was the one question I asked you that wasn't really covered in your book. A large point estimate that is imprecise.
A All combinations exist, and it's -- I don't think -- again, I -- I -- both of those facts are -- are worthy of consideration when you're asking what the study contributes.

The point estimate has value, even when there's a lot of noise around it. It's your very best guess. It's just that it's, you know, it's not nailing it down quantitatively.
Q At it is -- for these particular numbers the author also provided the number of cases?
A Right.
Q -- which is additional information that's helpful, correct?
A Again, for forming an intuitive impression of, you know, would it be a big deal if there was one case more, one case less. You know, it's -- it's a different -- it's a less formal or statistical way to say how -- how -- how certain are we this is the right value.

And I at least find it helpful to have both of those in there.

Q And with the fewer cases that you have, the less certain you are; is that right?
A Of course, that's right. And the less -- the wider the confidence interval will be, the less precise it is.
Q Okay. Okay. You can close that for now.
A Okay.
Q I've handed you what has been marked as No. 14. It's General Causation Expert Report of Timothy M. Mallon.
Do you see that?
A Yes, I do.
Q If you can turn to Page 11.
Do you see there's a section on the Bove 2014A, 2014B Cancer Mortality Study?
A Yes, I do.
Q And do you see at the end of that paragraph it says, Monotonic exposure responses were found for Marines for cumulative exposure to total volatile organic compounds, TVOCs, and kidney cancer with risk ratios for high cumulative exposure of 1.54, 95 percent confidence interval 0.63 to 3.75.
And there is another figure after that log 10 symbol equals 0.06.
Do you recognize what that is?
Can you describe what that means?

A I assume it is some quantification of the gradient. Now, again, as I said, I -- I -- and this is -- this is speculation without, you know, based on what that provides.

I assume it's some quantification of linear trend. The data is usually -- that it's the symbol there, log 10 beta. It's the coefficient of a slope.

I don't know how -- how that's defined, you know, but that's a way of -- instead of just looking in categories, it's -- it's saying we estimate that for a, you know, a certain increment in exposure the risk will go up by a certain amount, and it's looking at it across the whole spectrum.

It's a reasonable approach. It -- it requires a little more information to really fully interpret.

Q Okay. So it's looking at -- at the exposure response analysis and doing some type of statistical analysis of it?

A That's right. It's modeling what the dose response curve -- the shape of the dose response curve. And it's often used just how linear is it, what is the predicted increment in risk for each unit change in exposure.

Q And the last sentence of that paragraph says, Civilian employees were even higher at 4.44

95 percent confidence interval 0.52 to 38.19.

Do you see that?

A I do.

Q And neither of those associations are statistically significant, right?

A Again, that -- that would be a -- considered a very substantial elevation -- you know, evidence of -- a substantial -- substantially elevated relative risk with a great deal of imprecision.

Q And you're referring to the 4.44 number?

A That's correct, yes.

Q Both of those numbers, 1.54 and 4.44, don't have statistical significance, correct?

A That's correct.

Q Okay. Turn to Page 35.

Do you see -- this is in a section in your report discussing cohort studies if you turn to the prior page. And I want to ask you about the last paragraph of that section discussing the Ruder, et al study 2001.

Do you see that?

A Yes, I do.

Q And if you see at the end of that paragraph, it says, The results show that there was an increased risk of death from kidney cancer in the cohort as the SMR was

elevated at 1.41, 95 percent confidence interval, 0.46 to 3.30 with the analysis was restricted to only those with PCE exposure history the SMR increased to 1.73, 59 percent confidence interval, 0.21 to 6.25.

Do you see that?

A Yes, I do.

Q And this Rudder study being done in 2001 would have been one that your committee had access to, right?

A Presumably, yes.

Q And it was a cohort study of 1,708 dry cleaning workers identified from union records that were exposed to PCE who worked for at least a year before 1960, right?

A That's correct, yes.

Q And you recall that your committee did not -- the committee of which you were chair did not place kidney cancer in either the category of sufficient evidence of causation or sufficient evidence of association?

A Again, as I recall, we had a number of suggestive associations, but did not have at that time sufficient information to -- to consider them conclusive.

Q So was -- it may have been in the suggestive category?

A It -- again, I'd have to look at the list, but I believe, again, this is recall of something that I haven't looked at for some time, but I believe those -- those were in the sudden category.
Q We went through that in detail in your last deposition, as I recall.
A I did. I did. I just, I -- you know, a little more recent but I don't recall it off the top of my head. I would need to see the report.
Q Okay. Those numbers cited there, neither of those are statistically significant, correct?
A That's correct.
Q And the confidence intervals are both wide, correct?
A Right.
Q That's correct?
A Yeah, no, that's correct. And again, it's -- as you go through the litany of -- you know, these findings, it's just a reminder of -- that it becomes, you know, again, it's a matter of interpreting the individual results but also then looking collectively across the studies and where there's an elevated point estimate, even if it's imprecise, it's that repetition or the pattern that one would be looking for.
Q Okay. Turn to Page 37.
Do you see at the top of that page -- and this is

discussing -- I believe this is still discussing case -- or this is discussing case control studies.

If you look back to Page 35, the section is on case control studies.

A Okay. Yes, I see.

Q And at the top of Page 37, there's a reference to the Delahunt Study 1995.

Do you see that?

A Yes, I do.

Q And it states, The authors noted an increase in kidney cancer risk with an elevated odds ratio of 1.92, 95 per confidence interval, 0.27 to 13.89.

Do you see that?

A Yes, I do.

Q And this study having been done in 1995 would be one that your committee would have presumably have had access to, right?

A I -- again, we certainly would have had access to it and I presume that it was identified and considered.

Q And these -- or this point estimate is not statistically significant, is it?

A That's correct.

Q And the confidence interval is wide, correct?

A I would say so, yes.

Q Okay. Done with that one.

MR. JOHNSON: Can I put a bid in for the DOJ paper contract in this case?

MR. BAIN: You should have been at the Bird deposition. This is a tiny bit.

MR. JOHNSON: I can only imagine.

MR. BAIN: We're getting toward the end of the exhibits.

(Deposition Exhibit No. 15, General Causation Expert Report of Timothy M. Mallon on Leukemia, was marked for identification.)

BY MR. BAIN:

Q I'm showing you what has been marked as Exhibit 15. This is the General Causation Expert Report of Timothy M. Mallon on Leukemia.

A Yes, I do.

Q And if you turn to Page 21 -- first of all, turn back to 20 to see what this section is.

Do you see there's a section -- and this is all under the broader section of benzene and leukemia.

Do you see that?

A Yes, I do.

Q And under the subsection is Systematic Reviews and Metaanalyses.

Do you see that?

A Yes, I do.

Q If you turn to Page 21, do you see there's a reference to Savitz, et al, 1997?
A Yes, I do.
Q And I assume you are the same Savitz as that is referring to?
A That is correct.
Q And do you recall that meta analysis or systematic review that was done to assess the association between benzene exposure and lymphatic and Hematopoietic cancers?
A I recall it generally. This was so long ago, to be honest, I don't think we even used the term "systematic review," but I recall what we did and generally what we found.
Q And do you see where it states toward the bottom of that paragraph, An exposure response analysis noted that the highest exposed individuals with 720 PPM months had the greatest risk of leukemia with a risk ratio of 2.8, 95 percent confidence interval, 0.6 to 8.1.

Do you see that?

A Yes.
Q And do you recall whether you and your coauthors considered that finding to be significant?
A You know, what I do recall, and I think it's there in

the lessens, we were asking a fairly narrow of question of the literature at the time that benzene had been acknowledged pretty universally as a cause of acute of acute myeloid leukemia, but there was a perception that it only caused acute myeloid leukemia.

And so again, as I recall, we -- we simply stratified the outcomes into AML versus any other kind of leukemia, we didn't even try to subdivide them, and found that the -- based on the epidemiologic evidence that the magnitudes were similar.

Now, these were rare diseases, again the literature has evolved quite a bit in the last, what, 30 years, but there was really kind of a narrow question. I would hesitate to call it a -- sort of a comprehensive review in meta analysis; it was really asking about one question, the specificity of the Benzene/AML association.

Q This particular finding that was pulled out of 2.8, 95 percent confidence interval, .6 to 8.1, that finding was not statistically significant, correct?

A Again, I -- I'd have -- it was not -- if it's quoted correctly, and I have no reason to doubt that it is, that would not be statistically significant.

Q And the confidence interval is fairly wide, correct?
A Yes, it is.
Q And can you recall as you sit here today what significance you placed on that particular finding in your -- in your review?
A I think -- you know, again, I -- as I recall -- I honestly don't -- I should just say, I don't recall the interpretation of that, other than the -- the evidence that any benzene effects were -- were specific to AML, the data were not supportive of that where you would have expected to see a clear association with AML and an absence of association with other leukemias, and that was not what we saw.

And, again, it doesn't validate the study, but over subsequent years there's been increasing evidence that benzene does cause diseases other than AML.

Q Okay. You can put that one aside.
A Okay. At some point -- you know, it's up to you how you want to do the scheduling, but at some point in the not distant future, a break would be good.

MR. BAIN: Okay. Let's go off the record for just a minute.

VIDEOGRAPHER: We're going off record at 11:59.

(Whereupon a recess was held at 11:59 a.m., and

resumed at 11:59 a.m.)

Deposition Exhibit No. 16, General Causation Report of Lukasz Gondek, Leukemia, was identified for the record.)

VIDEOGRAPHER: Going back on record at 11:59.

BY MR. BAIN:

Q Dr. Savitz, I'm showing you what has been marked as Exhibit 16.

You see it's a General Causation Report of Lukasz Gondek, Leukemia?

A Yes, I see that.

Q Turn to page -- actually -- okay.

Turn to Page 16.

A Okay.

Q Do you see that there is a section, and this is discussing, if you look back at the prior page, epidemiological studies?

A Yes.

Q This is discussing in Subsection C, a study of Norweigian off shell -- offshore oil industry workers?

A Okay.

Q And this study was done in 2015. So your committee would not have had access to this study, right?

A That's correct, yes.

Q And if you look toward the end, do you see where it says, The hazard ratio HR of AML for exposed versus never exposed to benzene was 2.18, confidence interval 0.41 to 10.00?
A Yes.
Q And the risk estimate was substantially higher in the highest tertile of cumulative exposure, 0.124 to 0.948 PPM years compared with the lowest tertile, less than 0.001 to 0.037 PPM years, with a hazard ratio of 4.85, confidence interval 0.88 to 27.88.
Do you see that?
A Yes, I do.
Q And those two associations, 2.18 and 4.85, are not statistically significant, are they?
A That's correct.
Q And the confidence intervals are very wide, correct?
A That is correct.
Q Would you be comfortable relying on those findings to support an inference of causation?
A Again, I've said that if I was making an overall assessment of causation, I would consider this study to provide some supportive evidence based on the overall aggregate result of, let's say, 2.2 and the tendency for higher exposures to be associated with higher risk.

I'd have to look at the study to know what the last sentence indicates with -- now we're getting into a range where I recognize it's -- P is technically greater than .05 but just barely.

To me that is adding some -- I'd have to reconcile all those numbers, but it certainly is providing some support for accumulative exposure of benzene being related to AML.

Again, the weight of that, how that fits in with other studies and so on, I can't tell you in isolation, but I would not dismiss that as an uninformative study or certain not as a -- a nonsupportive study. It adds some weight to me in a positive direction.

Q Okay.

(Deposition Exhibit No. 17, General Causation Expert Report of Dean W. Felsher, Leukemia Non-Hodgkin's Lymphoma, was marked for identification.)

BY MR. BAIN:

Q This will be last one before lunch.

A Okay.

Q I'm showing you what has been marked as Exhibit 17, General Causation Expert Report of Dean W. Felsher, Leukemia Non-Hodgkin's Lymphoma.

Do you see that?

A Yes, I do.

Q Can you turn to Page 22?

And if you look back at the prior page, Page 21, you see this is a section on PCE and hematopoietic malignancy.

Do you see that?

A Yes, I do.

Q And I want to direct your attention to Page 22, the first full paragraph in which there's a reference to the case control studies of Morton and Mannetje, I think that is.

Do you see those?

A Yes, I do.

Q And do you see where it referenced the -- the two case control studies observed slightly elevated risks for CLL, slash, SLL, with Morton reporting an OR of 1.10, 95 percent confidence interval, 0.15 to 8.12 for ALL.

Do you see that?

A I do. I don't know if it's going to matter, but I'm not sure what SLL is.

Q Okay. It may be -- well, I don't want to speculate, but since it discusses ALL in the next phrase it may be a typo.

A That was my guess, as well, but I don't know that for sure.
Q Well, with respect to the particular point estimate for ALL of 1.10 with a confidence interval of 0.15 to 8.12, first of all, that's not statistically significant, right?
A That's correct.
Q And the point estimate is modest at most with a very wide confidence interval; would you agree?
A Yes, but in terms of, you know, how informative it is, it's kind of odd to do a pooled estimate with only two studies. That's -- in other words, I think that's what he's -- he or she -- I guess he, is describing.

Oh, no, I guess that's separate. That's just for Morton. Okay. I'm sorry, I misstated that.

Q So that's just referring to the separate Morton case control study apparently?
A That's my understanding, yes, you're right.
Q So the point estimate is -- is modest, correct?
A That's correct.
Q And the confidence interval is wide, right?
A That's correct.
Q And that would provide little support for an inference of causation; would you agree?

A Again, we'll talk about association, but I would agree that it provides very little support for an association.
Q Okay. For even an association, right?
A That's right. I mean, again as I said, we've got to separate out -- the causal effect is something that would require a -- a more, you know, comprehensive assessment and judgment.
Q And then you can see on that page it goes on to discuss in Section E Water Contamination Studies.
Do you see that?
A Yes, I do.
Q And if you turn to the next page, do you see in bold the Aschengrau study?
A Yes, I do.
Q And we -- you recall we referenced that study earlier in your deposition?
A Yes.
Q And that's a study that your committee at the National Academy of Sciences had access to and considered, right?
A I believe so, yes.
Q And at the end of that paragraph -- the first paragraph discussing Aschengrau study, do you see where it says, After adjusting for confounding

factors, the relative risks rose to 1.96, 95 percent confidence interval 0.71 to 5.37 for all exposed individuals and 5.84, 95 percent confidence interval, 1.37 to 24.91 for those with highest cumulative exposure.

Do you see that?

A Yes, I do.

Q And those point estimates -- either of those point estimates were statistically significant, correct?

A I'm sorry, the 5.84 apparently is.

Q Okay. Excuse me. I didn't mean to --

A No, no, that's --

Q -- to do that.

A Again, and, you know, we've been going through how I would characterize it; that is a notably elevated magnitude of risk. And even though in this case there is a great deal of imprecision, it's covering a pretty high range.

It's -- you know, as I've -- as I've said I don't -- I'm not saying the exact right value is 5.8, but it's -- you know, you could say it's probably somewhere between, you know, I don't know, 3 and 15 or whatever. You -- you would not be out of -- out of line to assume that it's something that would -- you know, giving pretty good evidence of a

substantial elevation.

MR. BAIN: Okay. We can break now.

THE WITNESS: Okay.

(Colloquy off the record.)

VIDEOGRAPHER: Going off the record at 12:08.

(Whereupon a recess was held at 12:08 p.m., and the deposition was resumed at 12:53 p.m.)

(Deposition Exhibit No. 18, Excerpt of the Evaluation of Cancer Incidence Among Marines and Navy Personnel and Civilian Workers Exposed to Contaminated Drinking Water At USMC Base Camp Lejeune a Cohort Study, was marked for identification.)

VIDEOGRAPHER: We're now going back on the record. The time is 12:53.

BY MR. BAIN:

Q Okay. Dr. Savitz, we're back from lunch now.

You understand you're still under oath?

A Yes, I do.

Q I'll show you what's been marked as Exhibit 18. And this is an excerpt of the Evaluation of Cancer Incidence Among Marines and Navy Personnel and Civilian Workers Exposed to Contaminated Drinking Water At USMC Base Camp Lejeune a Cohort Study. This is the preprint version of the cancer incidence study.

Do you see that?
A Yes, I do.
Q I'd like you to turn to Table 2. It's about mid part of the exhibit.
A Okay.
Q In Table 2 is the Standard Incidence Rates and Poisson Regression Results for the Marine/Navy Personnel Subgrade?
Do you see that?
A Yes, I do.
Q And for urinary bladder cancer the standard incidence rate for Camp Lejeune is .90.
Do you see that?
A Yes, I do.
Q So that result shows that adjusted for sex, race and age there are 10 percent fewer bladder cancers in the Camp Lejeune cohort than for the general population, correct?
A I -- I -- they don't list what they adjusted for. Oh, here it is on the next page.
Q Mm-hmm.
A Sex, race and five-year age groups. Yeah, that would be correct, what you just said.
Q So just so the record is clear, it would show a 10 percent fewer incidence of bladder cancer in the

Camp Lejeune cohort than for the general population adjusted for sex, race and age, correct?

A That's right, yes.

Q And the confidence interval is -- it's narrow, isn't it?

A Yes, it's based, as you see, on a large number of cases.

Q And, in fact, the decrease is statistically significant because the upper end is less than 1, correct?

A Again, it's not what I would find to be helpful and important, but by conventional measures, yes, anything that excludes 1.0 would be defined as statistically significant.

Q And that result does not reflect or support an association between exposure to contaminants at Camp Lejeune and bladder cancer; would you agree with that?

A Well, again, this is where the -- I'm trying to think of a simple way to get into this.

The -- the judgment is -- this is comparing one population to -- you know, a -- a military population to the US population and observing, as you said correctly, that they have a somewhat lower risk.

The question always though is, is that a -- is

that a valid comparison. Let's -- let's take the issue of water contamination and so on out of the equation. You know, there's a judgment of whether the military population, its baseline risk may be different than the US.

What you'd like in an ideal world, of course, when you're interested in exposure is compare the same people had they been exposed or unexposed.

This is a little different in it's comparing a military population to the US population; but nonetheless, it does not in and of itself indicate increase in risk relative to the US population.

Q Okay. And if you look at the next row, do you see kidney and renal pelvis cancer?

A Yes, I do.

Q And the standard incidence rate of the Camp Lejeune cohort is 1.03.

Do you see that?

A That's correct, yes.

Q So that result would show that adjusted for sex, race and age there are 3 percent more kidney and renal pelvis cancers in the Camp Lejeune cohort than in the general population?

A Again, right, taking those numbers at face value, that's what the SIR of 1.03 would indicate.

Q And the confidence interval is narrow, correct?
A Yes, again based on a large number of cases.
Q But given that the lower end of the confidence interval is less than 1 under traditional understanding of statistical significance, that result or that increased risk is not statistically significant, correct?
A That is correct.
Q Would you agree that that result in and of itself does not reflect a strong association between exposure to contaminants at Camp Lejeune and kidney and renal pelvis cancer?
A Again, you know, taking in isolation, this is saying that the incidence rate is similar in the Camp Lejeune population and the US population again as an isolated finding. I wouldn't draw broader inferences about it, but that -- that is what the 1.03 would indicate.
Q And if you see the NHL for non-Hodgkin's lymphoma row; do you see that?
A Yes, I do.
Q The standard incidence rate for the Camp Lejeune cohort is 0.86?
Do you see that?
A Yes, I do.

Q So that result would show that adjusted for sex, race and age there are 14 percent fewer non-Hodgkin's lymphoma cases in the Camp Lejeune cohort than in the general population, right?
A Again the -- taking the number exactly at face value, that's what the .86 would signify.
Q And given that the upper end of the confidence interval is less than 1, that result is statistically significant, correct?
A As conventionally defined, that is correct.
Q That result in and of itself would not support an association between exposure to contaminants at Camp Lejeune and non-Hodgkin's lymphoma, correct?
A It would not add positive evidence. Again without a lot of other information, I don't know to what extent it would tend to, you know, be -- be a meaningful indication of a lack of an affect. Again, that requires knowing more about the study.

As it is though, it does not indicate an increased risk.

Q And then finally for leukemias, do you see that row?
A Yes, I do.
Q And do you see that the standard incidence rate for the Camp Lejeune cohort is .87?
A Yes, I do.

Q So that result would show that adjusted for sex, race and age, there are 13 percent fewer leukemias in the Camp Lejeune cohort than in the general population?
A That would be correct, yes.
Q And the confidence interval there is narrow, correct?
A Yes.
Q And given that the upper end of the confidence interval is less than 1, that result is statistically significant?
A Again, that is the -- by the conventional way that's defined, that is correct.
Q And in and of itself that result does not reflect an association between exposure to contaminants at Camp Lejeune and leukemias?
A Taken in isolation, it does not indicate an increased risk.
Q So let's look over at the third column of this chart, which is the relative risk of Camp Lejeune versus Camp Pendleton.

Do you see that?

A Yes, I do.
Q And so in this particular instance there's a comparison between two cohorts of military or people who were on military bases; is that your understanding?

A That is my understanding, yes.
Q And the assumption in making this comparison is that the people who were at Camp Lejeune had an exposure that was different from the people who were at Camp Pendleton?
A Right. I mean, the intent was to find a comparable -- a population that's comparable in other ways aside from the chemical exposure as a referent or comparison group for the Camp Lejeune population.
Q If you look at urinary bladder cancer, the relative risk in comparing Camp Lejeune to Camp Pendleton is 1.08.
Do you see that?
A Yes.
Q And that's less than 1.1, correct?
A That is true.
Q And you would not consider that to be a strong association, would you?
A Again, by absolute magnitude of effect, no.
It's a -- you know, again, it's got very good precision and I would say it suggests a small increase in Camp Lejeune relative to Camp Pendleton.
Q The lower end of the confidence interval is .98, correct?
A That's correct, yes.

Q So under traditional understanding of statistical significance, that result of an increased risk is not statistically significant, correct?
A That's correct.
Q The next row, do you see for kidney and renal pelvis cancer, the relative risk in comparing Camp Lejeune to Camp Pendleton is 1.08?
A Yes, I see that.
Q And that's not above 1.1, is it?
A That is not.
Q You would not consider that to be a strong association, would you?
A Again, it's a small magnitude association that is with good precision.
Q The lower end of the confidence interval is .99, right?
A That's correct.
Q So under a traditional understanding of statistical significance, that result is not statistically significant?
A Again, it's a -- that's correct, and it's a good illustration of how arbitrary that is that if it was 1.01 those who value that as a criterion would conclude differently, but this is just barely below 1.0, so under the formal definition, you know,

arbitrary cutpoint, it is not statistically significant.

Q Looking at NHL, the relative risk in comparing Camp Lejeune to Camp Pendleton is 1.05.

Do you see that?

A Yes, I do.

Q And that is not a strong association, is it?

A Right, it's essentially no association.

Q Take a look at leukemias. The relative risk in comparing Camp Lejeune to Camp Pendleton is 1.09, right?

A I believe 1.08?

Q Oh, thank you.

A That's correct at 1.08.

Q And that reflects eight percent greater risk for Camp Lejeune -- or 8 percent more incidence of leukemias at Camp Lejeune than at Camp Pendleton; is that right?

A That's correct, yes.

Q And that result is not above 1.1, is it?

A That's right.

Q Would you agree that that's not a strong association?

A Right. Again, it's a small association.

Q And the lower end the confidence interval is .96, correct?

A That's correct.
Q So as we've discussed, that result is not statistically significant under the traditional application of that?
A That's correct.
Q Okay. You can put that aside.
A Okay.
Q I want to turn back to your book which is Exhibit 4.
As we saw earlier, risk ratios and confidence interval are also considered in dose response analyses, correct?
A That's correct.
Q And if you turn to Page 76 of your book...
A Okay.
Q Do you see a section there entitled, Evidence of a dose response gradient?
A Yes, I do.
Q And, again, that's under your overall section, Commonly Used Arguments in Support of a Judgment of Causality, correct?
A That's correct yes.
Q You state in the first sentence of that section on evidence of a dose response gradient that, Beyond presenting the statistical results from evaluating a dichotomy of exposure, present, slash, absent,

higher, slash, lower, there are often opportunities to study a spectrum of exposure across multiple levels, e.g., none, low, medium, high.

Do you see that?

A Yes, I do.

Q And is that correct?

A Yes, it is.

Q And then you go on to say that, When exposure can be subdivided this way with more than two levels ordered from low to high, we can see whether there is a stepwise increase in risk across those levels, correct?

A Yes, that's correct.

Q And then you go on to say, Our confidence in an association being present is supported when stepwise increases in exposure are associated with stepwise increases in risk of disease, right?

A Yes.

Q And why is that?

A The -- again, the reasoning is simply that if the agent is harmful, more of the agent should be more harmful. Again, I also give, later on, reasons that may not be the case, but it is sort of at least a starting point for looking at the issue of whether there's a graded response.

Q You state further down that, If we find that the relative risks using the comparison group of no exposure is 1.2 for the lower exposure group, 1.5 for the medium exposure group, and 2.0 for the high exposure group, this would strengthen the evidence that an association is present; is that correct?
A Yes, it is.
Q By the same logic, if you don't see a stepwise increase in exposure that are associated with a stepwise increase in disease, the dose response analysis does not support the conclusion that an association is present; is that true?
A It -- it doesn't -- it doesn't add evidence to support it, but as -- as discussed in the next paragraph, it doesn't negate the possibility either.

It's one of those things when it's present, yes, it is positive and supportive. When it's not, there are multiple possible ways that a real cause may still not show up in that graded response that are indicated there.
Q So if you do a dose response analysis and there isn't this stepwise increase, then you couldn't cite the dose response analysis to support an inference of causation, right?
A It would not be odd adding, as I said, positively to

that argument. It requires -- it's a useful exercise to look. It's -- regardless of what you find, and -- but its absence should not be in -- you know, interpreted as strong evidence against there being an effect.

There really are these thresholds or ceiling effects and so on that have been documented where reasons that, across a certain range, more is not necessarily worse; but you have to -- but it does -- it does point you towards giving a closer consideration when -- when the sort of default-graded response is not observed.

MR. BAIN: Can you -- can you read back that last part of the answer?

(Reporter read back requested testimony.)

BY MR. BAIN:

Q So dose responses is one of the Bradford Hill considerations, right, in inferring causality?

A It's one of the factors that he lists, yes.

Q And if you do not have a dose response then that consideration does not weigh in favor of finding causality, correct?

A I'm just trying to think about it. It is not -- when it is present, it is supportive; when it is absent, it may be indeterminate. But I agree that if it's

present, it's supportive and if it's not present, it's not supportive.

Q If you look on Page 82, and there you have a section called absence of dose-response gradient, correct?

A That's correct.

Q And the -- it looks like the third sentence of that section says, But just as a dose response gradient supports a causal effect, the absence of such a gradient calls it into question.

Is that correct?

A That is -- yeah, that is what I said, yes.

Q So the absence of a dose response effect calls into question -- excuse me.

The absence of a dose response gradient calls into question there being a causal effect; isn't that correct?

A Again, I probably could have phrased that better.

It raises questions; it does not support a causal effect, but when you don't see that kind of a pattern, there are -- again, the caveats are that you may not have measured exposure well, there may be other factors acting there.

But based as an isolated observation when you have meaningful gradients in exposure and there is no corresponding gradient in risk, it would argue

against there being a positive -- a causal effect. That's -- that's correct. And that's consistent with the Hill consideration of dose response.

Q Okay. Go back to Page 76.

In that section on evidence of a dose response gradient, the last sentence that you have there in that first paragraph says, The potential for random error to result in the appearance of an association based on a dichotomy is considerably reduced as a cause for observing a dose response gradient.

Do you see that?

A Yes, I do.

Q Can you elaborate on what that means?

A Sure. That -- that when you're dichotomizing results, just higher and lower exposure, there is -- it's generating a single number that -- you know, the relative risk, let's say, and that depending on the -- the numbers of cases, the precision of that may be very limited.

If you're looking instead at none, low, medium, high, even with the same volume of data, there can be more statistical precision in asking is there a linear affect across those levels.

In fact, that may be an illustration. I can't remember the exact article that we were looking at.

But where there was a great deal of imprecision in the individual estimates and yet the P value for a trend was something like .1 or .11. And it was sort of discordant because it was looking a lot more precise than any one individual estimate. And it's because it's integrating across the whole range that way.

Q So then would you agree that examining multiple levels of exposure is better than examining a dichotomy of no exposure versus exposure or low exposure versus high exposure?

A I think there's -- there's value in doing, you know, in doing both. You know, there's the assumption when you put people into groups, you know, let's say, low and high, that everybody in the low group is the same and everybody in the high group is the same.

Well, there may be very low and somewhat low, and there may be somewhat high to very high. And if you're able to look across all those groups, then, yes, it can be informative. But it's a tradeoff of how much precision, how big the numbers are and so on.

There often is value in looking at -- looking at things both ways, with a dichotomy and with a -- a range of exposure.

Q When you have a range of exposures though, don't you reduce the chance that seeing a trend is a result of chance because when you have two, there might be a greater opportunity that one is higher than another based on chance alone?

A Again, if there truly is a graded response and that's what you look for, you'll -- you'll have a better chance of detecting it. It will be more -- if -- if in reality, you know, that's of course unknown, higher exposures lead to higher risk, you may or may not be able to capture that in a dichotomy but you would likely capture it in a graded response.

And in terms of the degree of random error, it's -- you know, it's certainly with a single estimate of one, you know, risk ratio relative risk calculation that may bounce around a bit, but intuitively if you're looking at three or four levels and you're seeing this pattern, even if each is noisy, the pattern can emerge more clearly.

Q Okay. And let me go back to Page 82 where I directed you to before regarding the absence of a dose response gradient.

A Yes.

Q And I should, you know, for clarity in the record state that this is under your section on Commonly

Used Arguments In Opposition to a Causal Judgment --
A Right.
Q -- correct?
A That's correct, yes.
Q And we -- we talked about the sentence, but just as a dose response gradient supports a causal effect, the absence of such a gradient calls it into question, right?
A That's correct.
Q And then below that you say -- and you're talking about, whereas a dichotomy high versus low exposure may produce a positive association, examining multiple levels of exposure sometimes reveals an uneven and thus far less compelling pattern.

Do you see that?
A Yes, I do.
Q And then you end that paragraph saying, For example, when intermediate exposures appear to be more strongly associated with the health outcome than high exposures, there is reason to question whether the results are supportive of a causal effect, since it seems unlikely that a little bit of exposure is harmful but a lot of exposure is not.

Correct?
A That's correct.

Q And can you elaborate on that?
A Sure. It's -- yeah, we're trying to -- again, this is the -- any -- any inferences about causality or just that. They're inferences based on the data.

And when the -- when there is an opportunity to look at multiple exposure levels and there's a clear -- when it's clearly not monotonic, when it goes up, let's say, in the -- maybe it's highest in the low exposure group and lower in the medium and high.

It's hard to argue that that supports a causal inference because we would normally expect, unless there's some compelling reason to think otherwise, that if a little bit is bad more is going to be worse.

It's sort of a -- again, it's not that there aren't situations where that's untrue, but sort of as a sort of default baseline intuitive expectation, more is worse is usually a safe starting point.

Q Okay. Do you have Exhibit 18?
A Yes, I do.
Q Okay. If you take a look behind the table that we discussed earlier there's a Table 6.

Do you see that entitled, Duration Stationed at Camp Lejeune Camp Pendleton as a reference marines

navy personnel subgroup.

Do you see that?

A Yes, I do.

Q And does it appear to you that this reflects a dose response analysis looking at risk ratios for low duration, medium duration, medium/high duration and high duration?

A Right. The duration is the -- if you will, being used as the indicator of -- of dose.

Q Okay. If you turn to the second page, do you see urinary bladder?

A Yes, I do.

Q And would you agree that for urinary blader there is not a monotonic dose response relationship?

A That's -- that's correct. It -- it is fairly stable for low, medium, slash, high and high fairly consistent with a somewhat lower -- with a lower estimate for the medium duration. So it doesn't follow a graded response in that sense.

Q And if you look to kidney and renal pelvis cancer; do you see that?

A Yes, I do.

Q And there is not a monotonic dose response relationship for kidney and renal pelvis cancer, is there?

A No, there is not.
Q In fact, it's an inverse relationship, right?
A That is the -- again, that's the pattern. There are ways to look at that more formally, other than just visually, you know, eyeballing it, if you will. But it -- the overall pattern it shows does go from higher to lower values with increasing duration.
Q And then do you see non-Hodgkin's lymphoma about two-thirds of the way down?
A Yes.
Q And non-Hodgkin's lymphoma does not show a monotonic dose relationship, does it?
A That's correct.
Q So would you agree that the absence of monotonic dose response relationships here calls into question there being a causal effect?
A Again, it's a back -- I would narrow that. It's one study, one set of results, and I don't even really, you know, fully know all the context of it. It does not add positive support.

What I can't say without knowing a bit more is whether it really is an evidence against there being an association. That -- you know, I'd need to know more about how accurate is the exposure estimation and how different are the groups really.

That's getting into the details of whether it's a -- a really good test of higher exposure versus lower exposure, which I don't know.

Q But you can -- you can say based on what you see here that these numbers don't add positive support for causation.

A The gradient does not suggest that. That -- again, just in isolation. That's all I can do is look at it one piece at a time given, you know, I haven't looked at the whole set of results. But those isolated results in that table do not add evidence of a positive relationship.

Q Look to the next page.

Do you see leukemia?

A Yes, I do.

Q And for leukemias generally as a group, there's not a -- not a monotonic dose response relationship, is there?

A Let me look. That is correct.

Q And do you see that the different subtypes of leukemia are broken out underneath that?

A Yes, I do.

Q And none of these subtypes of leukemia show a monotonic dose response relationship either, do they?

A No, they do not.

Q So would you agree that these analyses do not add support to a finding of causation?
A Again, in isolation this pattern across duration groups does not add positive support.
Q But again you would have to know more to determine whether it calls causation into question.
A Right. I mean, it's -- you know, it's predicated on again there being accurate assignment of exposure and that there are meaningful differences across the groups that are -- across the exposure groups. And that I don't know.

(Deposition Exhibit No. 19, Evaluation of Mortality Among Marines/Navy Personnel and Civilian Workers Exposed to Contaminated Drinking Water at USMC Base Camp Lejeune: A Cohort Study, was marked for identification.)

BY MR. BAIN:
Q Okay. I'm showing you what has been marked as Exhibit 19.

Do you see this as the Evaluation of Mortality Among Marines/Navy Personnel and Civilian Workers Exposed to Contaminated Drinking Water at USMC Base Camp Lejeune: A Cohort Study?
A Yes, I do.
Q And you see it's dated 2024?

A Yes, I see that.
Q Do you recall having reviewed this study before?
A I do not.
Q And do you see where the -- this study in the abstract, as with the cancer incidence study we looked at earlier, that ATSDR used a benchmark of adjusted hazard ratios of greater than or equal to 1.20 with confidence interval ratios of less than or equal to 1 to identify certain diseases for callout in this abstract?
A Yeah, again, I think you said confidence interval ratio less than -- you mean less than or equal to 3.
Q Yes.
A Yes, that's correct. That's what they say in the results abstract that that was the -- what they decided to highlight in the results.
Q Okay. If you look at Table 2, which is on Page 6.
A Okay.
Q This table shows the standard mortality rates of disease in the Camp Lejeune and Camp Pendleton population suggested for sex, race and age; is that correct?
A That is correct, yes.
Q And do you see where urinary bladder cancer is indicated?

A Yes.
Q Do you see that the standard mortality rate for urinary bladder in Camp Lejeune population is .97?
A Yes, I do.
Q So that result would reflect that adjusted for sex, race and age there are 3 percent fewer deaths from bladder cancer in the Camp Lejeune cohort than for the general population, correct?
A Again that would be the precise calculation. I would say that there is -- it's very -- it's essentially the same as the US general population.
Q Because it's so close to 1?
A Yes. The same way I would say if it's 1.03, I would say the same thing. You're awfully close to equal risk.
Q And would you agree that the confidence interval is narrow?
A It's good, yes. Again, this -- yeah, there's not a -- there's not a formal definition of when it's narrow or not, but it's a -- it's a reasonable size study, yes.
Q This result in and of itself would not reflect a strong association between exposure to contaminants at Camp Lejeune and death from bladder cancer, correct?

A Again, this is -- there's -- I'd have to look at, you know, the methods in greater detail and make a judgment about that.

Statistically, it is not providing statistical support for there being an association. I wouldn't go beyond that from -- you know, just this isolated finding, though.

Q Understood. Thanks.

Take a look at kidney and renal pelvis cancer, which is right above bladder cancer.

Do you see that?

A Yes, I do.

Q And the standard mortality rate for the Camp Lejeune cohort is 1.11; is that correct?

A That is correct, yes.

Q And that would reflect that adjusted for sex, race and age, there are 11 percent more deaths from kidney and renal pelvis cancer in the Camp Lejeune cohort than in the general population?

A Right. Again, that number, but I would say it's a small increase in risk.

Q Okay. So you wouldn't say that's a strong association?

A No.

Q The confidence interval is relatively narrow?

A It is, yes.
Q Given that the lower end of the confidence interval is below 1, that result under traditional understanding is not statistically significant, correct?
A That's right. By that definition it's not statistically significant.
Q Okay. Can you look at non-Hodgkin's lymphoma? Do you see that?
A Yes.
Q For non-Hodgkin's lymphoma, the standard mortality rate for the Camp Lejeune cohort is .73; is that correct?
A That is correct, yes.
Q The result shows that adjusted for sex, race and age, there are 27 percent fewer deaths from non-Hodgkin's lymphoma in the Camp Lejeune cohort than in the general population, right?
A That's correct, yes.
Q Would you agree that the confidence interval is narrow?
A Yes.
Q And would you agree that the result of a decreased risk is statistically significant given that the higher end of the confidence interval is less than 1?

A Again, technically true, yes.
Q This result in and of itself would not reflect a strong association between exposure to contaminants at Camp Lejeune and death from non-Hodgkin's lymphoma?
A Well, you -- again, you could say that it does not support there being a positive association taken in isolation.
Q Okay. Finally, if you look at leukemias do you see that line?
A Yes, I do.
Q And the standard mortality rate for the Camp Lejeune cohort is .87, correct?
A That's correct, yes.
Q So that result would show that adjusted for sex, race and age, there are 13 percent fewer deaths from leukemia in the Camp Lejeune cohort than in the general population, right?
A Again, that would be quantitatively correct.
Q The confidence interval is narrow, correct?
A Yes, I'd say that's a good precision.
Q But given that the upper end of the confidence interval is greater than 1, that result of a decreased risk is not statistically significant, correct?

A Again, technically that is true. I'm not sure how that helps, but the -- as I said, it's -- that is correct by the standard definition of significance testing.

Q Okay. Let's look at the relative risk comparing the Camp Lejeune cohort to the Camp Pendleton cohort.

Do you see the number for bladder cancer?

A Yes, I do.

Q And that relative risk ratio for bladder cancer is 1.02, correct?

A That's correct, yes.

Q And that would reflect 2 percent greater incidence of death from bladder cancer in the Camp Lejeune population compared to the Camp Pendleton population, right?

A Right. I mean, that would be the quantification. I would say it's essentially saying -- it's saying they have essentially the same risk.

Q Okay. So not a strong association certainly, right?

A Correct.

Q Okay. Look right above that for the risk ratio for renal and kidney -- well, let me strike that.

Right above that is the risk ratio for kidney and renal pelvis cancer.

Do you see that?

A Yes, I do.
Q And the risk ratio is 1.21, correct?
A That's right.
Q And given that the lower end of the confidence interval is less than 1, under traditional understanding, that's not a statistically significant result, correct?
A That's right.
Q Take a look at NHL. Do you see that line again for the comparison of Camp Lejeune versus Camp Pendleton?
A Yes, I do.
Q And there the relative risk is .87, correct?
A That's right.
Q That would mean that there were 13 percent fewer deaths from NHL at Camp Lejeune in comparison to Camp Pendleton adjusted for race, age and sex?
A Yes, that's the definition of the risk ratio.
Q And then for leukemias, do you see where the risk ratio for comparing Camp Lejeune versus Camp Pendleton is 1.13?
A Yes, I do.
Q And that would represent a 13 percent greater risk of death from leukemias at Camp Lejeune versus Camp Pendleton, right?
A Yes, that's correct.

Q The lower end of the confidence interval is .89, right?
A That's right.
Q And since that's less than 1, that means under traditional understanding, that result is not statistically significant?
A That's right.
Q Okay. You can put that exhibit aside.
(Deposition Exhibit No. 20, Supplemental Materials from the 2024 ATSDR Mortality Study, was marked for identification.)
BY MR. BAIN:
Q I'm showing you what has been marked as Exhibit 20 and I'll represent to you that these are the supplemental materials from the 2024 ATSDR mortality study.
Do you see that?
A Yes, I do.
Q And would you agree that this appears to be a dose response analysis based on low duration, medium duration and high duration?
A That is -- again, according to the headings, that's the -- those are the categories that they're describing there.
Q And this is for the Marine/Navy personnel subgroup

for 1975 to 1985 at Camp Lejeune with Camp Pendleton as a reference group.

Do you see that?

A Yes, I do.

Q If you look at the bottom of the first page, do you see bladder cancer and kidney cancer?

A Yes. I -- again, I'm sorry. In looking at what they're doing there, though, analysis of base duration...

So I'd have to look up the details. I just was trying to clarify if they compared low duration Camp Lejeune personnel to low duration Camp Pendleton personnel and then medium duration Camp Lejeune to Camp Pendleton, and high duration Camp Lejeune to Camp Pendleton, that -- I -- I'm assuming that, but I'd have to look to verify that.

Q Okay. But you don't question that they were trying to do a dose analysis through this type of calculation?

A They were clearly interested in what the effective duration would be on the hazard ratios.

Q And is duration sometime used as a -- a proxy for exposure?

A Yes, it is. It's -- it's one of the ways you can try to capture greater and lesser amounts of exposure.

Q And that's -- that's not uncommon in epidemiological studies, correct?
A That's correct.
Q If you look at bladder cancer, would you agree that there's not a monotonic dose response relationship shown in this analysis?
A Again, technically not, but there is -- again, if I were describing it, I would say some indication that the -- the risk rises in the high duration group relative to the others. But no, it's not a -- it's not a monotonic relationship because it's a little lower in the middle.

But it's -- again, it's technically not a -- a purely monotonic relationship, but I do think it's showing some indication of being a bit higher in the high duration group.
Q Would you cite that analysis as being supportive of causation -- of an inference of causation?
A Weakly so, yes, I would. I would mention that -- in other words, I would take note of that high duration hazard ratio of 1.24 as a -- you know, possible or some indication that long duration may be associated with a greater risk.
Q If you look at the next line, which is kidney cancer, do you see that there appears to be an inverse dose

response relationship reflected in that analysis?
A I do see that, yes.
Q So would you agree that that would not be supportive of an inference of causation?
A Again, not in and of itself. It suggests that there's a somewhat greater risk in low and medium duration but not in high duration personnel.
Q And that's not typically what you see when there's a causal relationship, correct?
A Again, subject to all the caveats about measuring exposure accurately and so on, all other things equal, that is not supportive.
Q Okay. Turn the page.
Do you see non-Hodgkin's lymphoma?
A Yes, I do.
Q And with non-Hodgkin's lymphoma there is actually an invert dose response relationship, correct?
A Yes, that's correct.
Q So that would not be supportive of inference of causation, would it?
A That's correct.
Q And if you look at leukemias -- do you see that line?
A Yes, I do.
Q And for leukemias generally, there's not a monotonic dose response relationship, is there?

A That's right, there is not.
Q And do you see that it's divided into subtypes?
A Yes.
Q Are you familiar with MDS, what that stands for?
A Myelodysplastic syndrome, I believe.
Q Is that a subtype of leukemia?
A This is -- again, it's a subtype -- it's certainly a -- a type of blood cancer. And you know, I don't know if it's considered a subtype of leukemia, but it's a -- it's certainly a lymphatic -- I mean, it's a hematopoietic cancer.

I just -- I'd have to look up exactly how that's defined in the literature.

Q Okay. Well, excluding that particular condition, if you look at the other -- well, just to be complete, if you look at that particular condition, MDS, there appears to be a monotonic dose response relationship, correct?
A Yes, with again relatively high levels across and getting higher as you go from -- to longer duration.
Q But if you look at all of the other leukemia subtypes, ALL, CLL, AML and CML, none of those subtypes in this analysis show a monotonic dose response relationship, do they?
A That -- that's right. Again clearly as expected for

these subtypes you're getting into very small numbers problem. They don't show the number of cases, but I suspect we're getting into a rather low range given the width of the confidence intervals.

And so you could say it's not a -- it's not finding sort of a -- a gradient, but it -- it -- given that imprecision, you didn't have much of a chance to do so. In other words, it's not showing there's no gradient.

It's saying we have small numbers of cases. I'd want to see the numbers in each group, but I think it's probably in the, you know, three- or four-case range in each of those categories.

Q Well, if you look at ALL -- well, strike that.

For leukemias generally, the confidence intervals are fairly narrow; would you agree with that?

A Right. In the aggregate the leukemias certainly have enough data to be a -- that -- that's a meaningful analysis. I'm just trying to distinguish in the subgroups whether you want to say anything about them, you know, based on the number of cases and the degree of precision.

Q Okay. So we've talked a lot about the statistical effect and association of the dose response analysis.

You'd agree that it's important also to consider

the quality of the study when you're looking for an association or -- or trying to infer causation?

A Right. Interpreting the study -- you can't interpret the study results without looking at the study methods.

And, in fact, you can argue that you should look at the methods first to decide is this going to be an informative study based on the quality of the work. So if it's a good study, whatever it finds is worth paying attention to.

Q Okay. I wanted to ask you about a few other things in your book. So if you have Exhibit 4.

A Okay.

Q And turn to Page 77.

A Okay.

Q Do you see where you have a section, See the quality of the study's finding and association?

A Yes.

Q And you state there, first of all, Epidemiological studies can vary substantially in their quality and hence vary in the confidence that can be placed in their results, right?

A That's correct.

Q And next you say, Even when findings are mixed across studies, some supportive of an effect and others not,

if those that are methodologically strongest tend to provide the most support for a potential causal association, the overall weight of evidence tips in that direction.

Correct?

A That's correct, yes.

Q What are the factors that make a study methodologically sound?

A You know, it's -- it's the whole constellation of -- of the -- the sources of bias being minimized. So that with regard to random error, larger study size is beneficial.

Very often the quality of exposure assessment in particular, in environmental epidemiology at least, is often a major determinant on how accurately exposure was ascertained. Similarly, the accuracy of disease diagnosis, susceptibility to confounding. If -- selection bias is sometimes a factor depending on if people are lost to follow up in a selective manner. But all those factors are considered.

Now, in any given topic area some may be much more important than others. And so, as I said, a lot of the work I do is in environmental epidemiology where it's almost always the case that exposure assessment is the limiting factor. And when you can

group the studies into those that do a better and worse job, that's often going to drive the overall -- overall value of the study for assessing a potential causal effect.

Q So are you saying that in environmental studies, exposure assessment is one of the most important factors in evaluating the strength of the study?

A It very often is. It's often a limiting factor, yes.

Q And you haven't, I don't think based on your prior testimony, evaluated the ATSDR studies with respect to the strength of their exposure assessment?

A I have not, no.

Q You go on to say in that paragraph that, Note that a selective focus on supportive studies is not cherry-picking so long as the reason for placing more faith in those studies is clear. Correct?

A That's right, yes.

Q So when a scientist is focusing on certain studies and not all the studies, it's important for the scientist to explain why they're focusing on those studies?

A Yes. I mean, I think the key point is that this is where it sort of -- to me cherry-picking is when you -- you find results that you like and emphasize the studies that generate the results that you like.

What I'm saying is when you focus based on the quality of the methods, you know, you could even -- you should not be attending to what the results are. The methods determine the quality of the study. And then the results are whatever -- however they come out.

And so it's -- it's saying that that can be done, and it doesn't mean that you consider the studies equally. Sometimes there's a literature where there may be 20 studies and only three -- three of them are so much better than the others they actually carry more weight than the other 17 put together, and you need to explain it. But it's one of the arguments against just counting studies or saying these five were statistically significant and these weren't.

This is, I think, a more informative approach is -- is having it be driven -- the weight is being driven by the quality of the methods.

Q Would you agree that if an expert selectively focuses on supportive studies and ignores methodologically strong studies that find no association, that would be cherry-picking?

A Again if it's a -- anytime that the selection of -- or the weighting of studies -- let's say you're doing either formally or informally a weighted assessment

of the evidence, if the weight is determined by the results and how they happen to come out, that I consider to be, you know, a -- an inaccurate weighting. A weighting should be by the quality of the methods.

Q Not by the results?

A That's right, not by the results. The -- right. That -- that's right.

Weighting it by the results is -- you know, if you -- if you focus on the studies that are negative then -- or focus on the studies that are positive, you're not giving an accurate presentation of what the overall set of studies has to say.

Q So if an expert were to ignore methodologically strong studies that find no association in support of an opinion of causation or alternatively were to ignore strong studies finding an association but just focusing on ones that found no association in support of an opinion finding no causation, in either of those cases, that would be cherry-picking, wouldn't it?

A That's right.

Q If the methodologically stronger studies find no association with only the weaker studies indicating a possible effect, would you agree then that the

overall weight of the evidence tips in the direction of no causal association?

A Again, you know, if -- it depends on the relative merits of the, you know, higher and lower quality studies. I mean, sometimes there's -- they're kind of all in the same ballpark, and there may be a little bit, these are a little better, these are a little worse. Then you can argue that they're roughly equal and you can look at them as a group.

I'm -- I'm making the distinction when there are times that there really are qualitatively superior studies. And as I said, in this -- it has to be explained.

I mean, you -- but that if it can be explained on its merits and there are clearly a subset of studies that are going to carry the most weight, those would override the studies that are weaker in design and again you would be assigning them less weight. And, again, it should be for logical reasons and explainable reasons.

So if it's exposure assessment and some of them do a poor job that may well have missed -- you know, that may be inaccurate and we know that, others do an excellent job, then you can explain that and say, you know, why you -- why you pay more attention to the

latter.

Q If an expert is rendering a general causation opinion that chemical X produces the effect Y, how would an expert appropriately conduct a literature search?

A Well, I mean, again you would start off with identifying all studies that have -- that are informative on that question. You know, there -- there's searches and, you know, computerized searches and so on to identify studies based on -- again, initially at least I would tend to not be concerned about the exact design or methods.

It's if they address this question. And once those are in hand, then you can begin to, you know, examine them and organize them based on their methods. And so you may divide them into studies that assess exposure by self-report versus measurements or other -- other attributes, but creating these subgroupings that are informative regarding how accurate the study is likely to be.

Q So -- so gathering all the relevant peer-reviewed literature on the question and then organizing them based on the quality of the studies, is that part -- are those parts of the analysis?

A That's right. And, again, not just on quality like good/bad --

Q Mm-hmm.
A But at least I find it more helpful. I've written on this, and I think it's more helpful to consider multiple axes of quality that -- you know, that -- those that do a better job of accessing exposure versus a worse job, those that control for an important confounder, those that don't.

Because then in that spirit of triangulation -- so let's say I'm worried about smoking as a confounder. Well, if I find the studies that do and don't address that it makes no difference, I may be less worried about it now, and I can focus on other things.

So it -- it not only says which is good and bad. It -- you get more insight into what -- what's making them good or bad.

Q And I'm almost getting close to the end here, I think.

You have a statement on Page 81 of your book. Turn to that page.
A Yes.
Q At the bottom of -- and this again is in the section on Commonly Used Arguments in Opposition to a Causal Judgment.
A Yes.

Q And this is in Section A, Statistical uncertainty and cherry-picking.

Do you see the sentence at the end of that -- second paragraph that says, If the data are analyzed in enough different ways and a large enough array of results are presented, it is almost inevitable that some glimmer suggestive of a positive association will be found.

Correct?

A Yes, that's correct.

Q Can you elaborate on what you mean by that?

A Yes. I mean, if -- if -- again there's various examples of this. We do a lot of studies that look at biomarkers and we may look at 10 biomarkers and we may look at the association with a number of different health outcomes we're looking at the relationship again in this hypothetical example to, you know, cholesterol and other lipids and thyroid hormones and so on.

And then we may look among males and females separately. We may look among younger and older people separately. Well, you generate an array of results. Every one of those questions may be reasonable, but at the end when you say, oh, it's this chemical with this hormone, in women who are age

40 to 49 this is the meaningful takeaway from the study, it is -- it's a form of within study cherry-picking.

And, you know, it's probably better to say, well, we -- you know, if it's true, we didn't see anything overall. There's some uncertainty. There may be some glimmers here, but, you know, we'll -- you know, it will take more research to figure it out.

And it's sort of a -- it's reasonable to do the calculations, it's reasonable to interpret them, but there can be a -- sort of a -- I want to say -- not -- it's almost bias in the conventional sense, not like in the epidemiologic sense --

Q Mm-hmm.

A -- but I am looking for positive results and any glimmer I find, I'm going to cite.

Or the other way around. I've seen it where there's a -- you know, you can look at studies, you know, established hazards and say, well, we're not quite sure, in this group it may not be there. That might not be the most important sort of overall message from the study.

Q Is it true that when you're doing, you know, multiple comparisons across a study that it's possible that you may have some findings either in a positive or a

negative direction that are even statistically significant that are actually the result of chance?

A Oh, I mean, this is where, again, statistical significance is sort of besides the point. There will be variation in the results due -- to some extent, due to random error alone. And so that's why I think it's important to look at the patterns.

And that -- there's a lot of dimensions to what, you know, the patterns -- it can include looking at dose response gradients, or there may be, you know, different aspects of the analysis that are helpful in a given situation.

And so you don't just isolate and zero your attention in on a single number and a single table, you're describing the overall constellation of evidence. That I think is a more informative approach.

Q And part of looking for that pattern is looking for consistency across studies, right?

A Again, now we're looking at a whole array of research --

Q Uh-huh.

A -- and unless there -- if there -- if the methods would lead you to believe that they will generate similar results -- that's a big if...

In other words, if you see a difference between good studies and bad studies, you shouldn't be worried; you just focus on the good studies. But when there's no other good reason for that variation and it starts to look -- and they really bounce around a lot on either side of the null, you may reasonably conclude that it's not overall supporting an association.

Q And consistency of results across studies is one of the Bradford Hill consideration, right?

A It is, but again, it's like all the others; it's yes but...

And consistency in the sense that -- that if there is not a methodologic reason to expect them to generate different results, if -- if -- then you might be worried about in consistency. In fact, I would go the other way, though. If there is a good reason to expect differences, I -- I expect to see inconsistency.

That doesn't mean it's not causal, it just means that all the studies are not zeroing in on the same estimate or result.

So it's -- it's unexplained inconsistency, I think you could say, is the concerning factor.

Q What would be a good reason to expect inconsistency?

A Again, if -- in my hypothetical example, if some studies measure exposure poorly and they -- under many assumptions, they're not going to be able to detect an association even if one is really operating.

And other studies, let's say, of the same issue have a much better approach or a much better method of estimating exposure. The poor studies are going to be very close to the null, the good studies are going to generate a positive association.

You don't throw your hand up and say, we can't draw any conclusions because they're inconsistent; you are able to understand and explain why -- in fact, you could say the inconsistency is informative.

We expect bad studies to do that. We expect good studies to zero in on the accurate result. If of course they all find null findings, that's different, but -- or they -- sometimes up get into situations where the higher quality studies are -- are closer to null and the poorer studies that have biases that are more supportive.

It's a matter of going back to the methods, or starting with the methods, I should say, to say, what -- what would we predict? If this is a big issue, what would we expect? And then reconciling

the results with the -- the consistency reconciling that with -- with the prediction of what would be expected.

Q And I know you say you haven't reviewed the ATSDR Camp Lejeune studies at least recently in detail, correct?

A I -- I've never reviewed them in detail.

Q Okay.

A I haven't -- I have at most a passing familiarity with them having been done, and I really couldn't speak to any of the details at this point.

Q But you do understand that there were several Camp Lejeune studies done at different points of time and mainly focusing on the same population?

A I'm aware there's research on both the military population, the civilian population, there's data on mortality, there's data on cancer incidence. That's about as much of -- you know, that's sort of the broad understanding that I have.

Q And you don't have any understanding whether the findings across those studies showed any consistency or inconsistency?

A Again, I've not had a -- I've not been asked to and have not looked at that issue.

Q And in fact in this case, what the plaintiffs have

asked you is fairly limited, which is to opine much of what we've been talking about today, which is statistical significance and the effect of random error, correct?

A That's correct. It's exclusively on that more technical issue, which obviously I understand has bearing on this or maybe other -- any other case as well, but it's really trying to explain why it is that -- sort of a -- explaining the methods and arguing and making the case for a certain methodologic approach to analyzing and interpreting data that I believe is more informative.

Q And how much time did you put into -- putting together your report for this case?

A Oh, boy, that's -- I have somewhere in my records -- I'm -- .

Q It would be reflected in the invoices that you gave to counsel?

A Oh, yes, it definitely would. And I -- honestly, off the top of my head, I'm not sure what that would have been. I mean, I could guess, but I -- it's probably better to go to the invoices to clarify that.

Q Okay. Did you meet with counsel in preparation of the -- this deposition?

A Very briefly I had a discussion, yes.

Q Okay. Have you communicated with any other experts in this case, as far as you know, with respect to your work in this case?
A I have not.
Q Have you discussed this case with any of your colleagues?
A I have not.
Q Okay. Do you have any support staff assisting you with your work on this case?
A I do not.

MR. BAIN: What I would like to do is take a break now, consult with my colleagues, see if I have anything else, but I think I'm just about done.

VIDEOGRAPHER: All right. We're going off record. The time is 2:02.

(Whereupon a recess was held at 2:02 p.m. and the deposition was resumed at 2:11.)

VIDEOGRAPHER: We're going back on record at 2:11.

MR. BAIN: Thank you, Dr. Savitz. I have no further questions. Thank you very much.

THE WITNESS: Thank you.

MR. McGOWAN: Dr. Savitz, one brief topic.

EXAMINATION

BY MR. McGOWAN:

Q Is it fair to say that science needs to be done in the context of the question that is presented or the question to be answered, including the degree of certainty required by the question at hand?

A Again, I would say that science has to be interpreted in reference to some purpose or benchmark. So you know, if there's a charge or there's a standard set -- and we may look at the same body of evidence regardless of what that standard is, but judging whether it meets the standard for causal inferences or other sorts of factors absolutely depends on the way the question -- what the exact question is that's being asked.

MR. McGOWAN: All right. Thank you.

MR. BAIN: No further questions from me. Thank you.

VIDEOGRAPHER: All right. We're going off record. The time is 2:12.

(A discussion was held off the record.)

(It was indicated that the deponent would read and sign a copy of his deposition transcript.)

(Concluded this deposition at 2:12 p.m. this date.)

CERTIFICATE

I, Angella D. Clukey, a Notary Public in and for the State of Maine, hereby certify that on May 16, 2025, remotely appeared before me David A. Savitz, Ph.D., the within-named deponent, who was sworn to testify to the truth, the whole truth and nothing but the truth, in the cause of action Camp Lejeune Water Litigation, now pending in the United States District Court for the Eastern District of North Carolina, and that this deposition was stenographically reported by me and later reduced to typewritten form with the aid of Computer-Aided Transcription, and the foregoing is a full and true record of the testimony given by the witness.

I further certify that I am a disinterested person in the event or outcome of the above-named cause of action.

I further certify that the adverse party was duly notified according to law to attend at the taking of said deposition and did attend.

IN WITNESS WHEREOF, I subscribe my hand and affix my seal this 2nd day of June 2025.

<%10015,Signature%>

_____

ANGELLA D. CLUKEY, NOTARY PUBLIC

Court Reporter

My commission expires March 17, 2031

DEPOSITION ERRATA SHEET

Assignment No. 7351617

In Re: Camp Lejeune Water Litigation

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding

that I offer these changes as if still under oath.

Signed on the_____ day of

_____, 20__.

_____

DAVID A. SAVITZ, Ph.D.

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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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