Exhibit 601

	Page 1
1	IN THE UNITED STATES DISTRICT COURT
	FOR THE EASTERN DISTRICT OF NORTH CAROLINA
2	SOUTHERN DIVISION
	No. 7:23-CV-897
3	
4	
	IN RE:
5	CAMP LEJEUNE WATER LITIGATION)
6	
7	
8	
9	The videotaped deposition upon oral
L 0	examination of GAIL H. VANCE, M.D., a witness
L1	produced and sworn before me, Valerie
L 2	Fillenwarth, RPR, a Notary Public in and for
L3	the County of Shelby, State of Indiana, taken
L 4	on behalf of the Plaintiffs in the offices of
L5	the US Attorney's Office, 10 W. Market Street,
L 6	Suite 2100, Indianapolis, Marion County,
L7	Indiana, taken on July 8, 2025, commencing at
L 8	9:00 a.m., pursuant to Indiana Rules of
L9	Procedure, with Notice as to the time and place
20	thereof.
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23 24	
24 25	
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25	
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10	(Reporter's Note: Quotation marks are	
	used for clarity and do not necessarily reflec	t
11	a direct quote.)	
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1	THE VIDEOGRAPHER: We are now on the
2	record. My name is Kelly Herring. I'm the
3	videographer for Golkow, a Veritext division.
4	Today's date is July 8, 2025, and the time is
5	9:20 a.m.
6	This deposition is being held at 10 West
7	Market Street in Indianapolis, Indiana, in the
8	matter of In Re: Camp Lejeune Water
9	Litigation, for the United States District
10	Court, for the Eastern District of
11	North Carolina, Southern Division.
12	The deponent is Dr. Gail Vance.
13	Will counsel please identify themselves?
14	MR. ROBERTS: Jim Roberts, appearing on
15	behalf of the plaintiff, Jacqueline Tukes.
16	MR. WHITE: Lucas White and Camille
17	Johnson on behalf of the United States.
18	
19	GAIL H. VANCE, M.D.,
20	having been first duly sworn to tell the truth,
21	the whole truth, and nothing but the truth,
22	testified as follows:
23	DIRECT EXAMINATION,
24	QUESTIONS BY MR. ROBERTS:

Q.

25

Could you state your full name for the record,

Page 6 1 please? Gail Vance. 2 3 Okay. Dr. Vance, my name is Jim Roberts. I'm Q. a lawyer from North Carolina --4 Uh-huh. 5 Α. -- and I represent Jacqueline Tukes in the 6 Q. claims that she has against the United States 8 government. 9 I understand, ma'am, that you have testified prior to today, is that correct? 10 11 Testified? Α. Yes, ma'am, in deposition. 12 0. 13 Oh, not for this case. Α. 14 No. Ο. Correct. In other cases? 15 16 Yes, ma'am. 0. Yes, I have. 17 Α. 18 Ο. Okay. So you understand some of the ground 19 rules we're going to be following today. 2.0 You understand that you're under oath, 21 correct? 22 Α. Yes. 23 And if I ask you a question that you, for Q. whatever reason, don't understand, would you 24

please let me know, and I'll be happy to go

25

Page 7 1 back and rephrase it, fair? 2 Α. Correct. And if you don't ask me to do that, I'll assume 3 Q. that you understand the question, fair enough? 4 That's fair. 5 Α. Dr. Vance, let me ask you, first of all, what 6 Q. 7 do you understand about Jacqueline Tukes' allegations in this case? 8 9 MR. WHITE: Object to form. Go ahead, Doctor. 10 11 I understand that she's claiming that her Α. kidney cancer was a result of toxic water she 12 13 was exposed to at Camp Lejeune. BY MR. ROBERTS: 14 15 Okay. Do you know what chemicals were found in 0. 16 the groundwater at Camp Lejeune? 17 I do not. Α. Do you know the levels that Jacqueline Tukes 18 Ο. 19 was exposed to? 2.0 Α. No. 21 Do you know whether or not the chemicals that Ο. 22 Mrs. Tukes was exposed to have the potential to

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cause disease?

MR. WHITE:

I do not.

Object to form.

Page 8 1 I'm sorry. Just give me a --2 THE WITNESS: A pause. MR. WHITE -- quick half second --3 4 THE WITNESS: Yeah. MR. WHITE: -- to get the objection in. 5 But --6 7 THE WITNESS: Yeah. MR. WHITE: -- object to form. 8 Go ahead. Sorry. 9 BY MR. ROBERTS: 10 11 Ma'am? Q. 12 Α. No. So I'm trying to understand, Dr. Vance, sort of 13 Ο. the basis of your opinions. 14 15 Are you telling us that it was not 16 important in reaching your opinions to know the 17 levels of carcinogens that Mrs. Tukes was 18 exposed to and the nature of those carcinogens? 19 MR. WHITE: Object to form. 2.0 Α. Correct. 21 BY MR. ROBERTS: Okay. So that's not something that you even 22 Q. 23 wanted to consider? 24 MR. WHITE: Object to form. 25 Α. No.

- 1 BY MR. ROBERTS:
- 2 Q. Why is that?
- 3 A. Because of her clinical presentation. It was compatible with hereditary renal carcinoma.
- Q. Okay. Have you ever had a patient that was exposed to carcinogens?

7 MR. WHITE: Object to form.

- A. Not to my knowledge. I mean, most people are exposed to some kind of carcinogen.
- BY MR. ROBERTS:
- 11 Q. Right. But have you ever had a patient walk

 12 into your office, like Ms. Tukes, that says,

 13 "Dr. Vance, I was exposed to carcinogens. I

 14 think I might be sick from that exposure"? Has

 15 that ever happened during the course of your

 16 career?
- 17 MR. WHITE: Object to form.
- 18 A. No.

8

9

- 19 BY MR. ROBERTS:
- Q. Okay. Did you read Mrs. Tukes's deposition in this case?
- 22 | A. Yes.
- Q. Did you read how she -- how she testified how she was exposed to the chemicals at Camp Lejeune?

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- 1 | A. Yes.
- 2 Q. Did you read the depositions of any -- of
- 3 Mrs. Tukes's treating physicians or medical
- 4 providers?
- 5 A. Yes.
- 6 Q. Which ones did you read, ma'am?
- 7 A. Dr. McCarthy.
- 8 Q. Okay.
- 9 A. And -- she's a genetic counselor, Katie
- 10 Gabarini.
- 11 Q. Okay. Anyone else?
- 12 A. Their depositions?
- 13 | O. Yes, ma'am.
- 14 A. No.
- 15 Q. Okay.
- 16 | A. Dr. Allen.
- 17 Q. Okay. So --
- 18 A. He's not a treating physician, but --
- 19 Q. That's correct.
- 20 A. Yes.
- 21 Q. So I'm just trying to get an understanding in
- 22 my mind of what you read to form your opinions
- in this case.
- 24 So you read three depositions, is that
- 25 correct?

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- 1 MR. WHITE: Object to form.
- 2 A. Dr. Allen, Dr. McCarthy, Jacqueline Tukes, and
- 3 Katie Gabarini. That's four.
- 4 BY MR. ROBERTS:
- 5 Q. Okay. Four, okay. Thank you.
- 6 Any other depositions?
- 7 A. No.
- 8 Q. Okay. Can you tell us who Dr. McCarthy is?
- 9 A. He's a urologist.
- 10 Q. Okay. Did he treat Ms. Tukes?
- 11 | A. Yes.
- 12 | Q. And what was the nature of his treatment of
- Jacqueline Tukes?
- 14 A. Multiple surgeries, both partial and full
- 15 nephrectomies.
- 16 Q. And he -- Dr. McCarthy treated her over a
- 17 period of years, fair?
- 18 A. Correct.
- 19 Q. Did you -- I don't guess you read the
- 20 deposition of Mrs. Tukes's oncologist, did you?
- 21 A. No.
- 22 | Q. Dr. Jayaram?
- 23 A. No.
- 24 | Q. Were you aware that he'd even been deposed in
- 25 this case?

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- 1 | A. No.
- 2 Q. Nobody told you that?
- 3 A. No.
- 4 MR. WHITE: Object to form.
- 5 (WHEREUPON, Deposition Exhibit 1 was
- 6 marked for identification.)
- 7 BY MR. ROBERTS:
- Q. Now, in your report -- and I'll go ahead andmark this as Exhibit 1 to your deposition.
- 10 | A. Okay.
- 11 Q. And for the record, Dr. Vance, if you could
- identify Exhibit 1 as a copy of your expert
- report that you prepared in this case?
- 14 A. Yes, this is a copy of my expert report.
- 15 | O. Yes, ma'am.
- 16 And does this report have all the
- opinions that you intend to offer in this case?
- 18 A. Well, yes.
- 19 0. Okay.
- 20 A. I mean, it composes the basis of my conclusion.
- 21 Q. Okay. Well, Dr. Vance, today is the day that
- 22 my side gets to ask you questions to make
- 23 sure --
- 24 A. Correct.
- 25 | Q. -- that we completely and fully understand all

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the opinions that you're going to offer at

- 2 trial.
- 3 | A. Yes.
- 4 | O. You understand that?
- 5 A. Correct.
- 6 | Q. My question to you again is: In looking at the
- 7 report, is that the complete universe of
- 8 opinions that you're going to offer at trial in
- 9 this case?
- 10 A. Complete universe? I mean, do I have another
- opinion that's not in this report? I might
- 12 state it differently, but this is my report.
- 13 Q. Okay. So it's complete, as we sit here in
- 14 | your --
- 15 | A. Yes.
- 16 Q. -- deposition today?
- 17 | A. Yes.
- 18 Q. All right. In your report on pages 15 and 16,
- 19 you go through Mrs. Tukes's background and
- 20 medical history, is that fair?
- 21 A. Yes.
- 22 Q. And you don't mention in any of the background
- her exposure to carcinogens, do you?
- MR. WHITE: Object to form.
- 25 A. I read her medical records. That was not a

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- 1 part of her medical records that I reviewed. BY MR. ROBERTS: 2
- 3 Well, ma'am, you understand that we're here Q. today to get your opinions on what you say the 4 cause of her kidney cancer is, fair enough?
- Yes. 6 Α.

5

- And my question again is: In your background Q. 8 and history of Mrs. Tukes, you nowhere mention 9 her exposure to carcinogens, do you?
- MR. WHITE: Object to form. 10
- 11 Α. No.
- 12 BY MR. ROBERTS:
- 13 Ο. Okay. Have you ever offered an opinion in a 14 case that a patient's cancer was likely the 15 result of exposure to a carcinogen as opposed 16 to having a hereditary --
- 17 MR. WHITE: Object to form.
- BY MR. ROBERTS: 18
- 19 -- component? 0.
- 2.0 MR. WHITE: I'm sorry. Object to form.
- 21 I didn't mean to interrupt you, sir.
- 22 No. Α.
- 23 BY MR. ROBERTS:
- Okay. How would you define a carcinogen? 24 Q.
- 25 MR. WHITE: Object to form.

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- A. A carcinogen would be something, as the name implies, that's capable of causing cellular damage and potentially cancer.
- 4 BY MR. ROBERTS:
- 5 | Q. And how would you define the term genotoxicity?
- 6 A. Just as the name implies. It's toxic to the gene structure itself.
- 8 Q. Okay. And --
- 9 A. And the gene function.
- 10 Q. And how would you define a tumor suppressor 11 gene?
- 12 A. A tumor suppressor gene is a gene that we can

 13 contain in our genome that works to control the

 14 cell cycle.
- Q. All right. You say "control the cell cycle."

 What you do mean by that?
- 17 A. It will interrupt the cell cycle from
 18 proliferation if it senses damage. It will
 19 interrupt so that there's not overproliferation
 20 of cells.
- Q. Have you read any literature during the course of your career that carcinogen can impact tumor suppressor genes?
- 24 MR. WHITE: Object to form.
- 25 A. We know that there are mutating substances in

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- the universe that we're exposed to, and a carcinogen can be one of those.
- 3 BY MR. ROBERTS:
- 4 Q. Okay.
- 5 A. UV radiation is another one. Your natural
 6 mutation or your natural proliferation or
 7 replication of cells can also cause mutations.
- Q. Do you know if trichloroethylene can cause those mutations?
- 10 A. Not specifically.
- 11 Q. Did you look into that at all in rendering your opinions?
- 13 A. No.
- Q. How about tetrachloroethylene, also known as

 PCE, did you look into the characteristics that
 they can -- that that chemical can put on DNA
 or genes?
- 18 A. No.
- Q. Same question with respect to vinyl chloride,
 did you give any consideration to the effect of
 vinyl chloride on DNA or genetic material?
- 22 A. No.
- Q. Same question with benzene, did you consider
 the potential effect that benzene could have on
 DNA repair genes or other genes in the body?

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- 1 | A. No.
- 2 | Q. All right. What is an oncogene?
- A. An oncogene is -- a proto-oncogene is a normal gene within our genome that controls
- 5 proliferation and replication.
- Q. And if that replication is interrupted for some reason, can that cause cancer?
- 8 A. Typically not by itself.
- 9 Q. What do you mean by that?
- 10 A. So damage to one oncogene by itself does not
 11 usually lead to cancer. It may cause
 12 instability in the genome but not frank cancer.
- Q. Okay. Now, what percentage of cancers would you say, in your opinion, Dr. Vance, are associated with a genetic predisposition?

MR. WHITE: Object to form.

Go ahead.

- 18 A. What kind of cancer? All cancers?

 19 BY MR. ROBERTS:
- 20 Q. Well, let's stick to renal cell carcinoma.
- A. Okay. Renal cell carcinoma, as a small component, are heritable. It's usually between 3 and 5 percent is what's been quoted.
- Q. So I guess the question is whether or not
 Mrs. Tukes falls within that 3 to 5 percent.

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- 1 | Would you agree with that?
- 2 MR. WHITE: Object to form.
- 3 A. That's the question?
- 4 BY MR. ROBERTS:
- 5 Q. Yes, ma'am.
- 6 A. I believe she does.
- Q. Okay. So you have -- you have reached the conclusion that she does not fall in the other roughly 95 to 97 percent?
- 10 A. That's correct.
- 11 Q. Okay. Now, in your report, you also discuss
- what I think you say are features suggesting an
- inherited predisposition to cancer. Do you
- 14 recall discussing that in your report?
- 15 | A. Yes.
- 16 Q. And the first one was early age at onset. Do
- 17 you remember discussing that one?
- 18 A. Yes.
- 19 Q. And another one you discussed was cancers of a
- 20 specific type occurring together?
- 21 A. Yes.
- 22 | Q. And multiple or bilateral cancers?
- 23 A. Yes.
- 24 | O. And rare cancers?
- 25 A. Yes.

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Q. Now, would you agree that these conditions can be caused by exposure to carcinogens?

MR. WHITE: Object to form.

A. Not solely, no. Typically when we see that, we look for a predisposing inherited gene mutation.

BY MR. ROBERTS:

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- Q. Well, I guess my question is: Is it your testimony that someone that does not have a predisposition to cancer cannot get cancer if they're exposed to carcinogens, such as TCE and PCE?
 - MR. WHITE: Object to form.
- A. I don't know. I'm not an expert in exposures, toxic exposures.

16 BY MR. ROBERTS:

Q. All right. But I guess my question is, you're not suggesting, are you, ma'am, that of the 95 percent of cancers that are not related to a genetic predisposition, okay, for renal cell carcinoma, you're not telling this court, are you, ma'am, that exposure to carcinogens, without having a predisposition, cannot cause cancer, are you?

MR. WHITE: Object to form.

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A. I'm not telling you that, but typically cancer occurs because of a susceptible genetic background and exposures, lifetime of exposures.

BY MR. ROBERTS:

- Q. Okay. And in your report I believe you talk about both a genetic and an environmental component to cancer. Do you remember talking about that?
- 10 A. I do.

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- 11 Q. And would the enviro- -- one of the
 12 environmental conditions, could that
 13 potentially be exposure to carcinogens such as
 14 exist at Camp Lejeune?
- 15 | A. Yes.
- MR. WHITE: Object to form.
- 17 BY MR. ROBERTS:
- Q. Dr. Vance, do you have an opinion as to whether or not carcinogen exposure contributes to sporadic cancer?
- MR. WHITE: Object to form.
- 22 A. No, I don't have an opinion on that.
- BY MR. ROBERTS:
- Q. Do you have an opinion as to whether or not carcinogen exposure contributes to inherited

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Page 21 1 cancer? 2 MR. WHITE: Object to form. 3 No, I don't have an opinion on that. BY MR. ROBERTS: 4 5 Do you have an opinion as to whether exposure Q. to carcinogens contributes to hereditary 6 7 cancer? MR. WHITE: Object to form. 8 9 Α. No, I don't have an opinion on that. BY MR. ROBERTS: 10 11 Okay. Now, in your report I believe you talk Ο. 12 about something known as Knudson's two-hit 13 theory. Do you recall talking about that --I do. 14 Α. 15 -- in your report, ma'am? O. 16 Go t.o --Α. 17 And, in fact, if you could turn over -- I Q. believe it starts on page 10. 18 19 Correct. Α. 20 And is that a well-accepted causation model for Ο. 21 cancer? 22 MR. WHITE: Object to form. 23 Α. Yes. 24 BY MR. ROBERTS:

Is it -- it's well accepted in your field,

Q.

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1 correct?

- 2 MR. WHITE: Same objection.
- 3 A. Yes.
- 4 BY MR. ROBERTS:
- Q. And you give an example, I think, in your report, if I'm -- if I'm not mistaken, about children with bilateral eye cancer having a predisposition to that cancer?
- 9 A. Yes.
- Q. Now, in the two-hit model, would you agree that carcinogen exposure can be the second hit in the model?
- MR. WHITE: Object to form.
- 14 A. It can contribute to the second hit.
- 15 BY MR. ROBERTS:
- Q. So let me ask you this: If -- and, again, I'm not trying to put words into your mouth, but
- 18 it's your opinion that Ms. Tukes had a
- 19 predisposition for renal cell carcinoma,
- 20 correct?
- 21 A. Correct.
- 22 Q. And if she was exposed to the carcinogens that
- we talked about, based on what you just said,
- that could be the second hit that caused her
- 25 cancer, right?

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- 1 MR. WHITE: Object to form.
- 2 A. Could be.
- 3 BY MR. ROBERTS:
- Q. Can a chemical that causes a DNA mutation cause cancer?
- 6 MR. WHITE: Object to form.
- 7 A. Can you say that again?
- 8 BY MR. ROBERTS:
- 9 Q. Yes, ma'am.
- Would a genetic mutation that causes a loss of -- let me restate that.
- Would a mutation that causes a loss of
 function in a tumor suppressor gene, which
 you've explained previously, increase the
 susceptibility of a person exposed to a
 carcinogen?
- MR. WHITE: Object to form.
- 18 A. So we've now moved away from retinoblastoma.
- So you're talking about any tumor suppressor
- 20 gene?
- 21 BY MR. ROBERTS:
- 22 Q. Yes, ma'am.
- 23 A. It will lead to instability.
- Q. Okay. And I think you've given us examples of that in your report of APC mutations?

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- 1 A. That is correct.
- 2 | Q. BRCA1?
- 3 | A. Yes.
- 4 | Q. And p53?
- 5 A. Yes.

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Q. And would you agree that a mutation that causes a loss of function in a tumor suppressor gene would result in someone being susceptible to cancer at lower levels of carcinogens?

MR. WHITE: Object to form.

- A. I can't agree to that because I don't know the -- the first mutation in a tumor suppressor gene, as I've given an example in my report, leads to instability. Now, that instability itself could remain for years, or there could be exposures. There could be something that causes the loss of the second tumor suppressor gene. That's hard to put your hand on, so you really don't know what the cause was. But then it's usually after the second hit that the cancer would develop but not after the first. BY MR. ROBERTS:
- Q. Okay. But the second hit, under your example, could be an exposure to a carcinogen, right?

 MR. WHITE: Object to form.

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- 1 A. As one of the possible --
- 2 BY MR. ROBERTS:
- 3 Q. Yes, ma'am.
- $4 \mid A$. -- causes of the second.
- Q. Which is -- which is exactly what Ms. Tukes is saying in this case, right?
- 7 MR. WHITE: Object to form.
- 8 A. I don't think she's saying the same thing.
- 9 BY MR. ROBERTS:
- 10 | Q. Okay.
- 11 A. She's not saying that carcinogens cause the
- second hit of her allele for a gene that we
- have not been able to identify.
- 14 Q. Well, she's just saying that she drank water
- that was contaminated with carcinogens and it
- gave her cancer, right?
- MR. WHITE: Object to form.
- 18 A. I believe that's what she's saying. I -- I
- mean, I read her deposition, but she didn't say
- 20 that exactly.
- 21 BY MR. ROBERTS:
- 22 Q. Can a chemical that increases cell
- 23 proliferation or reduce cell death cause
- 24 cancer?
- MR. WHITE: Objection to form.

- 1 | A. Yes.
- BY MR. ROBERTS:
- 3 | Q. Would you agree that a mutation that causes
- 4 loss of function in a gene that controls DNA
- 5 transcription increases the susceptibility of a
- 6 person that is exposed to a carcinogen?
- 7 A. It really depends on the gene. Not every gene
- 8 would do that.
- 9 Q. Okay. How about the genes in the 30-gene panel
- 10 that Mrs. Tukes was tested for?
- 11 A. Well, not all of those genes either. Some of
- 12 those are recessive. Some of those are
- dominant.
- 14 O. What about PSM2 (sic) and SMARCA4?
- 15 A. Okay, PMS2 is one of the five Lynch genes. So
- 16 your question again?
- 17 | O. Can a chemical that increases cell
- 18 proliferation or reduce cell death cause
- 19 cancer?
- 20 MR. WHITE: Object to form.
- 21 A. Say that again.
- BY MR. ROBERTS:
- 23 | Q. All right.
- 24 A. Yeah, one more time.
- 25 \ Q. Can a cell -- can a chemical that increases

Page 27 of 177

cell proliferation or reduce cell death cause cancer?

- MR. WHITE: Same objection.
- 4 A. Well, you're saying the chemical itself is doing that. I don't know.
- 6 BY MR. ROBERTS:
- 7 | Q. You don't have an opinion on that?
- 8 A. No.

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- 9 Q. And you won't have an opinion on that at trial, then, right?
- 11 A. No, not that I'm aware of.
- 12 Q. We may have discussed this briefly. I think we touched on it. On page 11 of your report --
- 14 | A. Okay.
- 15 Q. -- at the bottom of the page, you say -- you

 16 state that, and I'm quoting, "Familial cancer

 17 represents 15 to 20 percent of cancers and is

 18 usually associated with more common cancers

 19 such as breast, colon, and prostate cancer," is

 20 that correct?
- 21 A. Correct.
- Q. And I believe you'd indicated previously that renal cell carcinoma is much rarer than the forms of cancer that I just described, is that fair?

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- 1 A. That's fair.
- Q. Okay. In the first sentence of that last paragraph on page 11 --
- 4 A. Uh-huh.

8

9

Q. -- you state, "In addition to hereditary cancer and sporadic cancer, there's a third classification called familial cancer."

Did I read that correct?

- A. That's correct.
- Q. And do you recall stating in here -- and,
 again, I think we touched on this previously -that environment has an effect on all of these
 cancers that we just discussed?
- 14 A. It could have an effect on them, because,
 15 again, most cancer is a cause of your genetic
 16 background and your exposures throughout your
 17 lifetime.
- Q. Now, you understand that -- and I've read it in your report, that Mrs. Tukes underwent genetic testing, is that correct?
- 21 A. Yes.
- Q. And the testing was done by Invitae, which is now Labcorp, is that correct?
- 24 A. Yes.
- 25 Q. And it was ordered by her treating physicians

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1 and healthcare providers at UNC-Chapel Hill Healthcare? 2

- 3 Α. Yes.
- And what do you know about UNC-Chapel Hill, the 4 Ο. hospital? 5
- 6 MR. WHITE: Object to form.
- 7 Well, it's a really well-known, exceptional Α. university and academic center. 8
- 9 BY MR. ROBERTS:
- Okay. Now, the 30-gene panel that was tested, 10 O. 11 was it done in August of 2018?
- 12 Α. It's 2018. I'm not sure if it was August.
- 13 Do you know it was ordered by Dr. McCarthy? 0.
- 14 No. Α.
- 15 Okay. And I believe in your report you agreed 0. 16 that the genes were inclusive for all known 17 hereditary renal cell disorders as outlined in the National Comprehensive Cancer Center 18 19 Network, is that true?
- 2.0 MR. WHITE: Object to form.
- 21 That is true. Α.
- 22 BY MR. ROBERTS:
- 23 And would you agree that the renal urinary Q. tract cancer panel was the standard test to 24 25 evaluate for hereditary renal cell disorders?

- 1 MR. WHITE: Object to form.
- 2 | A. Yes, at -- in 2018.
- 3 BY MR. ROBERTS:
- 4 Q. Yes. And it still is today, correct?
- 5 MR. WHITE: Object to form.
- 6 A. No. It's been changed slightly.
- 7 BY MR. ROBERTS:
- 8 Q. Okay. How has it been changed?
- 9 A. Some of the genes have been replaced.
- 10 | Q. Okay.
- 11 A. I think I put that in my report.
- 12 Q. All right. Well, let ask you this: Have you
- ever, in your practice, ordered the Labcorp
- 14 renal urinary tract cancer panel?
- 15 A. I may have. I typically use the laboratory
- 16 called Ambry Genetics.
- 17 Q. Do they do the same panel that Mrs. Tukes --
- 18 | A. Similar.
- 19 | Q. -- had?
- 20 A. Similar.
- 21 Q. Okay. Now, you said that some genes had been
- 22 added. Where is that in your report, ma'am?
- 23 A. Let's go -- okay, if you look on page 19.
- 24 Q. Uh-huh.
- 25 A. So it says that the changes include removal of

Page 31 of 177

MITF, PALB2, SDHA, SDHD, and the addition of BLM, REST, TRIM28, and TRIP13.

- Q. And you further state, do you not, that "It is unlikely that the new panel would identify a pathogenic variants in any of the genes tested for Ms. Tukes"? Is that correct?
- $7 \mid A$. That is correct.
- Q. Okay. What were the results of the genetic testing on Mrs. Tukes?
- 10 A. Which genetic test are you referring to?
- 11 Q. Let's talk -- I thought we were talking about the one in 2018.
- 13 A. Well, she had one previous.
- 14 Q. We'll get to that one.
- 15 A. Okay.

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- 16 Q. That was the VHL gene?
- 17 | A. VHL.
- 18 Q. Okay. We'll get to that one.
- I'm talking about the 2018 panel of 30
 genes that were tested. What were the results
 of that?
- A. The results were negative except for two variants of unknown significance; one in PMS2, and one in SMARCA4.
- Q. Okay. And I believe in your report you state,

Page 32 of 177

1 do you not, that "the genetic testing did not

- 2 reveal a gene mutation that could be a
- potential cause of her renal cell carcinoma"?
- 4 Did I read that correctly?
- 5 A. That is correct.
- 6 | Q. So as you sit here in your deposition today,
- 7 Dr. Vance, would you agree that the only
- 8 objective genetic testing that was done in this
- 9 case for Mrs. Jacqueline Tukes was negative?
- 10 MR. WHITE: Object to form.
- 11 A. I agree.
- 12 BY MR. ROBERTS:
- 13 | O. All right. Now, on -- let me ask this
- 14 question: When that report of the genetic
- testing came back, Mrs. Gabarini communicated
- with Ms. Tukes, right? Do you recall those
- 17 letters that she wrote?
- 18 | A. Yes, I do.
- 19 Q. And according to Ms. Gabarini, the results of
- 20 those tests being negative, she said, was good
- 21 news. Do you recall that?
- 22 | A. I do.
- 23 Q. Do you disagree with what Ms. Gabarini said?
- 24 A. I wouldn't have stated it that way.
- 25 | Q. Okay. Why not?

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A. Because a negative test result in the face of her clinical phenotype would not dissuade me from thinking she had an underlying genetic

- 4 susceptibility.
- Q. But all of the genetic testing that was done onMrs. Jacqueline Tukes was all negative, right?
- 7 A. Of 30 genes.
- 8 O. And VHL?
- 9 A. Uh-huh.
- 10 Q. And another test. What was the other one she had? She had three of them, right?
- 12 A. Yes. She had the VHL first. Then she had the 30-gene panel. And she also had -- what was it? RYR4 rhabdomyolysis.
- 15 Q. And they were all negative, correct?
- 16 A. They were all negative.
- Q. So my question again, in Jacqueline Tukes's position, she would take that as good news, wouldn't she?
- A. I don't know what Jacqueline Tukes would do,
 what she would say. I don't know what her
 opinion would be. I know what my opinion would
 be.
- Q. Do you know what Dr. McCarthy's opinion was?
- 25 A. Not really, no.

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Q. Well, in your report you use the word "unfortunately." On page 18, you say, "Unfortunately, genetic testing, performed during her cancer care, was unable to identify a gene mutation as a potential etiological explanation for her disease."

> Now, Dr. Vance, why -- why was that unfortunate?

- Α. I would -- I would say that was unfortunate because it would be very helpful in her case to pin down the gene responsible for her disease. Not only could we identify that for her as an etiological agent, but also we could see if any other family members might be at risk for renal cancers if they carried a similar or the same mutation in the gene that was identified.
- So is it your testimony that it would have been Q. better for Jacqueline Tukes if the genetic testing would have come back positive? Is that what I'm understanding you to say?

MR. WHITE: Object to form.

- I would object to your form, too. I would Α. say it's not better, it's that it was not informative.
 - BY MR. ROBERTS:

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Q. But all -- again, all the objective genetic
test results that were done on Jacqueline Tukes
for hereditary renal cell carcinoma were
negative?

- A. That is correct, for those that were done, yes.
- Q. Well, I mean, I thought you said that that panel is the standard panel. Isn't that what you said?

9 MR. WHITE: Object to form.

- 10 A. I did say that's a standard panel.
- 11 BY MR. ROBERTS:
- 12 | Q. Okay. And that was negative again, right?
- 13 A. That is correct.
- Q. And the genes that you talked about on page 19
 of your report, you stated that it was unlikely
 that the new panel would identify any
 pathogenic variance in any of the genes tested,
 correct?
- 19 | A. Yes.

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- 20 (WHEREUPON, Deposition Exhibit 2 was
- 21 marked for identification.)
- 22 BY MR. ROBERTS:
- Q. Now, I would like to hand you a portion of the deposition of Dr. McCarthy. And I'm going to mark this, ma'am, as Exhibit 2 to your

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		Page 36
1		deposition.
2		MR. ROBERTS: Madam Court Reporter, I
3		will be happy to handle the marking of these
4		exhibits so we don't have to throw these papers
5		across this big table. Do you want to thank
6		you.
7		MR. WHITE: You enjoy throwing something
8		at us.
9		THE WITNESS: I can help you.
10		BY MR. ROBERTS:
11	Q.	And, again, for the record, Dr. McCarthy had
12		been treating Jacqueline Tukes for years,
13		right?
14	A.	Yes.
15	Q.	And he's obviously not a paid expert, right?
16	A.	I don't know.
17		MR. WHITE: Just just before we go a
18		little further, I just want to note an
19		objection to completeness grounds for the
20		MR. ROBERTS: Sure.
21		MR. WHITE: on the partial thing. I
22		didn't I wanted to get that in before I
23		interrupted you at a worse time

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I can only carry so much material on the plane.

MR. ROBERTS: Look, I hear ya. You know,

1 BY MR. ROBERTS:

- Q. So the portion of Dr. McCarthy's deposition that I want to direct your attention to is on page 128.
- A. All right.

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Q. And I believe you said you read his deposition.

Did you read the question that was asked: "To

the extent that there is genetic testing and

that genetic testing comes back negative or

with no mutations, that type of thing, does

that -- what does that tell you in terms of an

inherited or genetic-type cancer?"

Answer: "I would say that would lead me to believe that this is probably not related to her mother's cancer."

Question: "Okay."

Answer: "She did not inherit anything from her mother predisposing her to kidney cancer."

Did I read that correctly?

- A. You did.
- Q. So I take it you disagree with Dr. McCarthy,
 who was Mrs. Tukes's treating physician for her
 kidney cancer for years? Is that your
 testimony?

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Page 38 1 Α. Yes. 2 MR. WHITE: Object to form. I'm sorry, Doctor. Just give me half a 3 4 second --THE WITNESS: Yeah. 5 MR. WHITE: -- to get in there. 6 7 THE WITNESS: Yeah. MR. WHITE: It makes it much easier on 8 9 the court reporter. BY MR. ROBERTS: 10 11 All right. You never -- you have never heard Ο. 12 of Dr. Nagesh Jayaram, have you? 13 Object to form. MR. WHITE: 14 He's in her reports, but I don't know him. Α. 15 BY MR. ROBERTS: 16 Did you know even what he -- the nature of the O. 17 care and treatment he rendered to Ms. Tukes before you walked in your deposition today? 18 No, I don't. 19 Α. 2.0 (WHEREUPON, Deposition Exhibit 3 was 21 marked for identification.) BY MR. ROBERTS: 22 23 Q. I'm handing you what's been marked as Exhibit 3. 24 25 Α. Okay.

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MR. WHITE: Same objection on completeness grounds.

BY MR. ROBERTS:

- Q. And do you see, beginning on line 17 of page 7 -- 71, it states, "And we discussed earlier that a genetic test cannot definitively rule out a predisposition for cancer." Do you see that?
- 9 A. Uh-huh.

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- Q. And he says, "I think we kind of say when the genetic test is negative, we rule out the predisposition."
- Did I read that correctly?
- 14 | A. You did.
- Q. So I take it you would also take issue with Dr. Jayaram?
- 17 | A. Yes.
- Q. Okay. Let me see if I can understand better in my mind, Dr. Vance, the opinions that you offer in this case. And I'm just trying to understand the basis for your opinions.

And on page 20 of your report, I believe you say, "A negative test result in an individual with a suspected hereditary cancer syndrome does not exclude a heritable cause for

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1 the cancer. Advances in genetic testing

2 technology and genetic knowledge may later

3 identify gene mutations not currently

4 recognized."

- Did I read that correctly?
- 6 A. Yes.

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 $7 \mid \mathsf{Q}.$ All right. So correct me if I'm wrong,

8 Dr. Vance, what you're saying is that at some

9 indeterminate time, some unknown gene will have

some unknown mutation that could potentially

11 explain Mrs. Tukes's renal cell carcinoma as

being hereditary? Is that your testimony?

- MR. WHITE: Object to form.
- 14 A. Yes.
- 15 BY MR. ROBERTS:
- 16 Q. All right. Dr. Vance, you would agree that
- that is absolutely pure speculation, wouldn't
- 18 you?
- 19 MR. WHITE: Object to form.
- 20 A. No.
- 21 BY MR. ROBERTS:
- 22 Q. Okay. All right. You can't identify the gene,
- 23 correct?
- MR. WHITE: Object to form.
- 25 A. Not at this time.

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Page 41 1 BY MR. ROBERTS: 2 You can't identify the mutation? MR. WHITE: Same objection. 3 BY MR. ROBERTS: 4 Correct? 5 Ο. Not at this time. 6 And you can't say when this unknown gene or Q. unknown mutation will be discovered, can you? 8 MR. WHITE: 9 Object to form. 10 Α. That is correct. 11 (WHEREUPON, Deposition Exhibit 4 was 12 marked for identification.) 13 BY MR. ROBERTS: 14 I would like to shift gears, if we could. I'm Ο. 15 going to mark Exhibit 4 to your deposition, 16 which I will represent to you are the National 17 Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Is that correct? 18 19 Yes. Α. 20 Dr. Vance, if you could turn over -- let me 0. 21 exchange this one for yours because I had the 22 page marked, so we won't have to be fumbling 23 around. 24 To make it easier for you, Dr. Vance, I 25 have tabbed the page that I'm going to be

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	Page 42
1	talking to you about.
2	MR. WHITE: Is there a page number you
3	can give
4	MR. ROBERTS: Yeah.
5	MR. WHITE: me so I can follow along?
6	MR. ROBERTS: It's and I'll give you a
7	moment, Luke, to find that. It's H-E-R-E-D,
8	HERED-RCC-1.
9	MR. WHITE: Okay. I may need a moment to
10	find that.
11	THE WITNESS: It's after the KID.
12	MR. ROBERTS: Let me know when you're
13	there, Luke.
14	MR. WHITE: I'm really sorry, I cannot
15	find that.
16	THE WITNESS: It was after KID. It's
17	about 30 pages in.
18	MR. WHITE: This one goes from KID-E to
19	ST-1.
20	MR. ROBERTS: Let me give you this one.
21	THE WITNESS: Yeah, that's not correct.
22	MR. ROBERTS: Here you go.
23	THE WITNESS: You're missing
24	MR. WHITE: I'm sorry, that's got my
25	little exhibit not on that. I'm sorry.

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MR. ROBERTS: See if you can find it now.

I apologize for that.

MR. WHITE: No, it's okay.

There we go. I got HERED-RCC-1?

MR. ROBERTS: Yep.

6 MR. WHITE: All right. Thank you, sir.

I appreciate that.

BY MR. ROBERTS:

- Q. Now, in your report that you've given in this case, you've mentioned that the National Comprehensive Cancer Network lists different criteria when evaluating someone for hereditary renal cell carcinoma. Do you recall that?
- A. Yes.

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Q. And I'd like to direct your attention to the subheading that states: "Criteria for Further Genetic Risk Evaluation for Hereditary Renal Cell Carcinoma Syndromes."

Did I read that correctly?

- A. Yes.
 - Q. Now, I have read this document several times.

 And, Dr. Vance, I did not see anywhere in the document that said you could diagnose someone as suffering from hereditary renal cell carcinoma based solely on the clinical picture.

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1 Did I miss that?

MR. WHITE: Object to form.

- 3 I would point your attention to number 2.
- BY MR. ROBERTS: 4
- 5 Okay. Q.

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- Any individual with RCC, renal cell carcinoma, 6
- with any of the following, any of the
- following: One, diagnosed less than or equal 8
- 9 to 46 years; two, bilateral or multifocal
- tumors; three, greater or equal to one first-10
- 11 or second-degree relative with RCC.
- Ms. Tukes has all three. 12
- 13 Ο. All right. But if we look at the heading that
- 14 I just read to you --
- 15 Uh-huh. Α.
- 16 -- those criteria are for further genetic risk 0.
- 17 evaluation, are they not?
- That is correct. 18 Α.
- 19 So as I read this document, if you present with Ο.
- 2.0 one or more of these criteria, then according
- 21 to the NCCN guidelines, then you go to genetic
- 22 testing, isn't that correct?
- 23 MR. WHITE: Object to form.
- That -- that is the most direct and the 24 Α.
- 25 strongest component under evaluation, but

evaluation includes more than just genetic testing. It includes their medical history. It includes their family history. And it also includes genetic testing. And then it may, depending on those results or what you find, then include management.

BY MR. ROBERTS:

- Q. Dr. Vance, are you telling us that these NCCN guidelines allow you to diagnose hereditary renal cell carcinoma based solely on clinical features?
 - MR. WHITE: Object to form.
- 13 A. They're guidelines. So that the -- do they
 14 allow me to? Yes.
- 15 BY MR. ROBERTS:
- Q. All right. In your expert report, you also talk about differential diagnosis. That's something a clinician does, correct?
- 19 A. Correct.

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- Q. And what do you understand a differential diagnosis to be?
- A. Differential diagnosis has what you are
 thinking about as the etiology -- and actually
 not only the etiology, but the presentation and
 possible management of an illness.

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- Q. So when you're doing a differential diagnosis as a clinician, is it important to you to consider other causes of renal cell carcinoma or any cancer that you're involved with?

 MR. WHITE: Object to form.
- 6 A. Yes. 7 BY MR. ROBERTS:

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- Q. All right. So in other words, in Jacqueline
 Tukes's case, and you focus on the second
 criteria of the NCCN guidelines, which you said
 diagnosed at 40 years -- 46 years old or less,
 bilateral multifocal tumors, first- or
 second-degree relative with RCC. That's the -that's the main component or criteria of the
 NCCN guidelines that you are relying on in this
- 17 A. All three, yes.

case, correct?

- 18 Q. Okay. But there's four boxes, right?
- 19 A. Uh-huh.
- Q. And the only one that Mrs. Tukes fits in is
 number two, "an individual with RCC with any of
 the following criteria," correct?
- 23 A. That is correct.
- Q. And -- so let me -- let me ask this question.

 I think you were asked earlier, and I don't

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want to repeat myself, but have you seen any medical literature that people 46 years of age or younger that are exposed to carcinogens can develop renal cell carcinoma or other cancers? Object to form. MR. WHITE:

Α. No.

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BY MR. ROBERTS:

- Okay. Do you know if bilateral or multifocal Q. tumors can be present in people that are exposed to carcinogens?
- 11 Α. No.
 - Do you know -- let me -- let me strike that and 0. back up.

If that is the case, would that alter 14 15 your opinions in this case?

> MR. WHITE: Object to form.

I -- I don't think so. My experience leads me Α. to believe that Ms. Tukes had classical hereditary renal cell carcinoma. She met every box. She had extensive disease. She's not like any of the renal cancers that we typically I mean, I just think that -- I see in clinic. was describing this earlier, that of the bell She's on the one tail of the bell curve. She has extraordinary disease.

1 BY MR. ROBERTS:

Q. Would it change your opinions if her treating oncologist testified that the other patients that fit the description that you just gave for Ms. Tukes are also people that were exposed to carcinogens at Camp Lejeune?

MR. WHITE: Object to form.

8 A. No.

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- 9 BY MR. ROBERTS:
- Q. Okay. All right. So you didn't -- in reaching your opinions in this case, you based it solely on clinical features because all of the genetic testing was negative, true?
- 14 A. Clinical features and my experience.
- Q. Okay. You did not give any consideration
 whatsoever, did you, doctor, to whether or not
 her cancer could have been due to exposure to
 carcinogens at Camp Lejeune, did you?
- 19 MR. WHITE: Object to form.
- 20 A. No.
- MR. ROBERTS: Okay. Let's take a quick break.
- MR. WHITE: Sure.
- 24 THE VIDEOGRAPHER: Off the record
- 25 10:09 a.m.

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1 (WHEREUPON, at this time a brief recess was taken.)

THE VIDEOGRAPHER: We are back on the record at 10:15 a.m.

BY MR. ROBERTS:

- Q. Dr. Vance, when we took our brief break, we were talking about the NCCN guidelines. Do you recall that discussion we were having?
- A. Yes.

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Q. I guess what I'm trying to understand -- and, again, I don't want to belabor this point, but as I look at the guidelines, I did not see anywhere in those guidelines that said that you can diagnose renal cell carcinoma based solely on clinical presentation. Did I miss it or is it not there?

MR. WHITE: Object to form.

- A. She has renal cell carcinoma. So we're not diagnosing renal cell carcinoma. She had multiple incidences of renal cell carcinoma.

 BY MR. ROBERTS:
- Q. Let me restate the question. Hereditary renal cell carcinoma.
- 24 A. So can you say the full question then?
- 25 Q. Yes, ma'am.

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In looking at the National Comprehensive

Cancer Network Guidelines that we've been

talking about --

A. Yes.

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- 5 Q. -- does it anywhere say in this document that
 6 you can diagnose someone to be suffering from
 7 hereditary renal cell carcinoma based solely on
 8 the clinical presentation in the face of a
 9 negative genetic test? Does it say that
 10 anywhere?
- MR. WHITE: Object to form.
- 12 A. No.
- 13 BY MR. ROBERTS:
- 14 Q. Okay. All right. Let's go back to RCC-1. I
 15 think you've got it open there, right?
- 16 | A. Yes, I do.
- Q. And you see -- we talked about this before our break -- Criteria for Further Genetic Risk

 Evaluation for Hereditary --
- 20 A. Uh-huh.
- 21 Q. -- Renal Cell Carcinoma Syndromes, correct?
- 22 A. Correct.
- Q. So as I read this document, Dr. Vance, it says if a patient or person meets the criteria that are in those boxes on page RCC-1, then you go

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- to genetic testing. Am I reading that correctly?
 - A. No. As I said earlier, it's genetic risk evaluation, and genetic risk evaluation includes more than genetic testing. It includes an assessment of personal history, the family history, and then, if appropriate, genetic testing.
 - Q. Well, again, maybe I'm misunderstanding you.

 These criteria, if somebody meets them, would you then not do the genetic testing?
- 12 A. It's unlikely.
- Q. You would -- that would lead you to do the genetic testing, right?
- 15 | A. Yes.

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Q. So my question to you is, if you can diagnose hereditary renal cell carcinoma based solely on these criteria that are in the NCCN guidelines, why even do the genetic testing?

20 MR. WHITE: Object to form.

A. I think I've mentioned this before, but I'll say if again. When you do genetic testing, what you're trying to understand is etiology. With etiology, you sometimes will see that they're at risk for other things other than

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renal cell carcinoma, such as skin disorders or, you know, an increased risk for breast cancer as well as renal cell carcinoma.

The other reason you do that is to help with your management, because you understand the disease a little bit more, and also for family risk assessment so that individuals that are first- and second-degree relatives can then potentially be tested, if they so desire, and then be screened for the cancers associated with that gene mutation.

BY MR. ROBERTS:

Q. Well, I think in your report you indicated that there was some question about whether

Mrs. Tukes's mother's renal cell carcinoma was primary or had it -- it was the result of a metastasis, is that fair?

MR. WHITE: Object to form.

- A. It's in my report because that was in the medical records, that there was some ambiguity about her mother's cancer. However, in reading Ms. Tukes's deposition, she clearly states her mother had renal cell carcinoma.

 BY MR. ROBERTS:
- Q. But the question is: Was it primary or was it

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the result of a metastasis, correct? And that was -- that was the question.

- 3 A. I don't know.
- 4 Q. So you don't -- all right.
- 5 A. I don't know.
- Q. All right. Well, let me -- let me ask you this question: When did Mrs. Tukes's mother develop her kidney cancer?
- 9 A. It's stated in the medical record that she developed it at 67 and she died at 67.
- 11 Q. Now, so for her to get hereditary renal cell

 12 carcinoma -- I'm sorry. I didn't mean to cut

 13 you off.
- 14 | A. No. I meant years, is what I meant to add.
- Q. All right. So for Mrs. Tukes's mother to have hereditary renal cell carcinoma, she would have had to have inherited it from one of her parents, correct?
- MR. WHITE: Object to form.
- 20 A. Most likely.
- 21 BY MR. ROBERTS:
- Q. Okay. And hers did not develop until she was 67, correct?
- 24 A. That is correct.
- 25 | Q. So to what weight do you give the fact that

Page 54 of 177

1 Mrs. Tukes's mother did not -- was not 2 diagnosed with renal cell carcinoma until 67?

- A. There are so many reasons for that. So I don't give a lot of weight to that. I don't know Mrs. Tukes's mother's care. I don't know how she presented. I don't know the rest of her medical history. All I know is what I read in the medical report, Ms. Tukes's -- Jacqueline Tukes's medical report, that her mother had renal cell carcinoma, and then Ms. Tukes herself repeats that in her deposition.
- Q. Look, my question is: If Mrs. Tukes's mother had hereditary renal cell carcinoma, based on what we're looking at in the NCCN guidelines, isn't your testimony that that should have presented prior to the time she was diagnosed at 67?

MR. WHITE: Object to form.

A. It is not my testimony, no. I tried to explain this. I -- her renal cell carcinoma could have presented later. It could have presented earlier and she decided not to see a physician about it.

BY MR. ROBERTS:

Q. That's, again --

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- 1 A. I don't know.
- 2 | Q. -- that's pure speculation, right?
- 3 A. Yeah. I have no idea.
- Q. And it's pure speculation as to whether or not her mother's renal cell carcinoma was a primary or whether it was a metastasis, correct?

7 MR. WHITE: Object to form.

- A. I don't know that it's speculation. There might be evidence somewhere in a medical record, but I don't know it.
- 11 BY MR. ROBERTS:

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- 12 Q. Okay. Again, so you can't base your opinion on it if you don't know it, right?
- MR. WHITE: Object to form.
- 15 A. I cannot base my opinion on whether Ms. Tukes's

 16 mother was -- renal cell carcinoma was primary

 17 or metastatic disease without further
- 18 information.
- 19 BY MR. ROBERTS:
- Q. Okay. Now, let's turn over to the second page RCC-2.
- 22 | A. Okay.
- Q. And do you see this discusses hereditary renal cell carcinoma syndromes? Do you see that?
- 25 A. I do.

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Q. And, again, all the genes that are listed in the first column, Mrs. Tukes was tested for and

- 3 they were all negative, correct?
- 4 A. That is correct.
- Q. Such as, I think you mentioned,von Hippel-Lindau, that was negative, along

with the other genes, correct?

8 A. Correct.

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- 9 Q. All right. Now, let's turn to the third page.
- 10 And I'm -- and what I want to ask you,
- 11 Dr. Vance, is whether or not the guidelines,
- the NCCN guidelines, were followed over at
- NC -- over at UNC to the letter. They were,
- 14 were they not?
- MR. WHITE: Object to form.
- 16 A. I actually can't answer that.
- 17 BY MR. ROBERTS:
- 18 | Q. Okay.
- 19 A. I don't know if they followed them to the
- 20 letter.
- 21 Q. Okay. Is there anything that you think UNC
- 22 hospital should have done with Mrs. Tukes that
- 23 they didn't do?
- MR. WHITE: Object to form.
- 25 A. Are you referring to her appointment in 2018?

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1 BY MR. ROBERTS:

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Q. Well, just any -- based on any of the medical records that you've seen.

MR. WHITE: Same objection.

- A. Well, I can't make that statement because she was treated -- she was tested in 2018. I don't know if she was seen by genetics subsequent to that. I didn't see any report to that. And then she transferred her care elsewhere.
- 10 BY MR. ROBERTS:
- 11 Q. Okay. Well, let's go -- let's go to the -12 would you say this is a decision tree --
- 13 | A. Yes.
- 14 | Q. -- over on the second page?
- MR. WHITE: Is this page GENE-1?
- MR. ROBERTS: Yes, GENE-1. Sorry.
- 17 BY MR. ROBERTS:
- 18 Q. So the first column says, "Individuals with" -19 "Individuals with syndrome features," correct?
- 20 A. Correct.
- Q. And based on what we saw on the table, item 2, diagnosed at age 46 or younger, bilateral, multifocal tumors, first- or second-degree relative, so that was the basis for -- for
- wanting to assess her further, correct?

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- 1 | A. Yes.
- Q. All right. And then as we move through the
- decision tree, it talks about psychological
- 4 assessment and support, risk counseling,
- 5 education, discussion of genetic testing,
- 6 informed consent. That was done, correct?
- 7 A. Yes.
- 8 Q. And then we go to "No known familial
- 9 pathogenic/likely pathogenic variant." We
- 10 didn't -- because Ms. Tukes's mom wasn't
- 11 tested, we don't know that, correct?
- 12 A. Correct.
- 13 Q. So we continue on down the decision tree,
- 14 correct?
- 15 A. So are we talking about Ms. Tukes or her
- 16 mother?
- 17 | Q. I'm talking about Ms. Tukes.
- 18 A. Ms. Tukes herself?
- 19 Q. Yeah, correct.
- 20 A. Okay.
- 21 Q. So that leads us to "Consider testing of
- 22 individuals with kidney cancer-focused
- 23 multigene panel or clinically directed
- 24 | single-gene testing." She had all that done,
- 25 correct?

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- A. Well, she did have a multigene panel. There are others.
- Q. Right. But in your report, you said it was unlikely that would have yielded any useful information, correct?
- 6 MR. WHITE: Object to form.
- 7 A. Yes.
- 8 BY MR. ROBERTS:
- 9 Q. All right. So let's continue down the decision tree.
- All right. "No pathogenic/likely

 pathogenic variant found." That's Mrs. Tukes,

 right?
- 14 A. Correct.
- Q. And so the next -- the final item on the decision tree is "Offer research and individualized recommendations, according to personal and family history," correct?
- 19 A. Yes.
- Q. So you would agree with me that UNC-Chapel Hill followed the NCCN guidelines to the letter?
- MR. WHITE: Object to form.
- BY MR. ROBERTS:
- 24 O. Correct?
- 25 A. Well, I don't know if they offered her

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1 research, and I don't know what their

2 individual recommendations are. So -- and

3 that's why I'm saying I believe she transferred

4 her care.

- 5 Q. So are you -- are you saying that you
- 6 UNC-Chapel Hill Hospital and the genetic
- 7 professionals there failed to do something that
- 8 they should have done with respect to the care
- 9 of Jacqueline Tukes?
- MR. WHITE: Object to form.
- 11 A. I see where you're going. Okay. Now I
- 12 understand more clearly.
- So the folks at UNC genetics department
- did their appropriate work, that is correct.
- 15 BY MR. ROBERTS:
- 16 | Q. Okay.
- 17 A. The care was then left to the urological team.
- 18 | O. Dr. McCarthy?
- 19 A. Was -- I don't believe he was at UNC.
- 20 Q. He was not.
- 21 A. So then we're leaving USC, correct?
- 22 | O. UNC.
- 23 A. UNC.
- 24 Q. Yes, ma'am.
- 25 | A. Yeah.

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- 1 | Q. Okay.
- 2 A. So if we're -- I'd like clarification. So
- 3 | we're talking about UNC genetics, is that
- 4 correct?
- 5 Q. Yes, ma'am.
- 6 A. So --
- 7 | Q. Everything -- everything was done
- 8 appropriately, in your opinion, correct?
- 9 MR. WHITE: Object to form.
- 10 A. At UNC --
- 11 BY MR. ROBERTS:
- 12 Q. Genetics --
- 13 A. -- genetics?
- 14 | 0. -- correct.
- 15 A. Yes.
- 16 Q. And did you note that Ms. Gabarini, in one of
- her letters to Mrs. Tukes, stated that, "This
- 18 normal result is reassuring and indicates that
- 19 you do not likely have well understood
- 20 hereditary predisposition to renal cancer"?
- 21 Did I read that correctly?
- 22 A. I believe so.
- 23 Q. All right. Would you agree with Ms. Gabarini?
- 24 A. No.
- 25 Q. What is it about that statement that you don't

Page 62 of 177

1 agree with?

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- A. I believe that -- I wouldn't consider her negative testing good news. I would consider, as I stated in the report, that her result was indeterminate. She has the features of hereditary cancer. We're unable, at that point in time, was which was 2018, to find a gene responsible for her disease. And what I would have recommended is that she return to our service in five years or so to see if there is updated testing, which we do because genetic knowledge continues to expand.
- Q. I don't want to go back over what we covered previously, but as you sit here today -- well, just strike that. There's no need to go back over that again.

But the question I was asking you is the statement that Ms. Gabarini made about her genetic testing -- I didn't say anything about fortunate or unfortunate.

"This normal result is reassuring and indicates that you do not likely have well understood hereditary predisposition to renal cell cancer." Would you agree with that statement or not?

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A. I would say, no, but I think the adjective "well understood" is correct.

BY MR. ROBERTS:

Q. Okay. And you stick by your testimony that the fact that her objective genetic testing was all negative was not good news for Mrs. Tukes, is that your testimony?

MR. WHITE: Object to form.

- A. That is not the words I used. I wouldn't say "good news." It was not good news. I would say it was an indeterminate result and that she still had features of hereditary cancer and should be treated as such.
- 14 BY MR. ROBERTS:

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- Q. Okay. Let me ask you about the PMS2 gene. I'd like to start by asking you: What is the function of the PMS2 gene?
 - A. The PMS2 gene is one of the Lynch genes that is involved in hereditary non-polyposis colon cancer. It is considered a DNA repair gene.
 - Q. Okay. Let me back up and ask you: In response to one of my previous questions, Dr. Vance, is it your -- is it your testimony that you believe that Mrs. Tukes got wrong advice from the geneticist at UNC-Chapel Hill?

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1 MR. WHITE: Object to form.

- A. I wouldn't say it was wrong. I think I stated this previously. I would state it differently. But she was correct in saying that they didn't identify a gene mutation.
- 6 BY MR. ROBERTS:
- Q. Well, you're not suggesting that the geneticist at -- over at UNC-Chapel Hill didn't comply with the standard of care, are you?
 MR. WHITE: Object to form.
- 11 A. No.

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- 12 BY MR. ROBERTS:
- Q. All right. Getting back to the function of the PMS2 gene, it's involved in DNA mismatch repair, is that correct?
- 16 A. That is correct.
- 17 | Q. And what is DNA mismatch repair?
- A. Well, it was first discovered in E. coli, the
 bacteria. And what happens is that when
 there's a mismatch of a nucleotide, this
 machinery, PMS2 being one of them, will come in
 and repair the mismatch of the nucleotide.
 - Q. Is -- the process of DNA mismatch repair, would you consider that important in cancer?

MR. WHITE: Object to form.

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- 1 Α. Yes.
- 2 BY MR. ROBERTS:
- 3 Why is that important? Q.
- Because it's one of the mechanisms the cell has 4 Α. 5 to repair damage.
- And would a loss of function mutation in PMS2 6 Q. impact the process of mismatch repair?
- It could. 8 Α.
- 9 And would a loss in PMS2 function be expected 0. to result in an increase in cancer developments 10 11 following exposure to carcinogens or other 12 agents that damage DNA?
- 13 MR. WHITE: Object to form.
- 14 I'm not aware of that specifically. Α.
- 15 BY MR. ROBERTS:
- 16 Okay. So you don't have an opinion one way or 0. 17 the other on that, do you?
- Α. 18 No.
- 19 Okay. You're not going to come to trial and 0. 2.0 offer any opinion on that subject, right?
- 21 On what subject? Α.
- On the one we just talked about, whether a loss 22 Ο. 23 of function could result in increased cancer development following exposure to agents or 24 25 carcinogens that damage DNA.

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1 I would -- I would testify that loss of function can increase the risk of development 2 3 of cancer, not necessarily to a carcinogen.

- Okay. But do you have an opinion as to whether Q. a carcinogen can cause that loss of function?
- No. 6 Α.

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- And you're not going to have an opinion at Q. 8 trial on that subject, are you?
- Α. Well, you know, I believe, as I've said 10 previously, that there are multiple reasons 11 for, like, for instance, a second hit. are multiple reasons people develop cancer, and 12 most likely it's not heritable cancer. 13 14 related to your genetic background and your 15 That's the bulk of what we call exposures. 16 sporadic cancer.
 - Okay. So, again, the second hit that's in Ο. Dr. Knudson's model, it could be exposure to carcinogens, correct?
- 2.0 MR. WHITE: Object to form.
- 21 Yes, it could be. Α.
- 22 BY MR. ROBERTS:
- 23 It could be -- the second hit could be exposure Q. to the carcinogens at Camp Lejeune, correct? 24 25 MR. WHITE: Object to form.

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- A. Specifically, I don't know. But a carcinogen, yes.
- 3 BY MR. ROBERTS:
- 4 | Q. All right. Now, what is a missense mutation?
- A. A missense mutation is a change of one nucleotide for another that will change the amino acid.
- Q. And can a missense mutation result in a loss of function?
- 10 A. A missense mutation can result in a loss of function, yes.
- 12 Q. And what is the effect of a loss of function due to a missense mutation?
- 14 MR. WHITE: Object to form.
- 15 A. Okay. A missense mutation causing a loss of
 16 function can then impair the protein associated
 17 with that gene.
- 18 BY MR. ROBERTS:
- Q. And if that happens, do you have an opinion as to whether or not that person would be more susceptible to cancer from a carcinogenic exposure?
- MR. WHITE: Object to form.
- 24 \mid A. I do not have an opinion on that.
- 25 BY MR. ROBERTS:

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- 1 Q. One way or the other?
- A. No, because I don't know what the missense mutation was and I don't know the degree of loss of protein. So that's just pure speculation. It's not specific.
- Q. Well, you know Ms. Tukes has a missense mutation in the PMS2 gene, correct?
- 8 A. Yes.
- 9 Q. Okay. And where does this mutation occur in
 10 the gene and protein with respect to Ms. Tukes,
 11 do you know?
- 12 A. Say that again.
- Q. Yes. Where does this mutation occur in the gene and protein?
- MR. WHITE: Object to form.
- 16 A. I -- I don't know. I don't recall -- well, I

 17 don't recall what exon that missense change

 18 occurred of the gene. It's in the report, but

 19 I don't recall what that was.
- BY MR. ROBERTS:
- Q. With a missense mutation, is it expected to change the structure of the protein by substituting one amino acid for another?
- 24 A. No, it is not expected.
- 25 Q. Does that ever happen?

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- 1 A. It can.
- 2 | Q. Okay. So why would it not be expected?
- 3 A. Because, in this case, it was a neutral change.
- 4 | Q. A neutral change meaning what?

individuals, humans.

- 5 A. A substitution of one amino for another that did not affect the protein.
- Q. And what is the basis for that opinion?
- 8 A. In the fact -- the basis is looking at
 9 functional data that's available, looking at
 10 family histories of people with the same
 11 variant, looking at how that missense
 12 mutation -- or missense change, rather, is
 13 conserved in -- over species and conserved in

So there's different functional criteria that help to understand whether the missense change is neutral or affects the protein.

- Q. And in Ms. Tukes's case, you're saying it's neutral?
- 20 A. I'm saying it is benign.
- Q. Okay. So there would be no loss of function, is that what you're saying?
- 23 A. That is what I'm saying.
- Q. All right. What is the basis for your opinion that it's benign and it would not result in a

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1 loss of function?
2 MR. WHITE: Object to form.

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A. My basis for my opinion is the Invitae report that in 2018 first identified a missense change, called then a variant of uncertain significance because they didn't know if it was associated with a protein change or not.

Then over time, and I forget the time, it's in my report, it was changed to likely benign, meaning neutral, no -- no association with disease.

BY MR. ROBERTS:

Q. Would Invitae have taken into account the effect of that missense change when you introduce a carcinogenic exposure?

MR. WHITE: Objection to form.

- A. I can't -- I can't comment on what Invitae would do.
- 19 BY MR. ROBERTS:
- 20 Q. Do you know whether or not Invitae even considered carcinogenic exposure?
- MR. WHITE: Object to form.
- 23 A. I have no opinion as to that.
- MR. ROBERTS: We're up to Exhibit, what,
- 25 | 5?

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Page 71 1 MR. WHITE: I believe so, yes. 2 THE WITNESS: Yes. 3 (WHEREUPON, Deposition Exhibit 5 was marked for identification.) 4 BY MR. ROBERTS: 5 Dr. Vance, I'm showing you what we've marked as 6 Q. 7 Exhibit 5 to your deposition. And this is --8 is this the Invitae report that you just 9 alluded to? Yes, this is the first one. 10 Α. 11 Okay. And directing your attention to page 2 Q. 12 of this document. 13 Α. Pretty small font, but, yes. Do you see the PMS2, Exon 14, uncertain 14 Ο. 15 significance? Do you see that? 16 Uh-huh, I do. Α. 17 And do you see the language that says, "An O. 18 algorithm developed specifically for the PMS2 19 gene suggests that this missense change is 2.0 likely to be deleterious"? Do you see that? 21 Α. I do. So did you understand that Invitae had run an 22 Ο. 23 algorithm specifically for the PMS2 gene? That's what it says there. 24 Α.

And the fact that Invitae later came back and

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said it was likely benign, that would not change the algorithm, would it, that was run by Invitae that found the missense change would be likely deleterious, would it?

MR. WHITE: Object to form.

- A. I can't say for certain. I do see that they only list one article as the foundation of their opinion. And they state clearly that the prediction had not been confirmed by published functional studies or clinical significance.

 BY MR. ROBERTS:
- Q. Now, you've looked at the ClinVar data for this variant, is that correct?
- 14 A. Yes.

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- Q. And what is the rationale for stating that the variant is not likely to be pathogenic?
 - A. The data that the laboratories have that they report in ClinVar is based on what I stated previously, the incident of the missense, if it travels with disease, if there are any functional studies to show that it's damaging in culture, et cetera.
 - Q. Did you look -- when you looked at the ClinVar data, did you find any evidence of any studies that determined that there was a deleterious

1 effect on the protein structure and the function in the comments section of the ClinVar 2 data? 3

> Object to form. MR. WHITE:

- I looked at -- as I stated in my report, Α. there were 11 other laboratories that had data on this mutation, and I forget how many of them, of that 11, stated that it was also likely benign.
 - BY MR. ROBERTS:
- Did you see any laboratories that concluded Q. that the missense variant has a deleterious effect on protein structure and function?
- That specific missense, no, I did not. Α.
- 15 Did you bother to pull down the comments on the 0. 16 screen in the ClinVar data?
- 17 MR. WHITE: Object to form.
- I'm not sure what you're referring to. 18 Α.
- 19 MR. ROBERTS: Okay.
- 2.0 (WHEREUPON, Deposition Exhibit 6 was
- 21 marked for identification.)
- 22 THE WITNESS: Are these comments from
- 23 2018 or 2021? Okay.
- BY MR. ROBERTS: 24
- 25 Q. See there, 2021. Do you see it?

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- 1 A. Yes, uh-huh.
- 2 | Q. Is this the first time you've seen this
- 3 document?
- 4 A. In this format, yes.
- 5 Q. In any format.
- 6 A. Well, this is from ClinVar, correct?
- 7 Q. Right.
- 8 A. It's not identifiable.
- 9 Q. Right. Well, I mean --
- 10 A. It looks like it's from ClinVar.
- 11 Q. It is from ClinVar. And the ClinVar is very --
- it's very -- as you're probably aware, when you
- pull it off the computer, it's very small,
- 14 right?
- 15 A. Uh-huh.
- 16 Q. And I tried to help us out here. But the first
- document is from a lab called GeneDx. Are you
- 18 familiar with GeneDx?
- 19 A. Yes.
- 20 | O. What is GeneDx?
- 21 A. It's a national laboratory.
- 22 | Q. Well respected, well renowned, correct?
- 23 A. Yes.
- MR. WHITE: Object to form.
- 25 BY MR. ROBERTS:

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- 1 | Q. GeneDx does a lot of genetic testing, correct?
- 2 A. Yes.
- Q. One of the world's leaders in genetic testing?

 MR. WHITE: Object to form.
- 5 A. I don't know if it's a leader. It's a well-known, well-respected lab.
- 7 BY MR. ROBERTS:
- Q. Okay. Do you see the statement that "In silico analysis supports that this missense variant has a deleterious effect on protein/function"?
 Do you see that?
- 12 A. I do.

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- Q. Is that the first time you were aware that GeneDx had reached that conclusion?
 - A. I actually would say probably, yes, because what I looked at was likely benign as of June 2021, and it was one of several labs either stating it was likely benign or of uncertain significance.
 - Q. So what significance, if any, do you put in GeneDx's comment with respect to the PMS2 variant that analysis supports this missense variant has a deleterious effect on protein structure and function?
 - A. Well --

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- 1 MR. WHITE: Object to form.
- 2 A. -- I find it confusing, I guess.
- BY MR. ROBERTS:
- 4 Q. Okay.
- 5 A. Because I don't know why they would call it
- 6 likely benign and then have a comment that it
- 7 could be deleterious.
- 8 Q. Let's look at the second page. Have you ever
- 9 heard of Color Diagnostics, LLC?
- 10 A. Yes.
- 11 Q. Another well-renowned, well-regarded genetic
- 12 testing laboratory?
- MR. WHITE: Object to form.
- 14 A. Not as well known or well regarded.
- 15 BY MR. ROBERTS:
- 16 | O. As GeneDx?
- 17 | A. Correct.
- 18 Q. Okay. Let's go to the page before that. Do
- 19 you see Genetic Services Laboratory, University
- 20 of Chicago?
- 21 A. Yes.
- 22 Q. Have you heard of them before?
- 23 A. Yes.
- 24 Q. Very well regarded?
- MR. WHITE: Object to form.

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Q. Well known, correct?

MR. WHITE: Object to form.

A. I would think so.

BY MR. ROBERTS:

Q. All right. And do you see the comment -Dr. Vance, I'm trying to understand. When you
looked at the ClinVar data, what actually did
you look at? What -- you appear to -- to be
surprised with the information that I'm handing
you here.

You hadn't seen that prior to your deposition today, had you?

MR. WHITE: Object to form.

A. I saw -- I would correct you. I saw it, but I didn't take much significance in it because I believe the laboratory is unable to make a conclusion. They are waffling and they are saying there has been some evidence of a deleterious effect, but we can't conclude that, as you can see by saying uncertain significance or likely benign.

So I think that they're covering their bases and showing you the evidence that they do have, but they can't make a conclusion.

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1 BY MR. ROBERTS:

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- How would you go about making a conclusion as 0. to whether or not this missense variant has a deleterious effect on protein structure and function? How would you -- how would you investigate that further?
- Well, there are functional studies. And as I Α. was saying, functional studies, you put them in, like, a zebra fish or something -- some other model. And what you see is if that -that missense mutation or that gene itself causes a deleterious effect to either the structure of the organ or the development of the model.
- So you're saying on animal studies it would --0.
 - It could be animals. In silico is -- in silico Α. means that they tested different theories on a computer.
 - Okay. Right. Ο.

So one way to determine whether this missense mutation in PSM2 (sic) has a deleterious effect would be to do animal studies. Do you agree with that?

- Yes. Α.
- 25 Q. Okay. Did you see any animal studies that were

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done in this case on the PMS2 variant that

- 2 Mrs. Tukes had?
- 3 A. No.
- 4 | Q. Did you see Dr. Allen's rebuttal report --
- 5 A. Yes.
- 6 0. -- about the animal studies?
- 7 A. Yes.
- Q. Okay. And what were your opinions about the animal studies that Dr. Allen relied on?
- 10 A. I did not know if his studies were in general or if they were specific for this variant.
- 12 Q. Do you know now?
- 13 A. No.
- 14 | Q. What if they were specific to this variant?
- 15 A. I'd say that that was one level of evidence.
- 16 Q. That would support Dr. Allen's opinions
- regarding the effect of this variant, true?
- 18 MR. WHITE: Object to form.
- 19 A. I can't say that it would support what he
- thinks, but I could say that it would support
- that the variant may have a deleterious effect,
- as stated also in ClinVar, but it's not
- 23 conclusive.
- BY MR. ROBERTS:
- 25 Q. So we've got GeneDx, we've got Genetic Services

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Laboratory, University of Chicago, and we've got Color Diagnostics that apparently noted that this variant in PMS2 has a potential deleterious effect, fair?

- A. That's fair, yes.
- Q. And we also saw in the algorithm that was in the Invitae report found that the mutation is likely to result in a loss of function. Do you recall us looking at that?
- 10 | A. Yes.

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- 11 | Q. Okay.
 - A. But I would correct you and say that Invitae, and despite that comment, has determined that this missense mutation or this missense change is likely benign, meaning not associated with disease.
 - Q. Let me -- let me ask you this: When you say it's likely benign, you would agree with me that ClinVar doesn't take into account the effect of that missense change when you have a carcinogen -- carcinogenic exposure, such as what we've got in this case, correct?

 MR. WHITE: Object to form.
 - A. ClinVar, I don't know what they take into consideration in the sense that usually ClinVar

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reports with the laboratory reports. And then additionally there is ClinGen, which are expert panels that make decisions about specific changes in genes.

BY MR. ROBERTS:

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Q. All right. But ClinVar did not offer any evidence or opinions, did they, about whether or not this missense variant in the PMS2 could have an impact if that person was later exposed to a carcinogen, fair?

MR. WHITE: Object to form.

- A. That's fair. They did not offer an opinion about that.
- 14 BY MR. ROBERTS:
- Q. Okay. And ClinVar, that's not something that ClinVar does, right?
- 17 A. That is correct.
- Q. All right. Okay. Now, if the mutation on the
 PMS2 gene, that Mrs. Tukes had, occurred in a
 region that was critical for forming
 heterodimers with the MLH1 protein, would you
 expect that to impact mechanisms associated
 with DNA repair?
- MR. WHITE: Object to form.
- 25 A. I can't speculate because the data that I have

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1 states that this most likely does not impair

- the function of PMS2; therefore, MLH1 and PMS2
- 3 should go about in forming normal heterodimers.
- 4 BY MR. ROBERTS:
- Q. Well, do you know that Mrs. Tukes is heterozygous for this mutation?
- 7 A. She -- it's not a mutation. It's a variant.
- 8 It's called likely benign variant, and it is in
- one of her PMS2 genes and not the other, that
- 10 is correct.
- 11 Q. That means she has one normal copy of the gene
- and one copy of the missense variant, fair?
- 13 A. That's fair.
- 14 Q. And I believe you indicated that to conduct a
- functional study to determine if being
- 16 heterozygous for this gene or gene variant, you
- would do animal studies, fair?
- 18 A. That's one component.
- 19 Q. All right. And have you ever looked at animal
- 20 studies and determined them to be an
- appropriate approach to determine toxicity or
- 22 carcinog- -- carcinogenicity?
- MR. WHITE: Object to form.
- 24 A. No.
- 25 BY MR. ROBERTS:

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- 1 Q. Never done that before?
- I have not. 2 Α.
- 3 Did you see Dr. Allen's animal study on PMS2 Q.
- that found that heterozygous mice were more 4
- susceptible to carcinogen exposure than 5
- 6 compared to controls?
- I'm -- I did not. And I don't know what he's 7 Α. calling heterozygous mouse -- mice. 8
- 9 Ο. So you're not here to criticize Dr. Allen and
- his opinions regarding the study of the PMS2 10
- 11 variant and its potential impact on Mrs. Tukes,
- 12 correct?
- 13 MR. WHITE: Object to form.
- 14 I'm not here to criticize Dr. Allen. He has Α.
- 15 his own opinion --
- BY MR. ROBERTS: 16
- 17 Q. Okay.
- -- as I do mine. 18 Α.
- 19 Right. I'm trying to understand what you're 0.
- 2.0 saying. You're not saying Dr. Allen is wrong,
- 21 are you?
- Object to form. 22 MR. WHITE:
- 23 Α. No, I'm not saying Dr. Allen is wrong.
- 24 just saying this is what he's interpreted from
- the literature. 25

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- 1 BY MR. ROBERTS:
- Q. All right. Let's take a look at SMARCA4, if we could.
- 4 A. All right.
- 5 | Q. What is the function of the SMARCA4 gene?
- A. It's a protein that works in, like, rhabdoid cells. I'm not that familiar with SMARC or SMARCA4. I know the disease it's associated with.
- 10 0. Is it involved in chromatin remodeling?
- 11 A. It can be.
- Q. Okay. Well, what is the importance of chromatin remodeling in cancer?
- 14 MR. WHITE: Object to form.
- 15 A. Well, chromatin remodeling needs to occur for 16 the DNA and proteins, which are chromatin, to 17 function properly.
- 18 BY MR. ROBERTS:
- 19 Q. And what is the importance of SWI/SFN complex 20 in cancer?
- A. That works on chromosome segregation. Those
 are the proteins associated with kinetochore on
 chrome -- chromosomes. And for replication,
 normal replication and division to occur, those
 proteins are important.

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1 Q. And, you know, I want to back up just a moment. You said that -- when somebody says a 2 variant is likely benign, correct, would you 3 agree with me that that determination is made 4 in the absence of the possibility that the 5 variant could make a person more susceptible to 6 cancer when exposed to a carcinogen?

> Object to form. MR. WHITE:

Α. I don't believe that's what they're saying. "Likely benign" means from the laboratory that they do not have conclusive evidence that this variant is associated with disease, and it's not as specific as carcinogens.

BY MR. ROBERTS:

Right. So you would agree with me that saying O. something is likely benign would not rule out a subsequent study that shows that the variant could make a person more susceptible when exposed to carcinogens, is that fair?

> MR. WHITE: Object to form.

So a subsequent, you're assuming that whenever Α. these were revised, that would be after that -the call for likely benign? BY MR. ROBERTS:

Q. As I understood -- and, again, Dr. Vance,

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I'm -- if I misunderstand you, I apologize.
I'm just trying to figure out what your
opinions are in this case.

The -- when you say a variant is likely benign, right, that does not mean that that variant could not predispose a person to cancer if that person is exposed to carcinogens, is that fair?

MR. WHITE: Object to form.

A. No, that is not fair. Likely benign means at this point in time there is no association with this variant as a cause for cancer, whatever that cause may be.

Likely benign is merely saying we don't have evidence at this point in time to call this pathogenetic, or associated with disease.

BY MR. ROBERTS:

- Q. But I thought you said that that designation would not take into account specific facts, such as exposure to carcinogens, is that fair?
- A. That -- that is correct.
- Q. Okay. Would a loss of function mutation -- or strike that.

Would a loss of function variant in SMARCA4 impact cancer development?

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- 1 MR. WHITE: Object to form.
- 2 A. It could potentially.
- BY MR. ROBERTS:
- 4 Q. Okay.
- 5 A. We have no evidence for that.
- 6 Q. Okay. Again, you didn't -- did you look at
- 7 Dr. Allen's animal study on the SMARCA4?
- 8 A. No.
- 9 Q. Okay. Are you even qualified to say whether
- he's right or wrong, Dr. Vance?
- 11 | A. No.
- 12 MR. WHITE: Object to form.
- 13 BY MR. ROBERTS:
- 14 | O. Ma'am?
- 15 A. No.
- 16 Q. Okay. And if you don't have an opinion on
- this, please let me know. Would a loss of
- 18 function mutation and -- or strike that.
- 19 Would a loss of function variant in
- 20 SMARCA4 be expected to result in an increase in
- 21 cancer development following exposure to agents
- 22 that impact cell death, such as carcinogens?
- MR. WHITE: Object to form.
- 24 A. I don't know.
- 25 BY MR. ROBERTS:

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1 Q. Do you know that Ms. Tukes has a missense

- 2 mutation in the SMARCA4 gene?
- 3 Α. Yes.
- And do you know where this mutation occurs in 4 Ο. the gene and the protein?
- 6 Yes. Α.

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- Where? Q.
- 8 Α. Exon 30.
- 9 Ο. Okay. Would this missense variant be expected
- 10 to change the structure of the protein by
- 11 substituting one amino acid for another?
- Yes. 12 Α.
- 13 And what is the amino acid change and what Ο.
- 14 impact would this have on the biochemistry of
- 15 the protein?
- 16 This amino acid change appears to be neutral, Α.
- 17 so none.
- 18 Ο. Okay. In the absence of exposure to a
- 19 carcinogen?
- 2.0 MR. WHITE: Object to form.
- 21 I can't say that specifically. Α.
- BY MR. ROBERTS: 22
- 23 Q. Okay. You don't have an opinion on that,
- right? 24
- 25 Α. No.

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Q. If the mutation occurred in the region of the SMARCA4 protein critical for ATPAs, would that likely impact protein function?

MR. WHITE: Object to form.

- 5 A. I have no opinion.
- 6 BY MR. ROBERTS:

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- Q. And, again, you know that Mrs. Jacqueline Tukes is heterozygous for this mutation, correct,

 SMARCA4?
 - A. I understand she's heterozygote for a missense variant that's been classified as likely benign, not a mutation.
 - Q. Would an animal study be an appropriate approach to determine the function of the SMARCA4 variant and its potential impact when a person is exposed to a carcinogen?
 - A. It could be a line of evidence. It would be -you'd have to set it up with a particular
 animal and case control. It could be.
- Q. And you have no opinions -- well, strike that.

 MR. ROBERTS: Let's take a quick break,
- if we could.
- MR. WHITE: Sure.
- THE VIDEOGRAPHER: We're going off the record at 11:04 a.m.

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Page 90 1 (WHEREUPON, at this time a brief recess was taken.) 2 3 THE VIDEOGRAPHER: We are back on the record at 11:26 a.m. 4 BY MR. ROBERTS: 5 Dr. Vance, we're going to go back on the 6 Q. 7 record, and there's a couple of questions I'd 8 like to ask you. 9 First of all, you have told us today all of the depositions that you read in this case; 10 11 is that correct? I think there were four of 12 them. 13 That is correct. Α. 14 Are there any other depositions you've read? Q. 15 No. Α. Okay. You did read a draft of -- a rough draft 16 0. 17 of Dr. Allen's, is that correct? 18 Α. Yes, I did, probably not to completion. It was 19 very difficult to read. 2.0 Q. Okay. Now, in Dr. Allen's report, he makes the 21 following statement, and I'd like to ask you if 22 you agree or disagree. Is that --23 Is this a report or the deposition? Α. 24 This is the report. Ο.

Α.

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Okay.

Q. Okay. "Thus, while it is not likely that the PMS2 mutation observed in the patient directly contributes to renal cell carcinoma and is likely benign in this context, there is compelling evidence that indicates dosage pathogenicity."

Object to form.

Do you agree with that?

- A. I have read that. I agree that I have read that. I don't agree with the conclusion.

 BY MR. ROBERTS:
- O. The concl- -- what conclusion?

MR. WHITE:

- A. That dosage pathogenicity would be deleterious in this situation because I don't believe that dosage pathogenicity relates to this variant.
- Q. Okay. What about his statement that "Based on the function of the PMS2 as a tumor suppressor, the predicted loss of function observed in the patient is sufficient evidence of dosage pathogenicity, haploinsufficiency score in the ClinVar database and the data related to carcinogen exposure in heterozygous animals, it is likely as not that this mutation results in insufficient DNA mismatch repair in the patient"?

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- 1 A. I disagree.
- Q. Okay. You didn't -- you didn't look at the animal studies or models, correct?

4 MR. WHITE: Object to form.

- 5 A. Correct.
- 6 BY MR. ROBERTS:
- Q. All right. So you really don't have a basis for disagreeing with that, do you?

9 MR. WHITE: Object to form.

- 10 A. I disagree in the sense that I don't believe
- 11 this -- there is dosage pathogenicity here.
- 12 There's no evidence of loss. So it has nothing
- to do with animal studies done.
- 14 BY MR. ROBERTS:
- Q. Well, you didn't look at the animal studies, though.
- 17 A. No, but I'm telling you that what Ms. Tukes
- carries, there is no haploinsufficiency, there
- is no deletion, there is no loss at all. So in
- 20 that situation, there is no dosage
- 21 pathogenicity for this variant.
- 22 And typically what ClinVar is talking
- about when they're talking about dosage
- 24 pathogenicity is the gene itself.
- 25 | Q. Okay. Now, we -- I don't want to cover old

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ground, but I thought you said ClinVar does not

- 2 take into account the potential effect of a
- 3 variant when you're exposed to a carcinogen.
- 4 Didn't you tell us that previously?
- 5 MR. WHITE: Object to form.
- 6 A. Yes.
- BY MR. ROBERTS:
- 8 Q. Okay. All right. Dr. Vance, I'd like to talk
- 9 to you briefly about your invoices that you've
- 10 submitted in this case. And according to my
- 11 notes, you've submitted seven. Is that a fair
- 12 statement?
- 13 A. I believe that's correct.
- 14 | Q. And you've billed, what, approximately
- 15 50 hours? Is that a fair statement?
- 16 A. I believe so. I don't have them in front of
- 17 me.
- 18 (WHEREUPON, Deposition Exhibit 7 was
- marked for identification.)
- 20 BY MR. ROBERTS:
- 21 Q. Okay. Let me hand you what we're going to
- 22 mark, I think, as Exhibit 7.
- 23 A. Yeah. Thank you.
- 24 Q. And I don't want to spend a whole lot of time
- on these invoices, but if you could confirm for

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Page 94 1 me that you've spent a total of about 50 hours, 2 correct? MR. WHITE: Object to form. 3 BY MR. ROBERTS: 4 Through the end of -- through the end of May of 5 Q. 6 this year. I think your last invoice was 7 through the end of May. That's correct. 8 Α. 9 Ο. How much additional time have you put in since the end of May? 10 11 I'm not absolutely sure, but it's about --Α. probably ten hours. 12 13 0. Okay. Was that preparing for your deposition? 14 Yes. Α. 15 Okay. All right. Have you spoken with any of 0. 16 the other experts that have been retained by 17 the United States in this case? 18 MR. WHITE: Objection. 19 MR. ROBERTS: I'm not asking what she 2.0 said. 21 MR. WHITE: Okay. 22 BY MR. ROBERTS: 23 Just have you spoken to any of the other Q. 24 experts? 25 MR. WHITE: Yeah, can I -- just so I can

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make that clear.

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If you've spoken to experts, you can testify that you've spoken to other experts, but any communications would be -- would be privileged, and you shouldn't divulge contents of any communications.

THE WITNESS: Okay.

MR. WHITE: If -- if there were any to begin with, but I just wanted to make that clear.

THE WITNESS: Okay. I appreciate that.

They're -- on one call, and I don't recall if it was April or March, a nephrologist was on one of the calls. I don't recall his name.

BY MR. ROBERTS:

- Q. I'm not asking you to divulge to me what you talked about, but did anything that this nephrologist said affect your opinions one way or the other?
- A. No.
- Q. Okay. All right. Have you seen a document that we were provided that is called a "Materials Considered List"?
- 25 A. I don't believe so.

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- 1 Q. Okay. I'm trying to understand exactly what you have looked at in reaching your opinions in 2 this case. And as I understand it -- you know, 3 I don't want to go back over the four 4 depositions, but there was -- there was 5 information that was provided to us that you 6 looked at documents, such as the experts in the other cases. You haven't read any of those 8 9 depositions, have you?
- 10 A. Other than the four that I've talked to you about, I have not.
- (WHEREUPON, Deposition Exhibit 8 was
 marked for identification.)

 BY MR. ROBERTS:
 - Q. All right. Just so the record is clear on this, I'm going to hand you what was produced to us. I'm handing you what we're going to mark as Exhibit 8. Is there another copy under
- 19 there?

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- A. Yes.
- 21 Q. Okay. Thank you.
- MR. WHITE: Thank you.
- MR. ROBERTS: Yep.
- BY MR. ROBERTS:
- 25 | Q. Have you seen this document before?

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- 1 | A. No.
- Q. Do you see it's got your name, Gail Vance,
 M.D., in the left-hand corner of the page?
- 4 A. Yes.
- Q. And it says, "Attachments (Facts and Data Considered)." Do you see that?
- 7 A. Yes.
- Q. Then over on page 2, it's got expert reports, beginning with Steven Bird. There's six Phase 2 reports. Have you -- you haven't read any of those depositions, have you?
- 12 A. No.
- Q. So you haven't considered any of those expert reports in rendering your opinions in this case, have you?
- 16 A. No.

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- MR. WHITE: Object to form.
- 18 BY MR. ROBERTS:
 - Q. Let's go to Phase 3. You see the report of Dr. Allen. I believe you've stated that you have looked at that report. But what about Matthew Cooper, Michael Fryar, David Josephson, Timothy Mallon, Chad Staller, Armine Smith? You didn't consider any of those reports in rendering your opinions, did you?

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1 MR. WHITE: Object to form.

- 2 A. No.
- BY MR. ROBERTS:
- 4 Q. Let's go under DOJ Experts, Phase 2. Do you
- 5 see the reference reports for Julie Goodman,
- John Lipscomb, Michael McCabe, Peter Shields?
- 7 Would it be fair to say you didn't read those
- 8 reports?
- 9 MR. WHITE: Object to form.
- 10 | A. I don't know who the nephrologist was. I don't
- 11 recall the name.
- 12 BY MR. ROBERTS:
- 13 Q. Other than the nephrologist.
- 14 | A. Yeah. No.
- 15 Q. Do you see Lisa Bailey, Duncan Johnstone, Judy
- 16 LaKind, Michael Shahnasarian, Walter Stadler?
- Didn't -- didn't -- other than the potential
- nephrologist, you didn't read any of those
- 19 reports, did you?
- 20 A. No.
- 21 Q. Over on the -- on page 3 of the document,
- Depositions, do you know who FJ Bove is,
- Dr. Frank Bove?
- 24 A. No.
- 25 | Q. Never heard of him?

- 1 | A. No.
- 2 Q. How about David Savitz, Dr. David Savitz, ever
- 3 heard of him?
- 4 A. No.
- 5 | Q. Under "Tukes," you said you -- I'm moving down
- on page 3, down from the top.
- 7 A. Uh-huh.
- 8 Q. Are you with me there, under "Tukes"?
- 9 A. Yes.
- 10 Q. You indicated you read Jacqueline Tukes's
- 11 deposition, correct?
- 12 A. Yes.
- 13 Q. You didn't read Dr. -- Willie Tukes, her
- 14 husband's deposition, did you?
- 15 A. No.
- 16 Q. You did read Mary Garbarini's deposition?
- 17 | A. Yes.
- 18 Q. We talked about Dr. Jayaram, the oncologist.
- 19 He's listed on your materials considered. You
- didn't read his deposition, did you?
- 21 A. No.
- 22 Q. Heather Jones, do you know who Heather Jones
- 23 is?
- 24 A. No.
- 25 Q. Didn't read her deposition, did you?

- 1 | A. No.
- Q. Roc McCarthy, you read Dr. McCarthy's deposition, correct?
- 4 A. Correct.
- 5 Q. Thomas -- K.V.J. (sic) Thomas, Dr. KV George
- Thomas, M.D., do you know what he testified
- 7 about?
- 8 A. No.
- 9 Q. Turning over to the other -- the next page,
- page 4 of 7, "Other articles and literature,"
- can you tell us of those ten items that are
- 12 listed there which ones you considered in
- reaching your opinions, if any?
- 14 A. None.
- Q. Okay. And then there's documents produced in
- this litigation that are Bates stamped. Do you
- 17 | see that?
- 18 A. I see "Other documents produced." I don't see
- a Bates stamp with them.
- 20 Q. See the "Bates begins" and "Bates ends"?
- 21 | A. Oh, I see it, yes.
- 22 O. Okay. So other than Mrs. Tukes's medical
- records, as I understood your testimony, you
- have not looked at any other documents other
- 25 than literature, Dr. Allen's reports. Anything

else other than her medical records and the items I just mentioned?

MR. WHITE: Object to form.

- So I reference the materials I used for my Α. report. I have told you what I have reviewed. And then there were two other textbooks that I utilize just for content in thinking about when I was producing my report. You apparently received those, too.
- BY MR. ROBERTS: 10
- 11 Yeah. Okay. We're going to mark those next. Ο.
- 12 Α. Okay.

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- If I can see this -- so the -- as far as the 13 14 materials that were Bates numbered, the only 15 ones you recall would have been Mrs. Tukes's 16 medical records, is that fair?
 - MR. WHITE: Object to form.
- 18 Α. That's fair. There was about 289 pages of 19 records.
- 2.0 (WHEREUPON, Deposition Exhibit 9 was 21 marked for identification.)
- BY MR. ROBERTS: 22
- 23 I'm going to hand you what we're going to mark Q. as Exhibit 9 --24
- 25 Α. Okay.

- 1 Q. -- to your deposition, Dr. Vance.
- 2 MR. WHITE: Thank you.
- BY MR. ROBERTS: 3
- Are these the supplemental materials that you 4 Q. just alluded to a moment ago? 5
- Yes. 6 Α.

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- And you've got the reports of -- Dr. Allen's Q. 8 reports, his rough draft deposition. 9 about the "WHO Classification of Tumours of the Urinary System in Male Genital Organs, " tell us 10 11 about that. To what extent did you rely upon 12 that in reaching your opinions in this case?
 - Well, that's my textbook. The WHO comes out Α. with what they call the Blue Books. And what I looked at under there was the renal cell carcinomas and the different types, such as clear cell, papillary, papillary clear, et cetera, just to reacquaint myself with primarily papillary clear, the mixture of those two.
 - To what extent did that information Q. influence your opinions in this case? MR. WHITE: Object to form.
 - It didn't. I mean, my opinions weren't -- I Α. was just using it as information.

- 1 BY MR. ROBERTS:
- 2 | Q. Okay.
- 3 A. Just for clarification.
- Q. So nothing specific you can point to that you relied upon?
- 6 A. No.

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- 7 Q. Okay. How about Nussbaum?
- 8 A. Nussbaum.
- 9 Q. Again, it's -- yeah. And Willard, "Thompson and Thompson Genetics in Medicine," is there anything in there that was pertinent to the opinions that you have rendered in this case?
 - A. The materials in there are -- this is a general genetics textbook, and I was using those for some of the glossary that was provided in my report. I was looking at that for definition of terms.
- Q. And you're not holding yourself out today as an expert in toxicology or epidemiology, are you, ma'am?
- 21 A. No.
- Q. Now, Dr. Vance, I'd like to talk to you briefly
 about your prior experience as an expert. And
 I believe you've told me earlier this morning,
 and I could be wrong, but I thought you said

1 you've never testified at trial. Is that

- 2 correct?
- MR. WHITE: Object to form. 3
- No, that's incorrect. 4
- BY MR. ROBERTS: 5
- Okay. I mis- -- I misunderstood you. Okay. 6 Q.
- Tell me about when you've testified at trial.
- I testified a case -- I was a witness for the 8 Α.
- 9 defense, and it was a cytogenetic -- unbalanced
- 10 cytogenetic translocation.
- 11 Okay. Who was the -- who was your client in Ο.
- 12 that matter?
- 13 Α. Dartmouth.
- 14 Okay. And where did you actually testify? Ο.
- 15 I testified that --
- 16 Where? Where? 0.
- 17 Oh, where? Α.
- 18 Ο. Yes, ma'am.
- 19 Was it Connecticut? Α.
- 2.0 Was it in federal court or state court? Ο.
- 21 Oh, state. Α.
- 22 Okay. What was the issue that you opined on in Q.
- 23 that case?
- The issue was defense of the cytogeneticist and 24 Α.
- 25 his report of the cytogenetic report for an

- 1 infant.
- 2 | Q. So he was being sued for malpractice?
- 3 A. Correct.
- 4 | Q. All right. What was the result of that case?
- 5 A. He was dismissed from the malpractice.
- 6 | Q. Okay. So that was -- did that testimony have
- 7 any relevance to what we've been talking about
- 8 today?
- 9 A. Other than chromosomes, no, it has no
- 10 relevance.
- 11 | Q. All right. So that's your first time you've
- 12 testified in court.
- 13 A. Uh-huh.
- 14 Q. Any other occasions?
- 15 A. Not in court, no.
- 16 Q. Okay. All right. So that covers all of your
- 17 | court testimony, right?
- 18 A. Correct.
- 19 Q. All right. Let's talk about depositions.
- Other than the case that brings us here today,
- what other occasions have you had to testify?
- 22 A. I was deposed in that case.
- 23 Q. Okay.
- 24 A. And then the second one was, again, for the
- defense in the understanding of what's called

- 1 Li-Fraumeni syndrome.
- 2 Q. Okay. LFT?
- 3 | A. LFS.
- 4 Q. LFS, okay.
- 5 A. And it is a genetic predisposition syndrome.
- 6 Q. And you testified for the plaintiff or the
- 7 defense?
- 8 A. Defense.
- 9 Q. Okay. What was the result of that case?
- 10 | A. I think they settled out of court.
- 11 Q. Okay. All right. And that's the -- any other
- depositions we need to talk about? That's it?
- 13 A. No. I've had conversations, but
- 14 not depositions.
- 15 Q. Okay. Have you ever been retained by a
- 16 plaintiff as an expert?
- 17 A. Not to my knowledge, no.
- 18 Q. Okay. I'd like to circle back, but before I do
- that, you're being paid \$350 an hour, is that
- 20 correct?
- 21 A. That is correct.
- 22 | O. And I saw in one of the items that the
- government gave us that you're anticipating
- making, what, about \$100,000 on this
- 25 engagement?

- 1 MR. WHITE: Object to form.
- 2 | A. No.
- 3 BY MR. ROBERTS:
- Q. No. You didn't recall seeing a document that -- where you were --
- A. I saw the contract, and it had a top limit, but that wasn't the anticipated amount.
- 8 Q. Okay. Well, let's just -- let's clarify that.

9 MR. ROBERTS: What exhibit are we up to

10 now?

- 11 THE WITNESS: We're on 10.
- 12 (WHEREUPON, Deposition Exhibit 10 was
- marked for identification.)
- 14 BY MR. ROBERTS:
- 15 Q. I'll hand you, Dr. Vance, what we've marked as
- 16 Exhibit 10. Can you identify what this
- 17 document is?
- 18 A. Yes. It's a contract with the U.S. Department
- 19 of Justice.
- 20 Q. Okay. And do you see the block 14.k., Total
- 21 Estimated Expenses?
- 22 | A. I do.
- 23 | Q. Okay. What is that? If you could read into
- 24 the record that that says.
- 25 A. Well, I work in academia, so what we do is we

1 get purchase orders and we put a top limit

- 2 amount for whatever the expense would be. And
- 3 that was my understanding is that the top limit
- for this contract would be \$98,000.
- 5 | Q. So is that a -- is that an amount that you came
- 6 up with or is it an amount that the government
- 7 came up with?
- 8 A. That is an amount the government came up with.
- 9 Q. Okay.
- 10 | (WHEREUPON, Deposition Exhibit 11 was
- 11 marked for identification.)
- 12 BY MR. ROBERTS:
- 13 | O. For the record I'd like to introduce
- 14 Exhibit 11 --
- 15 A. Okay.
- 16 | Q. -- and ask you if this is your current CV?
- 17 | A. No. This is from April and I've updated for
- 18 July.
- 19 | O. Okay. What do we need to add to that?
- 20 A. Just publications.
- 21 Q. All right. Will you provide that to your
- 22 attorney?
- 23 A. I have.
- 24 Q. You have? Okay.
- 25 A. Uh-huh.

1 MR. WHITE: That may have been in the

2 stuff that was recently produced, but I can run

3 that down for you.

4 MR. ROBERTS: Yeah, that's no problem.

5 BY MR. ROBERTS:

- 6 | Q. Are there any publications that you have
- 7 authored that you think have particular
- 8 pertinence --
- 9 A. Yes.
- 10 | Q. -- to the Jacqueline Tukes case?
- 11 A. Well, I have a lot of publications. 98 is
- 12 establishing a hereditary renal syndrome
- clinic. One is -- this was a presentation. I
- 14 should go to the --
- MR. WHITE: If you could tell me the page
- 16 numbers.
- 17 THE WITNESS: Okay, yeah. Let me go to
- the articles. That was -- hold on.
- 19 BY MR. ROBERTS:
- 20 Q. We've got them -- why don't we go numerically.
- 21 A. Yeah, yeah.
- 22 Q. The first one are journals, I think.
- 23 A. Yeah, peer-reviewed. Hold on.
- MR. WHITE: I think that would be, what,
- 25 page 14?

- 1 MR. ROBERTS: Yeah.
- 2 MR. WHITE: Or that's when the journals
- 3 begins.
- THE WITNESS: Yes, but that's -- I don't 4
- know. I mean, pertinent to Jacqueline Tukes 5
- would be anything with hereditary cancer, but 6
- more pertinent would be specifically renal cell
- carcinoma. 8
- 9 BY MR. ROBERTS:
- All right. What publication? If you give me 10 Ο. 11 the --
- 12 Yep. Hold on. Let me go through these. Α.
- 13 The biomarkers in some of the cancers,
- 14 but they're not specifically renal cell cancer
- 15 in some of these that I have.
- 16 If you would just -- as you go through, O.
- 17 ma'am --
- 18 Α. Okay.
- 19 -- if you could identify them for me. Ο.
- 2.0 Sure, sure, sure. Α.
- 21 Because I need to understand, you know, what Q.
- 22 your testimony is about --
- 23 Okay. Α.
- -- what has relevance to this case. 24 Q.
- 25 Α. So peer-reviewed, reference 32, "Validation of

		Page 111
1		scales to measure: benefits of and barriers to
2		colorectal cancer screening."
3	Q.	That's 32?
4	A.	Uh-huh.
5	Q.	Okay.
6	A.	For hematological cancer, 33, is "Role of
7		potential hematopoietic stem cell
8		transportation transplantation in children
9		with secondary acute lymphocytic leukemia."
10		Then there's the biomarker HER-2, which
11		is number 34.
12	Q.	Okay.
13	A.	That's typically in breast, but it's also seen
14		in prostate, colon, and endometrial.
15		Again, 36, "HER-2 expression in germ cell
16		tumors."
17		37, "HER-2 amplification."
18		Let's see. Number 40, "late relapse of
19		germ cell tumor. "
20		44, "Secondary leukemias in refractory
21		germ cell tumor patients undergoing autologous
22		stem cell transportation transplantation."
	I .	

Number 47, "Acute Panmyelosis and

Myelofibrosis: An entity distinct from acute

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from megakaryoblastic leukemia."

The next one is "Chronic lymphocytic leukemia/small lymphocytic leukemia with trisomy 12."

49, "AML-FOG2 Fusion Protein in Myelodysplasia."

Number 50, "Large cell -- large cell lung carcinoma mimicking a germ cell tumor."

Number 54, "A 37-year-old man with pleural mass."

- It appears that you're talking about a number Q. of things that don't have anything to do with renal cell carcinoma.
- Right. I get -- there are cancer and cancer Α. biomarkers and also hereditary disease. why I'm producing these. There's a lot of -in here. But specific to renal cell carcinoma is our clinic. And let me try and find that here for you.

120, JD McFadden, "Referral Here we are. patterns and genetic testing outcomes in a contemporary hereditary renal cancer clinic," Urological Oncology, 2024.

So that's -- what that is is 142 patients that came through our renal -- hereditary renal clinic, and we did genetic testing and we

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determined that most likely gene mutation in
that group of patients was the fumarate
hydratase mutation associated with HLRCC, which

- 4 is here in your NCCN.
- Q. So were all of those patients that were -- that came through the clinic, that you just described, they underwent genetic testing?
- 8 A. Most of them did.
- 9 Q. And were most of them positive?
- 10 A. No, the majority were not.
- 11 | Q. Okay.
- 12 A. But none of them had the clinical phenotype as 13 extensive as Ms. Tukes.
- 14 Q. Okay.
- 15 A. I forget the percentage of those that had -
 16 I'd have to look at the article.
- 17 Q. Okay. Are you through?
- 18 A. I'm done.
- Q. Okay. Dr. Vance, when -- have you ever had a patient come into your office that has a clinical picture that would suggest renal cell carcinoma but yet you dug deeper to try to figure out if something other than a hereditary component was involved in the cancer?

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- 2 BY MR. ROBERTS:
- $3 \mid Q$. All right. Tell me about that.
 - A. Well, it's not a patient. Typically, as I've previously said, when a patient comes to us, particularly in the renal cell carcinoma clinic, they usually have renal cell carcinoma. We look at what their medical history is, what their cancer history is, what their family history is, and if there's any rationale for why they developed cancer, i.e., exposures, again family history, anything of that nature.
 - Q. Okay. What type -- when you say "exposures," I mean, if somebody walks in and presents with sequelae that would be -- lead you to believe that perhaps there's hereditary renal cell carcinoma, okay, what other factors do you look at, or do you automatically say it's renal cell carcinoma if they -- if the clinical picture presents in the way that we've been discussing today?

MR. WHITE: Object to form.

A. Again, I look at their personal history, their medical history, their family history, any kind of history that might indicate that there was a

reason other than a gene mutation or to support
a gene mutation. It's a complete medical
history.

BY MR. ROBERTS:

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Q. Okay. All right. Well, so again, I thought you asked this -- answered this question earlier in your deposition, but I could be mistaken.

Have you ever had someone that presented with multi -- multifocal bilateral kidney cancer that was of the age of Ms. Tukes, and looked at it and said, well, you know, it looks like it might be hereditary -- hereditary renal cell carcinoma, but yet there's another factor out here that could also be at play, such as exposure? Has that ever happened in your clinical practice?

MR. WHITE: Object to form.

- A. Has it ever happened?
- BY MR. ROBERTS:
- 21 Q. Yes, ma'am.
- 22 A. Most likely, yes.
- 23 Q. Can you tell me about that?
- A. Well, I don't remember the exact case, but there are many people -- I mean, we live in

rural Indiana. Many people have been exposed to farming pesticides.

- 3 Q. Right.
- 4 A. Things of that nature.
- 5 Q. Right.
- 6 A. So that's what I'll ask about.
- 7 Q. Okay. And if somebody -- let's take a farmer that's been --
- 9 A. Excuse me for interrupting.
- 10 | Q. I'm sorry.
- 11 A. But like smoking history.
- 12 | O. Yeah.
- 13 A. That -- we get that, because that's predisposed
- 14 to renal cancer. Smoking, obesity,
- 15 hypertension, et cetera.
- 16 Q. Of course, Mrs. Tukes wasn't a smoker, was she?
- 17 MR. WHITE: Object to form.
- 18 A. Not to my knowledge. She did have
- 19 hypertension, and I don't know what her BMI
- 20 was.
- 21 BY MR. ROBERTS:
- 22 Q. All right. So, again, getting back to my
- 23 question, when these farmers, you say, that
- would come into your office that have been
- around pesticides, did you attempt to determine

whether those pesticides were known carcinogens?

MR. WHITE: Object to form.

- A. No, that was not my role.
- 5 BY MR. ROBERTS:

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- Q. Okay. Did you attempt to determine whether or not, as opposed to some hereditary component, that the cancer could be related to carcinogen exposure?
- 10 A. No. My role was to document things and then to
 11 perform the genetic testing and interpret the
 12 genetic testing.
 - Q. Well, as we sit here today, in Jacqueline

 Tukes's case, you've got a lady that you say

 fits the diagnostic criteria that you say makes

 her -- her cancer is hereditary, correct?
- 17 | A. Correct.
- Q. And on the other side of the table, we've got a known exposure to carcinogens, correct?

 MR. WHITE: Objection.
- 21 A. I don't know about that exposure.
- BY MR. ROBERTS:
- Q. Okay. That's what I'm trying to delve into,

 Dr. Vance. I mean, if you don't know about the

 exposure and whether the exposure can result in

multi- -- you know, bilateral, multifocal cancer, that it can manifest at an early age, right, how can you rule that out in rendering your opinions? Aren't you ignoring the other side of the equation?

MR. WHITE: Object to form.

- A. No, I'm not ignoring the other side. I'm telling you that she has credible evidence, clinical phenotype, extraordinary phenotype, that could be compatible with a hereditary disposition.
 - BY MR. ROBERTS:
- 13 | O. Could be?

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- A. Uh-huh.
 - Q. But don't you think, in making a differential diagnosis, in this case it would have been appropriate for you to dig into: Well, what are the carcinogens that Jacqueline Tukes was exposed to? What were the levels? How long was she exposed? Was it dermal? Was it inhalation? I mean, isn't that something that you would need to do to really make a differential diagnosis as to the cause of her renal cell carcinoma?

MR. WHITE:

Object to form.

No, that was not my role. That is not my expertise. My expertise is in genetics. asked: Does she fit a criteria for hereditary cancer? And the answer is yes and should be treated as such.

BY MR. ROBERTS:

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Well, were you -- well, I'm trying to Q. understand what you're saying.

> You weren't told to ignore her exposure to these carcinogens, were you? I'm trying to understand how that fits into your opinions here.

> > MR. WHITE: Object to form.

- It doesn't fit into my opinion. My opinion is Α. exclusive of that. There are experts to testify in this case about that. My role is to testify about the credibility of a possible underlying genetic predisposition. opinion, she should be treated as she has one, even though we cannot, at this point in time, identify an underlying mutation. BY MR. ROBERTS:
- Well, what if Ms. Tukes brings forward a Q. credible toxicologist and people that study the

25 effect of cancer as it relates to exposure to

carcinogens and they say, look, her clinical features that you rely upon are consistent with exposure to carcinogens, wouldn't you be willing to reexamine your opinion in light of that evidence?

MR. WHITE: Object to form.

- A. No. I would consider it, but you cannot still, at this point in time, rule out that she doesn't have an underlying predisposition.

 BY MR. ROBERTS:
- Q. Well, under the scenario that I just outlined for you, would you agree that it's equally likely as not that her cancer could be resulting from exposure to carcinogens as opposed to renal cell carcinoma if those experts say that her exposure was sufficient to cause her disease?

MR. WHITE: Object to form.

A. I would say -- I would not say it was as likely as the hereditary, but I would say it would be a consideration.

BY MR. ROBERTS:

- Q. All right. A consideration that you haven't -you haven't given?
 - A. It would be a consideration in this case.

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- Q. All right. Is it information that you would like to have?
- MR. WHITE: Object to form.
- 4 A. Not necessarily.
- 5 BY MR. ROBERTS:
- Q. All right. Okay. Now, we've talked about the genetic testing that UNC Health did in this case, right? And we've talked about Katie Gabarini, right?
- 10 | A. Yes.
- 11 Q. And I believe you indicated that you read the letters that she wrote to Mrs. Tukes, right?
- 13 A. They were in the medical records, yes.
- Q. And do you recall that she said, "Testing did not reveal a known pathogenic mutation in any of these genes"?
- 17 | A. Correct.

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Q. "Since the current test is not perfect, it is possible there may be a mutation that current testing cannot detect, but that chance is small."

Would you agree with what her genetic consultant over at UNC-Chapel Hill told her, Katie Gabarini? Would you agree with the statement that I just read?

- 1 | A. I --
- 2 MR. WHITE: Object to form.
- 3 A. I would agree to everything but the last two
- 4 letters, "but that chance is small," I think is
- 5 what you read.
- 6 BY MR. ROBERTS:
- 7 Q. All right. I'll read it again.
- 8 A. Yeah. I would agree with the first part of that statement.
- Q. You would agree that "Testing did not reveal a known pathogenic mutation in any of these
- genes." You agree with that, correct?
- 13 A. Correct.
- 14 Q. "Since the current test is not perfect, it is
- possible there may be a mutation that current
- testing cannot detect." You agree with that?
- 17 | A. Yes.
- Q. But you disagree with Katie Gabarini when she
- says, "that chance is small"?
- 20 A. Correct.
- MR. ROBERTS: Okay. Give me about five
- 22 minutes, and I think we can wrap up.
- MR. WHITE: Sure.
- MR. ROBERTS: Thank you.
- THE VIDEOGRAPHER: We're going off the

1 record at 12:04 p.m.

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(WHEREUPON, at this time a brief recess was taken.)

THE VIDEOGRAPHER: We are back on the record at 12:10 p.m.

BY MR. ROBERTS:

Q. Dr. Vance, I appreciate your time today, and I've just got just a couple more, hopefully brief, questions to ask you.

Now, before we took our break, you talked about, you know, making a differential diagnosis. And I think you talked about the farmers that were exposed to pesticides, and you were trying to determine whether or not there was a genetic component to the cancer or perhaps another cause. Is that a fair statement?

MR. WHITE: Object to form.

- A. Yes.
- BY MR. ROBERTS:
 - Q. All right. Now, in this particular case, would it be fair to say that you were not provided sufficient information about Jacqueline Tukes's exposure, her level of exposure, her method of exposure, whether it was inhalation, dermal,

ingestion? So would you agree with me that you aren't really able to make a differential diagnosis to rule out carcinogenic exposure causing Mrs. Tukes's kidney cancer?

MR. WHITE: Object to form.

- A. I cannot determine whether Ms. Tukes's renal cancer was due to her exposures.

 BY MR. ROBERTS:
- 9 Q. Okay.

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- 10 | A. I'm not an expert in that field.
- 11 Q. Right.
 - A. But I can tell you that she has extraordinary evidence, clinical phenotype, not a genotype, evident at that time to be compatible with hereditary renal cell carcinoma.
 - Q. But, again, you know, you can't rule out her exposure to the carcinogens at Camp Lejeune because you don't know what she was exposed to or any of the underlying facts that would allow you to rule out that as a potential cause of her renal cell carcinoma, is that fair?

MR. WHITE: Object to form.

A. I'm not ruling it out. I wasn't asked to look at it. I wasn't provided that information.

That -- I'm not an expert in the field, so that

1 is not my determination.

BY MR. ROBERTS:

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But in these cases where the farmers were Q. exposed to pesticides and so forth, as I understood your previous testimony, you were able to dig down and get that information that would allow you to make a differential diagnosis, fair?

> MR. WHITE: Object to form.

- That's incorrect. What we do is we take the Α. medical history to say, were there exposures? Was there smoking? Was there -- is there hypertension? Is there obesity, et cetera, that might have predisposed? I put that in the medical record along with my counseling. BY MR. ROBERTS:
- All right. But as I understood what you told Q. me previously -- and, again, I don't want to --I don't want to misstate anything, but I thought you said to make a differential diagnosis you need to look at other potential causes other than hereditary, correct?
- Α. That is correct.
- And so in able to -- for you to make that Q. differential diagnosis, you're not able to do

that, are you, without having the underlying facts and data that would support a cause other than renal cell -- hereditary renal cell carcinoma, correct?

MR. WHITE: Object to form.

A. I was not asked to make a differential diagnosis. I was asked to look at the case and -- asked to look at the case and see if it was compatible with an underlying genetic predisposition.

BY MR. ROBERTS:

Q. Did you raise the question with anyone about,

"Whoa, time-out. I need to -- I need to

consider whether or not exposure could be an

explanation for this bilateral multifocal

cancer presented at a young age, " all the

factors that you relied on in the clinical

presentation, did you ever say you'd like to do

that to anybody?

MR. WHITE: Object to form. I'm also going to direct the witness not to discuss any conversations or communications that she's had with counsel.

But with that caveat, to the extent that you can answer the question, please feel free.

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1 Α. My understanding was others were doing 2 that.

BY MR. ROBERTS:

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- Okay. So, again, you didn't do a differential 4 Q. diagnosis in this case, did you? 5
- A differential diagnosis in the sense that I Α. didn't have all the information. But, again, I was asked to say was her presentation compatible with hereditary renal cell carcinoma, and my conclusion was yes. 10
 - All right. But, again -- and, again, I don't Q. want to repeat the same question, but you did not, did you, ma'am, have sufficient evidence to even do a differential diagnosis in this case, correct?

MR. WHITE: Object to form.

I only looked at the genetics, her medical Α. history, and from my experience -- and the genetic testing reports, and from my experience what I would conclude, in a patient such as this, if she were in my clinic.

BY MR. ROBERTS:

But, again, my question is -- and I don't think Q. you answered it. You did not have enough information to actually do a differential

diagnosis, correct?

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MR. WHITE: Object to form.

- I think I've repeated this. I did not have the toxicology information. I am not an expert in the field. I could not conclude with certainty whether that exposure was sufficient to cause cancer. I don't have that expertise.
- BY MR. ROBERTS: 8
 - Okay. Well, how did you do it in your -- in Q. your farmers that were exposed to pesticide cases?
 - MR. WHITE: Object to form.
 - Α. I -- I put that -- because it's very hard to quantitate any kind of exposure for pesticides, et cetera. So what I do is I put that in the report, that this man was a smoker or how many smoking years or was exposed to pesticides, et cetera. So it's just documented there, but I can't make a conclusion as to that.

BY MR. ROBERTS:

- Okay. But in your reports -- let's just stay Q. with the pesticides as an example.
- 23 Uh-huh. Α.
- 24 Have you ever looked at the exposure of, you Q. 25 know, persons that sprayed pesticides for 30 or

40 years and comes in with a cancer and said,
"I can't determine whether it's hereditary as
opposed to exposure to carcinogens"? Has that
ever happened in your career?

MR. WHITE: Object to form.

A. Not exactly that way. What I would do is say this -- this person has had exposures, we've tested them, and they're negative at this point, yet their disease is such that their follow-up needs to be intensive whether -- irrespective of the cause.

BY MR. ROBERTS:

Q. Okay. So but -- okay. Maybe that answered my question.

So there are circumstances in cases that you've had, like the farmers using pesticides, where, you know, you look at it, you look at the exposure to the pesticides, you look at the criteria that would suggest a hereditary component, and you say, "I just -- I can't tell based on what I've got now whether it's hereditary or exposure to carcinogens." Is that fair?

A. That's fair. I think sometimes it's very difficult to determine with certainty the cause

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- 1 of cancer --
- All right. 2 0.
- 3 Α. -- in any situation.
- 4 MR. ROBERTS: I think that's all I've
- 5 got. Thank you.
- 6 MR. WHITE: Okay.
- 7 CROSS-EXAMINATION,
- 8 QUESTIONS BY MR. WHITE:
- 9 Q. Thank you, Doctor. I just have a few questions
- for you real quick. 10
- 11 Α. Okay.
- 12 Ο. What was the -- what was your assignment in
- 13 this case?
- 14 To review the case of Jacqueline Tukes and Α.
- 15 determine if I thought it was credible that she
- 16 had an underlying genetic predisposition.
- 17 Okay. Was there -- did that assignment include Q.
- any toxicological analysis? 18
- No, it did not. 19 Α.
- 2.0 Did it include any exposure analysis? O.
- 21 No, it did not. Α.
- Did it include any factual category beyond the 22 Q.
- 23 genetics?
- 24 Α. No.
- Okay. Did it include a differential diagnosis 25 Q.

1 between genetic versus other non-genetic 2 causes?

Α. No.

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- Okay. Mr. Roberts went through a list of Q. materials that you said you did not read, like Dr. Bird's report or a couple of the Phase -or some of the Phase 2 depositions. I won't go through each of them one by one, but are you aware of any information in those materials or, in fact, anywhere -- elsewhere in the case that has information related to these genetic questions that you have not seen or were not provided?
- 14 No. Α.
- 15 Okay. Ο.
- 16 MR. WHITE: I will pass the witness back 17 if that's spurred a whole new line of 18 questioning or not.
- 19 MR. ROBERTS: No, no, no. I'm going to 2.0 be brief.
- 21 REDIRECT EXAMINATION,
- 22 QUESTIONS BY MR. ROBERTS:
 - You said you were not asked to do a Q. differential diagnosis. Did I hear that correctly?

Α. That is correct.

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- Well, would you agree with me you can't say how Ο. likely it is that Mrs. Tukes's cancer is hereditary if you haven't considered the other alternative causes, such as her exposure to carcinogens?
- I can't --Α.

MR. WHITE: Object to form. 8 Sorry. Ιf 9 you can --

THE WITNESS: Yeah.

MR. WHITE: -- get my second in there. I'm sorry.

THE WITNESS: Yeah. I'm sorry. I should have paused.

But I can't conclude either that toxic exposure, even though I don't know about it, I'm not an expert in that field -- you know, I can't conclude that the toxic exposure was a cause of her cancer. I can't conclude with certainty that genetics was a cause of her cancer.

I'm saying, based on my experience and what I know about genetics and genetic knowledge in 2025, given this woman's presentation, that there is a very high

	Page 133
1	likelihood that she has an underlying genetic
2	predisposition; we just don't know it at this
3	day.
4	MR. ROBERTS: I think that's all I've
5	got. Thank you.
6	MR. WHITE: I have nothing further.
7	We'll read and sign.
8	THE VIDEOGRAPHER: This marks the
9	conclusion of the video-recorded deposition.
10	We're off the record at 12:21 p.m.
11	THE COURT REPORTER: Do you want a copy
12	of the transcript, Luke?
13	MR. WHITE: Yes, please.
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15	(Deposition concluded at 12:21 p.m.)
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	Page 134
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	Page 136
1	ACKNOWLEDGMENT OF DEPONENT
2	
3	I, GAIL H. VANCE, M.D., do
4	hereby certify that I have read the
5	foregoing pages, and that the same is
6	a correct transcription of the answers
7	given by me to the questions therein
8	propounded, except for the corrections or
9	changes in form or substance, if any,
10	noted in the attached Errata Sheet.
11	
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14	GAIL H. VANCE, M.D. DATE
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	Page 137
1	STATE OF INDIANA)
2) SS:
3	COUNTY OF SHELBY)
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5	CERTIFICATE
6	
7	I, Valerie Fillenwarth, RPR, a Notary
8	Public in and for the County of Shelby, State
9	of Indiana, maintaining an office in Shelby
10	County, Indiana, do hereby certify the
11	following:
12	
13	That the witness herein, GAIL H. VANCE,
14	M.D., was first duly sworn to tell the truth,
15	the whole truth and nothing but the truth in
16	the foregoing deposition;
17	
18	That all testimony was taken down in
19	stenographic notes and afterward reduced to
20	typewritten form under my direction and then
21	presented to counsel for the purpose of
22	obtaining the deponent's signature;
23	
24	That I recorded and transcribed any and
25	all objections made by counsel and the reasons

Page 138 1 therefore; and 2 That I am not a relative or employee, 3 attorney or counsel of any of the parties, nor 4 a relative or employee of such attorney or counsel, nor am I financially interested in 6 this action. 8 9 IN WITNESS HEREOF, I have hereunto set my hand and affixed my Notarial Seal this 25th day 10 11 of July 2025. 12 13 14 Valen Lillenwan 15 16 Valerie Fillenwarth, RPR 17 Notary Public 18 (Electronically signed) 19 2.0 21 22 23 Commission Number: NP0749965

My Commission Expires on: July 5, 2031

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County of Residence:

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Federal Rules of Civil Procedure Rule 30

- (e) Review By the Witness; Changes.
- (1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:
- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.
- (2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES

ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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