

# Exhibit 587

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IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA

IN RE: CAMP LEJEUNE WATER )  
LITIGATION ) Case No. 7:23-cv-00897  
)  
This Document Relates to: )  
ALL CASES )  
)  
\_\_\_\_\_ )

VIDEOTAPED DEPOSITION

OF

IRVING COY ALLEN, Ph.D.

Tuesday, June 17, 2025

Raleigh, North Carolina

Reported by: Christine A. Taylor, RPR

Job No.: 7404349



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Exhibit 2	Dr. Irving Allen's Response to "Expert Report on the Case of Jacqueline Y. Tukes for the Department of Justice" prepared by Gail H. Vance, M.D., dated April 8, 2025	17
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P R O C E E D I N G S

\* \* \*

THE VIDEOGRAPHER: On record at  
9:22 a.m. Today's date is June 17, 2025.  
This is the deposition of Dr. Irving Allen  
in the matter of Camp Lejeune Water  
Litigation, Case Number 7:23-CV-00897.

Counsel please introduce yourselves,  
after which the court reporter will swear  
in the witness.

MR. CARPENITO: Good morning. Joshua  
Carpenito on behalf of the United States.

MR. BU: Nathan Bu for the United  
States.

MR. ORTIZ: David Ortiz for the  
United States.

MR. ROBERTS: Jim Roberts appearing  
on behalf of the plaintiffs.

\* \* \*

IRVING COY ALLEN, Ph.D.,  
having first been duly sworn, was examined  
and testified as follows:

\* \* \*

EXAMINATION

BY MR. CARPENITO:

1 Q. Could you please state your full name  
2 for the record.

3 A. Irving Coy Allen, Jr.

4 Q. Can you please state your current  
5 address? And business address is fine.

6 A. 3981 Buck Mountain Ridge, Blacksburg,  
7 Virginia.

8 Q. Dr. Allen, my name is Joshua  
9 Carpenito. I'm a trial attorney with the United  
10 States Department of Justice. Do you understand  
11 that?

12 A. I do, yes.

13 Q. Do you understand that I represent  
14 the United States in the case of Tukes versus the  
15 United States?

16 A. Yes.

17 Q. Have you ever had your deposition  
18 taken before?

19 A. Not in this case, but I have had  
20 depositions taken before.

21 Q. You've had depositions taken in prior  
22 cases?

23 A. Yes.

24 Q. Okay. Were you an expert in those  
25 cases?

1 A. I was.

2 Q. In all of them?

3 A. Yes.

4 Q. Okay. And we'll turn back to those  
5 cases, but I'm going to go over some ground rules  
6 just to ensure that you understand how this  
7 deposition will proceed. Okay?

8 A. Okay.

9 Q. You understand that you just took an  
10 oath to tell the truth?

11 A. Correct.

12 Q. You understand that's the same oath  
13 that you would take in court?

14 A. Yes.

15 Q. And it's subject to the same  
16 penalties of perjury?

17 A. Yes.

18 Q. Madam Court Reporter is here. She's  
19 transcribing everything that we say today. To  
20 ensure that everything is transcribed accurately,  
21 I will ask that you answer all of my questions  
22 verbally. Okay?

23 A. Okay.

24 Q. We should try to avoid things like  
25 head shakes and head nods. Do you understand

1 that?

2 A. I do.

3 Q. We should also try to avoid  
4 interrupting one another. Do you understand  
5 that?

6 A. Yes.

7 Q. Only you are testifying today. You  
8 must answer to the best of your ability. And you  
9 can't ask other people for help.

10 Do you understand that?

11 A. I do.

12 Q. If you don't understand one of my  
13 questions, let me know. I'll do my best to  
14 either restate or rephrase it. Okay?

15 A. Okay.

16 Q. But if you answer one of my  
17 questions, I'm going to assume that you  
18 understood it. Is that fair?

19 A. Sure. Yes.

20 Q. During the deposition you may hear  
21 Mr. Roberts object to some of my questions.  
22 Unless he specifically instructs you not to  
23 answer my question, I'm going to ask that you  
24 answer it after he makes his objection. Okay?

25 A. Okay.

1 Q. Is there any reason why you're unable  
2 to give your most truthful and accurate testimony  
3 today?

4 A. No.

5 Q. Is there any reason your memory might  
6 be impaired today?

7 A. No.

8 Q. Have you taken or do you intend to  
9 take any medication that might affect your  
10 ability to testify today?

11 A. No.

12 Q. I will try to build in some breaks  
13 throughout today about once an hour. But if you  
14 need a break at any other point, just let me  
15 know. Okay?

16 A. Okay.

17 Q. My only request, Dr. Allen, is that  
18 if there's a pending question, you answer it  
19 before we go on break.

20 A. Okay.

21 Q. You understand that?

22 A. Yes.

23 Q. What field or fields do you hold  
24 yourself out as an expert in?

25 A. Sure. So I am an immunologist and

1 cancer biologist. I also have education and  
2 training in the fields of molecular biology and  
3 genetics.

4 Q. Can you repeat that last part that  
5 you said?

6 A. Sure. I have training and education  
7 in the fields of molecular biology and genetics.

8 Q. And what area of expertise was  
9 relevant for the opinions that you proffered in  
10 this case?

11 A. Genetics, molecular biology, and  
12 cancer biology.

13 Q. Is it correct that you've been  
14 retained by the plaintiff's leadership group as  
15 an expert witness in the Tukes case which is  
16 pending in the United States District Court for  
17 the Eastern District of North Carolina?

18 A. Yes.

19 Q. When were you first contacted about  
20 serving as an expert witness in Ms. Tukes's case?

21 A. Would have been in early December of  
22 2024.

23 Q. Who contacted you?

24 A. This was through the Expert  
25 Institute. I'm not sure who facilitated the

1 contact. The first people I came in contact with  
2 related to the case, Mark Mandell, Mark -- I  
3 think -- I see you guys nodding. So Mark Mandell  
4 and Zachary Mandell.

5 Q. Okay. You mentioned the Expert  
6 Institute. Can you explain what that is to me?

7 A. Sure. I have a profile listed on  
8 their website. To the best of my knowledge, it's  
9 how expert -- it is a way for experts and  
10 attorneys to match with one another, find one  
11 another.

12 Q. Do you pay a fee to be a part of this  
13 website?

14 A. I do not, no.

15 Q. Okay. When were you formally  
16 retained?

17 A. I don't know. It would have been  
18 sometime late in December. I don't have any sort  
19 of retainment agreement. So it would have been  
20 sometime late in December. I believe I began  
21 working on the report in early January. I feel  
22 like I did some work over Christmas Day related  
23 to this. But so it would have been late in  
24 December, sometime around then.

25 Q. So you were formally retained

1 approximately late December 2024?

2 A. That would be close to being correct.

3 Q. Do you recall who formally retained  
4 you?

5 A. The Mandells.

6 Q. Okay. Prior to your formal  
7 retainment, do you have any notes from the  
8 meeting that occurred from that initial meeting  
9 that you had with the Mandells?

10 A. I don't -- I'm not sure. I don't  
11 have any like formal notes, no. I may have some  
12 questions that the expert institute provided, but  
13 that would be -- that would be it. So I answered  
14 some questions related to my areas of expertise  
15 from the Expert Institute.

16 I'm not sure. Was that what you were  
17 asking?

18 Q. Did those questions come from the  
19 Expert Institute or did they come from the  
20 attorneys?

21 A. I don't know.

22 Q. Okay.

23 A. I don't know the source of those.

24 Q. Do you still have copies of those  
25 questions and answers?

1 A. I'm sure I could find them.

2 Q. Okay. What was the assignment that  
3 the Mandells gave to you for Ms. Tukes's case?

4 A. They asked me to evaluate the UNC  
5 records from Mrs. Tukes related to the genetic  
6 testing.

7 Q. Did your assignment ever change?

8 A. No, not to my knowledge.

9 Q. When they were asking you to  
10 interpret the genetic testing in the UNC records,  
11 do you recall if there was anything else that  
12 they asked you to do?

13 A. I don't think so. I think they just  
14 wanted me to evaluate the genetics, the genetics  
15 testing for Mrs. Tukes.

16 Q. Okay.

17 A. So that's -- that's all I can  
18 remember.

19 Q. What is your understanding of the  
20 purpose of evaluating the genetic testing in  
21 those UNC records?

22 A. They wanted to determine if  
23 Mrs. Tukes' renal cell carcinoma was inherited or  
24 heritable in nature.

25 Q. Were you able to come to an opinion

1 in this case?

2 A. I was, yes.

3 Q. And what is that opinion?

4 A. That it is more likely than not that  
5 Mrs. Tukes' renal cell carcinoma is not due to an  
6 inherited or heritable mutation.

7 Q. Okay. Before being retained, had you  
8 heard about Camp Lejeune?

9 A. So I'm from North Carolina and so I  
10 just the -- there were a lot of law firm  
11 commercials related to Camp Lejeune, but I don't  
12 know any of the specifics.

13 Q. What, if anything, did you know?

14 A. That there was a lawsuit related to  
15 Camp Lejeune.

16 Q. Okay. And do you know about when you  
17 heard that information?

18 A. Oh, I don't know. It's through the  
19 years. So I don't know.

20 Q. Did you consult with any treating  
21 providers in forming your opinions in this case?

22 A. I did not, no.

23 Q. Did you consult with any clinical  
24 geneticist in forming your opinions in this case?

25 A. I did not, no.

1 Q. Did you consult with any other health  
2 care providers in forming your opinions in this  
3 case?

4 A. No.

5 Q. Dr. Allen, I'm going to introduce a  
6 few exhibits now. The first of which I'd  
7 represent to you is going to be a copy of your  
8 initial report.

9 A. Okay.

10 Q. And just bear with us as we get these  
11 marked.

12 A. That's fine.

13 (Allen Exhibit 1 marked for  
14 identification.)

15 BY MR. CARPENITO:

16 Q. I'll ask you to review that and let  
17 me know if you recognize this as the initial  
18 report that you offered in this case?

19 A. This appears to be the original one  
20 that I submitted, yes.

21 Q. And I'm going to introduce now what's  
22 going to be marked as Exhibit 2. And, Dr. Allen,  
23 I would represent to you that this is a copy of  
24 the rebuttal report that you submitted in this  
25 case.

1 (Allen Exhibit 2 marked for  
2 identification.)

3 BY MR. CARPENITO:

4 Q. And I'll ask you to do the same.  
5 Briefly take a look at that and let me know if  
6 you recognize that as such?

7 A. Used to seeing this on double pages,  
8 so it's look twice as long as it was when I sent  
9 it in.

10 Yes. This appears to be the rebuttal  
11 report that I submitted.

12 Q. Okay. Those two exhibits you can  
13 hang on to. We'll refer back to them throughout  
14 the day. Okay?

15 A. Okay.

16 (Allen Exhibit 3 marked for  
17 identification.)

18 Q. And for now I'm going to introduce  
19 what's hopefully the last one for a moment is  
20 Exhibit 3. And I represent to you that this is  
21 the materials considered list that you submitted  
22 with your report. Would you agree with that?

23 A. So, yes, except for I was also  
24 provided the report from Dr. Vance.

25 Q. Understood. Dr. Allen, you did not

1 review the exposure modeling report disclosed by  
2 the United States; correct?

3 A. Correct.

4 Q. That exposure modeling report is not  
5 listed in your materials considered; right?

6 A. It is not, no.

7 Q. You did not review the exposure  
8 report served by the plaintiffs in this case;  
9 right?

10 A. Correct.

11 Q. And that exposure report is not  
12 listed in your materials considered list?

13 A. It's not, no.

14 Q. You didn't review Ms. Tukes's housing  
15 records, did you?

16 A. I did not, no.

17 Q. And those housing records as they  
18 relate to Ms. Tukes are not listed on your  
19 materials considered list; right?

20 A. They are not, no.

21 Q. Are you relying on other experts'  
22 review of Ms. Tukes's personal history?

23 A. I am not, no.

24 Q. And are those cited in your materials  
25 considered list?

1 A. They are not, no.

2 Q. Where did you receive Ms. Tukes's  
3 personal history from, if at all?

4 A. The UNC record. If that's what  
5 you're referring to, I received from the  
6 attorneys.

7 Q. Okay. So is it fair to say that your  
8 understanding of Ms. Tukes is contained to what  
9 is contained in those UNC medical records?

10 A. Correct. Everything I know about  
11 Ms. Tukes is in that UNC record.

12 Q. And other than Dr. Vance's report,  
13 which you just mentioned before, are there any  
14 other materials that you reviewed that are not  
15 cited in your materials considered list?

16 A. Not to my knowledge.

17 Q. You don't offer any opinion in your  
18 report in this case as to whether the  
19 contaminants alleged to be present at Camp  
20 Lejeune are genotoxic carcinogens; right?

21 A. Correct.

22 Q. You are not a toxicologist; correct?

23 A. Correct.

24 Q. You did not search for toxicological  
25 literature in preparing your report, did you?

1 A. No.

2 Q. You did not research the scientific  
3 literature relating to TCE specifically; right?

4 A. Not specifically to TCE, no.

5 Q. You did not research the scientific  
6 literature relating to PCE; right?

7 A. No.

8 Q. You did not research the scientific  
9 literature relating to benzene; correct?

10 A. Correct.

11 Q. You did not research the contaminated  
12 water at Camp Lejeune; right?

13 A. Correct.

14 Q. You did not research the levels of  
15 contamination in the water at Camp Lejeune;  
16 right?

17 A. Correct.

18 Q. You did not research what areas of  
19 the base were contaminated, did you?

20 A. I did not.

21 Q. You didn't research which wells on  
22 Camp Lejeune were contaminated; right?

23 A. Correct.

24 Q. And you did not determine whether PCE  
25 is genotoxic; right?



1       been exposed to genotoxic carcinogens other than  
2       Camp Lejeune water; right?

3                   MR. ROBERTS:  Objection.

4                   THE WITNESS:  It's possible.

5       BY MR. CARPENITO:

6               Q.     In fact, she almost certainly was;  
7       right?

8                   MR. ROBERTS:  Objection.

9                   THE WITNESS:  I can't -- I can't say  
10       that with any degree of certainty.

11       BY MR. CARPENITO:

12               Q.     Would you agree that most people are  
13       exposed to some level of genotoxic agents in  
14       daily life?

15               A.     Sure.  Yes.

16               Q.     You agree that it's impossible to  
17       avoid all genotoxic carcinogens?

18               A.     Yes.

19               Q.     You would agree that there are  
20       multiple known risk factors that could increase  
21       the likelihood of developing cancer; right?

22               A.     Yes.

23               Q.     But the presence of a risk factor  
24       doesn't mean that it was the cause of the  
25       person's cancer; right?

1 A. Correct.

2 Q. In fact, cancer is often just the  
3 result of many contributing factors, not just  
4 one; right?

5 A. It tends to be multifactorial, yes.

6 Q. People can develop cancer for a wide  
7 range of reasons, some of which may be unknown;  
8 right?

9 A. Correct.

10 Q. In fact, cancer occurs through the  
11 culmination of a series of defects in biologic  
12 signaling pathways and functions; right?

13 A. That's correct.

14 Q. It is often not caused by a single  
15 defect for example; right?

16 A. Again, it's -- it tends to be  
17 multifactorial, correct.

18 Q. You would agree that the causes of  
19 cancer are -- strike that. I'm sorry.

20 Would you agree that cancer is a  
21 highly individualized disease?

22 A. Yes. And -- in most cases, yes.

23 Q. And on page 8 of your report you  
24 state --

25 MR. ROBERTS: Which report?

1 Exhibit 1?

2 BY MR. CARPENITO:

3 Q. The initial -- Exhibit 1, the initial  
4 report. Page 8, the second paragraph. The  
5 second sentence there starts with "Cancer is a  
6 highly individualized disease with significant  
7 heterogeneity between patient populations."

8 Did I read that correctly?

9 A. Can you tell me -- sorry. Which line  
10 were you referring? I mean I can find it.

11 Q. Certainly.

12 A. Oh, I see it. It's the second  
13 paragraph. And can you repeat what you just --

14 Q. Certainly. It's the second sentence.  
15 And it reads "Cancer is a highly individualized  
16 disease" --

17 A. Yeah.

18 Q. -- "with significant heterogeneity  
19 between patient populations."

20 Did I read that correctly?

21 A. You did, correct. Yes.

22 Q. Would you agree that assumptions used  
23 in epidemiology are minimal?

24 A. Can you rephrase that?

25 Assumptions in the field of

1 epidemiology or are you talking about --

2 Q. Assumptions in epidemiological  
3 studies are minimal, would you agree with that?

4 MR. ROBERTS: Objection.

5 THE WITNESS: I don't -- I think  
6 that's kind of a -- too general of a  
7 statement.

8 BY MR. CARPENITO:

9 Q. Okay. Well, I'll read this sentence  
10 for you --

11 A. Sure.

12 Q. -- in that same paragraph. It is a  
13 couple of sentences down. It starts with "The  
14 drivers of this heterogeneity are largely  
15 undefined. Thus, any assumptions used in  
16 population scaled modeling in epidemiology  
17 studies are minimal" --

18 A. Yes --

19 Q. -- did I read?

20 A. You did. That's referring back to  
21 individualized nature of cancer.

22 So because cancer is such a highly  
23 individualized disease, assumptions in the  
24 epidemiology studies of these do tend to be  
25 minimal, yeah. So I would agree with that.

1 Q. So it's fair to say an intrinsic  
2 factor identified at a population level might not  
3 play the same role at an individual level; right?

4 A. Correct. Yes.

5 Q. For example, individual factors that  
6 affect the microbiome could contribute to cancer;  
7 right?

8 A. They could, yes. This is the  
9 microbiome in this context is -- it will be what  
10 we would call an enabling characteristic. So it  
11 doesn't necessarily mean that it causes cancer,  
12 but it can contribute.

13 Q. And that would mean that any  
14 extrinsic agent, such as a chemical that alters  
15 the composition of the microbiome, has the  
16 potential to significantly contribute to cancer;  
17 right?

18 A. Well, it's an enabling  
19 characteristic. Again, enabling characteristics  
20 include changes in genetics. It includes  
21 microbiome changes. It also includes  
22 inflammation. And so those can be factors that  
23 we all have. They contribute to cancer, but they  
24 don't necessarily cause it.

25 Q. So I'll ask you to turn to page 10 of

1 your report. Right before you get into that  
2 first big full paragraph, the last sentence  
3 states, "Thus any extrinsic agent, such as a  
4 chemical that alters the composition of the  
5 microbiome has the potential to significantly  
6 contribute to cancer."

7 Did I read that correctly?

8 A. You read that correct. And in the  
9 next statement -- in the next big paragraph down  
10 talk about enabling characteristics. They're  
11 considered enabling characteristics. So they're  
12 not necessarily causative. They enable. You can  
13 think of it as predisposing.

14 Q. Your report discusses the PMS2 gene;  
15 right?

16 A. It does.

17 Q. And it also discusses a specific PMS2  
18 variant that was identified in Ms. Tukes'  
19 germline testing; correct?

20 A. It does, yes.

21 Q. Germline mutation would mean it is a  
22 mutation that Ms. Tukes was born with; right?

23 A. Yes.

24 Q. And you'd agree that germline  
25 mutations would not be caused by Ms. Tukes'

1 exposure to Camp Lejeune water as an adult;  
2 right?

3 A. Correct.

4 Q. You'd agree that not all PMS2  
5 variants are the same; right?

6 A. Correct.

7 Q. For example, some PMS2 variants may  
8 be missing substitutions; right?

9 A. Correct.

10 Q. Other PMS2 variants may be  
11 deleterious; right?

12 A. So there's a difference. So missense  
13 is a type of mutation. There are two other types  
14 of mutation. Silent mutations and also  
15 deleterious in that -- in that it causes what's  
16 called a truncation. So that only a partial part  
17 of the protein is made.

18 So those are three very clear types  
19 of mutations. A missense mutation can lead to a  
20 loss of function or be deleterious. It's just --  
21 it's simply a substitution of an amino acid  
22 versus the silent mutation is a change that has  
23 no effect on protein structure versus the true  
24 deleterious protein is basically a stop. And it  
25 tells the sequencing to make a partial protein

1 that's not functional. It's -- usually that's  
2 broken down.

3 Q. So to go back to my question. Some  
4 PMS2 variants can be deleterious; correct?

5 A. Yes.

6 Q. And some PMS2 variants may lead to a  
7 loss of function; right?

8 A. Correct.

9 Q. While other PMS2 variants may have no  
10 effect; right?

11 A. Correct.

12 Q. And your report also discussed the  
13 SMARCA4 gene; right?

14 A. Correct.

15 Q. And it also discusses a specific  
16 SMARCA4 variant that was identified in Ms. Tukes;  
17 right?

18 A. Correct.

19 Q. And you'd agree that not all SMARCA4  
20 variants are the same; right?

21 A. Correct.

22 Q. Some SMARCA4 variants may be  
23 missense; right?

24 A. Correct.

25 Q. And others may be deleterious; right?

1           A.     Well, again, a missense can be a  
2 deleterious or a loss of function.

3           Q.     Right. Right. And some SMARCA4  
4 variants, as you just said, may lead to a loss of  
5 function; right?

6           A.     Correct.

7           Q.     And others may have no effect; right?

8           A.     Correct.

9           Q.     Would you agree that not all missense  
10 variants alter protein function?

11          A.     Correct.

12          Q.     In other words, some missense  
13 variants may have no effect on protein function;  
14 right?

15          A.     Correct.

16          Q.     You agree that a variant could be  
17 deleterious without also leading to a loss of  
18 function; right?

19          A.     No. By definition, if it's a  
20 deletion mutation, then it typically would lead  
21 to a loss of function. There's nuance there. It  
22 could create a truncated protein that actually  
23 has a gain of function. So I think there's a lot  
24 of nuance in the question you asked.

25          Q.     And that leads me to my next

1 question. A gain of function could also be  
2 deleterious; right?

3 A. It could, yes.

4 Q. Right. So by nature, because a  
5 mutation or a variant is deleterious does not  
6 also mean that it is a loss of function; right?

7 A. Correct.

8 Q. Dr. Allen, are you a licensed  
9 physician?

10 A. I am not, no.

11 Q. Have you ever diagnosed a patient  
12 with hereditary renal cell carcinoma?

13 A. No.

14 Q. Have you ever treated a patient with  
15 hereditary renal cell carcinoma?

16 A. No.

17 Q. Do you hold any clinical  
18 certifications such as board certifications from  
19 the American Board of Medical Genetics?

20 A. I do not.

21 Q. Are you licensed to practice medicine  
22 in any U.S. state?

23 A. No.

24 Q. You did not attend middle school;  
25 correct?

1 A. Correct.

2 Q. You are not an MD; right?

3 A. Correct.

4 Q. You are not a DO?

5 A. No.

6 Q. Do you currently practice in a  
7 clinical setting where you interpret genetic test  
8 results for patients?

9 A. So I don't practice. I'm not a  
10 medical doctor.

11 Are you asking have I interpreted  
12 genetic test results before? I have interpreted  
13 human -- or clinical data from humans.

14 Q. Let me ask this: Have you ever  
15 personally counseled a patient regarding the  
16 results of an Invitae genetic test?

17 A. No.

18 Q. Do you see patients in a clinical  
19 genetic setting?

20 A. No.

21 Q. Do you see patients in a clinical  
22 oncology setting?

23 A. Again, I don't see patients.

24 Q. So would the answer to that question  
25 be no?

1 A. Yes.

2 Q. In other words, you're not a treating  
3 physician; correct?

4 A. Correct.

5 Q. And you are not a clinical  
6 geneticist; right?

7 A. Correct.

8 Q. Have you ever published peer-reviewed  
9 research specifically on the genetics of renal  
10 cell carcinoma?

11 A. No.

12 Q. You've never made treatment  
13 recommendations based on Invitae genetic testing  
14 results; right?

15 A. Correct.

16 Q. Have you ever published peer-reviewed  
17 research on the clinical significance of PMS2  
18 variants in human populations?

19 A. No.

20 Q. Have you ever published peer-reviewed  
21 research on the clinical significance of SMARCA4  
22 variance in human populations?

23 A. No.

24 Q. Have you ever published peer-reviewed  
25 research specifically on germline genetics and

1 renal cell carcinoma risk in human populations?

2 A. No.

3 Q. Would you agree that your expertise  
4 is not diagnosing hereditary cancer risk in  
5 patients?

6 A. Yes.

7 Q. Prior to your retention in this case,  
8 had you previously researched the clinical  
9 significance of PMS2 variants?

10 A. No.

11 Q. When did you begin, if at all, to  
12 research the clinical significance of PMS2  
13 variants?

14 A. Upon seeing them in the UNC report  
15 related to Mrs. Tukes.

16 Q. And about what time would that have  
17 been?

18 A. Again, early -- early January.

19 Q. And is that January 2025?

20 A. Yes. Yeah.

21 Q. Prior to your retention in this case,  
22 had you previously researched the clinical  
23 significance of SMARCA4 variants?

24 A. No.

25 Q. And when, if at all, did you begin

1 your research into the clinical significance of  
2 SMARCA4 variants?

3 A. Upon -- again, upon seeing  
4 Mrs. Tukes' UNC report.

5 Q. And would that have been --

6 A. Early January.

7 Q. And just --

8 A. Sorry, I cut you off.

9 Q. That's okay. Just to ensure we have  
10 a clear record --

11 A. Sure.

12 Q. -- you're referring to January of  
13 2025; correct?

14 A. Correct. Yes.

15 Q. Prior to your retention in this case,  
16 had you previously researched PMS2 genes?

17 A. I don't believe so. I was aware of  
18 PMS2 because it functions as a -- in the context  
19 of cancer biology. But in terms of any in-depth  
20 research of PMS2, no.

21 Q. And when would that research, if at  
22 all, had begun.

23 A. I can't -- I don't know. I had heard  
24 of PMS2 before, but not in any detail.

25 Q. Okay. When did you begin researching

1 the PMS2 gene in detail?

2 A. With Ms. Tukes' report.

3 Q. And would that have been about  
4 January of 2025?

5 A. Yes. Correct.

6 Q. Prior to your retention in this case,  
7 had you previously researched the SMARCA4 gene?

8 A. No.

9 Q. And when, if at all, did that  
10 research into the SMARCA4 gene begin?

11 A. Again, January 2025.

12 Q. You reviewed Ms. Tukes' genetic  
13 testing results from Invitae; right?

14 A. Correct.

15 Q. And that report included an analysis  
16 of multiple genes associated with heritable renal  
17 cell carcinoma; right?

18 A. Correct.

19 Q. And that test included the PMS2 gene;  
20 right?

21 A. It did.

22 Q. And it included the SMARCA4 gene;  
23 right?

24 A. Correct.

25 Q. Dr. Allen, I'm going to introduce

1 Exhibit 4 to the extent that we'll be referring  
2 to this.

3 A. I don't know where to place things.  
4 (Allen Exhibit 4 marked for  
5 identification.)

6 BY MR. CARPENITO:

7 Q. Dr. Allen, I would represent to you  
8 that these are the UNC medical records in  
9 Ms. Tukes's case that are also listed on your  
10 materials considered list.

11 You would agree that the original  
12 Invitae test returned a variant of uncertain  
13 significance in the PMS2 gene; right?

14 A. Correct. Did you want me to verify  
15 that this was the report I reviewed. I mean I  
16 think it is.

17 Q. You certainly can if you need to.  
18 I'll ask that you do it briefly.

19 A. Okay. No, it looks like -- this  
20 looks like the one that I reviewed, yes. I'm  
21 just checking to make sure it has the -- yep.  
22 Yes.

23 Q. You'd also agree that a variant of  
24 uncertain significance was returned in the  
25 SMARCA4 gene in that Invitae test; right?

1 A. Correct. Yes.

2 Q. That testing did not identify any  
3 pathogenic variants known to be associated with a  
4 risk -- a genetic risk of renal cell carcinoma;  
5 right?

6 A. An inherited or heritable risk,  
7 correct.

8 Q. The variant of uncertain significance  
9 in the PMS2 gene was given a new variant  
10 classification being one of likely benign;  
11 correct?

12 A. Yes.

13 Q. And the variant of uncertain  
14 significance in the SMARCA4 gene was also given a  
15 new variant classification being one of likely  
16 benign; right?

17 A. Correct. Both of those were updated  
18 as the -- you can see it as the record moves  
19 forward. I believe the most recent -- in both  
20 cases, the most recent reports they are likely  
21 benign.

22 Q. In other words, you, Dr. Allen,  
23 considered these genetic testing results to be  
24 negative; right?

25 A. For an inherited or heritable risk of

1 renal cell carcinoma, correct.

2 Q. In your report, you refer to these  
3 genetic test results as negative; right?

4 A. Correct.

5 Q. Where does that definition of  
6 negative come from?

7 A. Throughout the reports in  
8 interpreting this, the definition of negative is  
9 how I interpret these -- these reports. So in  
10 looking at the genetic results, the genes that  
11 were tested because those genes that were tested,  
12 there were only two variants found, both of those  
13 are likely benign.

14 So, in my opinion, those are --  
15 they're negative for the -- for renal cell  
16 carcinoma risk. I'm not sure if I described how  
17 I defined negative well enough for you.

18 Q. When Invitae describes negative  
19 findings, they are referring to the 30 genes  
20 tested for variants; right?

21 A. Yes. Correct.

22 Q. And that's different than concluding  
23 there's no genetic disorder; right?

24 A. That is different -- so the -- so  
25 yes. The Invitae results are different than

1 concluding there is no risk.

2 I'm sorry. Can you rephrase your  
3 question for me?

4 Q. So --

5 A. My apologies.

6 Q. That's fine. I'm going to restate  
7 the previous two questions.

8 A. Sure. Please.

9 Q. When Invitae describes the negative  
10 findings, they're referring to the 30 genes  
11 tested for variants in Ms. Tukes's case; right?

12 A. Correct.

13 Q. And that is different than concluding  
14 there is no genetic disorder; right?

15 A. Correct.

16 Q. Would you agree that the results of a  
17 genetic diagnostic test is not a diagnosis  
18 itself?

19 A. Correct.

20 Q. The diagnostic test results are just  
21 one of many aspects used by the health care  
22 provider to help with a diagnosis and treatment  
23 plan; right?

24 A. Correct.

25 Q. Would you agree that diagnostic

1 testing results should be interpreted within the  
2 context of additional laboratory results, family  
3 history, and clinical findings?

4 A. Yes.

5 Q. That interpretation would generally  
6 be conducted by a health care provider such as a  
7 genetic counselor; right?

8 A. It's usually a team. A genetic  
9 counselor. There's usually a medical doctor as  
10 well that would oversee that. And then depending  
11 on the condition, you would have an oncologist,  
12 you would have a -- sometimes a general  
13 practitioner. It's a team of folks that would be  
14 involved.

15 Q. Would you agree that a genetic  
16 counselor is one of the individuals who should be  
17 interpreting the genetic test returned by  
18 Invitae?

19 A. They can, yes.

20 Q. Would you agree that even where no  
21 reportable genetic variants are identified by a  
22 30-gene diagnostic test, a patient may still be  
23 at risk for hereditary renal cell carcinoma based  
24 on other factors?

25 A. It depends. So that is where this

1 is -- this is a little more nuanced. In this  
2 case, the panel from Invitae contained, in my  
3 opinion, most of the known genes that I am aware  
4 of or were able to find related to renal cell  
5 carcinoma that have been validated by the  
6 literature in the field.

7 So, in this case, this 30-panel  
8 gene -- or this 30-gene panel is -- is as  
9 comprehensive as I can -- as I can imagine it  
10 could be. That's in part I believe why both in  
11 my opinion and in the opinion of the genetic  
12 counselors here and even -- I believe in  
13 Dr. Vance's statement that the comment is -- how  
14 is it worded here?

15 So the comment is that -- so this is  
16 in your Exhibit Number 4, the comment from the  
17 genetic counselor here is that --

18 MR. ROBERTS: Explain what you're  
19 looking at.

20 THE WITNESS: Sorry. Page 8 of  
21 Exhibit 4. The letter to Mrs. Tukes dated  
22 November 26, 2018.

23 MR. ROBERTS: From whom?

24 THE WITNESS: From Katie Garabini and  
25 James Evans. So this would be the genetic

1 counselor and the medical geneticist, so  
2 the M.D. Ph.D.

3 BY MR. CARPENITO:

4 Q. Just for purposes of the record, this  
5 is --

6 A. Page 8.

7 Q. -- Bates range 01553\_Tukes\_ending in  
8 441.

9 A. Okay. Correct.

10 For example, in this letter, since  
11 the current test is not perfect, it's possible  
12 there may be a mutation that current testing  
13 cannot detect, but the chance is small.

14 So I would agree with that statement.

15 Q. And what statement are you agreeing  
16 with? The statement that you just read from the  
17 letter?

18 A. Yes. Yeah.

19 Q. And we'll turn to that letter in a  
20 little bit.

21 A. Sure. So I believe to answer your  
22 question, the panel is the data that we have. I  
23 feel that it's as comprehensive as possible. And  
24 based on no additional variants being found, I  
25 believe that while it's possible there could be

1 other mutations, I don't think it's probable to  
2 assume that.

3 I believe also Dr. Vance had a  
4 similar statement in her report as well?

5 Q. Could a patient still be at risk for  
6 renal cell carcinoma based on family history?

7 A. It's possible. But the family  
8 history would have to also include things like  
9 environmental factors. So, for example,  
10 household living together. So family history can  
11 encompass lots of things, not just genetics. So  
12 it's genetics and environment.

13 Q. And you would agree a patient could  
14 still be at risk for renal cell carcinoma based  
15 on genetic causes that are not evaluated by the  
16 30-gene panel tested in this case; right?

17 A. Again, it's possible, but I think the  
18 likelihood is small.

19 Q. You've reviewed the letters written  
20 by Ms. Katie Garbarini in this case; right?

21 A. To the extent that they're included  
22 in this report, yes.

23 Q. And one of them is on Bates range 441  
24 which you just referenced a moment ago. You  
25 understand that Ms. Garbarini is a genetics

1 counselor; right?

2 A. Correct. This is also -- so there's  
3 also the note that this is James Evans as well.  
4 So I'm not sure who is related to -- it's  
5 cosigned by both.

6 Q. Understood.

7 A. One appears to be a genetic  
8 counselor. One appears to be a medical  
9 geneticist. So one's an M.D. and the other is  
10 CGC, certified genetic counselor.

11 Q. Would you agree that Ms. Garbarini is  
12 one of the medical professionals who advises  
13 Ms. Tukes's course of agreement based on  
14 hereditary or familial cancer syndrome?

15 A. I can't say that she's advising or  
16 providing medical advice. I believe the medical  
17 advice would likely come from Dr. Evans. The  
18 genetic counselor, to the best of my knowledge,  
19 typically helps the patient understand and  
20 interpret the genetics. I'm not sure what role  
21 she plays in recommending treatments.

22 Q. So you just stated that Ms. Garbarini  
23 interprets the genetics; right?

24 A. Yeah. I believe she interprets the  
25 genetic testing.

1 Q. Did the genetic counselor, Ms. Katie  
2 Garbarini, characterize the results as negative?

3 A. I'm not sure if she used that  
4 language. She states that testing did not reveal  
5 a known pathogenic mutation in any of these  
6 genes. And that's bolded in the letter you're  
7 referring to.

8 Q. And, as you pointed out earlier,  
9 Ms. Garbarini testified -- excuse me. She did  
10 not testify to this. This is in her letter.

11 A. I was going to say --

12 Q. Bates range 441. Since the current  
13 test is not perfect, it is possible there may be  
14 a mutation the current testing cannot detect, but  
15 that chance is small; right?

16 A. Correct.

17 Q. Are you aware that Ms. Garbarini gave  
18 deposition testimony in this case?

19 A. I'm not, no.

20 Q. Did you -- is it safe to assume then  
21 you did not review that deposition transcript?

22 A. I did not, no.

23 Q. Dr. Allen, you would agree that there  
24 are certainly limitations associated with genetic  
25 testing; right?

1 A. Yes.

2 Q. You'd agree that Ms. Garbarini  
3 recommended that Ms. Tukes remain in contact with  
4 UNC's cancer genetics department annually in case  
5 additional testing options became available;  
6 right?

7 A. I didn't remember seeing annual. I  
8 don't doubt it, but I don't remember seeing  
9 annual. I believe I certainly remember seeing  
10 follow-up recommended every eight to ten years  
11 mentioned, which I think is typical for genetic  
12 testing. I'm not sure where I saw any of this,  
13 but I believe I remember reading that in this  
14 report.

15 Q. Would you turn to Bates range --

16 A. When you're saying Bates range, is  
17 that the numbers in the very bottom?

18 Q. That's correct. Turn to Bates range  
19 480, please.

20 A. 480.

21 Q. And do you see just above the Bates  
22 Number there's a page number, and it lists  
23 page 47?

24 A. Correct. Yes.

25 Q. If you look at that last sentence

1 down there at the bottom. It reads, "We  
2 encourage Ms. Tukes to remain in contact with  
3 cancer genetics annually so that we can  
4 continuously update the family history and inform  
5 her of any changes in cancer genetics and testing  
6 that may be of benefit for this family."

7 Did I read that correctly?

8 A. You did read that correctly.

9 Q. And if you turn to the next page,  
10 Bates range 481, do you see Ms. Katie Garbarini  
11 signing off on this up at the top?

12 A. I do, yes.

13 Q. Okay. Do you have any reason to  
14 question that recommendation for Ms. Katie  
15 Garbarini?

16 A. I do not, no.

17 Q. You'd agree that Ms. Garbarini also  
18 recommended screening for Ms. Tukes's children;  
19 right?

20 A. I did not see that in the report.

21 Q. Okay. If you'll turn to Bates  
22 range --

23 A. I don't remember seeing it.

24 Q. -- 441. And that's the letter we  
25 were looking at earlier.

1 A. Okay.

2 Q. You let me know when you're there.

3 A. I'm there. Sorry.

4 Q. If you look down at the paragraph  
5 beginning with "cancer screening," it is the  
6 third sentence starting with "We strongly  
7 encourage you to stay in contact with us over the  
8 next few years so that we can plan for baseline  
9 renal imaging in your children. It is possible  
10 that your children are still at an increased  
11 chance to develop renal cancer because of your  
12 history."

13 I read that correctly, didn't I?

14 A. You did. Correct.

15 Q. Do you have any reason to question  
16 that recommendation?

17 A. I do not, no.

18 Q. You would agree that a negative  
19 testing result in the Invitae test does not  
20 guarantee that Ms. Tukes has no pathogenic  
21 variants at all; right?

22 A. So, again, I believe that -- it's  
23 possible, but in my opinion I think it's  
24 unlikely.

25 Q. In other words, Ms. Tukes could have

1 a genetic predisposition that's not detectable by  
2 current technology; right?

3 A. Again, it's possible, but that's just  
4 speculating.

5 Q. And that's because the Invitae test  
6 does not cover all possible variants and all  
7 possible genes; right?

8 A. The Invitae test covers the variants  
9 that are best described in the literature as  
10 being related to heritable renal cell carcinoma.  
11 There may be variants. There may be additional  
12 variants that are currently unknown to science.  
13 But, again, that's just speculating. We're stuck  
14 with the data that we have at the moment, which  
15 shows that in the genes most commonly associated  
16 renal cell carcinoma in the regions of those  
17 genes that are most associated with renal cell  
18 carcinoma, there are no mutations -- or there are  
19 no mutations beyond the two in PMS2 and SMARCA4.

20 Q. So you would agree that the current  
21 science has not identified all of the variants  
22 that could be associated with the genetic risk of  
23 renal cell carcinoma; right?

24 MR. ROBERTS: Objection.

25 THE WITNESS: And I can't agree to

1           that. We don't know. We may have  
2           identified all of the -- all of the  
3           variants. In all likelihood based on the  
4           science of today, we've identified --  
5           what's covered in the Invitae test are the  
6           ones that are currently known to be  
7           causative for or associated with heritable  
8           renal cell carcinoma. I would refer back  
9           to it's possible but not probable.

10       BY MR. CARPENITO:

11           Q.     The genetic testing technology has  
12           changed over the last few years; right?

13           A.     Yes.

14           Q.     And --

15           A.     It's -- however, it's all -- while  
16           it's changed, it's just gotten higher throughput,  
17           let's say. But, yes, the genetic testing  
18           technology has changed over the last 25 to  
19           30 years.

20                     The basic technology for all of the  
21           techniques, though, are based on some of the  
22           similar -- same principles. They've just evolved  
23           again to be higher throughput in most cases.

24           Q.     Let's turn to your initial report,  
25           which is Exhibit 1.

1 A. Okay.

2 Q. And turn to page --

3 A. Sorry. Let me get the UNC report put  
4 back together. You said my original report.

5 Q. Yes, sir. That's correct.

6 Turn to page 23, please.

7 A. Okay.

8 Q. One of your opinions in your initial  
9 report at Exhibit 1 falls on page 23, and it  
10 states "Thus, it is more likely than not that the  
11 patients are cc'd. It's not directly associated  
12 with an inherited or congenital genetic  
13 mutation"; right?

14 A. Correct. Yes.

15 Q. But you would agree that some of the  
16 clinical features of Ms. Tukes's disease are  
17 consistent with an inherited nature; right?

18 A. So in reviewing the records related  
19 to this, Mrs. Tukes' renal cell carcinoma  
20 occurred at a relatively early age, and it's  
21 bilateral. Multifocal. So my assumption is that  
22 upon seeing this, that was part of the reason why  
23 the UNC team ordered the genetic testing.  
24 Because those features or presentations of the  
25 disease are consistent with an inherited form of

1 the disease. I believe also Mrs. Tukes' mother  
2 had cancer as well.

3 Q. Are you familiar with the NCCN  
4 guidelines?

5 A. I am. Not -- not as familiar as  
6 Dr. Vance, I would say, but based on Dr. Vance's  
7 report, I did review the guidelines.

8 Q. Are you aware that the NCCN  
9 guidelines are commonly used by physicians in  
10 treating cancer?

11 A. I am, yes.

12 Q. And are you aware that the NCCN  
13 guidelines are commonly used by physicians to  
14 treat renal cell carcinoma, including hereditary  
15 renal cell carcinoma?

16 A. Yes.

17 Q. Are you aware that the NCCN  
18 guidelines allow for a diagnosis of hereditary  
19 renal cell carcinoma syndrome based on clinical  
20 phenotype alone, even in the absence of an  
21 identified pathogenic variant?

22 A. Yes. There are guide -- the  
23 guidelines do have a checklist of features that  
24 if there's not an inherited or if there's not a  
25 mutation in a known gene related to renal cell

1 carcinoma, then the second level of those  
2 guidelines are based on clinical presentation.

3 Q. And I believe that you were touching  
4 on this earlier, but you would agree that  
5 Ms. Tukes's bilateral cancer clinical feature  
6 consistent with an inherited nature; right?

7 A. It can be. There are lots of other  
8 reasons why you can have bilateral kidney cancer  
9 or bilateral renal cell carcinoma. It can be due  
10 to -- it can be due to metastasis. So you can  
11 have metastases that end up in the kidney. Also,  
12 again, in the context of carcinogen exposure,  
13 bilateral and multifocal tumors are common. So  
14 it doesn't necessarily mean that it's due to  
15 inherited -- an inherited factor.

16 Q. I'm going to introduce exhibit --  
17 what will be marked as Exhibit 5.

18 A. 5. Sorry. My bad.

19 (Allen Exhibit 5 marked for  
20 identification.)

21 A. Are you done with the one for --

22 Q. For now. We'll go back to it.

23 A. Okay.

24 Q. Dr. Allen, I've handed you what's  
25 been marked as Exhibit 5. This is a copy of the

1 NCCN Clinical Practice Guidelines in Oncology as  
2 they relate to kidney cancer.

3 For the record, I have put a  
4 paperclip on the page that I'll ask Dr. Allen to  
5 turn to because these pages are not numbered.

6 A. Okay.

7 Q. So if you will grab Exhibit 5, which  
8 is the NCCN guidelines.

9 A. One second. I want to see if I  
10 reviewed this particular set of guidelines, as  
11 they change over time.

12 Q. And these are Bates stamped beginning  
13 Vance\_USA Bates ending in 83 through Vance\_USA  
14 Bates ending in 174.

15 A. The page that's paperclipped, you  
16 said?

17 Q. Yes, sir.

18 A. I'm assuming you're referring to the  
19 table here.

20 Q. That is correct.

21 A. Okay.

22 Q. If you see at the top there it reads  
23 "NCCN guidelines version 3.2025 hereditary renal  
24 cell carcinoma." Do you see that?

25 A. I do.

1 Q. And down below you see that table,  
2 which I believe you were referencing earlier; is  
3 that right?

4 A. Yes. I believe I recognize this  
5 table from Dr. Vance's report.

6 Q. And you would agree that Ms. Tukes  
7 was diagnosed at age 46; right?

8 A. I can't remember exactly, but it was  
9 around age 45 or 46, I thought.

10 Q. Would you agree that Ms. Tukes had an  
11 early age of diagnosis?

12 A. She did, yes. Relatively.

13 Q. And you agree that Ms. Tukes's cancer  
14 presentation was bilateral and multifocal?

15 A. Yes.

16 Q. And would you agree that Ms. Tukes's  
17 mother, as you stated earlier, had cancer?

18 A. She did, yes.

19 Q. Is it your position that all of these  
20 clinical features suggestive of hereditary renal  
21 cell carcinoma should be disregarded if no  
22 pathogenic mutation is found?

23 A. No, that's not my position.

24 Q. Is it your position that the genetic  
25 testing results in Ms. Tukes's case should be

1 given more weight than her clinical features?

2 A. In Ms. Tukes's case, perhaps. The  
3 reason why I say perhaps is because in these  
4 guidelines, there's no reference to carcinogen  
5 exposure. Nowhere in this report does the word  
6 "carcinogen" appear.

7 And so in the case of Mrs. Tukes,  
8 these are typical -- these would be the  
9 guidelines used to diagnose renal cell carcinoma  
10 but not necessarily to determine the causation or  
11 any underlying reasons for the development of the  
12 renal cell carcinoma.

13 So without considering carcinogen  
14 exposure, then carcinogen exposure can lead to  
15 early diagnosis. It can lead to multifocal  
16 bilateral disease. And so both of those elements  
17 in this diagnostic table are then no longer  
18 valid.

19 Q. Are there any clinical guidelines you  
20 relied on in weighing the test results against  
21 Ms. Tukes's clinical features?

22 A. No.

23 Q. Does Invitae recommend that clinical  
24 features be disregarded in the interpretation of  
25 genetic test results?

1           A.     I don't know if that appears in any  
2     of the reports that I'm aware of.  So I'm not  
3     sure.

4           Q.     Does the or do the NCCN guidelines  
5     recommend that clinical features be disregarded  
6     in the interpretation of genetic testing results?

7           A.     They do not that I'm aware of.

8           Q.     Do you cite in your report any  
9     clinical guidance that allows a genetic test to  
10    outweigh clinical phenotype?

11          A.     I do not, no.

12          Q.     Did Ms. Garbarini, the genetic  
13    counselor in Ms. Tukes's case, ever indicate that  
14    clinical phenotype should be ignored?

15          A.     She does not, no.

16          Q.     Would you agree that determining  
17    whether a patient has a hereditary cancer  
18    syndrome including renal cell carcinoma requires  
19    some clinical judgment?

20          A.     Yes.

21          Q.     Would you agree that determining  
22    whether a patient has a hereditary cancer  
23    syndrome, including hereditary renal cell  
24    carcinoma, requires integration of factors beyond  
25    just genetic test results?

1 A. Yes.

2 Q. I'm going to introduce what will be  
3 marked as Exhibit 6.

4 (Allen Exhibit 6 marked for  
5 identification.)

6 BY MR. CARPENITO:

7 Q. Dr. Allen, I've handed you what's  
8 been marked as Exhibit 6. This is a copy of  
9 Ms. Katie Garbarini's deposition transcript.

10 Do you see on that first page there  
11 the caption says Jacqueline Tukes, plaintiff?  
12 Top left.

13 A. Oh, yes, I see it.

14 Q. And versus United States of America,  
15 defendant. Do you see that?

16 A. I do.

17 Q. And do you see just below that is  
18 listed Mary Katherine Garbarini, MS, CGC?

19 A. I see that.

20 Q. And it bears the date Thursday,  
21 June 20, 2024; right?

22 A. Correct.

23 Q. I'm going to ask that you turn to  
24 page 83. Let me know when you're there?

25 A. I'm on page 83.

1           Q.     And if you look at -- beginning at  
2     line 14, Ms. Garbarini testifies "The incidence  
3     of the two cancers and the two renal cancers is  
4     very unusual, and the fact that the second cancer  
5     diagnosis involved, I believe, three separate  
6     tumors in the left kidney and given the young age  
7     of diagnosis as well, that's plenty of reason to  
8     do a genetic test for her in addition to having  
9     some family history of renal cancer."

10                    Did I read that correctly?

11           A.     You did.   Correct.

12           Q.     You would describe those features  
13     highlighted in that portion of Ms. Garbarini's  
14     testimony as clinical findings that are relevant  
15     to interpreting genetic test results; right?

16           A.     I do not.   Actually, I read this as  
17     justification for conducting the genetic testing.  
18     Again, that's without reading the other 82 pages  
19     of this.

20           Q.     On page 19 of your initial report,  
21     that's Exhibit 1.  Let me know when you're there.

22           A.     Sure.   Okay.

23           Q.     You acknowledge a disclaimer  
24     contained in the Invitae report; right?

25           A.     I'm not sure I know where you are.

1 Q. In the second paragraph on page 19.

2 A. Oh, I see, yes.

3 Q. And that part of your report reads,  
4 "The report also has a disclaimer attached that  
5 states that DNA studies do not constitute a  
6 definitive test for the selected conditions in  
7 all individuals. It should be realized that  
8 there are possible sources of error. Errors can  
9 result from trace contamination. Rare technical  
10 errors, rare genetic variants that interfere with  
11 the analysis. Recent scientific developments and  
12 alternative classification systems. The test  
13 should be one of many aspects used by the health  
14 care provider to help with a diagnosis and  
15 treatment plan but is not a diagnosis itself."

16 Did I read that correctly?

17 A. You did. Correct.

18 Q. You would agree that the testing lab  
19 itself recognizes that DNA studies like the one  
20 conducted in Mrs. Tukes's case have possible  
21 limitations?

22 A. Correct. Yes.

23 Q. You would agree that the testing lab  
24 itself recognizes that DNA studies like the one  
25 conducted in Ms. Tukes's case have possible

1 source of error?

2 A. Correct. Yes. And I list them as  
3 you read.

4 Q. Dr. Allen, I'm at a good place to  
5 take a break. Why don't we break for five or  
6 ten minutes and we'll come back.

7 A. Okay. Sure.

8 THE VIDEOGRAPHER: Off record at  
9 10:26 a.m.

10 (Recess taken from 10:26 a.m. until 10:46 a.m.)

11 THE VIDEOGRAPHER: On record at  
12 10:46 a.m.

13 BY MR. CARPENITO:

14 Q. Dr. Allen, earlier we were discussing  
15 the 30-gene panel in Ms. Tukes's case, do you  
16 remember that?

17 A. I do, yes.

18 Q. Is it your opinion that 30 genes  
19 tested in Ms. Tukes's case are likely the only  
20 genes could be associated with renal cell  
21 carcinoma?

22 A. They are the best characterized and  
23 validated genes that we know of to date.

24 Q. Is it your opinion that it's unlikely  
25 that we will discover additional genes that could

1 be associated with hereditary renal cell  
2 carcinoma?

3 A. Again, it's possible, but not  
4 probable.

5 Q. Is the scientific community confident  
6 that these 30 genes are the only genes that could  
7 be associated with the hereditary renal cell  
8 carcinoma risk?

9 A. To the best of my knowledge, the  
10 30-panel gene that's included is inclusive of all  
11 the genes known to date that are associated with  
12 hereditary renal cell carcinoma.

13 Q. Is the science exhaustive?

14 A. Can you rephrase that?

15 Q. Is science always evolving?

16 A. It is always evolving, yes.

17 Q. Okay. I want to turn back to another  
18 point discussed earlier, which was the annual  
19 follow-up recommendation from Ms. Katie  
20 Garbarini. Do you remember that?

21 A. I do.

22 Q. Is that recommendation for an annual  
23 follow-up unusual in your opinion?

24 A. I wouldn't think so, no.

25 Q. Okay. If you'll turn to page 24 of

1 Exhibit 1. Page 24 of your initial report. Let  
2 me know when you're there, please.

3 A. On page 24?

4 Q. Yes, sir.

5 A. I'm there.

6 Q. Okay. The bottom of that page,  
7 there's a sentence that starts with "Thus, while  
8 it is not likely that the PMS2 mutation observed  
9 and the patient directly contributes to RCC and  
10 is likely benign in this context, there is  
11 compelling evidence that indicates dosage  
12 pathogenicity in my opinion based on the function  
13 of PMS2 as a tumor suppressor, the predicted loss  
14 of function mutation observed in the patient is  
15 sufficient evidence for dosage pathogenicity  
16 haploinsufficiency score in the ClinVar database  
17 and the data related to carcinogen exposure in  
18 heterozygous animals models, it is as likely as  
19 not that this mutation results in insufficient  
20 DNA mismatch repair in the patient."

21 I read that directly, didn't I?

22 A. You did. Correct.

23 Q. And that is one of the opinions --  
24 one of your opinions in this case; right?

25 A. It is, yes.

1 Q. You agree that the Invitae results,  
2 as they relate to the PMS2 gene, are likely  
3 benign; right?

4 A. Correct. In the context of a  
5 hereditary association with renal cell carcinoma.

6 Q. You also agree that the PMS2 variant  
7 is not likely to directly contribute to renal  
8 cell carcinoma; right?

9 A. Correct.

10 Q. Despite that, you offer an opinion  
11 that the PMS2 variant could still result in  
12 insufficient DNA mismatch repair; right?

13 A. Correct.

14 Q. Part of that opinion relies on your  
15 assumption that the variant in the PMS2 gene is  
16 deleterious; right?

17 A. It's not just my assumption. There  
18 are six different reports related to this variant  
19 being a deletion mutation or resulting in a  
20 deletion mutation. Five of the six are in the  
21 ClinVar record. One report is actually in the  
22 UNC report related to the Invitae testing which  
23 used the PMS2 specific algorithm to predict that  
24 this would be a deletion mutation.

25 Q. And you further assume that the

1 variant causes a loss of function in the PMS2  
2 gene; right?

3 A. That's what the algorithms would  
4 predict, but the variant results in a loss of  
5 function. So deleterious -- so we're saying a  
6 deletion mutation. It would be a loss of  
7 function mutation. Again, that would be based on  
8 the six different algorithms and reports related  
9 to that variant.

10 Q. Are those algorithms related to the  
11 specific variant or the PMS2 gene?

12 A. One of the algorithms appears -- the  
13 one run by Invitae or LabCorp -- so I guess when  
14 I refer to it, I may refer to it as LabCorp, but  
15 I mean the Invitae. So I use though  
16 interchangeably.

17 One of the variants or one of the  
18 programs or algorithms used by LabCorp, which is  
19 referred to in the report, was stated to be PMS2  
20 specific. So it's specifically associated with  
21 the PMS2 gene.

22 Q. If you will turn to Bates Number 459  
23 in exhibit -- give me one second.

24 A. Sure.

25 Q. If you will pull the medical records,

1 the UNC medical records. I believe it's  
2 Exhibit 4.

3 A. Yes, marked as 4.

4 Q. My apologies. Yeah.

5 A. So I'm shuffling papers around, if  
6 you don't mind, if we refer back to it, just make  
7 sure you're letting me know which one. I'm  
8 closing them and opening them up.

9 Q. Of course. A moment ago you  
10 testified that one of the algorithms specifically  
11 related to the PMS2 gene; right?

12 A. Correct.

13 Q. What did the other five algorithms  
14 relate to?

15 A. The other five algorithms -- so it  
16 was more than just five algorithms. So in the  
17 ClinVar -- so ClinVar is a database that  
18 associated -- that's specific to this mutation.  
19 ClinVar has a record for 13 -- there are 13  
20 different records associated with the ClinVar  
21 reference for this gene.

22 In those records, for example,  
23 LabCorp has a record related to this mutation.  
24 And in that case for the LabCorp record in the  
25 comment section under in ClinVar it states that

1 five of five algorithms predicted this would be a  
2 deletion mutation.

3 A second reference in the ClinVar  
4 database shows that gene DX, which is another  
5 genetic testing company, also has a notation  
6 related to -- in the comment section related to  
7 an algorithm showing that this is a loss of  
8 function mutation. There's a third record, I  
9 believe this is from a Chinese group. This  
10 record was actually flagged, but that shows that  
11 this is a deletion or pathogenic mutation.

12 Then I can't remember the other two  
13 records off the top of my head. But both of  
14 those are in the ClinVar database. So, again,  
15 these are groups of algorithms that have  
16 predicted that this is a loss of function. The  
17 only reference to a specific one is this here --  
18 the one that's listed here in this data -- in the  
19 UNC record for this specific one. And this one  
20 refers back to a science study. It was a paper  
21 in the journal human molecular genetics that  
22 actually outlines -- provides an algorithm to  
23 evaluate -- specifically evaluate PMS2 and other  
24 genes related to the complex that PMS2 makes.

25 Q. In other words, five of the six

1 algorithms that you referenced don't relate to  
2 the specific variant identified in Ms. Tukes's  
3 PMS2 gene?

4 MR. ROBERTS: Objection.

5 THE WITNESS: Not correct. They all  
6 relate to the specific variant.

7 BY MR. CARPENITO:

8 Q. So the five algorithms that you just  
9 referenced are studying the same variant that was  
10 found in Ms. Tukes?

11 A. Correct. They've all predicted this  
12 is a deletion or loss of function mutation.

13 Q. If you'll look at Bates Number 459.

14 A. Okay.

15 Q. In Exhibit 4.

16 A. Oh, gosh, all right. I need glasses.

17 Q. And if you look under the PMS2  
18 variant detail section, it's about halfway down  
19 the page, the fourth bullet point down there, it  
20 discusses an algorithm developed specifically for  
21 the PMS2 gene; right?

22 A. That's correct.

23 Q. And is that the algorithms that you  
24 were referencing when you were discussing the  
25 algorithm utilized by Invitae earlier?

1 A. It was, yes.

2 Q. Okay. That statement was included in  
3 the initial version of the report at the time  
4 when Invitae classified the PMS2 variant as a  
5 variant of uncertain significance; right?

6 A. To the best of my knowledge and  
7 timeline, that's correct, yes.

8 Q. The Invitae consider anything in  
9 addition to the algorithm in determining the  
10 variant to be one of uncertain significance?

11 A. That's unknown because in the ClinVar  
12 database LabCorp has a -- has a notation. So  
13 ClinVar has a notation from LabCorp. In the  
14 LabCorp -- if my recollection is correct, I  
15 believe the LabCorp notation for this comment  
16 section refers to five of five algorithms  
17 predicting this to be a deleterious mutation.

18 Q. Since 2018, has there been any  
19 additional evidence looking at whether this PMS2  
20 variant is deleterious?

21 A. That LabCorp reference that I'm  
22 referring to was from January of 2025. So I'm  
23 going to say yes. I believe all of the -- I  
24 believe all five of the notations in the ClinVar  
25 record for this mutation, all five of them I

1 noticed between 2021 and today or 2021 and  
2 January of 2025. I can be more specific if I had  
3 it in front of me.

4 Q. If you look at that same portion of  
5 that same algorithm that's referenced --

6 A. Okay.

7 Q. -- on Bates range 459 -- excuse me.  
8 Let's turn to page Bates 435. I'm sorry.

9 A. Bates -- so same document, 435.

10 Q. That's correct.

11 A. I'll get you guys nomenclature here  
12 in a minute. 435.

13 Q. This is a letter from UNC Department  
14 of Genetics, would you agree?

15 A. This is a letter from Julianne  
16 O'Daniel and Jonathan Berg.

17 Q. That's right. And it is signed, as  
18 you stated, by Ms. O'Daniel, who is a certified  
19 genetic counselor; right?

20 A. Yes.

21 Q. And Mr. Berg, Jonathan Berg, is a  
22 medical geneticist; right?

23 A. Correct. Yes.

24 Q. And the purpose of this letter is to  
25 inform Ms. Tukes that SMARCA4 and PMS2 variants

1 have both been reclassified from variants of  
2 uncertain significance to likely benign; right?

3 A. Correct.

4 Q. Can you point me to any part of this  
5 letter where either of these licensed clinical  
6 genetics professionals describe either variant as  
7 likely to be deleterious?

8 A. I can't, but the record that they're  
9 referring to here, the reason why these were  
10 likely classified as likely benign isn't due to  
11 the prediction of this being a likely deleterious  
12 mutation for PMS2 specifically. It's due to the  
13 mutation not being found in -- it being found in  
14 the general population in addition to the study  
15 population. And studies related to pancreatic  
16 cancer, ovarian cancer, and I feel like there was  
17 another disease as well listed there.

18 But the reason why this was  
19 classified as likely benign is because, if you  
20 read in the record for ClinVar, it's because the  
21 variant was found in the control populations  
22 and -- and in the disease populations as well.  
23 So that's why it was likely benign, not because  
24 the mutation was classified as deleterious.

25 And that's important because these

1 are study populations for pancreatic cancer and  
2 for ovarian cancer. Doesn't mean they're not  
3 going to develop renal cell carcinoma or any  
4 other cancer. It just means for the particular  
5 study characteristics, these mutations were  
6 determined to be found in their control  
7 population for those studies.

8 Q. Can you point me to any part of this  
9 letter where either of those clinical genetics  
10 professionals describe either variant as a  
11 predicted loss of function?

12 A. I cannot. But the ClinVar record  
13 that goes with the -- both of these identify  
14 these as loss -- or there's at least one  
15 algorithm related to that in the record for these  
16 mutations which is, I assume, is where they're  
17 getting this information from related to ClinVar  
18 that shows it's at least a loss of function or  
19 deletion mutation.

20 Q. And if you look at the bottom of this  
21 letter, these two medical professionals actually  
22 inform Ms. Tukes that these two variants have  
23 nothing to do with cancer risk. Do you see that  
24 down there?

25 A. I do. Again, this is relating to

1 heritable cancer. So heritable renal cell  
2 carcinoma.

3 Sorry, I have an eyelash in my eye.  
4 Got to dig it out. I'm okay. You haven't  
5 reduced me to tears yet.

6 Oh, God, that's going to be on the  
7 record, too. Great.

8 Q. Were you able to confirm whether the  
9 PMS2 variant in Ms. Tukes was deleterious?

10 A. So in evaluating the mutation itself,  
11 this mutation incurs in exon 14 of the protein.  
12 So using the mapping, so the numbers that are  
13 associated with this -- with the mutation tells  
14 your road map of where this mutation is. This  
15 occurs at exon 14. That's actually a critical --  
16 we're talking about PMS2 at the moment; correct?

17 Q. That's correct.

18 A. So for PMS2, that's a critical  
19 residue critical area for interacting with MLH1.  
20 Basically, it's critical for the two -- for the  
21 multiprotein complex that forms. This  
22 multiprotein complex is critical in finding the  
23 DNA mutations, so mismatch mutations when, for  
24 example, we're exposed to carcinogen. So these  
25 are critical for mismatch repair. When that

1 protein is mutated, I've noted in my report what  
2 the biochemical change is. It changes the  
3 confirmation in charge of the protein making  
4 it -- imagine trying to push two magnets  
5 together. If you've changed it from a positive  
6 to a negative, the two magnets actually can repel  
7 each other rather than come together. Think  
8 about it kind of like that.

9 So this small change can impact the  
10 formation of this structure. This is just based  
11 on me looking at the protein and looking at  
12 the -- at where this mutation actually occurs.  
13 So I think -- I think, at least in my opinion,  
14 that could potentially have a significant change  
15 in how these proteins interact and come together.

16 Q. I appreciate that, Dr. Allen. You  
17 didn't answer my question. My question to you  
18 was whether or not you agree that you did not  
19 confirm that the PMS2 variant in Ms. Tukes was  
20 deleterious?

21 A. Define confirmation. I thought I  
22 just described how I confirmed that --

23 Q. Did you confirm it with any  
24 functional studies?

25 A. No, I did not.

1 Q. Did you confirm it with any clinical  
2 literature?

3 A. Beyond the algorithms that predict?

4 Q. Correct.

5 A. And the mutation and the -- actually  
6 the manuscript -- there's a manuscript cited in  
7 the document here. The PMID code refers to a  
8 peer-reviewed manuscript related to PMS2. That's  
9 the algorithm LabCorp used to predict that's a  
10 deletion mutation.

11 Q. You didn't confirm it with any  
12 patient specific data related to Ms. Tukes, did  
13 you?

14 A. Other than Ms. Tukes having the  
15 mutation.

16 Q. With any other patient specific data?

17 MR. ROBERTS: Objection.

18 THE WITNESS: I don't understand -- I  
19 guess I don't understand the question.  
20 Can you rephrase that?

21 BY MR. CARPENITO:

22 Q. We can move on. Did you confirm that  
23 the PMS2 variant in Ms. Tukes caused a loss of  
24 function?

25 A. Beyond what I've just described to

1 you?

2 Q. Correct.

3 A. So I have not conducted any  
4 functional studies.

5 Q. And as we discussed before, the  
6 original Invitae report explicitly notes that the  
7 clinical significance of the variant remains  
8 uncertain; right?

9 A. Correct.

10 Q. Which was later updated to likely  
11 benign; right?

12 A. Correct. Based on ClinVar record and  
13 I described why the ClinVar record has that as  
14 likely benign.

15 Q. The testing lab, the clinical source  
16 of this result, has not concluded that this  
17 variant causes a loss of function; right?

18 A. They actually state that. Invitae  
19 states this is likely to be a loss of function  
20 due to their algorithm used specific for PMS2.

21 Q. And that's at a time of the original  
22 report when the variant was described as one of  
23 uncertain significance; right?

24 A. It is -- yes, it's in that reports.

25 Q. That algorithm is not cited in the

1 reclassification reports, is it?

2 A. You mean in the -- the letter from --  
3 the letter on your 435?

4 Q. No. In the updated Invitae  
5 reclassification report, I can point you --

6 A. It's in the 2018 report. It's  
7 clearly -- it states that this is likely to be a  
8 deletion mutation.

9 Q. And that's the original Invitae  
10 report?

11 A. Correct.

12 Q. Would you agree with that, I should  
13 ask you first, that the 2018 Invitae report is  
14 the original Invitae report that classified both  
15 of the variants as variants of uncertain  
16 significance?

17 A. That's actually not correct. They  
18 were -- and I can't remember exactly. I think  
19 one was classified as -- oh, you know what, they  
20 then upgraded it to likely benign. Yeah. So,  
21 correct, that was the original report that  
22 identified them as variants of unknown  
23 significance, yes. Correct. It was the likely  
24 benign -- benign comment that was updated as the  
25 reports move forward.

1 Q. In the updated reports, did those --  
2 strike that.

3 In the updated Invitae report that  
4 reclassified the PMS2 variant to one as likely  
5 benign, Invitae, in that report, did not conclude  
6 that the variant caused a loss of function;  
7 right?

8 A. Can you provide me or show me in this  
9 what you're referring to as an updated Invitae  
10 report? I'm not entirely sure I know what you're  
11 referring to in terms of an Invitae report.

12 Q. I'd be happy to. Just give me one  
13 second.

14 A. Sure.

15 Q. If you would turn to Bates Number  
16 463, please, of Exhibit 4.

17 A. 463. Okay.

18 Q. If you look at the top right, you see  
19 the report date of December 6, 2022?

20 A. I do.

21 Q. Do you see the PMS2 gene listed down  
22 there about halfway through the page?

23 A. Yes.

24 Q. And it lists to the right of that  
25 "new variant classification likely benign"?

1 A. Correct.

2 Q. My question to you is the algorithm  
3 referenced in the original report is not  
4 discussed in the updated report, is it?

5 A. Correct. But the other five  
6 notations in the ClinVar database do encompass  
7 this. I believe two of those were prior to this  
8 date. Again, I don't have it in front of me.  
9 But I believe two of the records are from 2021.  
10 And so that likely drove this updated report  
11 would be my suspicion. They were around this  
12 time the records were entered.

13 Also, I do see here the negative  
14 result for the testing. So that may be where I  
15 got my language you asked about an hour ago.

16 I believe the most recent entry is  
17 the LabCorp entry from January of 2025 which  
18 lists five of five algorithms that predicted this  
19 would be deleterious.

20 Q. Did you perform any functional study  
21 showing that the variant impairs the PMS2  
22 protein?

23 A. Beyond mapping where this mutation  
24 would occur and -- no, I did not.

25 Mapping, I mean, just mentally

1 walking through where this mutation would occur  
2 in the protein and knowing its functional  
3 domains.

4 Q. Do you cite any published functional  
5 study showing that the variant found in Ms. Tukes  
6 impairs the PMS2 protein?

7 A. So there's an animal study that I do  
8 cite showing that animals that are heterozygous  
9 for the gene are more sensitive to carcinogens.  
10 Here, animals that have one functional copy of  
11 the gene and one nonfunctional copy of the gene  
12 are more sensitive to intestinal cancers  
13 following carcinogen exposure.

14 Q. Are you referring to the Qin study?

15 A. Yes. I believe I am.

16 Q. From the year 2000?

17 A. It is my -- I can tell you --

18 Q. It's cited in your report at page 24?

19 A. That sounds about correct.

20 Yes. So when the mice were exposed  
21 to N-methyl-N-nitrosourea, which is known  
22 carcinogen that causes damage to DNA, animals  
23 were more -- significantly more likely to develop  
24 intestinal tumors. They develop both adenomas  
25 and adenocarcinomas after treatment compared to

1 mice with normal copies of PMS2.

2 Q. Is the variant studied in that study  
3 the same variant identified in Ms. Tukes?

4 A. It's not, no.

5 Q. And you stated that the study  
6 evaluated tumor -- tumor formation in the  
7 intestinal tract; right?

8 A. Correct. Yes.

9 Q. The study does not report any kidney  
10 tumors in those mice; right?

11 A. Correct.

12 Q. And the study involved exposure to  
13 MNU; right?

14 A. Correct.

15 Q. And MNU is a compound not found in  
16 the Camp Lejeune water system; right?

17 A. I have no idea.

18 Q. You're not offering an opinion that  
19 Ms. Tukes was exposed to MNU, are you?

20 A. I am not, no. MNU is a common model  
21 of DNA damage. It's commonly used in the  
22 laboratory to study mismatch repair defects.

23 Q. You don't cite anywhere in your  
24 report any animal studies showing an increase in  
25 kidney cancer risk from PMS2 heterozygosity when

1 exposed to the contaminants alleged to be present  
2 at Camp Lejeune, do you?

3 A. Again, I'm not -- I don't know what  
4 contaminants are being -- are in the Camp Lejeune  
5 case. But, yeah, I don't know.

6 Q. You don't cite human data linking the  
7 variant found in Ms. Tukes to an increased  
8 susceptibility due to exposure to environmental  
9 carcinogens, do you?

10 A. Sorry, can you re -- I don't think I  
11 need you to rephrase it, just state the question.  
12 You caught me daydreaming.

13 Q. You did not cite any human data  
14 linking the PMS2 variant found in Ms. Tukes to  
15 increased cancer susceptibility due to exposure  
16 to environmental carcinogens; right?

17 A. Correct.

18 Q. In your opinion that this variant  
19 results in insufficient DNA mismatch repairs  
20 based on the computational prediction; right?

21 A. No. So the mutations in PMS2 lead to  
22 defects in mismatch repair. So that's a well  
23 characterized function of this protein. So any  
24 loss of function of this protein would -- has  
25 been shown to result in decreased DNA mismatch

1 repair. So the algorithms simply predict that  
2 this would be a deletion mutation. This is a  
3 deletion mutation, then the data in the  
4 literature would support that there's a defect in  
5 DNA mismatch repair. There's no data I can think  
6 of that would counter that.

7 Q. If the assumption in your report that  
8 the PMS2 variant in Ms. Tukes results in a loss  
9 of function is incorrect, then the PMS2 variant  
10 would not likely cause DNA mismatch repair;  
11 right?

12 A. Not -- sorry, it's a double negative,  
13 I believe. So can you restate that?

14 Q. Certainly.

15 A. Yeah.

16 Q. Assume that the PMS2 variant found in  
17 Ms. Tukes does not cause a loss of function?

18 A. Okay.

19 Q. Do you understand that piece?

20 A. I do, yes.

21 Q. Okay. If that is true, then the PMS2  
22 variant found in Ms. Tukes would not likely cause  
23 DNA mismatch repair; is that correct?

24 A. It would likely be a silent mutation.

25 Q. And being a silent mutation, does

1 that mean that it would likely -- not likely  
2 cause DNA mismatch repair?

3 A. DNA mismatch repair would be expected  
4 to not be impacted by the mutation change in  
5 PMS2.

6 Q. If the PMS2 variant does not cause  
7 DNA mismatch repair, then it is not likely to  
8 affect Ms. Tukes's sensitivity to carcinogenic  
9 exposures; right?

10 A. If the mutation in PMS2 causes a  
11 change in DNA mismatch repair, then it would  
12 likely impact Mrs. Tukes' susceptibility to  
13 carcinogens. If it's a silent mutation, it's not  
14 likely to impact.

15 This is a mismatch. So when we --  
16 you originally about an hour ago or now getting  
17 to an hour and a half ago we talked about  
18 different kinds of mutations. Silent missense  
19 and loss -- and deletion. This is a mismatch  
20 mutation meaning that there is a change in the  
21 protein structure. That's clear. I believe  
22 that's in everyone's report.

23 So that tells us that Mrs. Tukes has  
24 a biochemical change in her protein. It is not  
25 the normal protein. So the question that you're

1 asking is that or the -- because this isn't a  
2 normal protein, period. It's not a normal  
3 protein. It's not the protein that most people  
4 have. This is a rare mutation. Because the  
5 protein is not optimal, it is -- it is as likely  
6 as not that this is going to cause a significant  
7 issue with mismatch repair.

8 Q. If you'd do me the favor and turn to  
9 page 24 of Exhibit 1. That's page 24 of your  
10 initial report.

11 A. I apologize. 24?

12 Q. That's right. Well, actually, we're  
13 going to look at the bottom of page 23 and  
14 page 24.

15 A. Okay. Okay. I'm there.

16 Q. If you look at the bottom of page 23  
17 of Exhibit 1, which is your initial report, there  
18 is a discussion regarding the ClinVar database;  
19 right?

20 A. Correct.

21 Q. And you go on to discuss -- discuss  
22 ClinVar's haploinsufficiency score to support  
23 your opinion at least in part regarding this  
24 variant; right?

25 A. Correct.

1 Q. And I assume, is it safe to say, that  
2 you reviewed ClinVar in drafting your report?

3 A. I did, yes. Then I reviewed it again  
4 in drafting the rebuttal to Dr. Vance.

5 Q. I'm going to introduce what's going  
6 to be marked as Exhibit 7.

7 (Allen Exhibit 7 marked for  
8 identification.)

9 BY MR. CARPENITO:

10 Q. Dr. Allen, does this page seem to  
11 reflect some of what you reviewed from ClinVar?

12 A. It does, yes. It looks like it's an  
13 updated copy. I believe I last reviewed this in  
14 April. This is dated from June.

15 Q. If you look towards the bottom of the  
16 page there, there's a haploinsufficiency score  
17 listed for the PMS2 gene; right?

18 A. Correct. Yes.

19 Q. And it lists that there's sufficient  
20 evidence for dosage pathogenicity; right?

21 A. That's correct.

22 Q. And this haploinsufficiency score  
23 reflects a general sensitivity to the PMS2 gene  
24 to dosage changes; right?

25 A. Correct. Yes.

1 Q. And it does not assess the  
2 pathogenicity of the specific variant in return  
3 to Ms. Tukes' genetic testing results, does it?

4 A. Correct. However -- and this is only  
5 a partial record. I'd like to point out you guys  
6 didn't give me a complete record. On the next  
7 page, page 2 of 4, we have the evidence that  
8 supports this under comment. You haven't clicked  
9 the more button. Under comment for this, there  
10 is the rest of the data here that outlines the  
11 algorithms related to the actual algorithms that  
12 are run. Five of the thirteen -- I think there  
13 are thirteen. Again, this is a newer version,  
14 but I believe there are thirteen here. Five of  
15 the thirteen list algorithm data related to the  
16 prediction that this will be a deletion mutation.  
17 So you would need to click on the more button to  
18 get the comments for each of these records.

19 Q. Could a variant still leave a patient  
20 with two functional copies?

21 A. It would be possible for that to  
22 occur. Again, we go back to missense versus  
23 style versus deletion. It is possible for  
24 missense change to not impact the protein -- the  
25 structure of the protein. That could occur if --

1 that's mostly likely the case. Typically the  
2 case is when the change changes if it's a  
3 positive amino acid, that's another positive  
4 amino acid. So if you have a change in polarity,  
5 that's the same. That's not the case here. For  
6 both of these variants, the change changes the  
7 polarity, what's known as hydrophobicity. So  
8 that's how the protein gets structured when it's  
9 in an aqueous environment. So how it kind of  
10 comes together. And so both of the mutations in  
11 this case alter those parameters.

12 What you just described would be  
13 true, but typically we see that in cases where  
14 you have one-to-one changes, where you have a  
15 positive being substituted as a positive or  
16 negative for a negative or neutral to neutral.

17 So -- so, in this case, we have an  
18 actual protein change that would be expected to  
19 alter the chemistry of the protein itself.

20 Q. Heterozygous doesn't mean a single  
21 functional copy; right?

22 A. No, it doesn't. So heterozygous in  
23 this case -- so heterozygous would be one  
24 functional copy and one copy that is altered.  
25 Heterozygosity simply refers to the genetic code.

1 Q. Heterozygosity doesn't assess whether  
2 a specific variant has a pathogenic effect;  
3 right?

4 A. No, it does it by itself. However,  
5 in this case we -- again, point back to the  
6 animal studies where we have data -- functional  
7 data showing that when you are heterozygous for  
8 this mutation, you have a greater susceptibility  
9 to carcinogens.

10 Q. And you aren't asserting that  
11 Ms. Tukes has a whole gene deletion to PMS2;  
12 right?

13 A. She does not. She has a missense  
14 mutation.

15 Q. Dr. Allen, I'm at a good place to  
16 take a break.

17 A. Okay.

18 Q. We can go off the record and figure  
19 out whether we want to take five- to ten-minute  
20 break or break for an early lunch.

21 MR. ROBERTS: Whatever.

22 THE WITNESS: I'm fine to power it on  
23 or breaking or whatever you guys to do.

24 THE VIDEOGRAPHER: Off record at  
25 11:25 a.m.

1 (Lunch recess taken from  
2 11:25 a.m. until 12:40 p.m.)

3 THE VIDEOGRAPHER: On record at  
4 12:40 p.m.

5 BY MR. CARPENITO:

6 Q. Dr. Allen, do you recall that we were  
7 discussing the various algorithms as it related  
8 to the PMS2 gene earlier?

9 A. Yes.

10 Q. Would you agree that those algorithms  
11 are predictive?

12 A. They are, yes.

13 Q. Would you agree that those algorithms  
14 are not functional tests?

15 A. Correct. Yes.

16 Q. Would you agree that those algorithms  
17 are not validated for each variant?

18 A. I can't say that. I'm not sure about  
19 the validation of the algorithms.

20 Q. Is there a known error rate?

21 A. Again, I'm not sure of known error  
22 rates. I would expect that there are some error  
23 rates. It's predictive in nature.

24 Q. Are the algorithms more accurate in  
25 predicting some variants versus others?

1           A.    I can't really answer that because  
2           there are lots of different kinds of algorithms.  
3           In this case, for example, the algorithm related  
4           to PMS2 that -- that LabCorp used is specific for  
5           PMS2 versus other algorithms, such as the ones  
6           for the SMARCA4 are more broad.  SMARCA4, for  
7           example, uses the sift algorithm.  That algorithm  
8           is better at predicting -- I believe that  
9           algorithm is better at predicting the function or  
10          change in genes across different species versus  
11          some of the other algorithms are better at  
12          predicting the effect of a specific gene.  Some  
13          of them are better at predicting than others.  So  
14          it really depends on the algorithm.  And I'm not  
15          sure as to the error rate.  It depends on the  
16          question, the gene of interest, the algorithm  
17          being used.  They're usually used in combination.  
18          So usually get multiple algorithms run for each  
19          variation that you have.

20          Q.    Were the algorithms utilized by  
21          ClinVar as it relates to the PMS2 gene the only  
22          thing ClinVar considered in determining the  
23          variant to be likely benign?

24          A.    No, it wasn't.

25          Q.    Okay.  What would some of that other

1 information have been that ClinVar relied upon?

2 A. Sure. So ClinVar actually -- so in  
3 the ClinVar record, again we're talking about  
4 PMS2 still. So the ClinVar record has several  
5 examples of algorithms that show this is a  
6 deletion mutation. Additional -- and that was  
7 one of the considerations in this being of  
8 unknown significance. But I believe in the  
9 comment section in my understanding of how  
10 ClinVar looks at this, it looks like the decision  
11 to make this benign or of -- and/or of unknown  
12 significance has to do with the mutate --  
13 specific mutation that Mrs. Tukes has. That --  
14 those mutations are -- are in other normal  
15 population or healthy -- I can't say healthy. So  
16 the controlled populations for the studies where  
17 it was compared or evaluated.

18 So, in this case, I believe it was  
19 evaluated -- you know what, it just dawned -- I  
20 think it was lynch syndrome, ovarian cancer, and  
21 pancreatic cancer. So I think those were the  
22 populations where this mutation has been found  
23 and compared against healthy or normal  
24 populations for those diseases.

25 Q. That other information, it sounds

1       like -- were you referring to other studies?

2               A.     That's in the ClinVar record.    What  
3     I've just described to you is part of the ClinVar  
4     record.   ClinVar -- so ClinVar itself is more  
5     likely a repository where people can upload their  
6     records of interest.

7               Q.     So in addition to the algorithms,  
8     there are -- is it fair to say there are other  
9     studies that ClinVar considered in its  
10    determination as it relates to PMS2 gene?

11              A.     Yes.

12              Q.     Okay.   Did you review that  
13    information?

14              A.     I did not outside of what's in the  
15    ClinVar record.   With the exception of the PMS2  
16    peer-reviewed paper from that I cited in my  
17    review.   I can't remember if that was part of the  
18    LabCorp record for PMS2 or if it was separate.

19              Q.     Is it your opinion that Ms. Tukes's  
20    loss of function in the protein that is coded by  
21    the PMS2 gene results in 100 percent loss of  
22    function in that protein?

23              A.     So -- so no.   It would result in --  
24    based on this being heterozygous, she would have  
25    roughly a 50 percent loss of function.   That can

1 vary a little bit. But it's going to be about --  
2 you can consider it about a 50 percent loss of  
3 function.

4 Q. Will you turn to page 25 of Exhibit 1  
5 which is your initial report?

6 A. Okay. 25, you said?

7 Q. Yes, sir.

8 A. Okay. Turned right to it.

9 Q. The bottom of that page you state,  
10 "Based on the function of SMARCA4," in  
11 parenthesis "BRG1 in the experimental data  
12 related to heterozygous loss of BRG1 if the  
13 mutation carried by the patient has a deleterious  
14 effect on the protein. And it is as likely as  
15 not that this mutation results in increased  
16 cancer development following exposure to  
17 carcinogens."

18 Did I read that correctly?

19 A. You did, yes.

20 Q. That is your opinion as it relates to  
21 the SMARCA4 variant found in Ms. Tukes; right?

22 A. Correct. Yes.

23 Q. You agree that that opinion is  
24 conditional on whether there is a deleterious  
25 effect of this variant; right?

1 A. In part, yes.

2 Q. Okay.

3 A. It doesn't necessarily have to be a  
4 deletion. It can be a loss of function. So if  
5 you have a less than optimal effects on the  
6 protein, that can also lead to similar effects.

7 Q. Okay. Is that stated in your report?

8 A. I'm not sure. It's a loss of  
9 function versus a deletion. I'm not sure if  
10 that's specifically stated.

11 Q. Do you cite any published functional  
12 studies showing that this variant carried by  
13 Ms. Tukes and pairs the SMARCA4 protein?

14 A. So for SMARCA4, there -- again, back  
15 to the algorithms, there are three algorithms  
16 that I found that evaluated the SMARCA4. One  
17 showed that it was a deletion. Two showed that  
18 it was benign or something to that extent.

19 Q. Other than that information, do you  
20 cite to any other information to rely upon --  
21 excuse me -- strike that.

22 Do you cite to any published  
23 functional study showing that this variant  
24 carried by Ms. Tukes impairs the SMARCA4 protein  
25 outside of that information that you just

1 testified to?

2 A. For the SMARCA4, that is the  
3 information that I have for this. So no.

4 Q. And on that same page of your report,  
5 page 25, you note that the algorithms employed by  
6 Invitae gave conflicting predictions about the  
7 variants impact; right?

8 A. Correct. I don't see it. But I  
9 remember citing that.

10 Q. And about a quarter of the page -- a  
11 quarter way down the page, it's a sentence that  
12 starts with however the algorithms employed by  
13 Invitae appeared to have produced conflicting  
14 results regarding the functional effect of the  
15 missense mutation on the BRG1 protein that is  
16 encoded by the SMARCA4 gene suggesting that this  
17 mutation could be either deleterious or benign.  
18 Did I read that correctly?

19 A. I don't know. I'm still looking for  
20 it. You said a quarter down the page.

21 Q. The sentence about a quarter of the  
22 way down the page it starts with "however."

23 A. All right. I don't know why I'm  
24 having trouble finding -- on page 25?

25 Q. Yes, sir.

1           A.    I see "however the algorithms."  
2    Okay.  I won't make you read it again because  
3    what you said sounds -- this is -- that's what  
4    this says, yes.

5           Q.    Okay.  And, again, that statement was  
6    included in the initial version of the report at  
7    the time when Invitae still classified SMARCA4  
8    variant as one of uncertain significance; right?

9           A.    To the best of my knowledge, correct.

10          Q.    Do you know if Invitae considered  
11    anything in addition to the algorithm in  
12    determining the variant to be one of uncertain  
13    significance?

14          A.    I don't know for this one.

15          Q.    Since 2018, are you aware whether  
16    there's been additional evidence looking at  
17    whether this SMARCA4 variant is deleterious?

18          A.    Again, in the ClinVar record, there  
19    are five records for this, I believe, when I last  
20    checked in April.  And so based on the five  
21    different records there -- to answer your  
22    question, yes, because there are additional  
23    records in the ClinVar database.  I can't  
24    remember the exact dates of those, though.

25          Q.    And did you review that information

1 in authoring your report?

2 A. In the rebuttal, I reviewed that part  
3 of the rebuttal. So I believe in April.

4 Q. And the Invitae report classifies the  
5 SMARCA4 variant as likely benign; correct?

6 A. Correct.

7 Q. And your opinion assumes deleterious  
8 effect; right?

9 A. Correct. Or loss of function.

10 Q. Right. If it turns out that the  
11 variant is not deleterious or does not result in  
12 a loss of function, how does that impact your  
13 opinion as it relates to the SMARCA4 variant in  
14 Ms. Tukes's case?

15 A. So SMARCA4 is a -- works in forming a  
16 complex that is associated with how DNA gets  
17 read. It's -- it impacts transcription -- the  
18 transcription process.

19 So, in this case, when SMARCA4 is  
20 heterozygous, what we see is an increase  
21 susceptibility to cancer. Again, there's an  
22 animal study that shows this. So being  
23 heterozygous for this protein would increase the  
24 risk of -- would increase the risk of develop --  
25 of developing cancer. If this was not a deletion

1 mutation or loss of function mutation, that would  
2 not -- that would be expected to not be the case.  
3 It would be expected to be more of a silent  
4 mutation here.

5 Q. What do you mean when you say if it's  
6 not deletion or loss of function, that would not  
7 be the case. If --

8 A. Sorry. If it's not a deletion or  
9 loss of function, then that process would expect  
10 it to be normal.

11 Q. And what process are you --

12 A. I'm sorry, the regulation of  
13 transcription.

14 Q. In other words, if Ms. Tukes's -- the  
15 variant in Ms. Tukes's SMARCA4 gene is not  
16 deleterious or does not result in a loss of  
17 function, is it true that then it is likely that  
18 the mutation would not result in increased cancer  
19 development following exposure to carcinogens?

20 A. Yes, that is true. Sorry. That took  
21 more work than I thought.

22 Q. That's all right. And you noted an  
23 animal study in your testimony just a few seconds  
24 ago, did you not?

25 A. I did.

1 Q. And that is the 2008 study by Glaros,  
2 which is cited on page 25 of your report; right?

3 A. Yes.

4 Q. And that variant studied in Glaros is  
5 not the same variant found in Ms. Tukes; right?

6 A. This also is not a variant. This is  
7 a heterozygous case, so the protein -- when the  
8 protein is knocked out or dysfunctional. SMARCA4  
9 is critical for embryonic development. And so  
10 completely -- it's really important protein. So  
11 being completely knocked out or having a complete  
12 deficiency is lethal. And so it has to be  
13 studied in the context of heterozygosity.

14 Q. This is a mouse study involving a  
15 lung specific knockout; right?

16 A. Correct. This was lung specific  
17 knockout showing increased sensitivity to  
18 ethylcarbonate. Carbonate.

19 Q. In other words, the organ system at  
20 issue in this study is not the same as the organ  
21 affected in Ms. Tukes; right?

22 A. Correct.

23 Q. Are you aware that the carcinogen  
24 used in the Glaros study is a carcinogen that is  
25 not alleged to have been present at Camp Lejeune?

1           A.    Again, I don't know what's been  
2           alleged at Camp Lejeune.

3           Q.    You're not offering an opinion that  
4           Ms. Tukes was exposed to ethylcarbonate, are you?

5           A.    I'm not, no.  Again, as before,  
6           ethylcarbonate is a common carcinogen used in  
7           animal studies.

8           Q.    Are you aware of any data linking  
9           SMARCA4 variants to renal cell carcinoma in  
10          development in humans?

11          A.    For that I'm going to refer back to  
12          my report on Table 7.  I'm not off the top of my  
13          head, but it's included on this panel, I believe,  
14          due to its relationship in a series of cancer  
15          predisposition syndromes.  They're not listed  
16          here.

17                    So these are related to cancer  
18          predisposition syndromes where I believe there's  
19          a possibility that kidney cancer can be a  
20          component of that which is why they're on this  
21          panel.

22                    Sorry, I see the two syndromes here,  
23          rhabdoid tumor predisposition syndrome 2 and  
24          hereditary cancer predisposition syndrome are the  
25          two that this gene has been associated with.

1 Q. Towards the top quarter of page 25 in  
2 Exhibit 1, there's a sentence on the right-hand  
3 side of the page that starts with "a review."

4 Do you see that?

5 A. Yes, I got it.

6 Q. And it reads "A review of the ClinVar  
7 database does reveal that there is sufficient  
8 evidence for dosage pathogenicity for the SMARCA4  
9 gene that has been confirmed."

10 Did I read that right?

11 A. You did, yes.

12 Q. Does that haploinsufficiency score  
13 that you reference in your report reference a  
14 haploinsufficiency score on a gene level  
15 assessment?

16 A. So the -- this comment is on the  
17 ClinVar database there -- under  
18 haploinsufficiency score. It states sufficient  
19 evidence for dosage pathogenicity.

20 Q. In other words, is it assessing the  
21 pathogenicity of a specific variant found in  
22 Ms. Tukes?

23 A. So -- so it is -- that's a good  
24 question. I believe this is related to the  
25 actual -- this is listed under the record for the

1 actual variant. So when you put in the variant  
2 information under ClinVar, this is what is shown  
3 for that record, which is her specific variant?

4 Q. And a variant could still leave a  
5 patient with two functional copies; right?

6 A. Yeah. So similar to PMS2, a variant  
7 could do that. Typically, we see that. And we  
8 see this when you have a variant that doesn't  
9 change the biological -- or the biochemical  
10 structure of the protein.

11 I believe with this one -- let me --  
12 let me review my report really quickly because I  
13 have the actual change here. So, yes, so this  
14 change is a valine residue which -- to a glycine  
15 residue. So where this is important is that  
16 glycine has a really small side chain. Valine  
17 has a much larger chain made up of an isopropyl  
18 group. But what this does is it makes it more  
19 nonpolar. So the valine make the protein more  
20 nonpolar. It impacts how the protein would fold.

21 This particular mutation is in the  
22 domain of the protein. It's in exon 24. And in  
23 this case, exon 24 is important. It's the ATPA's  
24 domain. It's basically how the machinery that  
25 gets formed with this protein generates power.

1 So because it actually changes the polarity of  
2 the protein and how it folds, it's likely that  
3 this would have an impact on the protein itself.

4 Q. I have may have asked you this  
5 related to the PMS2 gene, but as it relates here  
6 to SMARCA4, heterozygous does not mean a single  
7 functional copy; right?

8 A. Heterozygous means that you have one  
9 functional copy and one mutated copy or altered  
10 copy. Heterozygosity refers to the geno -- the  
11 gene level status.

12 Q. And it doesn't assess whether a  
13 specific variant has a pathogenic effect; right?

14 A. Correct. Being heterozygous does not  
15 equal pathogenicity in any way.

16 Q. And you're not asserting that  
17 Ms. Tukes has a whole gene deletion in SMARCA4;  
18 right?

19 A. She's not. And it's clear that this  
20 is also a missense mutation.

21 Q. At the beginning of the deposition, I  
22 asked you whether you had your deposition taken  
23 before in a previous case. Do you remember that?

24 A. You did, yes.

25 Q. And my recollection is that you

1 stated you had; right?

2 A. I have, yes.

3 Q. How many times?

4 A. I think we submitted that  
5 information. It's six or -- well, does court  
6 actually count? So I think it's between five and  
7 seven times.

8 Q. Is that anytime you've given  
9 testimony or just a deposition?

10 A. So testimony doesn't count, it's six  
11 or seven times. Yeah, I've been deposed six or  
12 seven times.

13 Q. What kind -- or I should say kinds of  
14 cases?

15 A. Sure. So these were cases related to  
16 glyphosate. So Roundup exposure. These were  
17 cases -- and then PFAS litigation. And then  
18 asbestos exposure.

19 Q. Were you serving as an expert in all  
20 of those cases?

21 A. I was, yes.

22 Q. In each of those cases, were your  
23 opinions ultimately presented at trial?

24 A. To the best of my knowledge, yes.

25 Q. Do you recall if any of your prior

1 expert opinions were ever subject to any kind of  
2 challenge?

3 A. Not to my knowledge. I don't know  
4 after -- what you all do after this.

5 Q. Are you aware if any of your opinions  
6 were ever excluded by any court in any way?

7 A. Again, not that I'm aware of.

8 Q. Have you ever been retained as an  
9 expert in a case and later withdrawn or not used  
10 by the party that retained you?

11 A. I believe there was one glyphosate  
12 case. I'm not sure if I was ever actually  
13 formally chose -- or whatever you do to disclose  
14 who your witnesses are. I don't know if that was  
15 actually the case.

16 Q. Okay. Do you know why you would have  
17 been withdrawn or ultimately not used by that  
18 party in that case?

19 A. I don't know.

20 Q. Okay.

21 A. It seems like I did submit a report  
22 for one of these cases, but I was never called to  
23 be deposed.

24 Q. Okay. In prior cases in which you  
25 served as an expert, have you offered opinions

1 involving genetic variants?

2 A. I have not, no.

3 Q. Have you ever offered any opinions in  
4 prior cases in which you've served as an expert  
5 regarding hereditary cancer syndromes?

6 A. Not hereditary cancer syndromes.  
7 These were all -- most of these were cancer  
8 cases, though, so cancer biology. The one  
9 exception to that is PFAS, which is there are  
10 multiple -- breast cancer is one of the cases,  
11 but there are also some other non-cancer related  
12 diseases as well. Roundup, I think it was  
13 non-Hodgkin's lymphoma.

14 Q. Doctor, let's take a 10-minute break,  
15 and I think I may be able to come back and wrap  
16 up.

17 A. Okay. Sure.

18 THE VIDEOGRAPHER: Off record at  
19 1:03 p.m.

20 (Recess taken from 1:03 p.m. until 1:20 p.m.)

21 THE VIDEOGRAPHER: On record at  
22 1:20 p.m.

23 BY MR. CARPENITO:

24 Q. Dr. Allen, earlier, do you recall we  
25 were discussing the protein loss of function as

1 it relates to the PMS2 gene?

2 A. I was, yes.

3 Q. And your opinion is that 50 percent  
4 of Ms. Tukes's proteins in the PMS2 gene is -- or  
5 are irregular; is that right?

6 A. Yes. Mrs. Tukes has a normal copy of  
7 PMS2 which means that in about 50 percent of her  
8 cells, she has a normally functioning PMS2.

9 Q. Is it your opinion that the irregular  
10 proteins are incapable of any mismatch repair?

11 A. So -- so, yes, if this is a loss of  
12 function deletion, this is a loss of function for  
13 the protein -- sorry. So -- so it would be --  
14 okay. So -- sorry, I'm formulating my answer  
15 here.

16 The answer to your question is PMS2  
17 mediated mismatch repair. There are other  
18 proteins that can conduct DNA mismatch repair.  
19 P53 is an example. She has a normal P53 gene.  
20 And so there are other mechanisms for other types  
21 of DNA mismatch repair that aren't relying on  
22 PMS2. P53 was one of the genes in the -- on the  
23 panel that was tested, and she has a normal P53  
24 gene.

25 Q. Do you have an opinion as to how

1       impaired the protein function in the PMS2 gene in  
2       Ms. Tukes is?

3               A.     Based on where the mutation is  
4       located, assuming the algorithms and the loss of  
5       function is correct, then it would likely be a  
6       significant loss of function because it would  
7       inhibit the interaction of the protein PMS2 with  
8       MLH1. So it would inhibit -- again, I go back to  
9       the positive and negative magnets trying to come  
10      together. They would repel each other. So it  
11      would keep from machinery from coming together.  
12      So there's not a numerical number I can give you,  
13      but the likelihood is high.

14              Q.     Is it possible that there is enough  
15      remaining function in the protein to adequately  
16      assist in DNA mismatch repair?

17              A.     I can't -- I can't say that. I don't  
18      know.

19              Q.     Do you recall earlier we were  
20      discussing the ClinVar database as it relates to  
21      the SMARCA4 gene?

22              A.     Yes.

23              Q.     Can different variants for the same  
24      gene have different haploinsufficiency scores?

25              A.     I'm not sure. Because in the ClinVar

1 database I could -- there was no actual core.  
2 ClinVar scores these on a scale of 0 to 3.  
3 There's no score that I could actually find with  
4 the numerical score for these.

5           Instead, if you look on the cover  
6 page for both PMS2 and for SMARCA4 here, the  
7 bottom says -- we have the notation here that  
8 this says sufficient evidence for dosage  
9 pathogenicity which is the HI score. This is the  
10 same, I believe, on both SMARCA4 and PMS2. This  
11 is your Exhibit Number 7.

12           Q. That's a hyperlink; right?

13           A. This? It is. And it goes to the  
14 evidence that supports this. For both of those  
15 records, it's incomplete or it hasn't been  
16 completely filled out. I was hoping there would  
17 be an actual score there, but there's not for  
18 either one of these.

19           Q. Right. When you say incomplete, are  
20 you referring to PMS2 or SMARCA4?

21           A. Both of them had areas of these  
22 records that had areas where there was no  
23 information available.

24           Q. Right. If you click on that  
25 hyperlink as it relates to SMARCA4, there were a

1 few studies looking at different variants in the  
2 SMARCA4 gene; right?

3 A. I believe so. I'm not 100 percent  
4 certain. If you have it, we could -- we could  
5 see, but --

6 Q. Do you recall if any of those  
7 variants were the specific variant found in  
8 Ms. Tukes?

9 A. To the best of my recollection, they  
10 were because it was hyperlinked from this page  
11 for this mutation. This is a specific record for  
12 this mutation. And so the same with SMARCA4,  
13 this is for mutation that Ms. Tukes has, not for  
14 the general gene. And that's the case for both.  
15 So my assumption is that everything linked to  
16 this is related to this mutation.

17 Q. Dr. Allen, I'm going to introduce  
18 what will be marked as Exhibit 8.

19 (Allen Exhibit 8 marked for  
20 identification.)

21 MR. BU: Tab 12.

22 MR. CARPENITO: Yes, I'm sorry.

23 BY MR. CARPENITO:

24 Q. Dr. Allen, does this at least in part  
25 look like some of the material you reviewed as it

1 relates to ClinVar and SMARCA4?

2 A. It does. This is Mrs. Tukes' genetic  
3 mutation at the top, I believe.

4 Q. Right. And as you and I were just  
5 discussing, if you click on the HI score, it  
6 brings you to different evidence; right, related  
7 to the gene?

8 A. It's -- yes. The HI score and under  
9 it, it says sufficient evidence for dosage  
10 pathogenicity. And when you click on that, it  
11 does -- it is a hyperlink that clicks you to a  
12 different location in the dataset.

13 Q. And I'm going to introduce what will  
14 be marked as Exhibit 9.

15 (Allen Exhibit 9 marked for  
16 identification.)

17 BY MR. CARPENITO:

18 Q. Dr. Allen, I'd represent to you that  
19 when you click on the hyperlink, this is the page  
20 that it brings you to. Can you turn the page and  
21 point me to where any of these studies are  
22 looking at the specific variant found in  
23 Mrs. Tukes?

24 A. So this is the hyperlink to there.  
25 Oh, I do see the haploinsufficiency score. This

1 is a 3. That means that it's highest level for  
2 haploinsufficiency for dosage. So the score is 0  
3 to 3 with 3 being the highest level. So this has  
4 a haplo score of 3. I have not seen this report  
5 before though. So I'm not sure -- I'm not sure  
6 why when I click on the link it shows me  
7 something slightly different. All right. So my  
8 apologies, I'm looking through this for the first  
9 time.

10 And what was your question again as I  
11 went through this?

12 Q. Can you point me to any of those  
13 studies on the next page that look at the  
14 specific variant found in Ms. Tukes?

15 A. So none of these variants that I can  
16 tell are those associated with Ms. Tukes. There  
17 are some studies where I don't see the variant  
18 listed where we have publications. The comment  
19 section for the haploinsufficiency evidence,  
20 there are some publications where there isn't  
21 actually the variability or the -- Mrs. Tukes'  
22 mutation. But without reading each of these  
23 articles, I can't say for sure.

24 Q. Okay. You can put that down if you  
25 prefer. I want to ask you some questions on a

1 different topic. What did you do, if anything,  
2 to prepare for today's deposition?

3 A. Wrote the report and studied the  
4 report.

5 Q. Did you meet with any attorneys  
6 before the deposition?

7 A. I had met with attorneys since  
8 submitting the report to now. So, yes, I've had  
9 some meetings with the attorneys to discuss the  
10 report.

11 Q. Did you meet the any attorney -- any  
12 of the attorneys in Ms. Tukes's case to prepare  
13 for your deposition today?

14 A. Sure. I would assume all of the  
15 meetings regarding the report were building up to  
16 this moment.

17 Q. Okay. How many times?

18 A. Four to five times over the course  
19 since -- since submitting the report.

20 Q. What attorneys did you meet with?

21 A. Jim, Matt, or Mark. I can't remember  
22 your partner here.

23 MR. ROBERTS: Matt.

24 THE WITNESS: Matt. And then the  
25 Mandells.

1 BY MR. CARPENITO:

2 Q. When you say the Mandells, do you  
3 mean Mark and Zach?

4 A. Mark and Zach, yes. Every now and  
5 again another attorney would pop on. I don't --  
6 I don't know them though.

7 Q. Okay.

8 A. I don't know which ones.

9 Q. Was it more than one additional  
10 attorney you're unsure of?

11 A. No, it's only one. It was -- I can't  
12 remember his name. He -- I can't remember his  
13 name though.

14 Q. Okay.

15 A. He was African American.

16 Q. Was it Randy Lee, by chance?

17 A. I believe that's correct, yes.

18 Q. After submitting your report in this  
19 case, did you conduct any additional research?

20 A. Yes. In response to Dr. Vance's  
21 report, I re-reviewed my information, re -- I  
22 reviewed her report and conducted additional  
23 literature search to address her findings.

24 Q. What was the additional literature  
25 that you researched?

1           A.    It is included in the rebuttal as  
2 references section.

3           Q.    Okay.  And outside of the information  
4 included in that references section, is there  
5 anything else that you researched after  
6 submitting your report?

7           A.    The ClinVar data to look at what was  
8 the more -- what had been updated since.  I can't  
9 recall anything else specifically.

10          Q.    Okay.  So outside of that information  
11 listed on your rebuttal report and the ClinVar  
12 data that we discussed, is there anything else  
13 that you researched after submitting your  
14 reports?

15          A.    NCCN guidelines.  Again, that was  
16 part of Dr. Vance's report.  So I wanted to find  
17 out what the most current guidelines were.

18          Q.    Okay.

19          A.    I'm sure -- I don't think anything  
20 that isn't listed in my references section.  I  
21 think I even listed the NCCN report.  Maybe I  
22 did.  Maybe I didn't.

23          Q.    Plaintiffs' leadership group paid you  
24 for your work on this report; right?

25          A.    They did, yes.

1 Q. How much did they pay you?

2 A. \$400 an hour.

3 Q. Are you aware off the top of your  
4 head how much in total?

5 A. 16,000 total not counting today.

6 Q. To the extent you can quantify, what  
7 percentage of your income from this past year was  
8 made from expert witness work?

9 A. So it's between 15 and 20 percent  
10 would be my guess. Somewhere in that range.  
11 That's total in all cases.

12 Q. Okay. Plaintiffs also, we just  
13 established, paid for your work on the report;  
14 right?

15 A. Correct.

16 Q. Did they pay for anything else?

17 A. The time working on the -- so I bill  
18 them for time working on the case. So it's the  
19 report and any meetings we had and deposition  
20 time today. Though I don't know who's paying for  
21 that now.

22 Q. Did they pay for your travel here?

23 A. They will be billed for my travel.

24 Q. And how did you get here today?

25 A. I drove.

1 Q. Where did you drive from?

2 A. Blacksburg, Virginia.

3 Q. Okay. Do you recall earlier we were  
4 talking about some of your previous testimony  
5 that you had given in other cases?

6 A. Yes.

7 Q. And I think you said you had been  
8 deposed approximately six or seven times?

9 A. I believe so, yeah.

10 Q. I want to take a step back and think  
11 about all of those cases as a whole. Do you  
12 recall whether or not they were for the  
13 plaintiffs or the defendants?

14 A. They've all been for the plaintiffs.

15 Q. Okay. Dr. Allen, that is all the  
16 questions that I have for you today. Thank you,  
17 sir.

18 A. Okay. Thank you.

19 MR. ROBERTS: I've got some very  
20 brief follow-up questions for you,  
21 Dr. Allen.

22 EXAMINATION

23 BY MR. ROBERTS:

24 Q. As you know, my name is Jim Roberts,  
25 and I represent the plaintiffs in the Camp

1 Lejeune litigation including Ms. Tukes.

2 Do you recall during the first  
3 portion of your deposition you were asked about  
4 your background --

5 A. Uh-huh.

6 Q. -- and qualifications, do you  
7 remember walking us through that?

8 A. I did. I walked through a lot of  
9 things I'm not.

10 Q. All right. Let me ask you this, if  
11 you could describe for me your education and  
12 background that you believe qualifies you to  
13 render the opinions that you've offered in this  
14 case.

15 A. Okay. So my Ph.D. is in molecular  
16 biology and genetics from UNC Chapel Hill. I  
17 worked in the library -- or at Library of  
18 Comprehensive Center and at the School of  
19 Medicine as well. So my -- my dissertation work  
20 focused on defining genes related to disease. So  
21 finding the genes related to disease and then  
22 trying to model them in various organisms and  
23 then trying to ultimately find cures for those  
24 diseases.

25 Prior to going back to school at UNC

1 or prior to entering my Ph.D. work, I also worked  
2 at Laboratory Corporation of America. I actually  
3 ran some of the assays or similar assays to those  
4 in the -- in the report provided by UNC.

5 I also worked at the Duke University  
6 Medical Center at the Center for Human Genetics  
7 where we conducted studies almost exactly like  
8 what we see here with Mrs. Tukes. Taking patient  
9 samples, processing those, sequencing them,  
10 looking for mutations, and then trying to  
11 associate those mutations with human diseases.  
12 Variety of different types of human diseases,  
13 everything from age-related macular degeneration  
14 to Alzheimer's disease and Parkinson's disease.  
15 So lots of different types of diseases where we  
16 actually develop the assays and develop the  
17 panels similar to what we see here with  
18 Mrs. Tukes.

19 Currently, my role is at Virginia  
20 Tech. I'm a professor there. Cancer biology in  
21 both the vet school and medical school. Work in  
22 my lab right now is focused on, again, we utilize  
23 genetics, we use microbiology all the time to  
24 characterize cancer and again trying to find  
25 cures for cancer.

1 Q. Okay. Let me ask you this: Why is  
2 genetic testing done typically?

3 A. Genetic testing is done to identify  
4 factors associated with or that drive the  
5 disease. And so in this case we have a panel of  
6 genes that are well characterized that are  
7 related to renal cell carcinoma. And so the  
8 whole purpose of doing the genetic testing here  
9 is to identify mutations that are causative for  
10 renal cell carcinoma in this case.

11 Q. All right. Now, I believe on page 13  
12 of your report, you set out the panel of genes  
13 that was tested; is that correct?

14 A. Correct.

15 Q. And if you could go down towards the  
16 bottom of page 13 --

17 A. Okay.

18 Q. -- of your report, you state, "Based  
19 on information from Invitae, this panel analyzes  
20 genes associated with the predisposition --  
21 predisposition to kidney and urinary tract  
22 cancer.

23 Did I read that correctly?

24 A. You did. Correct.

25 So this panel encompasses the genes

1 that are most likely to be directly associated  
2 with causing inherited or heritable renal cell  
3 carcinoma. That is my opinion. I think it's  
4 also expressed in the UNC health report. And I  
5 think it's also expressed in Dr. Vance's report  
6 as well. But this is a comprehensive panel  
7 evaluating the genes currently known to science  
8 to be drivers of renal cell carcinoma.

9 Q. And I believe you've also testified  
10 in response to Mr. Carpenito's question over on  
11 page 23 "It is more likely than not that the  
12 patient's renal cell carcinoma is not directly  
13 associated with an inherited or congenital  
14 genetic mutation."

15 Did I read that correctly?

16 A. You did, yes.

17 Q. And is that consistent with what  
18 UNC -- the genetic professionals at UNC  
19 concluded?

20 A. It is consistent with what was  
21 concluded by in the UNC report that we have here,  
22 yes.

23 MR. ROBERTS: That's all I've got.

24 Thank you, sir.

25 MR. CARPENITO: I don't have any

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follow-up.

THE VIDEOGRAPHER: This concludes the deposition. The time is 1:39 p.m. and we are now off the record.

- - -

(Read and sign reserved.)

- - -

(Deposition concluded at 1:39 p.m.)

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CERTIFICATE OF REPORTER

I, Christine A. Taylor, Registered Professional Reporter and Notary Public for the State of North Carolina at Large, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated in this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 30th of June, 2025.



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Christine A. Taylor,  
Registered Professional Reporter  
Notary Public 19960530077  
State of North Carolina

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