Volume 11

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Vince Chhabria, Judge

EDWARD HARDEMAN,	)	
	)	
Plaintiff,	)	
	)	
VS.	)	**NO. C 16-00525 VC**
	)	
MONSANTO COMPANY,	)	
	)	
Defendant.	)	
	)	

San Francisco, California
Monday, March 11, 2019

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

For Plaintiff:

ANDRUS WAGSTAFF PC
7171 W. Alaska Drive
Lakewood, Colorado 80226
BY: AIMEE H. WAGSTAFF, ATTORNEY AT LAW
DAVID J. WOOL, ATTORNEY AT LAW

MOORE LAW GROUP
1473 South 4th Street
Louisville, Kentucky 40208
BY: JENNIFER MOORE, ATTORNEY AT LAW

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

REPORTED BY: Marla F. Knox, RPR, CRR
Jo Ann Bryce, CSR No. 3321, RMR, CRR, FCRR
Official Reporters

APPEARANCES: (CONTINUED)

For Defendant:

WILKINSON WALSH ESKOVITZ LLP
2001 M Street, NW - 10th Floor
Washington, D.C. 20036
BY: BRIAN L. STEKLOFF, ATTORNEY AT LAW
RAKESH N. KILARU, ATTORNEY AT LAW
TAMARRA MATTHEWS JOHNSON, ATTORNEY AT LAW
JULIE RUBENSTEIN, ATTORNEY AT LAW
CALI COPE-KASTEN, ATTORNEY AT LAW

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Monday - March 11, 2019 **8:06 a.m.**

P R O C E E D I N G S

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(Proceedings were heard out of presence of the jury:)

THE COURT: Good morning. What do we need to talk about?

MS. WAGSTAFF: Good morning, Your Honor.

MS. MOORE: Your Honor, I just wanted to have a point of clarification before Dr. Levine takes the stand, given some of the issues on Friday with Dr. Mucci. And I wanted to make sure that she understands that she is not here to give general causation opinions; and she is not here to give opinions about the animal studies, mechanistic data, and that any opinion she has on epidemiology is solely based on what Dr. Mucci has already testified to. I want to make sure when I ask my questions, it doesn't elicit other testimony, like what happened on Friday.

THE COURT: Well, yeah, I mean, we had a pretrial ruling about that. We, of course, also had a -- not a pretrial ruling, but pre-testimony ruling about that with Dr. Levine. And, of course, we did with Dr. Mucci too.

You know, I don't know what -- is there anything I can say other than what I said in the ruling that I issued last week?

MS. MOORE: I understand, Your Honor. I didn't know if she was in the courtroom, if it could just be reminded to

her before she took the stand today.

MR. STEKLOFF: I think she is in the hall, and I'm happy to have her come in. I'm not -- I don't think one way or the other she had any opinions in her report -- she knows not to speak about general causation. I don't think she had opinions about animal studies or the cell studies, and I think that she knows not -- that she is here to rely on Dr. Mucci. I'm going to bring that out affirmatively on my direct with a yes-or-no question. She is going to explain that she reviewed her trial testimony; that she is relying on that, and that --

THE COURT: Mucci's trial testimony?

MR. STEKLOFF: Yes, Dr. Mucci's trial testimony. And so, look, if the wrong question is asked -- I'm not re-visiting Dr. Mucci. But if the wrong question is asked, Dr. Levine is going -- will -- you know, if a question asks her about her general causation views, she has general causation views about the epidemiology; but she knows not to speak about that otherwise.

THE COURT: Okay.

MR. STEKLOFF: I will reaffirm that with her now.

THE COURT: Just reaffirm that with her now.

MS. MOORE: Thank you, Your Honor.

THE COURT: Anything else?

MS. MOORE: I think the same applies to Dr. Arber too.

MR. STEKLOFF: I don't believe -- he knows as well and

he -- even less so did not sort of have opinions about the epidemiology, to the best of my recollection, in his report. So he is very -- he is here to talk about his report.

THE COURT: Okay. Anything else from either of you?

MS. MOORE: No. Thank you, Your Honor.

THE COURT: One quick thing that I wanted to mention.

You know, I -- I will tell you that I find this causation issue very difficult. I find it very confusing. It seems like California law -- and the law of many states -- is quite confused about how to instruct juries on medical causation.

And, you know, last night -- you know, I was trying to identify -- you know, I gave -- I put out my tentative instruction, I made clear there were two alternative instructions -- both of them were very tentative -- and it is something that requires further discussion this afternoon.

I was -- last night I was reading the cases, and I was trying to figure out, well, what is Monsanto's best case for this because it seems like they are a little bit behind the eight-ball on this causation question. And I guess I thought, you know, it was hard to -- I couldn't find any case directly on point involving a situation where there is, you know, one -- directly on point in Monsanto's favor, at least involving a situation where, you know, there are two -- there are two risk factors being argued about. And one side says this risk factor caused it, and the other side says that risk factor caused it.

And in that situation, you don't give some sort of multiple causation instruction. And in that instruction -- and in that situation you do give the but-for sentence. I think maybe Vecchione is their best case, even though it doesn't seem exactly on point.

So I just wanted to make sure that both sides are prepared to discuss the Vecchione case this afternoon. And also just if you think there is some case out there that involves this precise scenario that I'm missing, tell me about it.

And, again, it is a situation where the Plaintiff is saying, This risk factor caused my cancer; and the Defendant is saying, No, this other risk factor caused my cancer. And, you know, both risk factors are present. At least there is substantial evidence that both risk factors are present in the case. You know, what is your -- what is your case law for the proposition that in that scenario you don't give a multiple causation instruction, and in that scenario you do give that but-for sentence.

So that's what I want to discuss -- I want to make sure we focus on this afternoon.

MR. KILARU: Sure.

MS. MOORE: Your Honor, one case I would direct the Court's attention to -- it is a California State case. I don't know how to pronounce it. The first name is Logacz versus Limansky, and the cite --

THE COURT: Remind me the name of it.

MS. MOORE: L-O-G-A-C-Z versus Limansky. And, Your Honor, if you want, I can hand you this copy. It is not marked on.

THE COURT: No. That's fine.

MS. MOORE: That is a California Court of Appeals case.

THE COURT: What is the citation?

MS. MOORE: That's what I'm trying to find.

MR. KILARU: 71 Cal. App. 4, 1149, Your Honor.

MS. MOORE: There you go.

And it is the situation where the Plaintiff offers -- it is a medical malpractice case. Plaintiff offers one theory of causation, and the defense offers a different theory; and they said it was concurrent causes.

THE COURT: Well, I mean, again, we can get into it more this afternoon; but it seems like there is either no testimony or barely any testimony of concurrent dependent causation, right? The only -- it seems like the only evidence you have is of independent causation. There has been no testimony that hep C worked with Roundup to cause cancer.

So that is one of the difficulties of this case is that the model instruction seems targeted primarily at a situation where two things combined together to cause somebody's cancer. And at least as it relates to hep C, there has been no

testimony provided, no evidence provided that the two things combined together to cause Mr. Hardeman's NHL.

So that is one of the things that we have a problem with is that even if we were to give some sort of multiple causation instruction, it seems like it might be quite problematic to give the one that is -- that is provided in the model set. So that's what --

MS. MOORE: One --

THE COURT: -- one of the things we need to discuss this afternoon.

MS. MOORE: Thank you, Your Honor.

MR. STEKLOFF: While we have the record open, can I clarify a few exhibit issues?

THE COURT: Yeah.

MR. STEKLOFF: So last week after the depositions of Dr. Ye and Dr. Turk, we moved in TX38, TX41, TX42, TX43 and then TX1023, the following pages: 109 through 110, 113 through 115, 282 through 283, 381 through 382, 797 through 798, 841 through 861, and 1562 through 1564.

Ms. Moore appropriately wanted to take time to review those. She confirmed over the weekend -- that there was no objection to those being admitted.

MS. MOORE: That's correct.

MR. STEKLOFF: Then I just want to clarify, after the Reeves' deposition, I had mentioned Exhibit 95 because that was

the deposition exhibit that was referenced. It is actually TX1178. So we would move in TX1178 I think with no objection.

MS. WAGSTAFF: No objection.

(Trial Exhibits 38, 41, 42 43, 1023 and 1178 received in evidence)

THE CLERK: So get rid of 95?

MR. STEKLOFF: Get rid of 95. That was the wrong number. I apologize.

And then Ms. Wagstaff moved in a series of exhibits after the Reeves' deposition as well, and we have reviewed those and I have no objection to those coming in.

MS. MOORE: Those are Exhibits 505, 506, 508, 509, 510, 511, 512, 514 and 515.

THE COURT: Okay.

(Trial Exhibits 505, 506, 508, 509, 510, 511, 512, 514 and 515 received in evidence)

MR. STEKLOFF: And, Your Honor, Dr. Levine is now in the courtroom. So I will say it publicly with you here and her here that Dr. Levine understands she is not to opine on general causation or the epidemiology. She is here to rely on Dr. Mucci's testimony for that, and she will be offering opinions about Mr. Hardeman specifically and specific causation. And she knows that that is the case, both on direct and cross, unless on cross she is directly asked about general causation. And I will even tell her that before on cross if

she thinks there is something, maybe she should pause and look to Your Honor to get permission to say anything about general causation because she is not here for that purpose today.

THE COURT: Let the record reflect that she is nodding her head vigorously in response to all of those comments.

MR. STEKLOFF: Thank you.

THE COURT: Okay. I thought I had one other thing for you-all. Let me think. I was just going to ask: In terms of -- is there anything more you can tell me about scheduling, how long you think the various witnesses are going to take, how long you anticipate for closing arguments, things like that?

MR. STEKLOFF: Yes, Your Honor. On behalf of Monsanto I think we have approximately 45 minutes left this morning with Dr. Levine on direct. I don't know how long the cross will be. I think that Dr. Arber is 45 minutes or less on direct. So our expectation, depending on the cross, is that we would actually finish early today. We will be resting after Dr. Arber.

And then in terms of closing, I will say -- I would like it to be an hour, but probably give or take 10 or 15 minutes on either side. So I think -- if I go over an hour and 15 minutes, I won't be happy with myself. So I think that's what I would anticipate.

THE COURT: Okay.

MS. WAGSTAFF: And Plaintiff anticipates an hour to an hour and a half in closing as well tomorrow.

THE COURT: Do you -- is there anything you can tell me about cross-examination of these two witnesses? I know it is hard to predict.

MS. MOORE: That's true, Your Honor. I don't think Dr. Arber will be very long at all. I think it would be less than half an hour. And then on Dr. Levine, it is just going to depend on what she says about hepatitis C, but I would suspect it would be under an hour.

MS. WAGSTAFF: So, Your Honor, on scheduling --

THE COURT: I guess I should have told you to be prepared to close today, but I will not make you do that.

MS. WAGSTAFF: Your Honor, on scheduling for Phase Two, we are trying to get our live witnesses here. There are still some pending motions on the witnesses.

THE COURT: Uh-huh.

MS. WAGSTAFF: Specifically Dr. Benbrook. Do you know when we will expect a ruling on that?

THE COURT: I will bump it up to the top.

MS. WAGSTAFF: Okay. Thank you.

THE COURT: And, in fact, given that we are ending early today, it seems likely I will be able to deal with it today. And it is something that I have looked at before; but as I sit here, I don't remember what the issue is.

So I think that what we will -- so it looks pretty clear that we will be done -- by the way, are you calling any

witnesses in rebuttal?

MS. WAGSTAFF: We are figuring that out right now; and if we do, it is going to be something really small by video.

THE COURT: Okay. So it sounds like the evidence will be done with the Phase One evidence today for sure, and -- which means we will instruct them and proceed with closing arguments tomorrow morning, first thing, at 8:30. And then -- which means you should be ready to do your openings for Phase Two first thing Wednesday morning.

MR. STEKLOFF: Do you instruct the jury before or after closing arguments?

THE COURT: I instruct them before.

MR. STEKLOFF: And then do you have a -- a deadline and a process through which you would like us to provide you our closing argument slides?

THE COURT: Slides? Why don't we say 7:00 a.m. on Tuesday morning -- yeah, Tuesday morning.

MS. WAGSTAFF: Your Honor, do you allow rebuttal?

THE COURT: Tomorrow morning.

MR. STEKLOFF: I assume those are via e-mail to your chambers, without the other side?

THE COURT: That's correct. And any rebuttal slides you might use, you have to send those as well.

MS. WAGSTAFF: Rebuttal for my opening, you are talking about?

THE COURT: For closing.

MS. WAGSTAFF: For closing, yes.

THE COURT: Yes.

MS. WAGSTAFF: Thank you.

THE COURT: As then I said, this afternoon when we discuss jury instructions, we can also discuss any concerns that the other side has about -- and it is something that counsel might raise at closing -- that would not be appropriate, and we can try to pre-adjudicate some of those questions. Okay.

MR. STEKLOFF: Thank you.

THE COURT: See you at 8:30.

THE CLERK: Court is in recess.

(Recess taken at 8:21 a.m.)

(Proceedings resumed at 8:42 a.m.)

THE COURT: Go ahead and bring in the jury.

(Proceedings were heard in the presence of the jury:)

THE CLERK: Please be seated.

THE COURT: Good morning, everybody. Hope you had a nice weekend. We are ready to resume with Dr. Levine.

ALEXANDRA LEVINE,

called as a witness for the Defendant, having been previously duly sworn, testified further as follows:

DIRECT EXAMINATION (resumed)

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BY MR. STEKLOFF

Q. Good morning, Dr. Levine.

A. Good morning.

Q. Let's see -- okay. So when we left off on Friday, we were walking through a little bit of your background, and I think we had finished talking about this slide about your research experience, correct?

A. Yes.

Q. So on the next slide -- you had told the jury on Friday that you have published over 300 peer-reviewed articles, and I think we had -- on this slide you have published on lymphomas, including lymphomas caused by HIV, something called HTLV1 and hepatitis C, correct?

A. That is correct.

Q. And just -- can you explain for the jury what some of the journals are on this slide? And, first of all, are these journals in which you have published?

A. These are some of the journals in which I have published. On the top row are more general medicine articles. They are for people who are doctors who are engaged in all different kinds of specialties. The examples on the bottom are specialty journals. These would be read specifically by people who are hematologists or hematologists/oncologists or oncologists. So I have written in general medicine journals, some of the best ones, and also in specialty journals.

Q. Are these -- you mentioned "best ones." Are these some of the most read journals either in general medicine on the top, the *New England Journal of Medicine*, *Annals of Internal Medicine*, and the *Journal of the American Medical Association*?

A. Yes. They are rated by something called impact factor, and these are extremely high impact factor journals.

Q. And then with respect to the journals on the bottom, *Blood* and *Journal of Clinical Oncology*, are those, within the world of oncology and hematology, similarly high-impact journals?

A. Yes, they are.

Q. And have you -- apart from having published some of your research, have you -- the jury has heard about this from other witnesses -- have you also served as an editor on journals?

A. Yes, I have.

Q. And have you also served as a peer reviewer reviewing articles that are submitted to be published?

A. Yes. That is one of the responsibilities of doctors who work in academic medicine to review those articles, and I review perhaps one a week, maybe one every other week.

Q. And so you are still continuing to do that?

A. Yes.

Q. And, again, these are just -- you have published in and edited and peer reviewed in other journals other than these five. We just wanted to use this as some examples?

A. That's correct.

Q. Now, have you also, in your 40-year career, received various honors and awards?

A. Yes.

Q. And did we highlight some of those on this slide?

A. Yes.

Q. And it says here when you were at the Keck School of Medicine at USC, you received the Outstanding Clinical Professor Award, I think, six different times. Can you just explain why that was -- if it was, why that was meaningful for you?

A. I love to teach, and it is important to me to teach. When I do, I spend a lot of time doing it. They made a rule at a certain point that it can only be received every other year or every fifth year. So I received a few more but they were not valid.

Q. And then I see that you also received in 1994 something called the University of Southern California Presidential Medallion. Can you explain briefly to the jury what that was?

A. Yes. That is an award given by the president of the university to somebody who has gone outside of the university, if you will, to bring honor back to the school.

Q. And are we going to talk about some of the ways in which you -- in which you did that?

A. Yes.

Q. And then I see here that you were a member and chair of

research committee, the Presidential Advisory Council on HIV/AIDS and were appointed by President Bill Clinton. Again, just briefly can you explain to the jury what your role was there?

A. My role first was to recommend to the President the state of the AIDS epidemic, what the biggest issues and problems were, what we needed to spend money on, how we needed to research particular areas.

We spoke about his "bully pulpit." Sometimes the President can do things just by saying something, and we wanted to make sure that this was important to him and that he did use his "bully pulpit" to be able to educate the United States and to help us to end the epidemic.

Q. And then lastly I see here that in March 2019 the University of Texas, the MD Anderson Cancer Center -- just to pause there, is that another -- like City of Hope -- well-regarded, elite cancer center in the United States?

A. Yes, both the City of Hope, where I work now, and MD Anderson are comprehensive cancer centers funded by the National Cancer Institute to take care of patients; to teach and also to do research and bring the field forward.

Q. And it says here you are being recognized as the Margaret Kripke Legend Award for promotion of women in cancer medicine and cancer science. Can you just explain to the jury, again, why that is meaningful to you?

A. It is meaningful to me because it is a mentoring award. When I first started medical school, I was one of 12 women. Now maybe half of the people in medical school are women. The field has changed, and it was important to me to make sure that my fellow women were included in this field of medicine and research, so it felt good for me to get that award.

Q. And you mentioned some of -- how you were honored at USC. Have you done international public health consulting across the world specifically regarding HIV and AIDS?

A. Yes, I have. So --

Q. Without going through every single year and every single country, can you just describe generally when you have consulted for other countries what the work entailed?

A. The work entailed, first of all, meeting with the Public Health Department, the people in charge of the Public Health Department; ascertaining what they believed their needs were. I would always do research beforehand to look at the status of the AIDS epidemic in that particular country. I primarily assessed the situation in each of these countries with the Public Health Department.

My next step was to educate. I was -- I was taken to Mongolia even to educate the doctors there, the people there, the nurses there. So I educated a good deal.

And then I helped to propose policies that might be useful in the countries for trying to diminish the AIDS epidemic in

those countries.

Q. Now, did we prepare a slide just to explain to the jury what we are going to walk through next?

A. Yes.

Q. And so are the three things that we are going to cover next: First of all, what is non-Hodgkin's lymphoma; second, did Roundup cause Mr. Hardeman's non-Hodgkin's lymphoma; and third, what are Mr. Hardeman's risk factors for non-Hodgkin's lymphoma?

A. Yes, that's what I would want to discuss.

Q. And so did we prepare some slides so you could explain to the jury first what cancer is and how cancer develops?

A. Yes, and these are the slides.

Q. Okay. So using this slide, can you please explain to the jury what cancer is?

A. Yes. Just to start at the beginning, the cells in our body are beautifully controlled in terms of when they grow and when they stop growing. One example to talk about it is, for example, if you get a cut on your skin. And if you do, all of a sudden the cells on both sides of the cut get a message that, Oh, there is a defect there. I better grow and fill in that cut. And they do. And the cut heals and that's the end of your injury.

The cells don't keep growing and growing so that you have a whole mound of cells every time you cut yourself. So as soon

as the cells know to grow, they do. And as soon as one cell touched another, as they are healing that wound, they know how to stop.

And all of that tremendous regulation, specific regulation, control like that, comes from the DNA. And the DNA is shown on the right side of the slide. The DNA is your genetic material.

Half of the DNA comes from your mother; the other half of the DNA comes from your father. And all -- everything about you in a sense comes -- starts with that DNA. Things that are as easy as the color of your hair or the color of your eyes or how tall you are going to be, that kind of thing. And also it has complicated as how does a cell know how to grow, how to stop, how to live, how to die.

So that is the normal situation with cells and how their growth is controlled.

Q. And then what -- can you explain using this slide what a cancer cell is?

A. Yes. I will start on the DNA here on the right side. Cancer ultimately is caused by an accident, an error of some sort, on the DNA. And that error says to the cell, Divide, divide, divide, forever and never stop.

Now, that accident or error, we call that a mutation. And there are things that are commonly known. Radiation can cause those kinds of accidents or errors. Tobacco can cause that

kind of error. We will talk about it perhaps. But when that error occurs in forming cancer, if that accident occurs in a stomach cell, then the stomach cell divides over and over and over and you get stomach cancer. If that happens in a lung cell, the lung cell will divide over and over without control, and that's lung cancer. If that happens in a B lymphocyte, one of the cells of the immune system, then that B lymphocyte is going to grow over and over and won't know how to stop.

Q. And so what does this slide -- as compared to the slide that shows one cancer cell, what does this slide with numerous cancer cells demonstrate?

A. What it is trying to show is that as these cells are growing at a certain point, the person, the patient knows it. There is a lump. There is a big lymph gland someplace, or a lump in the stomach, in the belly. Or a lump in the chest X-ray, which you can't see; but it is seen as a mass, as a lump on a chest X-ray, for example. The other consequence is that -- let's just say that this occurred in a liver. It takes up space in that liver so that the normal liver cells don't have room to be functioning anymore.

So the liver won't work and the person can get in trouble with liver failure. If this occurs in bone marrow, crowds up -- that is the factory where all the blood cells are made. If that whole factory is filled with the cancer cells, there is no room for the normal cells to be made; and the person gets

anemic and gets in trouble with low white blood cells and low platelets. So that's what happens.

Q. Again, so the next slide says cancer requires two defects. So can you explain what this slide is -- how it is that cancer requires two defects?

A. Yes. I think this is an interesting area, and something that is being used very aggressively now as we develop new treatments. In any event, this starts -- the cancer starts, as I said, with the mutation or the error, the accident in the DNA. But that should be seen by our defense system, our immune system, as foreign.

So our defense system, for example, is supposed to see a germ, a foreign germ; know that it is foreign and kill it so that we don't die of that infection. Well, it turns out that an abnormal cell with that defect in the DNA, that is foreign to us also. That is not the same cell as me anymore, and the immune system should be able to see that cell as foreign and knock it down.

And so what we have learned is that the two defects that require actual clinical cancer to develop, number one, the defect; number two, some failure of the immune system, some weakness of the immune system so that it can't recognize that cancer cell as foreign and destroy it.

Q. And so just to be clear, on the left that is showing what you referred to as a mutation that leads to a cancer cell; is

that right?

A. Correct.

Q. And then on the right there are two sort of ribbons or pretzels, and they look like they are attacking the cancer cell; is that correct?

A. Yes. I was trying to draw an antibody molecule; but, yes, that was an attempt to show the immune system recognizing that cancer cell and killing it directly.

Q. And so for cancer to occur, those antibodies shouldn't be working; is that right? Or wouldn't be working?

A. For cancer to occur, it is more complicated than that. There will be some weakness perhaps in the antibodies, but also T-cells are many different components of the immune system. So many different aspects are not working properly.

Q. And what happens to all of us as we age with respect to our immune system and our ability to fight cancer cells, if they exist?

A. Yes. As we age, our immune systems weaken. And that is just a part of normal aging. Most cancers that we have of all kinds occur in people who are older. And one of the reasons for that is simply the immune system, the defense system, has weakened in an older person.

Q. Now, did you also want to discuss with the jury -- they have heard about the concept of latency and how long it can take for cancer to develop. Is that something you wanted to

discuss with the jury?

A. Yes, I would.

MR. STEKLOFF: Your Honor, may Dr. Levine step down to use the board?

THE COURT: Sure.

BY MR. STEKLOFF

Q. Just make sure that you face Ms. Knox, if possible. It is hard for her --

A. So this is my attempt to show what happens when cancer first begins. And on this side of the curve, along horizontally here, we have time going on. And on the vertical axis here, we have number of cancer cells. And this is any kind of cancer.

So the accident that I was talking about -- excuse me -- is right here. That's where the accident, error, occurs. What happens during that time then is potentially a long time where the cancer cell maybe is growing a little bit, but the immune system is also keeping it in check -- keeping it in check. In time if the immune system is weaker and the cancer is the winner, let's say, in time the amount of cancer in the body, quote, pops above the line of being diagnosed.

What I mean is this: All of this time here we can't find that tumor no matter how hard we look, nor does the patient have any symptom of any sort. So the patient would come into me, right now here, and say -- when it is below the level of

detectability, and say to me, I think I have cancer. You should take out every single organ in my whole body and find it. Obviously I wouldn't, but if I did that, we couldn't find it. It is completely hidden to the doctor no matter how hard we look and to the patient as well.

When it pops above that line, a certain number of cancer cells are required for anything clinically to be diagnosable; to the patient or to the doctor. When the patient comes in here, yes. The patient comes in because there is a big lump someplace or some other symptom. Comes to the doctor. The doctor does a CAT scan, a biopsy, blood test and can diagnose it.

One way to think about this long period that might be more familiar to you relates to smoking, tobacco. And so as an example here, what I'm trying to teach is that this is not unusual in any sense at all for this initial accident to take decades, a long, long time, before it ever pops above the line of the diagnosability.

So one of the guidelines in the United States right now for doctors such as myself, who take care of cancer patients -- there are new guidelines related to an attempt to cure and diagnose lung cancer early in people who have smoked for a long, long time. If you can diagnose lung cancer very early when it is just one little mass on the chest X-ray, that's curable. You can cut it out. That's easy. Nothing is easy,

but it is curable.

If you diagnose it late, when it has already spread into other areas of the body, that is a whole different ball game.

So the goal was if we in the United States could figure out how to find an early lung cancer among chronic smokers, that would really help everyone. Many studies were done. And the guideline is as follows: In people who have smoked cigarettes for 35 years or more and now stopped, and they stopped smoking for up to 15 years -- so they stopped smoking 14 years ago, 13 years ago, 10 years ago -- what we do now -- what we are asked to do now is to get CAT scans of the lungs each year to find these isolated, these simple little lung cancers. And it has worked. We have picked up about 20 percent of individuals who would -- if we had not done that early screening, who would have come in much later and not been cured.

In other words, they were smoking. They were exposed to something that caused accidents. They had 35 years to -- or more -- you know, to be exposed to those accidents, but they stopped smoking 15 years ago or 14 years ago. They are still at risk. They are at risk for developing lung cancer. They had it here. We couldn't find it. If you do those early CAT scans, you can catch it right above the line as opposed to catching it when the tumor cells are so high that you can't cure it anymore.

Obviously that is a tremendous advantage to the patients, to be cured, and it is a tremendous advantage to the United States as well. So Medicare, as an example, pays for this. It is going to be much cheaper for all of us if we simply do this.

MS. MOORE: Your Honor, I would just ask that she not get into that level of detail on Medicare.

THE COURT: Overruled.

BY MR. STEKLOFF

Q. Dr. Levine, are we going to talk later about hepatitis C as it related to Mr. Hardeman?

A. Yes, we are.

Q. And just briefly using this board, would it be helpful to talk about how latency -- that latency concept with respect to hepatitis C?

A. Yes. It is really true of all the different cancers, and it is certainly true of hepatitis C-related cancers. Accident occurs down here. Takes years and years and years and eventually -- eventually, that cancer may be seen.

Q. Okay. Thank you. You can take your seat.

Now, as the jury knows, we are here to talk about -- specifically about non-Hodgkin's lymphoma, correct?

A. Correct.

Q. And then even more specifically, Mr. Hardeman had diffuse large B-cell lymphoma, correct?

A. That's correct.

Q. And so can you just briefly, using this slide, explain to the jury what non-Hodgkin's lymphoma is?

A. Yes. Non-Hodgkin's lymphoma basically is a cancer of the immune system. So that is going to be difficult right off the bat. These lymphomas can come from either B lymphocytes, which make antibodies to kill germs, or from T lymphocytes, which directly can kill germs. I think it is exceedingly important to understand that if I say non-Hodgkin's lymphoma, that is not one disease. There are at least 60 different types of non-Hodgkin's lymphoma, and these are different diseases. They are potentially caused by different things. They are treated in a different way. The clinical illnesses that we see are different. The prognosis, how somebody will do with treatment, are different. So non-Hodgkin's lymphoma is a big name, and under it are very, very different discrete specific subtypes.

Lymphoma -- these lymphocytes, normally are developed in the lymph glands. They start to grow, as I demonstrated. And, again, this usually begins in the lymph glands; but those cells normally have to travel all over the body because they are looking for germs or foreign things. And the lymphoma cells, the malignant cells, will also travel all over the body just because that's what those lymphocytes do. So they travel.

Q. And in terms of non-Hodgkin's lymphoma here in the United States, can you just walk the jury through some of the statistics provided here?

A. Yes. There are about 75,000 people diagnosed with lymphoma in the United States each year. So about 1 in 47 people will get this. The most common type of non-Hodgkin's lymphoma is the type that Mr. Hardeman had, and that is diffuse large B-cell lymphoma. About 30 to 35 percent of them are diffuse large B-cell lymphoma.

Q. So, Dr. Levine, before we walk through your opinions about Mr. Hardeman -- and I want to explain to the jury what it is -- some of the materials that you reviewed in forming those opinions. Okay?

A. Sure.

Q. First of all, did you review all of Mr. Hardeman's available medical records?

A. I did.

Q. Did you also review Mr. Hardeman's deposition testimony?

A. I did.

Q. And then the jury has heard from three of Mr. Hardeman's treating physicians: Dr. Ye, Dr. Turk and Dr. Turley. Did you review their testimony?

A. Yes, I did.

Q. And are all of the opinions that you are going to offer here today, and have already offered, to a reasonable degree of medical certainty?

A. They absolutely are. Physicians, doctors are different maybe. It has to be reasonable. There -- you know, people's

lives are depending on us, and what we know and how we look at things and how carefully we look at things. So when I say that this is my opinion, it is based on data which is extensive and which I'm going to use to actually take care of people who need to be treated well and who need to live.

Q. And so are you going to tell the jury anything today that you -- are you going to tell the jury exactly what you would tell a patient if you were treating a patient?

A. Yes, I already have. I always draw that picture. I always do. And that's exactly what I will do here.

Q. And are you going to tell the jury exactly what you would go tell any doctor at City of Hope, an oncologist, a pathologist or any other specialty?

A. Certainly.

Q. So did you review -- Dr. Weisenburger testified last week. Did you review his testimony that he gave to the jury?

A. Yes, I did.

Q. And specifically did you review the testimony he gave about what he calls his differential method?

A. Yes, I did.

Q. Have you, in your 40-plus-year career as an oncologist, ever used that method to determine the cause of a patient's non-Hodgkin's lymphoma?

A. No. A differential diagnosis is used to figure out what the diagnosis is. Patient comes with all kinds of different

symptoms, and we get lab tests, other kinds of tests, and finally determine what is the actual illness, what is the diagnosis. But I have never used a differential diagnosis to try to figure out the cause of a certain tumor.

Q. So what Dr. Weisenburger did with the chart -- where he listed the risk factors and crossed them off -- have you ever done that for a non-Hodgkin's lymphoma patient to determine the cause -- the cause of his or her cancer?

A. No.

Q. Have you heard of someone else at City of Hope or at USC, another oncologist, who has used that method to determine the cause of a patient's non-Hodgkin's lymphoma?

MS. MOORE: Objection, Your Honor. Hearsay.

THE COURT: Overruled.

THE WITNESS: No, I have not.

BY MR. STEKLOFF

Q. And so do you think that what Dr. Weisenburger presented, his differential method, was a scientifically valid method to determine the cause of Mr. Hardeman's non-Hodgkin's lymphoma?

A. I do not.

Q. Now, you are here today specifically -- other than the background information that you provided -- but going forward, you are here to talk specifically about Mr. Hardeman, correct?

A. Correct.

Q. Have you reviewed the epidemiological literature that the

jury has heard about regarding glyphosate or Roundup and non-Hodgkin's lymphoma?

A. Yes.

Q. Have you also reviewed Dr. Mucci's testimony that she gave on Friday to the jury?

A. Yes, I did.

Q. Are you relying -- for a discussion of that epidemiological literature, are you relying on Dr. Mucci's explanation to the jury so that you can focus here today on Mr. Hardeman?

A. Yes, I am.

Q. And is Dr. Mucci's analysis that she provided to the jury consistent with your own professional and clinical experience as a practicing oncologist?

A. Yes, it is. She was careful in her evaluations. She is an epidemiologist; whereas I am not.

MS. MOORE: Objection.

I'm sorry, Dr. Levine.

Objection, Your Honor. It goes beyond the scope.

THE COURT: You can briefly finish your answer.

THE WITNESS: What was the question?

BY MR. STEKLOFF

Q. The question was: Is Dr. Mucci's analysis consistent with your own professional and clinical experience?

A. Yes, it is.

Q. What, if any, role -- now let's focus on your clinical practice. What, if any, role does Roundup play in -- Roundup or glyphosate play in your clinical experience, taking care of patients with non-Hodgkin's lymphoma?

A. No role at all.

Q. Now, let's talk about Mr. Hardeman specifically. Okay?

A. Yes.

Q. Do you believe that Roundup or glyphosate caused Mr. Hardeman's non-Hodgkin's lymphoma?

A. I do not believe that Roundup or glyphosate caused his lymphoma.

Q. And the jury has heard this phrase -- and will hear this phrase -- "substantial contributing factor." Do you believe Roundup or glyphosate was a substantial contributing factor to Mr. Hardeman's non-Hodgkin's lymphoma?

A. No, I do not believe that Roundup or glyphosate was a substantial contributing factor to Mr. Hardeman's lymphoma.

Q. And we are going to talk more in a moment about -- the jury has also heard the phrase "idiopathic." Are you familiar with that phrase?

A. Yes, I am.

Q. We will talk more about that in a moment. But for now what I want to ask you is in offering his opinion to the jury, do you think that Dr. Weisenburger appropriately considered the possibility that Mr. Hardeman's non-Hodgkin's lymphoma was

idiopathic?

A. No, I do not. There is nothing specific either under the microscope or clinically or history in terms of the development of the lymphoma that would indicate that this was anything other than, in his parlance, idiopathic. That is not my view. But he can't -- he did not distinguish the concept that idiopathic is seen in great numbers, great percentages of patients who have diffuse large B-cell lymphoma. We never know what the cause is. And if you can't determine Roundup versus idiopathic under the microscope or any other specific way, you have to consider idiopathic is a real possibility as far as the cause, i.e., we just don't know.

Q. Now, we are also going to talk more about hepatitis C and hepatitis B. But in offering his opinions, do you think that Dr. Weisenburger appropriately considered the possibility that Mr. Hardeman's non-Hodgkin's lymphoma was caused by hepatitis B or hepatitis C?

A. No, I do not think he was correct when he said that neither hepatitis C or B had anything to do with Mr. Hardeman's lymphoma.

Q. What, in your opinion, was the most likely cause of Mr. Hardeman's non-Hodgkin's lymphoma?

A. I believe without question that the most likely cause of his lymphoma was chronic infection by hepatitis C; 39 years of active infection by hepatitis C, allowing a real opportunity

for an accident to occur. It could have occurred on day one of the infection. It could have occurred on day one of year 39 of the infection. For 39 years he was infected with a virus which has been shown to cause diffuse large B-cell lymphoma.

Q. And what in your opinion is the second most likely cause of Mr. Hardeman's non-Hodgkin's lymphoma?

A. I think the second most likely cause is hepatitis B. We don't know a lot -- I don't know a lot of the detail about his hepatitis B infection. I know that he has been infected in the past with hepatitis B, based upon the very specific blood tests that were done. I believe Dr. Weisenburger said he was immune. What that means is he has been infected in the past with hepatitis B. Hepatitis B also causes accidents in that DNA. Hepatitis B could be a cause, but I just don't know enough about his hepatitis B from the records to be able to say that that is the primary cause. So I believe that the primary cause, or most significant factor, was hepatitis C, followed by hepatitis B. Either could have done this.

Q. Now, in your opinion is it also possible that Mr. Hardeman's non-Hodgkin's lymphoma was idiopathic?

A. Yes, it is also possible that it was idiopathic. You can't really tell under the microscope. It is conceivable that it was about 70 -- the literature is a bit different here, but between 70 and 90 percent of cases of diffuse large B-cell lymphoma are such that we don't know the reason. So it is

possible that it is just idiopathic. We don't know.

Q. Now, there has been testimony about oncologists who want to know the cause of their patients' non-Hodgkin's lymphoma. And my question for you is: If you, Dr. Levine, could know the cause of every one of your patients' non-Hodgkin's lymphoma, would you want to know?

A. I would absolutely want to know.

Q. And why is that?

A. Oh, all kinds of reasons. First of all, if I knew the exact cause of a given case, I might be able to treat that patient a little bit differently than I would be treating somebody else. If somebody had been, for example, infected by hepatitis C or hepatitis B, I would need to know that, even if they didn't have a lymphoma. So what I mean by that is hepatitis C -- if somebody is going to go on chemotherapy, I would want to be very, very careful because of hepatitis C hidden in the body someplace that might reactivate itself. I would want to know about that.

If the patient had been infected by hepatitis B in the past, as Mr. Hardeman, and that patient was then going to get chemotherapy, I also would worry -- just as Dr. Ye did -- that the hepatitis B might reactivate itself and because he knew at some level that hepatitis B could be hidden in the body, he chose to use a medicine. He gave Mr. Hardeman lamivudine, a drug, to try to suppress hepatitis B.

Even though he said that Mr. Hardeman was, quote, cured of his hepatitis C, that was a -- that was based on a blood test, which isn't sensitive to show hepatitis C very low in the body. And he knew that too. So we both are saying the exact same thing, but he is acting in the way that I would. I'm very respectful of him.

In other words, he spoke to Mr. Hardeman very carefully. And said to Mr. Hardeman, We have some extra issues in your case. One is you have chronic hepatitis C infection, a history of that. I'm going to have to watch you more carefully than usual to make sure that the chemo will be safe related to your hepatitis C. He wouldn't have said that if he believed that Mr. Hardeman was honestly cured; that there was not one last little HCV.

MS. MOORE: Sorry, Dr. Levine.

Objection, Your Honor. Speculation. Hearsay.

THE COURT: That last sentence will be stricken.

THE WITNESS: He gave Mr. Hardeman a medicine, a medicine that potentially has side effects. So every time we give a medicine, that's a big deal. You are thinking about the potential risks and the potential benefits of that medicine. He gave lamivudine to Mr. Hardeman who had a history of hepatitis B, who was, quote, cured of hepatitis B; but he gave that medicine, knowing he gave that medicine.

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BY MR. STEKLOFF

Q. Now, understanding your opinion that Roundup did not cause Mr. Hardeman's non-Hodgkin's lymphoma or contribute to his non-Hodgkin's lymphoma, let's say you could know that Roundup caused one of your patient's non-Hodgkin's lymphoma. Would you want to know that?

A. Oh, sure, I would.

Q. Okay. Now, if Mr. Hardeman had been your patient; and based on your review of the medical records, would you have ever told him that Roundup or glyphosate caused his non-Hodgkin's lymphoma?

A. No, I don't believe it does.

Q. Now, let's turn back to the idiopathic. And let's discuss that a little more for the jury.

What does it mean for a cancer or non-Hodgkin's lymphoma to be idiopathic?

A. It means that we don't know the cause. We are able to diagnose this under the microscope and so forth, but we don't know why it occurred. We don't know what caused that accident.

Q. And I think you mentioned a moment ago that the literature differs, but I think -- just to get this -- did you say between 70 percent and 90 percent of non-Hodgkin's lymphomas are considered idiopathic?

A. That's correct. The majority without question are idiopathic. And the literatures are somewhat diffuse in that

regard. Some of the papers say as low as 70 percent. Some say as high as 90 percent.

Q. And is that -- the 70 to 90 percent, does that also apply to specifically diffuse large B-cell lymphoma?

A. Yes, that applies to diffuse large B-cell lymphoma.

Q. What about in your practice, what percentage of -- not that you have done a scientific assessment -- but an estimate, what approximate percentage of your patients are idiopathic in your opinion?

A. I have not counted this up, but my belief is that my patients are more likely to have lymphomas -- non-Hodgkin's lymphomas with known cause, specifically HIV or hepatitis C or hepatitis B or HTLV1. My area of expertise is lymphomas caused by infectious organisms caused by germs.

So other doctors refer patients to me from locally or around the country or even around the world. So my belief is that my practice is a bit different and more heavily weighted towards organism, germ-related causes for the patients' lymphoma.

Q. And you mentioned that includes HIV?

A. Yes, it does.

Q. Does that include hepatitis C or hepatitis B?

A. It includes HIV, hepatitis C, hepatitis B, yes.

Q. Now, you said a moment ago, I believe, that it is possible that Mr. Hardeman's non-Hodgkin's lymphoma was idiopathic and

that you don't think Dr. Weisenburger fairly considered that. Can you explain to the jury why it is possible that Mr. Hardeman's non-Hodgkin's lymphoma was idiopathic?

A. It is possible because in his particular case we have not looked at his B lymphocytes or his liver cells to know that he has hepatitis C there. On the other hand, we do know that it was present for all of those years, the 35 years.

The other side of the coin, looking at the tissue alone, just the plain biopsy, you really can't tell. There is nothing that distinguishes the hepatitis C diffuse large B-cell lymphoma from an idiopathic case.

Q. So you mentioned hepatitis C. So let's now talk about hepatitis C. The jury has heard a lot about hepatitis C, but can you just briefly explain what hepatitis C is?

A. Hepatitis C is -- it is an RNA virus. One of the interesting things about it is that our immune systems are normally not very good at suppressing it. So when somebody is infected by hepatitis C, about 15 percent of the time, 1-5, the patient's immune system can clear it. And it is, quote, cured.

However, 85 percent of the time our immune systems cannot cure it, and the patient then develops -- as Mr. Hardeman did -- chronic infection by hepatitis C going on for years and decades. Well, with that chronic infection, the cells that are most involved are B lymphocytes and also liver cells. The virus gets into liver cells and it also gets into B

lymphocytes.

The presence of hepatitis C in the liver causes a whole reaction. It gets inflamed. All of these immune cells are in there trying to knock it off. As it gets inflamed, eventually the liver becomes scarred from all of that chronic infection and chronic inflammation. Big amounts of scar tissue come down on the liver, crowding out the regular liver cells so that they cannot work anymore, and the patient goes into what we call liver failure. So one outcome is liver cirrhosis, and it is an outcome of chronic -- of long-term infection by hepatitis C.

The hepatitis C can also cause those accidents that I was talking about. Hepatitis C can cause direct mutations in the cells in which it lives. And that includes B lymphocytes and liver cells. So hepatitis C is now a proven cause of liver cancer, but in our case here, a proven cause of non-Hodgkin's lymphoma and specifically diffuse large B-cell lymphoma.

Q. Mr. Hardeman had diffuse large B-cell lymphoma. Is hepatitis C a proven cause of diffuse large B-cell lymphoma?

A. Yes, it is.

Q. Now, did you also -- based on your review of the medical records, did you want to highlight a few of the medical records -- Mr. Hardeman's medical records for the jury?

A. Certainly.

Q. So this is Exhibit 1023 at page 114, and it is dated January 28th, 2005.

Dr. Levine, what does this record show?

A. This record shows that Mr. Hardeman was, in fact, infected by hepatitis C. There are various subtypes of the virus. His subtype was called genotype 2B. The amount of virus in his blood in January of 2005 was quite high. It was 732,000 copies for every drop of blood.

Q. So is this, in this January 2005 timeframe, when Mr. Hardeman's hepatitis C was first identified by his doctors at Kaiser?

A. This is when it was first identified, yes.

Q. Okay. Now, you also have this record from Dr. Turk dated January 25, 2005. And what did you want to highlight for the jury here?

A. The highlight here is that this hepatitis C could not have been a recent infection. For the patient to have had actual cirrhosis of the liver, that would have taken years. And that meant to me that this was a chronic infection, just as it meant to his doctor.

Q. So the jury has heard that Mr. Hardeman was first exposed -- likely first exposed to hepatitis C in approximately 1966. Is that your understanding as well?

A. Yes, it is.

Q. So between 1966 and 2005, that is 39 years, correct?

A. Yes.

Q. And what does the fact that Mr. Hardeman developed

cirrhosis of the liver during that 39-year period tell you about how long the hepatitis C was active in him?

A. The apparent exposure was in the 1960s. The first proof that he had the hepatitis C was in 2005, 39 years later, and it was chronic. He already had cirrhosis. And that says that from the time of his exposure to the time of first diagnosis was a very, very long time, similar to what I would have expected actually.

Q. And do you recall also that Dr. Weisenburger testified about this -- there was a record in the 1980s where Mr. Hardeman had increased liver enzymes?

A. Yes, I saw that as well. It was 1989, I believe. And so there were increased liver enzymes which would have been consistent with active hepatitis C infection, at that time as well.

Q. Okay. And you mentioned that it takes years for cirrhosis of the liver to develop from hepatitis C. Can you give -- does it take -- what is the sort of minimum amount based on the literature that it appears to take?

A. People will be different depending on the immune system and so forth. But this is long. It is at least a decade. It is not years or months. It is a decade or decades.

Q. And so is it your opinion that Mr. Hardeman's cirrhosis was caused by his hepatitis C?

A. Yes, I believe that is true. It is conceivable that

hepatitis B was involved as well, but I don't know enough about his hepatitis B to be able to say that definitively.

Q. Does that tell you that most likely Mr. Hardeman had active hepatitis C for at least ten years during that 39-year period?

A. At least ten years, and this would be consistent with other reports in the literature. I believe he had active infection for a good 39 years, a long, long time.

Q. And did you also -- you mentioned how hepatitis C can impact someone's body. Did you also prepare a board to walk the jury through that?

A. Sure.

MR. STEKLOFF: Your Honor, may Dr. Levine step down one more time?

THE COURT: Okay.

BY MR. STEKLOFF

Q. Dr. Levine, can you please walk the jury through what we are seeing here, and please speak up.

A. So this is just repeating what I said before so that you can get a visual image of it. When somebody is infected with hepatitis C, the minority, about 15 percent, can actually fully recover. The immune system can handle that and get rid of the virus.

The vast majority, 85 percent of people, develop what we were talking about: Chronic infection with that hepatitis C

that they cannot clear.

And there are two outcomes there. One is the patient just has chronic hepatitis: Yellow eyes, sick, liver enzymes elevated, liver not well, so to speak. So chronic hepatitis, fatigue, tired, and so forth.

The other outcome, more severe, is cirrhosis, scarring, chronic inflammation of the liver, scarring out at the liver, and eventually end-stage liver disease. In other words, dying of liver disease. So that is one outcome of chronic HCV infection.

The other outcome of chronic HCV infection is cancer. One of those cancers, the more common, is liver cancer directly caused by long-term infection by HCV. It causes accidents in the liver. It causes mutations in B lymphocytes because the hepatitis B also lives and gets into B lymphocytes; causes accidents in the B lymphocyte, and that may result in non-Hodgkin's lymphoma, specifically diffuse large B-cell lymphoma. So these are the usual outcomes of chronic hepatitis C infection.

Q. And where, based on your opinions, is it most likely that Mr. Hardeman fits in these various outcomes?

A. I think he -- I know he has cirrhosis. So I know that part of it. I know he has lymphoma. I believe he is here. He is cirrhosis with lymphoma.

Q. Thank you, Dr. Levine.

Dr. Levine, did you also prepare a slide to explain -- to visually explain to the jury how hepatitis C causes non-Hodgkin's lymphoma?

A. Yes, I did.

Q. Okay. So using this slide, what I'm hoping you can do is actually start on the right side of the chart that says marginal zone and explain what is happening there with hepatitis C.

A. First, I said a while ago that there were more than 60 different types of lymphoma; and they are caused by different things and different mechanisms, and this is going to be an example of that, and an important one in this situation.

So what we see on top is a B lymphocyte, and it turns out that the B lymphocyte has a -- I am going to call it a receptor. I will call it now a lock, a receptor, a molecule, a little structure on its surface.

This in orange is hepatitis C. And it turns out that hepatitis C has a molecule on its surface which fits exactly into the receptor on the B cell. One could think of it as a lock and a key. All of medicine, all of biology works that way. It has to be a perfect fit.

So what happens is the hepatitis C is the key. The B lymphocyte is the lock. If hepatitis C is in the environment, the key goes right into the lock. It attaches itself right away to the B lymphocyte, and it causes that B lymphocyte to

divide over and over and over and over again, so that there is a, quote, tumor, a mass, a lump of those cells.

This one is directly driven by hepatitis C. It needs the -- I'm going to say -- call the hepatitis C the foot on the gas pedal of these B cells, making them grow, making them divide over and over. In this example, if you remove the hepatitis C here, if you remove the hepatitis C, you are taking your foot off of the gas pedal. You are taking the key out of the lock, and the whole thing can go away. And it does. And that's what they are talking about when treatment for marginal zone lymphoma takes that tumor away 75 percent of the time. That's marginal zone lymphoma. And that is the mechanism in which it works.

Q. Let me stop you there. Did Mr. Hardeman have marginal zone lymphoma?

A. No, he did not.

Q. And the jury has heard about the antiviral therapy that Mr. Hardeman received between 2005 and 2006. You are familiar with that, correct?

A. I am.

Q. And does that therapy reduce the likelihood of marginal zone lymphoma?

A. Absolutely will reduce the likelihood of marginal zone lymphoma.

Q. And is that because, as you said, the hepatitis C is

attached to the B cells and has to be there?

A. Yes.

Q. Now, explain -- now, let's talk about the left side. First of all, I see DLBCL -- diffuse large B-cell lymphoma -- at the bottom. Is this the way in which you -- it is your opinion that hepatitis C may or would have caused Mr. Hardeman's non-Hodgkin's lymphoma?

A. Yes, it is.

Q. So can you explain that left side of the diagram, please.

A. Hepatitis C can directly cause accidents, mutations in the DNA. Mr. Hardeman had mutations in his DNA. Once that accident is there, the virus doesn't have to be there anymore at all. We call that a hit-and-run kind of a mechanism. It is what I was trying to explain when I was talking about tobacco.

So, again, people who stop smoking 15 years ago are still at risk for lung cancer. The accident has happened. Doesn't matter that they aren't smoking anymore. The accident happened 15 years ago, four years ago, whatever it is. This kind of error is what really causes the diffuse large B-cell lymphoma, and this is what Mr. Hardeman had.

In this particular case, if you get rid of hepatitis C entirely, it doesn't matter. The accident is there. If you get rid of smoking entirely, doesn't matter. The accident is there.

Q. And so when we heard about this antiviral therapy and

Mr. Hardeman's sustained virological response, he didn't have the positive hepatitis C test between 2006 and 2018. Does -- did the -- would the antiviral therapy have cured an accident that took place through this hit-and-run mechanism?

A. No. The presence or absence of hepatitis C in the blood or the body would have no effect. This accident, it wouldn't matter. Once the accident was there, it was there. His immune system would work with it well or not, but the accident is there. Doesn't need the hepatitis C anymore.

Q. Now, is there peer-reviewed literature? Are there articles that discuss exactly what you are showing on the left side here, this direct accident in the DNA or the hit-and-run?

A. Absolutely.

MR. STEKLOFF: Your Honor, I would like to publish two of those articles. The first is Exhibit 1448.

MS. MOORE: No objection, Your Honor.

MR. STEKLOFF: So I think we are going to pull that up. Mr. Holtzen is going to help me.

BY MR. STEKLOFF

Q. So, Dr. Levine, is this an article titled Hepatitis C Associated B-cell non-Hodgkin's Lymphomas, Epidemiology, Molecular Signature and Clinical Management?

A. Yes, it is.

Q. And are we talking here, in your opinion, about a hepatitis C associated B cell non-Hodgkin's lymphoma in

Mr. Hardeman?

A. Yes, we are.

Q. And if we can find the date at the bottom, is this article from 2013 in the *Journal of Hepatology*?

A. Yes, it is.

Q. Is hepatology -- hepatologists the people who treat hepatitis C?

A. Yes.

Q. And so if we turn to this first -- let me find the exact spot -- on the first page, I believe, there is a section that says -- that talks about B-cell non-Hodgkin's lymphomas. Here, does this explain right at the introduction in that second sentence: B-NHL subtypes most frequently associated with hepatitis C virus are marginal zone lymphoma and diffuse large B-cell lymphoma?

A. Correct, just what I was explaining before.

Q. Right. Is that consistent with what you just explained?

A. Absolutely.

Q. And then if we turn to page 172, do the authors of this article walk through the mechanisms through which hepatitis C can cause B-cell lymphomas?

A. Yes, they do.

Q. If we can pull that up, please.

They talk about three general theories have emerged to understand the HCV-induced transformation process. Do you see

that?

A. Yes, I do.

Q. The third says, Permanent B-cell damage, for example, mutation of tumor suppressor genes caused by transiently intracellular virus, the so-called hit-and-run theory. Do you see that?

A. Yes, I do.

Q. And so can you please explain to the jury what the authors are referring to there?

A. What they are saying is that HCV is capable of causing accidents or mutations within that -- the cell in which it lives, i.e., B lymphocyte in this case -- it will cause the accident, and that the mutation at that point, it leaves or can leave but the accident is still there.

The only thing that I would differ a bit on this last statement is he is talking about a certain kind of tumor suppressor genes. In fact, we have found that these mutations can occur all over. It doesn't have to be just in those genes.

Q. And now, if we turn to page 173, do they also include a diagram, the third diagram that explains this hit-and-run theory?

A. Yes, they did.

Q. And I don't need you to walk through, but does this show, consistent with what you explained to the jury, that the hepatitis C can cause the DNA damage, hit-and-run, and then

leave the cell but leave that DNA damage behind?

A. That's exactly what it shows; drawing much more nicely than my own, but there it is.

Q. Okay. So if we can please turn to -- did you -- in fact, were you part of a group that published on this as well?

A. Yes, I was.

MR. STEKLOFF: Can we please publish Exhibit 1343, Your Honor?

MS. MOORE: No objection.

THE COURT: Go ahead.

BY MR. STEKLOFF

Q. We see here that this article is called Hepatitis C Virus Induces a Mutator Phenotype, Enhanced Mutations of Immunoglobulin and Proto-oncogenes, correct?

A. That's correct.

Q. And Dr. Machida is the lead author, but do we see there that you are also part of the authors who published this article?

A. Yes.

Q. And this is dated March 23, 2004; is that correct?

A. Correct.

Q. And if we look at the summary of what you and your colleagues published, did it explain -- well, let's just read this for the jury. It says -- would you like to read it?

A. Sure.

Q. Okay.

A. We demonstrated here that acute and chronic HCV infection caused a five to tenfold increase imputation frequency in immunoglobulin heavy chain, BCL6, p53, and Beta-catenin genes of in vitro HCV-infected B-cell lines and HCV-associated peripheral blood mononuclear cells, lymphomas and HCCs.

So we looked at cell lines. We looked at living human living peripheral blood B-cells. We looked at human lymphomas, and we looked at human hepatic cancer cells, hepatocellular cancer cells.

Q. And then if we look at the bottom of this same paragraph, did you and your colleagues explain the following: These results indicate that hepatitis C virus induces a mutator phenotype and may transform cells by a hit-and-run mechanism. This finding provides a mechanism of oncogenesis for an RNA virus?

A. Yes, that's what it says; and that's what the data indicates, both then and subsequent to that.

Q. Can you just explain -- you have talked about it, but can you just explain to the jury what that -- what those two sentences mean?

A. It basically means that HCV is unusual and difficult in the sense that it has the ability to get into our DNA and cause all kinds of accidents, not any one specific. Some are more common. Some are less common. But it can cause accidents all

over the place in our DNA. It is a very difficult virus.

Q. Now, are there other articles that also explain this hit-and-run mechanism?

A. Yes, there are.

Q. We chose just one that you were involved in and then one that you weren't involved in; is that fair?

A. Yes. I think it is important to note that the field always moves forward. You're always learning more. So the first publication was in 2004, but that has consistently been shown. This is now very commonly understood by oncologists such as myself.

Q. Now, Dr. Levine, have you also -- if we can switch back to the PowerPoint.

Have you also been involved in research regarding the latency or how long it takes for lymphoma to develop from hepatitis C?

A. Yes, I have.

Q. And so -- actually we have one more study, I'm sorry, which is Exhibit 1598.

MR. STEKLOFF: If I can publish that to the jury, Your Honor.

MS. MOORE: No objection.

THE COURT: Go ahead.

BY MR. STEKLOFF

Q. And we see here the title of this article is Hepatitis C

Virus Infections in Patients with B-cell non-Hodgkin's Lymphoma; is that correct?

A. Yes.

Q. And, again, with Mr. Hardeman we are talking about a B-cell non-Hodgkin's lymphoma; correct?

A. Correct.

Q. This is by Dr. Zuckerman. And then I think we see that you were also part of this research in 1997, correct?

A. Right.

Q. And can you briefly explain to the jury how you, Dr. Zuckerman and the other doctors conducted this study, not with too much detail, but what you did?

A. We were interested in the potential relationship between hepatitis C and B-cell lymphomas because in our large group of patients with lymphoma at the county hospital in L.A., we were seeing quite a few patients who were infected by hep C.

We, therefore, did a study and looked at about 120 of our patients who had B-cell lymphoma from the county, we looked at about 150 patients who had other kinds of cancers of the blood system but not B-cell lymphoma, and then we looked at about 130 patients from our same clinics who had no cancer at all but they were patients at the county hospital.

We did hepatitis C antibody tests on all of them and HCV RNA. We looked at the RNA, the active virus in the blood, of all of them. And it turned out that the patients with B-cell

lymphoma were highly more likely -- 22 percent of them had been infected with hepatitis C versus only about 5 percent of the other two groups. This was highly significant and was our first little hint that perhaps hepatitis C was related in some sense to the development of B-cell lymphoma.

We went back to the patients who were hepatitis C infected, asked when they might have been infected or when they might have been exposed by hepatitis C, and it turned out that the average, the median time, between the exposure to hepatitis C and the B-cell lymphoma was 15 years. Again, long time. But the range went up to 30 -- 35 or 36 years. So, again, hepatitis C has a long latent period as it eventually develops into B-cell lymphoma.

Q. And so just to call out a couple portions of the article. First, did you explain at page 423 what you just said where it talks about risk factors for hepatitis C infection?

A. Risks --

Q. Yes. So it says (reading):

"Risk factors for hepatitis C virus infection were present in 15 patients (60 percent) with B-cell lymphoma and occurred a median of 15 years before diagnosis of lymphoma."

Correct?

A. Correct.

Q. And then if we go to the next portion of the results

section that we wanted to call out.

Did you explain -- you and your colleagues explain the period during which patients were at risk for percutaneous exposure to HCV preceded the diagnosis of B-cell lymphoma by a median of 15 years, range 5 to 35 years?

A. Correct.

Q. And if we can take that down.

With respect to Mr. Hardeman and that 5- to 35-year range with a median of 15, what does that tell -- what would you like to tell the jury about that?

A. I think that Mr. Hardeman's case was quite common. That's exactly what we expect, a very, very long latent period during which the accident, the cell with the mutation in it is starting to divide and the person's immune system is trying to keep it in check; but at a certain point, perhaps when the immune system weakens a little bit because the person is older, at a certain point it shifts and the immune system weakens, the lymphoma is allowed to express itself, to divide and divide, it pops above the line, and the patient is diagnosed with a clinical lymphoma. So I think that his case is quite consistent with the usual situation in that regard.

Q. When you say "usual," usual with respect to a hepatitis C diffuse large B-cell lymphoma?

A. Consistent with the fact that it's very -- it's expected that the time between infection by hepatitis C and the

development of B-cell lymphoma will be decade or decades long.

Q. Now, you mentioned earlier that you've reviewed Dr. Ye's testimony; correct?

A. That's correct.

Q. And are you aware that Dr. Ye said Mr. Hardeman was cured in 2006 of his hepatitis C?

A. Yes, he said that.

Q. Okay. And so I think you touched on this briefly but since we're talking about hepatitis C, is Dr. Ye's use of the word "cured" consistent or inconsistent with your opinions?

A. I think we're both saying the same thing. I'm very respectful of Dr. Ye. He did a beautiful job and he treated Mr. Hardeman beautifully. He used the word "cure," but in some way he knew -- I'm sorry.

He used the word "cure." He gave the patient some very specific information. He said to the patient --

MS. MOORE: Objection, Your Honor.

I'm sorry, Dr. Levine.

Again, speculation and hearsay.

THE COURT: Overruled.

BY MR. STEKLOFF:

Q. You can continue.

A. There is specific data in the literature in Mr. Hardeman's records in which Dr. Ye discusses what he discussed with Mr. Hardeman related to his lymphoma. He says that he

discussed with Mr. Hardeman the fact that he had chronic infection by hepatitis C and, therefore, he was going to have to watch him very carefully as it relates to his liver tests.

He also told Mr. Hardeman that he had been infected by hepatitis B and because of that, he wanted to avoid the reactivation of hepatitis B using a drug called lamivudine. This would be done simply because use of chemotherapy itself will weaken the immune system; and if there is virus, germs, hidden occult inside cells, inside a liver cell or inside a B-cell, the use of chemotherapy will decrease the immune system of the patient and allow the hepatitis B to reactivate itself, to show itself again as hepatitis and allow the hepatitis C virus to get active again and show itself as real hepatitis.

He was very specific in discussing that with Mr. Hardeman, and he wrote it into his note that he had discussed that. So his action indicated that he wanted to prevent --

MS. MOORE: Objection. Objection, Your Honor.

THE WITNESS: -- reactivation.

MS. MOORE: Dr. Levine, I'm sorry.

It calls for speculation.

THE COURT: Overruled.

BY MR. STEKLOFF:

Q. And, Dr. Levine, we'll come back through some slides, but you mentioned a medical record. Is this the medical record, 1023 at page 940, that you are referencing?

A. Yes.

Q. And so it says at the top (reading):

"We specific" --

This is Dr. Ye's record from February 19th, 2015; correct.

A. Correct.

Q. And it says (reading):

"We specifically discussed two additional concerns in his case."

This is what Dr. Ye was saying he discussed with Mr. Hardeman; correct?

A. Correct.

Q. And the first involved the impact of hepatitis C cirrhosis; correct?

A. Correct.

Q. But then explain just -- you just explained it, but just tell the jury what this says in the second bullet and how that's consistent with what you just explained.

A. So he says that he discussed these concerns with Mr. Hardeman, hepatitis B and C reactivation from rituximab. Some of the drugs -- one of the drugs that we will use to treat Mr. Hardeman is rituximab, and that definitely weakens the immune system; and so he's saying to Mr. Hardeman that because of the chemotherapy that we are going to start, the hepatitis B could reactivate itself and the hepatitis C hidden could reactivate itself.

He says (reading):

"We will monitor both diseases through the treatment. I recommend prophylactic lamivudine 150 grams daily."

What that means is lamivudine is a drug to try to keep the hepatitis B from reactivating itself, and he starts that drug in Mr. Hardeman.

Q. And if Dr. Weisenburger last week suggested to the jury that after that antiviral therapy hepatitis B and hepatitis C had been completely eliminated from Mr. Hardeman's bloodstream, do you agree with that?

A. I do not agree with it and I don't believe -- I did not agree with it at all.

MR. STEKLOFF: And I'm sorry. This may have not been published. So may I published this to the jury if it wasn't published?

MS. MOORE: No objection, Your Honor.

THE COURT: Go ahead.

BY MR. STEKLOFF:

Q. Okay. So sorry about that.

We don't need to belabor this record. Do you see here where it says, "We specifically discussed two additional concerns in his case," and then you were reading from that bottom bullet (reading):

"Hepatitis Bc reactivation from rituximab. Will monitor both diseases through the treatment. I

recommended prophylactic lamivudine, 150 milligrams once daily."

A. That's what he said, and he discussed it with the patient.

MR. STEKLOFF: And, Your Honor, I would move into -- move for the admission of page 940 and then the two other prior medical records also, page 114 and 192, of Mr. Hardeman's medical records.

MS. MOORE: Objection, Your Honor, just with the admission through an expert. I think she can testify that she relied it, but admission into evidence is not proper. I'd like a sidebar on that later.

THE COURT: Sure.

MS. MOORE: Thank you.

MR. STEKLOFF: Okay.

Q. Now, Dr. Levine, the jury -- I just want to talk -- since you've been talking about this antiviral therapy, the jury heard, and I think it's not in dispute, that Mr. Hardeman did not have a positive hepatitis C test after 2006; correct?

A. That is correct.

Q. He had something called a sustained virological response between 2006 and 2015; correct?

A. Correct.

Q. Does that in any way change your opinions about the role hepatitis C most likely played in Mr. Hardeman's non-Hodgkin's lymphoma?

A. No, for two reasons. First, if he had had that active hepatitis C for one year or for 39 years, at any one moment he would have had the opportunity for an error. He did have a mutation in his cell and, therefore, he didn't need the virus anymore. It was already -- the event had already occurred. That would be one concept -- or fact.

The other fact is that sustained virologic remission basically means that we cannot find evidence of the virus in the blood using the standard techniques that we have, and that is defined starting at six months after the end of antiretroviral -- I'm sorry -- antiviral therapy.

We -- on the other hand, we do know -- ask me again. I'm sorry. I lost my train.

Q. You were explaining there were two reasons why --

A. Oh.

Q. -- his sustained virological response doesn't change your opinions.

A. Right. The other fact is that sustained virologic response means that we don't see the virus in the blood using our standard techniques, but there are many studies published in the peer-reviewed literature that show very carefully that even though the virus is not visible by our techniques in the blood, if one does very careful ultrasensitive studies in the blood, you can often find it. If you look at the liver cells, it is there. If you look at the B lymphocytes, it is there.

And that's now called occult infection. It's there at a lower level. It's a real clinical benefit. No question, if you reduce the amount of HCV, the patient feels better. It's something that we should do, no question; but if that accident has already happened, it doesn't really matter whether the virus is still there or not.

Q. And so, Doctor, we're not going to walk through them, but Dr. Weisenburger showed the jury last week a series of articles that he used -- that he -- it was his opinion, based on those articles, that Mr. Hardeman would have had little to no risk for diffuse large B-cell lymphoma because of the sustained virological response. Do you recall reviewing that testimony?

A. I do.

Q. Have you reviewed all those articles?

A. I have.

Q. And do any of those articles change the opinions that you have offered here today about the possible role of hepatitis C in Mr. Hardeman's cancer?

A. They do not alter my opinion at all. The accident had 39 years to occur.

Q. Okay. So let's turn now --

THE COURT: Maybe now would be a good time for our morning break?

MR. STEKLOFF: I think that's perfect, Your Honor. I think I have ten minutes left, but I think this is a good time.

THE COURT: Okay. Sounds good.

Why don't we take our morning break. We'll be back in at about 10 after the hour. Thank you.

THE CLERK: All rise.

(Proceedings were heard out of the presence of the jury:)

THE COURT: Thank you. You can step down, Dr. Levine.

THE WITNESS: Thank you.

THE CLERK: Please be seated.

THE COURT: Be back in about ten minutes.

(Recess taken at 9:59 a.m.)

(Proceedings resumed at 10:14 a.m.)

THE COURT: Okay. Go ahead and bring them in.

(Proceedings were heard in the presence of the jury:)

THE CLERK: Please be seated.

THE COURT: Okay. You can resume.

MR. STEKLOFF: Thank you, Your Honor.

Q. Good morning, Dr. Levine.

A. Good morning.

Q. And so when we finished off, we were going to turn to hepatitis B. And can you just briefly explain to the jury what hepatitis B is?

A. Yes. Hepatitis B is actually an entirely different virus. It is a DNA virus. It also infects B lymphocytes and liver cells.

The interesting thing about hepatitis B, one of them, is

that it's very different than C in the fact that most people who get hepatitis B, the immune system can clear it and it's the minority that will go on with chronic hepatitis. So it's just the opposite in terms of chronic infection as far as the percentage of people with chronic infection. Very, very common in hepatitis C, not that common in hepatitis B.

But it certainly can lead to liver cirrhosis over time. Hepatitis B can cause the same kinds of accidents or genetic errors, mutations, in the DNA just as I was saying about hepatitis C; and hepatitis B has also been proven to be a cause of non-Hodgkin's lymphoma and specifically diffuse large B-cell lymphoma.

Q. And so this is a medical record, again, from Dr. Ye dated February 19th, 2015. And what does this medical record show?

A. It shows that he has been infected with hepatitis B in the past. So he does not have active hepatitis B surface antigen is what it's called, and that would be a sign of active infection. Just like in hep C, the RNA would be a sign of active. Here he does not have evidence of active hepatitis B infection, but he has had it in the past because he has antibody to what is called hepatitis B core. So he has been infected in the past.

MR. STEKLOFF: And, Your Honor, I would move for the admission of this exhibit as well, Exhibit 1023 at page 940.

MS. MOORE: Your Honor, same objection.

THE COURT: Okay. We'll discuss it at sidebar.

BY MR. STEKLOFF:

Q. Now, Dr. Levine, we've heard that Mr. Hardeman was, again, most likely exposed to hepatitis B in 1966 as well; correct?

A. Correct.

Q. Now, are you able, based on the fact that he had this positive test for the antibody in 2015, to tell how long he had active hepatitis B?

A. No, I can't tell how long he might have had active hepatitis B.

Q. So as compared to hepatitis C, is that why you are -- you said it was the second-most likely cause instead of the most likely cause?

A. Yes. I felt the most likely was hepatitis C. He had active infection for 39 whole years. I just don't have enough information from the medical records to know the duration of what might have happened with the hepatitis B, and that's why I put it second on my list.

Q. And here we can see in this medical record from Dr. Ye that when he was tested in 2015, Mr. Hardeman was positive for this hepatitis B core antibody; correct?

A. That is correct.

Q. And is there literature that discusses the risk of developing B-cell lymphoma if you are positive for that core antibody?

A. Yes, there is.

Q. And so -- well, this record we have discussed before; correct?

A. Yes, we have.

Q. So then we'll move past that.

Is the Wang paper from 2007 one of the articles that discusses that increased risk associated with being positive for that core antibody?

A. Yes. He's looking at patients with B-cell lymphoma, and on the bottom in yellow they have antibody to hepatitis C to the core portion of the hepatitis B virus, and that is the same status as Mr. Hardeman.

Q. And just to be clear so we're not confusing hepatitis C or hepatitis B, this article is about hepatitis B; correct?

A. This is B and "c" here means core. So this is the core part of the hepatitis B virus. And the antibody positive means that that patient was infected with hepatitis B at sometime in the past, and this particular highlighted area shows that people who developed B-cell lymphoma were statistically more likely to be positive for that hepatitis B core component.

Q. And this is Table 4. If we look at Table 5, does the highlighted portion also apply to the tests for hepatitis B that Mr. Hardeman had?

A. Yes. So the anti -- he did not have an antibody to hepatitis B surface. He did have antibody to core, and that

is -- if he had -- if he had antibody to surface, that would mean he had been vaccinated. Here he had real infection. He had infection --

Q. And so --

A. -- in the past.

Q. -- at the bottom here there's a quote from the article that says (reading):

"The same subgroup showed a significantly higher rate of positive anti-hepatitis B core status and negative anti-hepatitis B surface status compared with the control group (31 percent versus 17 percent)."

Statistically significant, correct?

A. Correct.

Q. So how does this article and the increased risk associated with it -- can you explain how that impacts your opinions about the role hepatitis B may have played?

A. It says to me that it is certainly possible that Mr. Hardeman's B-cell lymphoma and diffuse large B-cell lymphoma was associated with hepatitis B, but I have no further information about how long he might have been infected or whether he might have been chronically infected.

Q. And to be clear, are there other studies about hepatitis B that show no or little increased risk if you have this positive core antibody?

A. Yes, there are studies that show the opposite as well.

Q. And did you consider that in forming your opinions?

A. I did. And, again, that was why I chose to put this as a second possibility, not as the first possibility.

Q. But with respect to both hepatitis C and hepatitis B, based on everything that you have now told the jury, do you think that Dr. Weisenburger appropriately ruled out, what he claimed he ruled out, those possible causes of Mr. Hardeman's cancer?

A. I don't believe that he ruled out those causes at all. The data is very, very strong in my own mind that those are the significant factors in this case.

Q. Okay. So I just briefly want to touch on two other things about Mr. Hardeman the jury has heard about. The first is that when he was diagnosed with his non-Hodgkin's lymphoma in 2015, he was 66 years old; is that right?

A. Yes.

Q. Explain to the jury how, if at all, that impacts your opinions.

A. Older age is a risk factor for many, many kinds of cancer, including lymphoma; and as I said earlier, one of the reasons would be the weakening of the immune system as one ages.

Risk factor doesn't mean a causative factor. Getting old doesn't cause cancer. It's simply associated with it. We see patients with cancer who are older as opposed to young people.

Q. But if Mr. Hardeman had any of these DNA mutations from

hepatitis C or hepatitis B, what would have happened to his immune system to fight those off as he became older?

A. As he became older and his defense or immune system got weaker just because of age, he would be less and less able to keep that mutation in check, to keep that beginning of malignancy in check. He did not get the lymphoma when he was 20 or 30 or 40. He got it when he was 66. His immune system would have been weakened at that time just by his age.

Q. The jury has also heard a little bit about -- from Dr. Weisenburger about Mr. Hardeman's weight. Do you recall that?

A. Yes, I do.

Q. And what, if any, role does Mr. Hardeman's weight play into your opinions?

A. Very little. I certainly understand that extreme obesity is associated with diffuse large B-cell lymphoma. Obesity in young people has been associated with eventual development of diffuse large B-cell lymphoma.

I don't, again, believe that obesity causes cancer, but the fat cells release all kinds of chemicals and the chemicals from the fat cells can act as growth factors for some of these kinds of cancers. So there may be an indirect cause, but the relationship -- certainly there is a relationship. I looked at it. I did not take it as a major significant factor at all.

Q. And is that based on your review of Mr. Hardeman's weight

in the medical records?

A. That's based on several things. Number one, his weight in the medical records. He was not exceedingly obese; i.e., a BMI of 40 or greater. And also because he was not ever really grossly obese. It was something that I looked at, but with the other factors that were so prominent, this had very little meaning to me in terms of his lymphoma.

Q. Now, did you prepare a slide that summarizes your opinions for the jury?

A. Yes, I did.

Q. And can you please walk through -- you've discussed all this, but can you please walk through your summary of your opinions that you've offered today?

A. Certainly.

First, the cause of most diffuse large B-cell lymphoma is unknown, it's iatrogenic, and we can't tell -- or idiopathic. I'm sorry. Idiopathic. We can't tell whether a given case under the microscope is caused by hepatitis C or Roundup or anything. You can't tell, and so that always has to be considered if you're looking at the potential cause of diffuse large B-cell lymphoma in somebody.

My second point is that there is no medical evidence that Roundup or glyphosate caused or contributed to Mr. Hardeman's non-Hodgkin's lymphoma, specifically diffuse large B-cell lymphoma.

My third conclusion or summary is that hepatitis C, an active infection for 39 years before it was treated, was the most likely cause or contributing factor to Mr. Hardeman's diffuse large B-cell lymphoma. The virus is capable of causing mutations in the DNA. Mr. Hardeman had DNA changes, mutations. The long period between his infection and finally treating it is very much consistent with what we know in the literature.

Once he had that mutation, it didn't matter at all if his virus had been completely eradicated or not. The error was there.

I also believe that the hepatitis B was the most likely secondary factor simply because it's been shown to do that. It also can cause mutations in the DNA of B cells, B lymphocytes, just like hepatitis C. I don't know how long Mr. Hardeman had active hepatitis B and, therefore, because I did not have more information, I left that as my secondary significant cause for this lymphoma.

Q. And you've described before what you mean by reasonable degree of medical certainty. Are all these opinions offered to a reasonable degree of medical certainty?

A. Yes, they are. As a clinical physician, I can't be swayed by a little thing here or a little thing there. I need real data, and patients depend upon me to know real data and to have judged it carefully and to have discussed it with many colleagues and thought about it for a long time because the

treatment that I'm going to do depends on these kinds of things.

I don't take that lightly. I don't take that lightly in any sense at all. So when I say that this is the most significant factor, it's based on my opinions as a physician, as a clinician doing what I would do to take care of that patient as Dr. Ye did.

Q. And if Mr. Hardeman had been your patient and had asked you about any of these topics, would you have told him exactly what you told the jury today?

A. Absolutely.

MR. STEKLOFF: Your Honor, I pass the witness.

THE COURT: Okay. Any cross-examination?

MS. MOORE: Yes, Your Honor.

CROSS-EXAMINATION

BY MS. MOORE:

Q. Good morning, Dr. Levine.

A. Good morning.

Q. Let me get all my things up here. And I've got some more binders to have in front of you.

A. Okay.

MS. WAGSTAFF: May I approach?

THE COURT: Of course.

(Pause in proceedings.)

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BY MS. MOORE:

Q. Dr. Levine, I want to start off with just some general questions about you were asked several things about your practice as an oncologist. And when you're practicing as an oncologist, do you agree that when you're trying to determine the cause of cancer, that it would be important for you to consider all of the data before reaching a conclusion?

A. Without any question at all.

Q. And would you agree that it would be improper to ignore data when you're trying to determine the cause of someone's cancer?

A. I agree.

Q. And do you agree that sometimes there's more than one cause of someone's cancer?

A. As in Mr. Hardeman, hepatitis C and possibly B.

Q. In fact, I heard you tell the jury today that in your opinion, both hepatitis C and hepatitis B were causes of Mr. Hardeman's non-Hodgkin's lymphoma; is that correct?

A. I said that my primary belief was that hepatitis C was the primary significant contributing factor to his lymphoma. Hepatitis B could have been a secondary factor.

Q. Now, in this case when you were reaching your conclusion about the cause of Mr. Hardeman's non-Hodgkin's lymphoma, is it true that you're not here to give any opinions about the animal studies that looked at Roundup and glyphosate?

A. Correct.

Q. And you're not here to give any opinions regarding the mechanistic data or, as the jury has heard, the cell studies regarding Roundup and glyphosate?

A. That is correct.

Q. And you're not here to give an opinion as to whether Roundup is genotoxic; correct?

A. That is correct.

Q. And for the epidemiology, you are relying solely on Dr. Mucci's testimony from last Friday that I understand you've read; is that correct?

A. I have read it and I rely on it. I thought it was well done.

Q. And you understood that Dr. Mucci's testimony was that there was zero evidence that Roundup was a risk factor for Mr. Hardeman?

MR. STEKLOFF: Object to form. Misstates the testimony.

THE COURT: You can answer it. Go ahead.

THE WITNESS: Ask it again, please.

BY MS. MOORE:

Q. Sure. Based on Dr. Mucci -- did you understand Dr. Mucci's testimony to be that there is zero or no evidence that Roundup causes non-Hodgkin's lymphoma?

A. I believe that's true.

Q. And as such, you aren't giving any opinions to this jury as to Mr. Hardeman's exposure to Roundup?

A. I am not.

Q. And your opinion as to what caused Mr. Hardeman's non-Hodgkin's lymphoma would be the same whether Mr. Hardeman used Roundup for 1 day or 26 years; correct?

A. Absolutely. I don't believe it caused lymphoma. It doesn't matter if it's 1 day or 10 days.

Q. And the same would be true whether he used 1 gallon of Roundup or almost 6,000 gallons? It wouldn't matter to you?

A. It doesn't matter to me.

Q. And, Dr. Levine, you didn't perform what the jury has heard is the Bradford-Hill analysis; is that correct?

A. I did not perform that analysis.

Q. Dr. Levine, in your experience, you understand that pesticide use or exposure to pesticides is considered to be a known risk factor for non-Hodgkin's lymphoma; is that correct?

A. It's much too broad a statement. I can't answer that question properly.

Q. Well, you're familiar with pesticides; right?

A. Somewhat.

Q. Okay. And that's fair. Let me back up.

I notice from your curriculum vitae that your specialty as an oncologist is really focused in on HIV; is that fair?

A. HIV and other organisms. Basically it is a lymphoma as my

specialty.

Q. And your specialty has not been lymphoma that's caused by pesticides; is that fair?

A. That is not my specialty.

Q. When you have a patient come into your office that has non-Hodgkin's lymphoma, do you ask them about their pesticide use?

A. I do not.

Q. Is it possible that all those cases that you referred to earlier that you said, well, the cause is idiopathic or unknown, that it actually could be from pesticide use, but you don't know because you don't ask?

A. That's a total assumption. I can't answer that question. I don't know.

Q. But without asking your patient about their pesticide use, aren't you assuming that the cause is unknown?

A. No.

Q. Now, let's go back to pesticide use. Are you familiar that certain pesticides are known to be risk factors for non-Hodgkin's lymphoma?

A. Pesticides? Be specific. I really can't answer that.

Q. Okay. Are you familiar with the American Cancer Society?

A. In general.

Q. And is the American Cancer Society an organization that you turn to in your work as an oncologist?

A. For what purpose?

Q. Well, the research that the American Cancer Society has performed?

A. They don't perform research.

Q. For the information that the American Cancer Society gathers?

A. Occasionally.

Q. And, in fact, in this case you relied upon information from the American Cancer Society discussing non-Hodgkin's lymphoma; correct?

A. I did.

Q. In fact, you listed that as your number one resource on your materials list that you considered in forming your opinions in this case; correct?

A. No, that is not correct.

Q. Do you recall, Dr. Levine, providing a list of the materials that you reviewed in forming your opinions as to what caused Mr. Hardeman's NHL?

A. I do.

Q. Okay.

MS. MOORE: And, Ms. Melen, can I have the Elmo, please?

Q. Do you recall whether you listed the American Cancer Society as one of those resources?

A. I'm sure I did.

Q. Okay. And would it be helpful if I showed you that materials list?

A. Please do.

Q. Okay. I'll put that --

MS. MOORE: May I publish? I apologize.

MR. STEKLOFF: No objection.

THE COURT: Go ahead.

MS. MOORE: Thank you.

Q. Okay. And, Dr. Levine, do you see that the number one listing you have there in the literature that you -- materials you considered list for Hardeman is the American Cancer Society?

A. That is because this is an alphabetic list here. American and we go As, Bs, Cs. It's not the first in my priority. It is alphabetized.

Q. And I'm not saying it was number one that you relied on. I'm just saying it's on your list; right?

A. It's on my list definitely.

Q. Thank you.

And are you aware, then, that the American Cancer Society provides a list, then, of non-Hodgkin's lymphoma risk factors?

MR. STEKLOFF: Objection. Hearsay, Your Honor.

THE COURT: Overruled.

THE WITNESS: Yes.

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BY MS. MOORE:

Q. And you talked about a couple of those. You mentioned a few minutes ago age and I know you mentioned infections, but you didn't talk about on your direct exam pesticide exposure; is that right?

A. That is correct.

Q. Okay. And do you recall whether the American Cancer Society considers exposure to certain chemicals as a risk factor for non-Hodgkin's lymphoma?

A. I do recall that, yes.

Q. Okay. And do you recall that the American Cancer Society considers that chemicals, such as benzine and certain herbicides and insecticides, weed and insect-killing substances may be linked to an increased risk of non-Hodgkin's lymphoma?

A. Certain of these subjects may, yes.

Q. But in determining Mr. Hardeman's non-Hodgkin's lymphoma, you didn't consider any pesticide use; correct?

MR. STEKLOFF: Object. Form. I mean, objection. Misstates the testimony.

THE COURT: Overruled.

You can answer it if you --

THE WITNESS: Ask the question again, please.

BY MS. MOORE:

Q. Sure. In Mr. Hardeman's case, you didn't consider any pesticide use or exposure to Mr. Hardeman in determining his

cause of non-Hodgkin's lymphoma; correct?

A. I did not.

Q. Okay. Now, you talked about some of the risk factors for Mr. Hardeman, and I just want to make sure I understand. Risk factor is not the same as cause; is that correct.

A. That is correct.

Q. In other words, just because you have a risk factor, that doesn't mean that the risk factor will actually lead to the development of non-Hodgkin's lymphoma; correct?

A. It means that the risk factor is associated with an outcome but is not causing the outcome.

Q. Okay. Let me --

MS. MOORE: Your Honor, I'm going to bring the flip chart up.

Oh. And I'm sorry, Ms. Melen. I don't need the Elmo for this.

Let's see if I can get it up there in this maze.

Okay. And I just want -- and, Mr. Stekloff, I apologize.

MR. STEKLOFF: It's okay.

BY MS. MOORE:

Q. And can you see that, Dr. Levine?

A. Yes, I can.

Q. Now the question is whether you will be able to read my handwriting.

So I'm going to write "Hardeman Risk Factors for NHL."

And let's work backwards from what you just testified about. You mentioned age; is that right?

A. Correct.

Q. Okay. And you mentioned weight; is that right?

A. I did.

Q. And then you mentioned hepatitis B?

A. I did.

Q. And you mentioned hepatitis C; is that right?

A. Correct.

Q. Did I leave anything off?

A. Idiopathic.

Q. So idiopathic, that just means that we don't know what the cause is; is that right?

A. That's correct.

Q. And your testimony today is that in your opinion, you know what the cause is; right?

A. I can't exclude that this was idiopathic. If I have to say what is the most significant contributing factor here, it is clearly long-term hepatitis C active infection, but I can't exclude idiopathic.

Q. Okay. So you want me to write "idiopathic" down here?

A. I do.

Q. So in your opinion, any of these three could be a cause; is that right?

A. Yes.

Q. Okay.

A. Well, I don't know that idiopathic is a cause but, yes.

Q. All right. Exactly. By definition it's unknown; right?

A. Correct.

Q. All right. And would it be fair to say from your testimony that you ruled out age as a cause in Mr. Hardeman's non-Hodgkin's lymphoma?

A. Age was not a cause.

Q. So can I just scratch through that?

A. Sure. Well, actually, I would put a little -- not a scratch-out because it allowed his immune system to be lowered or weakened.

Q. Okay. But the fact of his age in itself did not cause his non-Hodgkin's lymphoma?

A. Absolutely true, correct.

Q. All right. And I believe Dr. Weisenburger testified, and I heard you say it this morning, about something called causative risk factors. And age is not a causative risk factor; right?

A. Correct.

Q. Okay. And that's what Dr. Weisenburger also testified, that age is not a causative risk factor, and you agree with him about that?

A. Yes, I do.

Q. Okay. So can I write "not causative"?

A. Fine.

Q. And I'm just going to do "RF" for risk factor. Okay?

A. Okay.

Q. All right. And then you also mentioned weight, and I think what you said was you gave it very little; is that right?

A. I considered it but did not think this was a significant factor in Mr. Hardeman's lymphoma.

Q. In fact, isn't it true you don't -- you agree with Dr. Weisenburger, weight was not -- well, let me back up.

Do you agree that weight is not a causative risk factor in this case?

A. I agree.

Q. All right. I'm going to mark through that. I know you'd rather have an asterisk, but artist's difference; right? But can I write "not causative risk factor" here (indicating)?

A. Correct.

Q. Okay. And so that really leaves on your board hepatitis B and hepatitis C. I'm not going to -- we're going to talk about idiopathic separate since it's not a cause; is that fair?

A. Yes. It depends on what the question will be but, yes, go ahead.

Q. Okay. And then you're aware that Dr. Weisenburger, he went through a similar process where he looked at, okay, what's all the known risk factors for non-Hodgkin's lymphoma and then what applies to Mr. Hardeman. And that's what you did here; is

that right?

A. In a sense.

Q. And I know that you were asked a question about differential and that that was the method that Dr. Weisenburger did. Isn't that essentially, Dr. Levine, looking at the known risk factors and figuring out what applies to Mr. Hardeman's case?

A. The nomenclature that's being used is not normally used. A differential diagnosis is not used to define the etiology of a disease, and that's not really what I use to define the etiology of a disease, the cause of a disease.

Q. Okay. And that's fair because in medicine when you hear the term "differential diagnosis," it's to figure out let's put up every possible diagnosis on the board when someone comes in. Let's say someone comes in with chest pain, and I know you're not a cardiologist, but let's say someone comes in with chest pain. You're going to put up every possible cause of that chest pain and you're going to rule out the most life-threatening first and work your way down to figure out is it really a heart attack; is that fair?

A. If I'm trying to do a diagnosis, if I'm getting a diagnosis, that's what I do.

Q. Okay. And that's what in the medicine world we call differential diagnosis?

A. That's correct.

Q. And then in the legal world what you did was you went through a process to figure out the cause of Mr. Hardeman's NHL, and you did that by figuring out what are the known risk factors that apply to Mr. Hardeman and which in your opinion was the cause; is that fair?

A. I went through my knowledge base of the various causes of non-Hodgkin's lymphoma. There was very strong evidence of a chronic infection by hepatitis C. That was a major fact when I was reading that case. It struck me in a big way.

Q. Okay. And my question really is about your methodology.

A. Uh-huh.

Q. And is it fair to say that you went through and you thought, okay, here are the risk factors in your opinion that apply to Mr. Hardeman, and then you decided which ones of those was a cause of the NHL? Is that fair?

A. I looked at all of the factors that he had been exposed to in his life and realized which ones were most significant in a clinical sense, as Dr. Ye did as well.

Q. Okay. And as Dr. Weisenburger did; correct?

A. I can't answer that. He wasn't doing a diagnosis. I don't know.

Q. Well, this is not a diagnosis; correct? The diagnosis in this case is undisputed; right?

A. I think so.

Q. Okay.

A. Diffuse large B-cell.

Q. Right. Everyone agrees that Mr. Hardeman has diffuse large B-cell lymphoma; right?

A. Correct.

Q. So we don't have to do a differential on the diagnosis; right?

A. I did.

Q. Well, and you agree with the Kaiser doctors?

A. I do.

Q. Okay. So what we're trying to figure out is what the cause is. And I understand you don't like the nomenclature that Dr. Weisenburger used on differential, but the process is what you went through was to look at what risk factors apply to Mr. Hardeman and then which of those was most likely the cause?

A. I don't know the process by which Dr. Weisenburger made his decision. I can't answer that. I don't know that.

Q. Okay. Well, I'll tell you that last week the jury heard from Dr. Weisenburger, and he testified that the risk factors that apply to Mr. Hardeman, he talked about age and weight. And you-all are in agreement age is not a causative risk factor; right?

A. Yes.

Q. And then he talked about weight, and he agreed with you. He didn't think it was the cause in this case. He thought it was a minor risk factor.

A. Correct.

Q. Okay. And he also had hepatitis B and hepatitis C. The only thing he had up on his board that you don't is -- and I'm going -- I've run out of space, but I'm going to write it down -- well, I'm going to write it right here (indicating). I think it will fit.

He had Roundup. And he had Roundup, which is a pesticide; right?

A. I thought it was an herbicide.

Q. Do you know that herbicides are a type of pesticide?

A. No.

Q. And so he had Roundup. So you-all had the same risk factors that apply to Mr. Hardeman, except you didn't put Roundup; is that right?

A. I did not put Roundup.

Q. Okay. And, Dr. Levine, you're here today to testify as an expert witness for Monsanto; correct?

A. Correct.

Q. Okay. And you understand that Roundup is Monsanto's product?

A. Correct.

Q. And Monsanto is paying you to be here for your time?

A. Correct.

Q. All right. So let's go into your opinions on hepatitis C. And I'm going to flip over.

And this was actually shown to the jury last week when Dr. Weisenburger was on the stand, and I just want to make sure that you agree with this. Because you reviewed Mr. Hardeman's medical records?

A. Yes, I did.

Q. Okay. And you agree that Mr. Hardeman, he went through what's been called antiviral therapy for his hepatitis C; is that right?

A. That is correct, Interferon and Ribavirin.

Q. And that he had a rapid response? In other words, within 12 weeks of getting that treatment, his viral load went to negative; is that correct?

A. Yes, similar to others.

Q. Okay. And so can I just check off that you agree with that?

A. I agree.

Q. And then -- and I'm just going to write your name here. I'll say "Dr. Levine."

Okay. And then do you agree that his doctors declared Mr. Hardeman cured of his hep C in 2006?

A. I believe that we are discussing a matter of words. Dr. Ye said that he was cured, but he treated him for hepatitis B. He took him to risk by giving him a drug that potentially has side effects, and he gave him that drug because deep down he was very concerned. He gave him the drug to

prevent reactivation of hepatitis B. That's what his note said and that's what he told Mr. Hardeman. I don't -- I would not give a drug to a person if I did not believe they needed that drug.

Q. Okay. And, Dr. Levine, several times in your testimony today you've been talking about what you believe Dr. Ye did and why he did it. Have you ever spoken to Dr. Ye?

A. I've never spoken to him. I read his words in the chart. His words in the chart said he was concerned about hepatitis C and he was concerned about hepatitis B. That's what he said and that's what he told the patient and that's how he managed and treated the patient.

Q. Okay. Well, let's actually look at the words.

MS. MOORE: And, Ms. Melen, can I have the Elmo again, please?

Q. Because you testified earlier this morning that -- and I wrote this down. Let me find it real quick.

(Pause in proceedings.)

BY MS. MOORE:

Q. You said that when Dr. Ye first saw Mr. Hardeman, they had a conversation, and this was about him undergoing chemotherapy for his non-Hodgkin's lymphoma. Do you recall that?

A. I do.

Q. Okay. And you said that Dr. Ye was going to start the hepatitis B prophylactic. And that means he gave him a drug to

make sure the hepatitis B didn't come back; isn't that right?

A. If he had no hepatitis B in his body, it could not come back.

Q. And, in fact, it did not come back; isn't that true?

A. That is correct. He got the drug.

Q. All right. And then -- now, he did not give him any drug for hepatitis C; right?

A. That is correct.

Q. Okay. And when you go through chemotherapy, you agree that that weakens your immune system?

A. Correct.

Q. And so your body is less likely to be able to fight off infection on its own; is that right?

A. That is correct.

Q. Okay. And Dr. Ye knew that Mr. Hardeman had a history of hepatitis C?

A. Correct.

Q. And so he monitored to see during chemotherapy if, in fact, when he had a weakened immune system if the hepatitis C would come back; is that right?

A. He monitored it, yes.

Q. And we know from his records that the hepatitis C never came back. It was never reactivated during chemotherapy; correct?

A. Correct.

Q. So --

A. That is the expectation.

Q. I'm sorry. Go ahead.

A. That's the expectation.

Q. Okay. And, in fact, the expectation was met --

A. No.

Q. -- that hep C did not come back?

A. No. You misunderstood me.

Q. Oh. I'm sorry.

A. We've actually published on this. Hepatitis -- we looked at patients with non-Hodgkin's lymphoma who are hepatitis C positive, and it turned out that only one patient out of 33 had real reactivation of the hepatitis C, 45 percent of those patients had no reactivation of hepatitis C at all and they were all known to be HCV RNA positive. So, no, it is not uniform that patients with hepatitis C will reactivate on chemotherapy.

Q. But Mr. Hardeman was not HCV RNA positive.

A. He was HCV -- he was HCV RNA negative in the blood. That doesn't mean that he was HCV cured in the body.

Q. Okay. And, Dr. Levine, when you say it doesn't mean he was HCV cured in the body, that's not based on any kind of tests or any evidence in this case; is that correct?

A. It is based on data in the medical literature where patients with HCV infection in the past with SVR, sustained

virologic response, are then tested by looking at their B lymphocytes and looking at their liver cells and looking at their blood in more sensitive tests, and those patients have been shown. But it doesn't really matter. All he needed was one hepatitis C one time to give him the mutation.

Q. Okay. And what you were just talking about is a hypothetical situation. That's not what the data or the evidence in this case shows with respect to Mr. Hardeman.

A. I don't know what you mean. It shows that he did not reactivate. I was saying that doesn't mean that he doesn't have hepatitis C in his body.

Q. Okay. You agree that from 2006 to the present, he has not had active hepatitis C; correct?

A. Not in the blood by these standard tests, correct.

Q. And when you say "HCV cured in the body," that's based on speculation in Mr. Hardeman's case; correct?

A. It's based on data in the literature. Those fancy special sophisticated tests, research tests, were not done in Mr. Hardeman nor would I expect them to be done.

Q. Okay. That's not something you do in your practice as an oncologist; correct?

A. No. Dr. Ye --

Q. That's something -- I'm sorry. Go ahead.

A. Sorry. No.

Q. That's something that's done in a laboratory when people

are doing research?

A. It's something that's done in a laboratory when people are trying to find the truth of a situation.

Q. Okay. But in this case -- and I just want to focus on the facts of this case -- the facts of this case is that as of 2006, Mr. Hardeman no longer had active hepatitis C in his blood; correct?

A. He did not. He didn't need it to get the lymphoma.

Q. Okay. I understand that. I just want to go through the facts. I understand what your opinion is.

So as of 2006, you agree that Mr. Hardeman no longer had active hepatitis C in his blood?

A. Yes, using standard tests.

Q. Okay. And what you're talking about in the literature are some highly sensitive tests that, even in your practice as an oncologist, you wouldn't order; correct?

A. They're not done for clinical tests. They're done to find the truth of a given situation.

Q. And so as you sit here in this courtroom today, when you say he may have hepatitis C in his body, you don't actually know that?

A. That's absolutely true.

Q. All right. So do you agree, then, that when he underwent chemotherapy, that the hepatitis did not come back?

A. It did not reactivate during chemo. That has been

described well in the past.

Q. Should I put in parentheses "reactivate" here then?

A. Yes.

Q. Okay. And then doing that, can I check off that you agree with that?

A. Yes.

Q. All right. And do you agree, then, that he was cured of the hep C in 2006?

A. I don't know if he was cured of it. I know he was infected by hepatitis. Are you talking about B or C? I'm sorry.

Q. C.

A. Okay. Repeat the question. I'm sorry.

Q. Sure. Sure.

Do you agree that in 2006, he was declared cured of hepatitis C?

A. His doctors used the word "cured." I don't agree that I believe he was.

Q. So you disagree with his doctors at Kaiser?

A. They used the word "cure." They treated him despite the fact that they used the word "cure." So in a functional way, they were concerned about his hepatitis C and they were concerned about his hepatitis B.

Q. Okay. Well, hold on. When you say they treated him despite him being cured, that's actually not accurate; right?

I mean, they never -- when you say "they," are you talking about Dr. Ye?

A. Yes.

Q. Dr. Ye didn't provide any treatment for hepatitis C; correct?

A. He provided follow-up and careful follow-up of his liver function studies during the chemotherapy.

Q. And, in fact, those liver function studies -- and this is actually what I wanted to show you. And this is -- actually, I think I might be able to do this.

MS. MOORE: Mr. Wolfe, can you pull up Exhibit 45, please?

Okay. And this is from --

I'm sorry, Your Honor. It's already in evidence.

So any objection to publishing?

MR. STEKLOFF: No, Your Honor.

MS. MOORE: Okay. I apologize, Your Honor.

If we could -- if you could highlight the date here, Mr. Wolfe, at the top right corner.

Q. And do you need a copy, Dr. Levine? It's on your screen.

A. No. I have it.

Q. Okay. Good.

So this is from February 19th, 2015. And this is a visit that Mr. Hardeman had with Dr. Ye; is that correct?

A. Correct.

Q. Okay. And if we could turn to the next page and, Mr. Wolfe, if you could highlight --

Dr. Levine, do you see where it says "Liver cirrhosis documented by sonogram" and then "Liver reserve excellent"?

A. Yes.

Q. And this is around the time of Mr. Hardeman's diagnosis of non-Hodgkin's lymphoma?

A. That's correct.

Q. Okay. And this was actually the same office visit that you highlighted on your direct, and I just wanted to point out I didn't recall you highlighting that his liver reserve was excellent around the time of his diagnosis.

A. Yes, it is. It's fine.

Q. Okay. And that's an important fact; correct?

A. Well, he has cirrhosis and he's making it through. He's not -- his liver is not end-stage liver disease. He has cirrhosis of the liver. He's maintaining his liver enzymes and his function, but he has cirrhosis. That's a sign of chronic disease there in the liver.

Q. But his treating physician said that his liver reserve was excellent.

A. Yes. It was important for the chemo.

Q. Okay. And this is the office visit that you stated that Dr. Ye talked about that the hepatitis C, I think you used the words, "hidden cells could reactivate." And I just wanted to

point out --

MS. MOORE: If we could go to the top paragraph, and if you could call that out, Mr. Wolfe, please.

Q. Okay. And, Dr. Levine, I didn't see Dr. Ye say on here anywhere about hidden cells, hidden hep C cells. I just want to make sure I understood your testimony.

Are you saying that Dr. Ye thought there were hidden hepatitis C cells?

A. No. I am saying, and certainly not by this statement, I am saying that Dr. Ye in a practical sense -- even though he said the patient was cured, in a practical sense he was -- he said he's looking at his liver. He's following his liver function in time. He's looking at his history of hepatitis B; he's treating that.

So I'm saying in a functional way, what he did, he did something to look at hepatitis C potentially reactivating and he did something to make sure that -- or to try to assure that the hepatitis B would not reactivate.

Q. And this is the office note that you had Monsanto's counsel pull out in your direct exam; correct?

MR. STEKLOFF: Objection, Your Honor. This isn't the portion that was pointed out.

BY MS. MOORE:

Q. One of them?

THE COURT: Sustained.

BY MS. MOORE:

Q. Did you have defense counsel pull out February 19th, 2015?

A. Yes. That was where the Dr. Ye discussed hepatitis B and hepatitis C with Mr. Hardeman.

Q. Okay. And in this paragraph -- and then I'm going to have you look at the whole office note from February 19th, 2015 -- does Dr. Ye mention at all that hepatitis C is hidden in Mr. Hardeman's body?

A. No. There would be no reason for him to do that and he did not.

Q. Okay. And that's because there's actually no evidence, no facts that tell us that there was hidden hepatitis C cells; correct?

A. That's correct. He's just going to take care and be very careful because of it.

Q. And when you say "be very careful," that meant getting blood tests while he was undergoing chemotherapy; correct?

A. Yes, and concern about his blood counts and so forth.

Q. Okay. And, in fact, the whole time he was going through chemotherapy -- and the jury will recall this blowup from last week -- now, this is really a test of my -- I got it.

MS. WAGSTAFF: Here.

MS. MOORE: I got it.

Q. Okay. And this is Exhibit 940 and, Dr. Levine, I'm going to turn this. The test is not over.

Okay. All right. Can you see that, Dr. Levine?

A. Yes, I can.

Q. And you're familiar with this? Have you been shown this by counsel for Monsanto?

A. Yes.

Q. Okay. And down here where it's shaded in gray, this is a summary, first of all, of Mr. Hardeman's test results for his hepatitis C viral load?

A. Correct.

Q. And you've looked at all those test results; correct?

A. I did.

Q. And you agree that in January 2005, he tested positive, meaning that he had active hepatitis C in his blood and serum; is that correct?

A. That was correct.

Q. Okay. And then he went through the antiviral therapy to get rid of the hepatitis C; correct?

A. Correct.

Q. And within the 12 weeks that we talked about, the rapid response, they did another test and he was negative?

A. Yes.

Q. So those levels -- and I think you showed this -- let's see... Those levels dropped from --

MS. MOORE: Ms. Melen, can I have the Elmo? This time I'm actually going to use it.

This is (indicating).

MR. STEKLOFF: Sure.

MS. MOORE: Okay.

MR. STEKLOFF: No objection, Your Honor.

BY MS. MOORE:

Q. And I'll just show the jury. This is January 14th, 2005. Do you see that on your screen, Dr. Levine?

A. I do.

Q. Okay. And that's the same date we have up on the top of the chart?

A. Correct.

Q. Okay. And if we look at -- this is the hepatitis C RNA test results. Do you see that?

A. Yes.

Q. And so January 14th it's the 731,784 number; is that right?

A. Correct.

Q. And so if we go -- and so that meant his levels were elevated?

A. Yes.

Q. He had active hepatitis C?

A. Yes, he did.

Q. Okay. And so if we go to the next date --

MS. MOORE: Counsel?

MR. STEKLOFF: No objection.

MS. MOORE: Okay.

Q. -- the February 23rd, 2006, date -- and you see that right here (indicating) -- and here's the RNA. And so by January 23rd, 2006, within 12 weeks of treatment starting, they noted that his RNA level was negative; right?

A. Exactly. Yes.

Q. So it went (snap) right back down?

A. Yes.

Q. And that's a good thing?

A. It's a very good thing.

Q. Okay. And the whole time he was going through chemotherapy, which is what we shaded in gray -- that's the time period; is that right?

A. Correct.

Q. -- the levels still stayed negative; correct?

A. That is correct.

Q. And that meant he still didn't have hepatitis C in his blood?

A. He did not.

Q. Okay. So from February 23rd, 2006, 2007, 2008, 2009, 2011, and then once he got diagnosed with NHL, they started checking it again, it was all negative?

A. That's true, uh-huh.

THE COURT: Ms. Moore, roughly how long do you have left?

MS. MOORE: That's dangerous, Your Honor. Probably 20, 25 minutes.

THE COURT: Okay. Why don't we take another five-minute break. We'll resume at 15 minutes after 11:00.

(Proceedings were heard out of the presence of the jury:)

THE COURT: You can go ahead and step down.

And so based on that, it looks like what we can do is finish up with Dr. Levine and then take our lunch break and do Dr. Arber after lunch.

Okay.

MS. MOORE: That sounds great.

MR. STEKLOFF: Your Honor, I'll probably ask for a sidebar before I start my redirect.

THE COURT: That's fine.

And one thing. On the admissibility of these medical records, I mean, assuming that the particular records that were being asked about on direct were properly authenticated by the treating physicians, it's not clear why there would be a problem admitting them. I mean, I'm happy to hear further discussion about that.

I mean, the question would be: Once they're properly authenticated, is there anything wrong with admitting them through an expert at a minimum for the limited purpose of allowing the expert to explain the basis of their testimony? I'm not sure there would be, but we can have further --

MS. MOORE: And my position is I don't think they were properly authenticated. Those were not pages that came in through the doctors' depositions.

THE COURT: And if that's the case, that may be a real problem with admitting them.

MS. MOORE: Yes.

THE COURT: But you didn't object to publishing them to the jury.

MS. MOORE: Absolutely, because I do think an expert can testify as to what they relied on, Your Honor, but whether it gets admitted into evidence is a different question. And I don't think she can authenticate the records because that's based on hearsay, and that would be admitted for the truth of what's in those records and that would be what's improper.

THE COURT: Well, I might have thought the distinction was between admitting them for a limited purpose and not admitting them at all. I mean, in other words, I think you might have been able to object to publishing them to the jury as well if they were not properly authenticated through one of the physicians.

MS. MOORE: I see.

THE COURT: But once you didn't object to that, then it seems to me the real distinction is not between publishing and admitting but between admitting for a limited purpose and admitting for the truth. I'm not sure. I'm just floating my

thoughts with you here.

MS. MOORE: I understand. It's probably a distinction without a difference to the jury, though. I mean, they're not going to understand that, oh, this is for the truth, this is not. That's a legal distinction.

THE COURT: So I'm just floating my sort of reaction to this issue that came up. I'm not making a ruling.

MS. MOORE: I understand. Okay. I'll think about that, Your Honor.

MR. STEKLOFF: If I can just say, Your Honor, I mean, we have affidavits from the custodian of records from Kaiser authenticating all of the medical records, and I think the doctors were asked about medical records. Just because a specific page was not shown does not change the authentication. Then there is a hearsay exception to medical records.

THE COURT: Right.

MR. STEKLOFF: So I think we have --

THE COURT: That's why I think, like, the biggest deal is whether they have been properly authenticated for purpose of admission, and they're supposed to be authenticated in front of the jury unless the parties stipulated to authentication. So, anyway, that's the issue to discuss at a later time I would think.

MR. STEKLOFF: I thought we had agreed that there were no questions about the authenticity of all of the medical

records, and we do have affidavits from the custodian of the medical records.

THE COURT: Okay.

MS. MOORE: And, Your Honor --

MR. STEKLOFF: I don't think it's the biggest deal in the world whether these records go back or not, but...

THE COURT: Yeah.

MS. MOORE: And, Your Honor, just a reminder to Dr. Levine that she cannot speak to counsel on the break because she's under her cross.

THE COURT: Well, she can speak to them but not about her testimony.

MS. MOORE: Okay. That's fair, Your Honor.

THE COURT: All right.

MS. MOORE: Thank you.

THE CLERK: Court is in recess.

(Recess taken at 11:12 a.m.)

(Proceedings resumed at 11:19 a.m.)

(Proceedings were heard out of presence of the jury:)

THE COURT: What I'm tentatively considering doing now is having the -- finishing up on the cross, and then whatever you want to talk, discuss at sidebar, maybe we will actually do that over the lunch break and have Dr. Levine come back after lunch for redirect. It kind of depends on, you know, the length of the discussion that we need to have about it.

MR. STEKLOFF: It might be quick.

THE COURT: Okay. Well, we will have a quick sidebar after the cross, and then we will see how it goes.

MR. STEKLOFF: Absolutely, Your Honor. Thus far, I would say the redirect is less than five minutes.

(Proceedings were heard in the presence of the jury:)

THE COURT: Okay. You can continue.

MS. MOORE: Thank you, Your Honor.

BY MS. MOORE

Q. Okay. Dr. Levine, right before the break, we were talking about hepatitis C; and I just want to make sure I said this correctly because we are talking about hepatitis B sometimes and hepatitis C sometimes.

A. Right.

Q. So let's make sure we are on the same page. So in 2006 when he underwent antiviral therapy for hepatitis C, he had a rapid response within 12 weeks; correct?

A. Correct.

Q. Okay. And that his doctors declared him cured of hepatitis C in 2006, correct?

A. Correct.

Q. Okay. And then his doctors determined that he was immune for hepatitis B in 2005; is that right?

A. That was the word they used.

Q. And then when he underwent chemotherapy, the hepatitis,

either the B or the C, did not reactivate?

A. That's true.

Q. I'm just going to put B and C here; is that fair?

A. Yes.

Q. Okay. Great. Now, you talked some about -- actually, I'm going to use your chart, if that's okay?

A. Sure.

Q. I think that would be helpful. I understood your testimony to be that he had an acute hepatitis C infection. That means you have active virus?

A. Correct.

Q. And we know that Mr. Hardeman hasn't had active virus since 2006, correct?

A. That's true.

Q. And you are saying some people have active virus and nothing happens and they are fine?

A. The minority, correct, 15 percent.

Q. And in -- some people may have active virus, and they may have it a long time; and they may not even know they have it, right?

A. Absolutely, just like Mr. Hardeman.

Q. I think you said Mr. Hardeman had active hepatitis C for something like 39 years?

A. That's correct.

Q. And just to be clear, those 39 years, he didn't know he

had hepatitis C?

A. That's a very common situation.

Q. And then you drew an arrow that if you have moderate, it goes to chronic hepatitis. And if you have severe, it goes to cirrhosis, right?

A. Correct.

Q. Okay. And we know Mr. Hardeman had cirrhosis?

A. We do.

Q. Okay. And then you went down to cancer from there. Now, Mr. Hardeman does not have liver cancer, correct?

A. He is still being evaluated for that routinely by his doctors. They get ultrasounds of his liver and alpha-fetoprotein. They are always going to be monitoring him for liver cancer.

Q. That is preventative, right? You just want to make sure that he doesn't have liver cancer because that's a risk, right?

A. It's not preventative. They are looking for an early diagnosis, just like with the lung cancer and smoking. They are looking for something early that might be curable that they know he is still at risk.

Q. And to be clear he does not have liver cancer?

A. No, he does not.

Q. And they never found any signs to say that he has liver cancer?

A. No. Thank goodness they haven't.

Q. And are you familiar with what's called -- I think it is ALT serum?

A. ALT is one of the enzymes that is present in liver cells.

Q. Okay. And Mr. Hardeman's ALT enzyme has been normal for the last 13 or so years, correct?

A. Yes, it has.

Q. Okay. And that's a good thing, right?

A. It's a very good thing for him.

Q. And then you got end-stage liver disease. Now, that's not Mr. Hardeman, right?

A. No, that isn't. He is on the left arrow there, a cancer arrow.

Q. Okay. And so just to be clear, this diagram is not Mr. Hardeman. It is just an example that you put together in general; is that fair?

A. Yes, it is the general outcome of patients with HCV infection.

Q. Okay. Now, you have got NHL under cirrhosis -- and I want to be really clear about this -- Dr. Levine, cirrhosis does not cause non-Hodgkin's lymphoma?

A. That's absolutely correct.

Q. Okay.

A. It's a sign of chronic infection of the liver.

Q. Okay. So isn't it misleading, though, to put non-Hodgkin's lymphoma right below cirrhosis?

A. Well --

MR. STEKLOFF: Objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: I put two basic outcomes. One for chronic infection by HCV, and the cirrhosis -- which is meant to mean that is how I know he has chronic infection by HCV -- and there are two outcomes of that. One is end-stage liver disease -- which luckily for Mr. Hardeman he did not have -- and the other was the development of cancer many years later. He is still being worked up and evaluated to make sure that they can catch liver cancer early if it happens, and he did develop non-Hodgkin's lymphoma.

BY MS. MOORE

Q. Well, what I heard you -- when you were down here with the diagram, you pointed to cirrhosis; and then you went down to the arrow to non-Hodgkin's lymphoma and you said cirrhosis with lymphoma. That's not accurate, is it?

A. If I said that, I'm sorry. Because I don't mean to imply that cirrhosis causes non-Hodgkin's lymphoma. What I meant was cirrhosis is a sign of chronic HCV infection. And once one has -- that is an objective kind of thing. And once you have chronic infection and cirrhosis proving that, there are two outcomes. One is cancer; one is end-stage, dying of liver disease.

Q. Okay. So really this diagram here, we have cirrhosis and

the arrows pointing down. NHL shouldn't be there, right?

A. I disagree. Cancer is an outcome with chronic hepatitis C infection as proven by the fact that he has cirrhosis, and there are two cancers that had been associated with hepatitis C at this point. One is liver cancer, and one is non-Hodgkin's lymphoma.

Q. I understand that, Dr. Levine. But cirrhosis does not cause non-Hodgkin's lymphoma?

A. No. Chronic infection by hepatitis C causes non-Hodgkin's lymphoma.

Q. But you didn't have -- I'm sure you have had experience with this -- that you can have people who have chronic hepatitis C infection and they never get non-Hodgkin's lymphoma, correct?

A. Certainly.

Q. Okay. Now you talked about these hit-and-run cells.

A. Hit-and-run virus.

Q. Sorry. Virus. Hit-and-run virus.

I want to talk actually just about hepatitis B first, okay?

A. Sure.

Q. Do you agree that hepatitis B -- that the virus actually infects the cell? In other words, the virus enters the cell?

A. Yes, it does.

Q. Okay. And by entering the cell, that's what actually

leads to the development of lymphoma cells or can lead to the development of lymphoma cells?

A. If the hepatitis B enters the cell, it can cause mutations in the DNA; and the mutations in the DNA of that cell may lead to non-Hodgkin's lymphoma.

Q. Okay.

A. Or liver cancer for that matter.

Q. And were you saying that those hit-and-run cells are in hep B or hep C?

A. Both. Both.

Q. And what is your evidence that there is something called a hit-and-run cell for hepatitis B?

A. There are data to suggest that hepatitis B does get into the B-cell; does cause mutations in the B-cell. This field is younger in a sense and more difficult because most patients with hepatitis B infection clear that infection. So you are looking at the minority.

On the other hand, we know by the scientific literature that hepatitis B infects B lymphocytes. It infects liver cells. It causes mutations in those cells associated with development of lymphoma.

Q. Okay. And in this case Mr. Hardeman's body, his immune system, actually kept the hepatitis B at bay, the virus; and that's why his doctor said he was immune in 2005.

A. It did keep it at bay. I don't know for how long.

Q. Okay. So you were about to tell me what evidence you have to support your theory that there is hit-and-run cells for hepatitis B.

A. The data really -- the hit-and-run mechanism has not been published for hepatitis B. What has been published is hepatitis B gets into the cell, causes mutations, and at that point conceptually it would be the same. Whether it is there or not, the mutation is there.

Q. So you don't have any evidence to support your theory as to this hit-and-run of hepatitis B cells?

A. I can't say that. I can say that for hepatitis C certainly.

Q. Okay. And we are going to get to hepatitis C in just a little bit.

A. Okay.

Q. So do you agree, though, that for hepatitis B, when someone like Mr. Hardeman's body can fight off the hepatitis B virus and is immune to hepatitis B -- I mean, he actually was vaccinated, right?

A. I'm not aware that he was vaccinated, and his blood tests are not consistent with having been vaccinated. His blood tests are consistent with having had an infection by that hepatitis B and his immune system clearing.

Q. You didn't see in the records the vaccination back in 2005?

A. No, I did not.

And if he did have a vaccination in 2005, it didn't take because the sign of vaccination of hepatitis B is antibody to the surface antigen of hepatitis B. His surface antigen antibody negative core, antibody positive; that is the signature of a past infection.

Q. Well, and we actually don't know if Mr. Hardeman had a past infection of hepatitis B, correct?

A. I disagree. The blood tests that were done are consistent, fully consistent. That is the definition of a past infection. He was exposed. Exposed means it got into his body. His body saw it. His body responded to it.

Q. And his body could have responded right then, correct?

A. I don't know. That's what I was saying. I have no idea when his body responded to it.

Q. Okay. And you don't know if the hepatitis B, in fact, did any type of damage to his B-cells?

A. I don't know that.

Q. Okay. So on hepatitis B, do you agree then, that for Mr. Hardeman, that once he went through the antiviral therapy and he had been declared immune, that he had no more risk -- no more increased risk for developing non-Hodgkin's lymphoma from the hepatitis B?

A. Let me say a few things. He never got anti-retroviral therapy for hepatitis B. On the other hand, there is

literature to suggest that if somebody has positive antibody to hepatitis B core without surface, they are at increased risk of developing non-Hodgkin's lymphoma and diffuse large B-cell.

Q. And what is your evidence to support that theory?

A. It's one of your -- can I take a moment to find this?

Q. Absolutely.

(A brief pause was had.)

BY MS. MOORE

Q. Are you in my binder, Dr. Levine?

A. Maybe I'm not. Let me see here.

Q. The white one? Yes.

A. Maybe it is in my binder.

Q. Do you know the name of the author?

A. Not off the top -- just one second.

MS. MOORE: Okay.

(A brief pause was had.)

THE WITNESS: I'm sorry I'm taking so much time.

MS. MOORE: That's okay.

(A brief pause was had.)

MR. STEKLOFF: Your Honor, because there are multiple binders, it might help if she looks at the other binder.

THE WITNESS: Pardon me?

MR. STEKLOFF: It might help if you looked at the other binder that we looked at this morning, Dr. Levine.

THE WITNESS: Okay.

(A brief pause was had.)

THE WITNESS: Okay. So it is tab 1555 on the Defendant's piece here. What we see --

THE COURT: The black binder then?

THE WITNESS: It is the black binder, yeah, 1555 and table --

BY MS. MOORE

Q. That's the Wang article?

A. That is Wang -- Feng Wang.

Q. Let's pull that up.

MS. MOORE: Mr. Wolfe, can you pull up Exhibit 1555, please.

May I publish please, Your Honor?

THE COURT: Sure.

BY MS. MOORE

Q. And is this the article that you believe supports your opinion that for hepatitis B there are hit-and-run cells?

A. No. The question was -- well, ask the question again, if you don't mind.

THE COURT: Would you like to have the question read back?

THE WITNESS: Please.

(Record was read as requested.)

THE WITNESS: I said I disagreed. And the data is an article by Wang and colleagues that is in the exhibit. And if

we can look at table 4 --

MS. MOORE: So if we can go, Mr. Wolfe, it is page 1363, let's pull up table 4.

THE WITNESS: And so Mr. Hardeman is antibody positive, anti-hepatitis B virus C positive. Anti-HBC positive.

BY MS. MOORE

Q. I'm sorry, Dr. Levine. If I can stop you right there for a second. So where it says anti-HBC, that is the core antibody for hepatitis B; is that correct?

A. Yes. So it is the antibody for the core protein of hepatitis B, indicating that this patient would have been infected by hepatitis B in the past --

Q. Okay.

A. -- for sometime.

Q. Now, isn't it true that that group of patients that are positive core antibody for hepatitis B, that would include patients who are positive antigen and negative antigen?

A. Yes.

Q. Okay. And let's make sure that we are using the same terminology, Dr. Levine. So when someone has hepatitis antigen positive, that means they have active virus?

A. Yes.

Q. Okay. And so when someone is negative hepatitis B antigen, that means they don't have active virus?

A. That's true.

Q. Okay. And so this group here for the core antibody positive that we have highlighted here includes both people who have active and not active hepatitis?

A. It may. Doesn't really say that. What it is really looking at is those patients who are pure hepatitis C antibody positive, but if we go to table 5.

Q. Hepatitis B?

A. B, sorry.

Q. Sorry. And let me stay right on table 4 for just a moment. Okay?

A. Sure.

Q. On that, would you agree that if someone is positive hepatitis B antigen, that would increase their odds ratio?

A. Oh, yes.

Q. And if someone is negative antigen hepatitis B, it would decrease their odds ratio?

A. Perhaps.

Q. Okay. And so this figure here, the 1.8 odds ratio, you pointed out on direct with Monsanto's attorney, that actually is misleading because it contains people who no longer have active virus and people who have active virus?

A. Yes, but it includes people who have had inactive virus as well.

Q. Right. And so we don't know what the odds ratio would be

if you take out the people who have active virus and core antibody, correct?

A. Yes, but there is further clarification on the next table.

Q. Okay. Well, let's go to table 5 then. Which line did you want to highlight there?

A. The last one. In other words, no antibody to surface antigen, and positive antibody to core. And that's what Mr. Hardeman had.

Q. Right. But that doesn't tell us the number of those patients -- well, it tells us 130 patients -- I didn't mean to touch that, I apologize -- but it doesn't give us the data as to whether an antibody -- core antibody for hepatitis B increases the risk?

A. It tells us -- this is the line that defines the serology, that defines the answers, the results of Mr. Hardeman's hepatitis B evaluation. So he had no antibody to the surface. He had antibody to the core. If he had had a vaccine, if he had been vaccinated, he would have had antibody to the surface and no antibody to the core.

So his serology, his blood tests, shows that he has had hepatitis B infection in the past. And this particular table looks at 130 patients with non-Hodgkin's lymphoma in whom that profile was met in the control group, far less -- and this was highly statistically significant.

So people who have been exposed to hepatitis B in the past

and have cleared it, are still at risk for B-cell lymphoma, and that would be consistent with a hit-and-go kind of a process.

Q. But that's not what this article is saying. This article doesn't talk about hit and run.

A. No. I'm just saying that this is -- in other words, there is no active virus there, and yet there is an increased risk of B-cell lymphoma, and those are the -- that is the serology. That is the blood test of Mr. Hardeman.

Q. Okay. But you would agree, though, that the rate actually was higher in the control group?

A. I don't agree that. This was statistically highly significant. Highly significant.

Q. So when we look at the table 5, it tells us that the rate was higher in the group with B-cell NHL than the control group?

A. Yes.

Q. Okay.

A. There were 31 out of 130 -- 31 lymphomas out of 130 lymphomas that had that profile versus 17 out of 208 in the control. So there were far more -- statistically more patients with this particular serology, these blood tests, who did develop B-cell lymphoma as opposed to the controls.

Q. Okay. Let's look at what the actual text and what the authors have concluded.

MS. MOORE: If we go on the same page, Mr. Wolfe.

\\\

BY MS. MOORE

Q. Dr. Levine, it is at the very bottom of the discussion section on that page, in the second column, starting with Conversely. There you go.

A. Okay.

Q. Do you see where it says Conversely, the combination of positive anti-hepatitis B -- I guess that is core -- the core antibody, correct?

A. Yes, correct.

Q. And negative surface antigen, correct?

A. Negative antibody for surface antigen.

Q. I'm sorry, negative antibody for surface antigen, which signifies occult HBC, hepatitis B, infection was higher in the control group than in the study group.

Now, that is an incorrect statement based on what we saw in the table or the table is incorrect and the text is right.

Do you know which one it is?

A. I cannot say other than to say the last sentence: Thus it is reasonable to postulate -- postulate that patients with B-cell lymphoma may have higher prevalence of chronic or occult HBV infection and a lower clearance of the virus.

Q. Okay.

A. So since that sentence goes with the table, I'm going to believe the table.

Q. Okay. But there is a contradiction between -- within the

study, this publication, correct?

A. Let me read the sentence before better.

Yes, so it is confusing.

Q. Okay. And then that last sentence, you emphasized the word "postulate." And that's really another way of saying this is a hypothesis, correct?

A. There are data. So they have statistically significant data, and they are being very careful with it, which is the right thing to do. And they are saying it is reasonable to postulate that patients with chronic or occult HBV infection and a lower clearance of the virus may be -- may be at increased risk -- or patients with B-cell lymphoma may have a higher prevalence of chronic or occult. And that was what was interesting to me. Occult HBV infection.

Q. Right. And, Dr. Levine, you said they were being careful, but we just pointed out at least one contradiction in the publication, correct?

A. Perhaps, uh-huh.

Q. Okay. And then when it is reasonable to postulate, that means they have a theory. They have a hypothesis. This is not based on any real data, correct?

A. No, I disagree. They have data -- statistically significant data showing what they said, that they are being conservative about it. And I think that is an appropriate kind of thing to do in a clinical sense. So they have -- they have

a finding, which is a pretty interesting finding, that even occult HBV infection may be related to development of B-cell lymphoma.

MS. MOORE: And we can take that down.

BY MS. MOORE

Q. Dr. Levine, what we are really talking about is a hypothetical. That is not the evidence with respect to Mr. Hardeman, correct?

A. I can't say that. The table showed his exact blood test results, and the table showed that with people with those exact blood test results may, in fact, develop B-cell lymphoma. He did.

And I say I have no idea how long he had the active hepatitis B infection. I know that he had infection. And knowing that he had infection, occult now, and that's what Dr. Ye was treating, he gave him lamivudine; gave him a drug to treat somebody who has hepatitis B on board. And what he is trying to do is prevent reactivation there. So he had occult -- he was believed, in a very practical way by the way he was treated, he was believed to have "occult hidden hepatitis B infection."

Q. Dr. Levine, none of Mr. Hardeman's treating physicians have diagnosed him with occult hepatitis B?

A. No. They just treated him for it.

Q. Well, now, Dr. Levine, isn't it fair that what Dr. Ye did

was give him a prophylactic, which was to make sure -- because he had at one point a history of hepatitis B at least a decade before his non-Hodgkin's lymphoma diagnosis, he gave him that prophylactic to make sure when he was weakened that hepatitis B did not reactivate; isn't that true?

A. Hepatitis B could not reactivate if it wasn't there. It can only reactivate if it is there.

Q. Exactly. It can't reactivate if it is not there. And lo and behold, it did not reactivate, correct?

A. He gave him a drug so that it would not reactivate, and it did not.

Q. And even after he stopped -- first of all, he stopped giving the drug, correct?

A. Correct.

Q. Even after he stopped giving the drug, it did not -- hepatitis B did not reactivate?

A. That's true.

Q. So you can't sit here and tell this jury that, in fact, Mr. Hardeman had occult hepatitis B infection?

A. He was treated in a sense for that. I can't prove that he had it.

Q. Okay. All right. Let's switch over to hepatitis C and -- first of all, was there any other evidence you had on your theory about the occult hepatitis B, other than that Wang article?

A. I don't have to discuss it now, no, it's all right.

Q. Okay. Are you sure?

A. That's fine.

Q. Okay. All right. Let's go over to hepatitis C then. Do you agree that once Mr. Hardeman reached the sustained virologic response, which we keep calling SVR -- you are familiar with SVR?

A. Yes, I am.

Q. Okay. And SVR means the active virus is no longer in the serum, the blood, correct?

A. Using the techniques, the standard techniques that we have, correct.

Q. And that -- do you agree, then, that after Mr. Hardeman reached SVR back in 2006 that all the -- if any abnormal cells existed in his body from the hepatitis C, they would have been killed off?

A. Say that again. I don't believe I agree with that.

Q. I will rephrase. Sometimes lawyers ask bad questions, sometimes.

In 2006 after Mr. Hardeman reached SVR, sustained virologic response, meaning he no longer had active virus in his blood --

A. Yes.

Q. -- do you agree then that his risk of non-Hodgkin's lymphoma was no longer there?

A. I disagree.

Q. With respect to hepatitis C?

A. I disagree. He had active infection for 39 years. He could have easily had a mutation at any time during the 39 years. And once that mutation was there, it did not matter whether he had a live virus in his blood or not. It didn't matter.

Q. And, Dr. Levine, to be fair that is your theory, correct?

A. It is not my theory. We know that. We know that.

Q. Well, let's make sure we are talking about the same thing. So for those 39 years that he likely had active virus, he did not get non-Hodgkin's lymphoma when he had active virus, correct?

A. No. That's when he got the mutation.

Q. Hold on. It's correct that he did not get non-Hodgkin's lymphoma when he actually had active hepatitis C?

A. He did not get it then.

Q. Okay. And in your theory is that he got a genetic mutation sometime within those 39 years?

A. Yes.

Q. Okay. Wouldn't you agree, though, that when he underwent antiviral therapy in December 2005 to November 2006, that the antiviral therapy would have wiped out -- would have eliminated those genetic mutations?

A. No. It would have -- it would have gotten rid of anything

related to disease in marginal zone lymphoma, but not in diffuse large B-cell, which is what he had.

Q. So you are saying that the antiviral therapy would have wiped out the genetic mutations that would lead to one cancer but not the other?

A. Yes, in a sense, uh-huh. That is what is described in the literature.

Q. Okay. And in what literature is it that you are relying on to say that antiviral therapy only eliminates the bad cells that cause one kind of cancer but not the bad cells that actually is the same kind of cancer Mr. Hardeman has?

A. There are different kinds of mutations that hepatitis C can cause. There are papers in the literature talking about an abnormality called translocation chromosome 14;18. That particular translocation or chromosome abnormality has been reported in marginal zone lymphoma. It is reported in mixed cryoglobulinemia, which is another hepatitis C-related illness. And translocation 14;18 in the blood has also been described in normal healthy individuals.

There are various studies that have shown that use of interferon and ribavirin can eradicate -- can kill those cells with 14;18 translocation. But that's not what Mr. Hardeman had.

Q. Well, let's back up. So what -- my question to you was: What evidence do you have that once Mr. Hardeman underwent

antiviral therapy and he was declared cured, he was SVR, what evidence do you have to support your theory that the genetic mutations were not wiped out?

A. He had a genetic mutation in his lymphoma cells. He had it. We saw it. It is in his lymphoma cells.

Q. You would expect to see genetic mutations in lymphoma cells of patients who have diffuse large B-cell lymphoma?

A. Absolutely.

Q. And that is a nonspecific finding?

A. It can be, certainly.

Q. Okay. All right. So what literature supports your theory?

A. Which theory?

Q. That antiviral therapy does not eliminate all of the abnormal cells caused by hepatitis C?

A. That antiviral therapy does not eliminate? Mr. Hardeman had antiviral therapy. It did not eliminate his risk for developing B-cell lymphoma.

Q. Okay. Let's look at the actual data. If you can turn --

MS. MOORE: Permission to publish 1531, please?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. Dr. Levine, are you familiar with this publication by Taborelli?

A. Yes, I am.

Q. And it actually covers hepatitis B and C. It says Hepatitis B and C Viruses and Risk of Non-Hodgkin's Lymphoma: A case control study in Italy.

And the jury saw this article last week with Dr. Weisenburger, and I wanted to direct your attention --

THE COURT: Ms. Moore, I'm sorry. I apologize for interrupting, but I just noticed that it is a couple minutes before noon. It seems like this is going on a little more than anticipated --

MS. MOORE: I apologize, Your Honor.

THE COURT: -- which is perfectly fine, but it seems like now might be a time to take a lunch break.

MS. MOORE: Okay. Thank you, Your Honor.

THE COURT: So why don't we take a lunch break until 12:45. Please remember all my commands about not talking about the case or exposing yourself to any information about it. And we will see you in about 45 minutes.

Thank you.

(Proceedings were heard out of presence of the jury:)

THE COURT: You can go ahead and step down. You said you were going to want to speak with me at sidebar.

Do you want to deal with this now? I mean, I assume you are going to make some argument about opening the door. Why don't we just have the discussion now?

MR. STEKLOFF: I'm fine with that.

THE COURT: Dr. Levine, I would suggest -- actually, I think it would be helpful if you stay for this discussion so that it would help you understand the parameters of the testimony you would be allowed to provide going forward.

THE WITNESS: Sure.

MR. STEKLOFF: Now I might have two issues. But the first issue I wanted to raise is that I think Ms. Moore on the prior chart made the suggestion, clearly implied to the jury, that somehow Dr. Levine just simply ignored Roundup. And that in listing the risk factors, she did an incomplete analysis because she didn't consider Roundup. She didn't consider pesticides. She didn't consider herbicides. And, in fact, wrote down Roundup in between the other risk factors that she did consider. I think that opens the door to the fact that, because we know Dr. Levine did consider Roundup -- and I think we can do this safely without going into the AHS and the details of the studies by proposing -- asking four yes-no questions that I think now are necessary to deal with this misimpression that has been made. I think I should be able to ask Dr. Levine, Did you review all of the available published epidemiology regarding Roundup or glyphosate and non-Hodgkin's lymphoma? Based on that review -- I assume she would say yes to that. Based on that review --

MS. MOORE: Well, Your Honor, now he is telling

Dr. Levine how to answer his questions too.

THE WITNESS: It is yes.

THE COURT: Let's lighten up a little bit.

MS. MOORE: I know.

MR. STEKLOFF: Based on that review, in your opinion is Roundup or glyphosate a cause of non-Hodgkin's lymphoma?

THE WITNESS: No.

MS. MOORE: Now she is answering his question.

THE WITNESS: I don't know what I'm supposed to do.

THE COURT: I don't need you to answer.

MS. MOORE: Your Honor, I mean --

THE COURT: It is obvious what your answer is going to be, but right now we are talking --

MS. MOORE: I mean, he is basically practicing his redirect with the expert witness standing --

THE COURT: Okay. So would you prefer that she be out of the room? Because the point of her being in the room is to make sure that she understands the parameters, but I would be perfectly -- if you prefer her to be out of the room, that's fine.

I mean, the whole thing seems a little silly to me because we all know what her answers are to these questions, but if you prefer her to be out of the room and want to increase the risk that she is going to not be able to clearly follow the parameters that we establish, we can do it that way.

MS. MOORE: I understand, Your Honor. I'm just lodging my objection.

THE COURT: Okay. But you know what her answers are to these questions. We all know what her answers are, right? You have deposed her about them.

MS. MOORE: We have not taken her deposition, Your Honor, but yes.

MR. STEKLOFF: That was their choice.

MS. MOORE: What was the second question? I'm sorry.

MR. STEKLOFF: Based on that review --

THE COURT: Hold on a second. Do you want her out of the room?

MS. MOORE: No. She can stay. I just ask her not to answer the question.

THE COURT: Okay.

MR. STEKLOFF: Based on your review -- based on that review, in your opinion is Roundup or glyphosate a cause of non-Hodgkin's lymphoma? Did you provide that opinion in your expert report? And is that why you did not consider Roundup a potential cause of Mr. Hardeman's non-Hodgkin's lymphoma?

THE COURT: Any objection?

MS. MOORE: Yes, Your Honor.

THE COURT: What could the objection be in light of what you did on that chart?

MS. MOORE: Well, I'm not done with my cross, too,

Your Honor.

She said on direct that she did not consider Roundup because Mucci said it was not a risk factor. That's what she -- and I don't know if that was direct or cross. I apologize, Your Honor.

And so she has already testified that she relied on Dr. Mucci's opinion in this case that there is no evidence that Roundup is a risk factor -- or causes cancer. So for her now to go back and be able to say, Well, actually not only did I look at Mucci but these studies, I did not open the door for her to go beyond that. I very clearly asked her, You did not list a risk -- Roundup as a risk factor. And that's what she -- she did not do that. She did not put in her report, she did not say, This is a risk factor for non-Hodgkin's lymphoma. She actually -- her opinion is it is not a risk factor for non-Hodgkin's lymphoma because that's what Dr. Mucci tells her. That's what has been the testimony. I did not open the door beyond that.

THE COURT: Okay. That -- your request to answer those questions -- ask those questions is granted.

MR. STEKLOFF: Thank you, Your Honor.

THE COURT: You can't answer the questions; you can only ask them.

MR. STEKLOFF: And I will let Dr. Levine know she should use one word to answer these questions.

And, then, Your Honor, I also think now that she has opened the door to BCL6. I understand that BCL6 doesn't only occur in patients with hepatitis C. She directly asked Dr. Levine what data she has.

And we know from the studies that we showed earlier, the study that showed the hit-and-run, direct hit-and-run mechanism, that BCL6 in that article -- in that drawing that we blew up, that -- and I think consistent with your order I didn't draw any attention to it -- but we know that BCL6 in the literature is associated with that direct hit-and-run mechanism. She has now asked what data there is. We know that Mr. Hardeman had a significant number of BCL6 mutations, and I think it is fair game on redirect now.

MS. MOORE: Your Honor -- go ahead.

THE COURT: And let me give you -- I'm happy to hear argument from them about this, and it may be something that I want to think about a little bit more over the lunch break and talk about it a little more before we resume.

But I guess my gut reaction is that given the way that cross-examination proceeded, you are -- you may well be right that the door was opened to that because I think the cross-examination created a little bit of a misleading impression about what Dr. Levine is basing her statements on, but it would have to be -- if, in fact, that is what I conclude -- and I will hear from them, and I will think more

about it over the lunch break -- but if, in fact, that is what I conclude, the important thing -- and this is why I wanted Dr. Levine to be here for this discussion -- the important thing is that it all has to be done, I think, to avoid a 403 problem. It all has -- in order to avoid a problem of misleading the jury about the significance of -- the BCL6?

MR. STEKLOFF: Yes, Your Honor.

THE COURT: -- mutation. It has to be done with sort of a clear statement that you cannot discern from the BCL6 mutation in the pathology what the cause of the cancer is. Does that make sense?

MR. STEKLOFF: Yes. And I agree with that, Your Honor. I'm happy to bring that out myself. And then obviously Ms. Moore can follow up on that. But I think that -- I mean, she can speak for herself, but that is consistent with Dr. Levine's opinions. So I agree with that.

THE COURT: Okay.

MS. MOORE: My response, Your Honor, is that when she provides testimony, I have to be able to ask her what is the basis for your testimony. And so I'm not trying to open the door to anything, but I do have the right to say she lodged this theory.

THE COURT: You absolutely have the right to ask her questions about what is the basis for her opinion. But if you ask the questions in a way that leave sort of a misimpression

about what her opinion is based on and what it is not based on, then you open the door.

In other words, because of Rule 403 -- and because of the rules about expert disclosure -- I said this type of testimony that we are talking about now is out. It would not be fair for Monsanto to elicit this type of testimony from their expert in light of her report and in light of 403 and in light of the misimpression that it creates.

But, of course, as with every witness, even if testimony is excluded before they take the stand, the door can be opened to it on cross-examination. And I think -- so -- it seems to me that you did open the door to it on cross-examination. I still have some concerns about the risk of this creating a misleading impression, which is why I made the statement that it has to be absolutely clear that you cannot tell from the pathology -- you cannot tell from the BCL6 damage what the NHL -- how the NHL was caused. That does not -- that doesn't tell you anything.

But it also potentially allows Dr. Levine to clear up sort of a misimpression about the lack of evidence that she has or to correct the suggestion that the evidence is actually inconsistent with what she is saying.

MS. MOORE: Your Honor, I would like to go back and look at the testimony. My understanding is that she was talking about her theory with respect to hepatitis B. And I

asked her What is your basis -- what data -- where in the literature --

THE COURT: You are talking about hepatitis C now, or B?

MS. MOORE: I thought it was B, Your Honor.

THE COURT: He is talking about hepatitis C.

MR. STEKLOFF: Yes, Your Honor.

MS. MOORE: Okay. Well, it was the same --

THE COURT: You are talking about what you just asked right at the very end.

MS. MOORE: I'm sorry, Your Honor.

So I think -- you know, when she lodges -- when she says her testimony, which I can't control what she says, my follow-up is, then, Where does it say that?

And I will go back. I would like to have an opportunity to look back through that and make sure that -- first of all, she is not a pathologist.

THE COURT: Well, your question at the end was What evidence -- something to the effect of what evidence do you have that once -- first of all, you asked a number of questions about -- you are not talking about the evidence in this case, right? You are not talking about the evidence with respect to Mr. Hardeman, right?

So even with respect to that, there is an argument that that opened the door. Then you say, Well, what evidence do you

have that once he was declared cured it didn't eliminate the abnormal cells?

How did that question not open the door to this?

MS. MOORE: Well, if you back up, Your Honor, in 156 I said, In what literature is it that you were relying on to say antiviral therapy --

THE COURT: But that's not the question I'm referring to.

MS. MOORE: Okay. I'm sorry.

THE COURT: I'm referring to the question where you said, What evidence do you have that once he was declared cured, it didn't eliminate the abnormal cells?

And, again, you asked a number of questions about the evidence in this case, the evidence as it relates to Mr. Hardeman which created an impression, and I'm -- it's not that it is an inappropriate line of questioning -- let me make clear. It is just that it is a line of questioning that, then, opens the door. It is a choice that you make to pursue that line of questioning.

MS. MOORE: Well, and also, Your Honor, I mean, when she lodges a theory, I can't just let it drop. And they know what the evidence has been excluded. I mean, I'm in a catch-22 in that sense.

THE COURT: I think you put her in catch-22 -- my sense -- like I said, I want to think about it more over the

break. But my sense is that you put her in a catch-22 by asking her that type of question.

MS. MOORE: Well, if you look at 157, what I said was: What evidence do you have to support your theory that the genetic mutations were not wiped out? And that was a follow-up when we were going through the literature, and she said: He had a genetic mutation in his lymphoma cells. He had it. We saw it. It was in his lymphoma cells.

And I said, You would expect to see genetic mutations in lymphoma cells of patients who have diffuse large B-cell lymphomas?

And she says, Absolutely.

And I said, And that's an nonspecific finding?

It can be, certainly.

THE COURT: Right.

MS. MOORE: So tell me --

THE COURT: So one point --

MS. MOORE: It is not misleading.

THE COURT: One point that that testimony has already come out.

MS. MOORE: That's right.

THE COURT: The only testimony that he wants to pursue has already come out naturally as a result of your cross-examination. So, again, I think that's another reason why it's fair game on direct -- as long as it continues to be

clear -- what you made clear during cross-examination -- which is that it is a nonspecific finding. That is the important thing.

MS. MOORE: It is, Your Honor. And I just want to make sure that there's not going to be any questions as to causation with respect to a BCL6 translocation on a pathology slide to her. That's really the crux of it. And -- because I don't know how else I can ask her questions about what her opinions are without saying what did you rely on. So, I mean, I'm in a real catch-22 there. But she did clearly state --

THE COURT: It sounds like we are all in agreement.

MS. MOORE: Well --

THE COURT: She is not offering -- she wouldn't offer, even in response to your questions, and she didn't offer --

MS. MOORE: That's right.

THE COURT: -- in response to your questions on cross-examination that you can draw any causation conclusion from the slides.

MS. MOORE: That's correct, Your Honor. And her report doesn't say that either.

THE COURT: Right. Right.

MS. MOORE: Okay.

THE COURT: So to the extent that that's all you are worried about, I think, you know, it is probably okay. You know, again, as long as that point is made clear because I

think if that point is not made clear or if the witness were to be sort of equivocal about that point, it could potentially be a 403 issue. And, again, it could be an issue that -- where, you know, they are testifying to something that is contrary to what is in their report.

MS. MOORE: Right. And that is my concern. I would like the opportunity just to think about it.

THE COURT: Yeah, we will all think about it during the lunch break. And why don't we resume at 40 after the hour. Okay.

MS. MOORE: Thank you, Your Honor.

THE CLERK: Court is in recess.

(Luncheon recess was taken at 12:14 p.m.)

AFTERNOON SESSION **12:44 p.m.**

(Proceedings were heard out of presence of the jury:)

THE COURT: Any further discussion on this?

MS. MOORE: No, Your Honor.

MR. STEKLOFF: Nothing from me, Your Honor.

THE COURT: Okay. Good. So the tentative ruling that I articulated before we left for lunch stands.

MR. STEKLOFF: Okay.

THE COURT: And Dr. Levine can testify about that, as long as she makes clear that the pathology is not specific.

MR. STEKLOFF: I will make very clear that that is a nonspecific finding and that she cannot, from that finding, say

that the cause was hepatitis C.

THE COURT: Okay. Sounds good. Now, I told the jury 12:45. They might not be quite ready. Let them take their time if they need to.

(A brief pause was had.)

(Proceedings were heard in the presence of the jury:)

THE COURT: Okay. Ms. Moore, you can resume.

MS. MOORE: Thank you, Your Honor.

BY MS. MOORE

Q. Dr. Levine, we -- you have used the term "occult cells," and I just want to make sure that we define that for the jury.

Is what you are saying that in Mr. Hardeman's case when he went through the antiviral therapy for the hepatitis C; that the purpose of that is to kill off the infected cells, right?

A. The purpose is to decrease the amount of virus in the body so that the patient obtains a clinical benefit; feels better.

Q. In other words, kill off the infected cells?

A. Yes.

Q. Okay. And in your theory is that some of those infected cells stayed behind or hid from the therapy; is that fair?

A. Yes, there is a name for that, occult hepatitis C infection.

Q. Okay. So when we are talking about occult cells, that means some cells that remained in the body -- possibly remained in the body and after antiviral therapy. And then the question

is what does that even mean, right?

A. It means it's not cured.

Q. Okay.

A. It means you are living with the virus. That's what it means.

Q. Okay. Well, let's back up. I mean, we have already gone through this, so I'm not going to rehash this, but his doctors declared him cured?

A. The doctors said he was cured, but then he treated him so that he would not reactivate hepatitis B. And he watched him carefully so he would not reactivate his hepatitis C.

Q. Okay. I want to -- my questions right now are only going to be about hepatitis C.

A. Okay.

Q. I think we have exhausted hepatitis B. All right?

A. Yes.

Q. So we are going to focus just on hepatitis C. And it is -- you agreed with me earlier, I just want to make sure this is true -- that his doctors declared him cured of hepatitis C in 2006?

A. That's what they said.

Q. Okay. And you are saying that there were some cells that may have been left behind after that antiviral therapy, right?

A. I'm saying that the literature supports the fact that there are often cells left behind even when the patient has

been in SVR for prolonged periods.

Q. And SVR meaning no active virus in the blood?

A. As it can be detected by standard techniques.

Q. Okay. And let's look at the literature -- I think what we are going to look at -- before we go there, in this case, for Mr. Hardeman, this is your hypothetical -- this is your theory that there were some cells left behind, but you don't actually know if that happened?

A. Yes, based on the scientific literature, I expect that there are cells left behind. I cannot prove that in Mr. Hardeman.

Q. And the jury heard from Dr. Weisenburger last week, and he said that even if there were some cells left behind, they weren't causing any problems because the immune system was keeping them in check.

In other words, Dr. Levine, Mr. Hardeman's risk of non-Hodgkin's lymphoma or hepatitis C went away after he went through antiviral therapy?

MR. STEKLOFF: Objection. Misstates Dr. Weisenburger's testimony.

THE COURT: Sustained.

Why don't you re-ask your question.

MS. MOORE: Okay. That's fine, Your Honor.

BY MS. MOORE

Q. Dr. Levine, when Mr. Hardeman went through antiviral

therapy in 2006 -- and even if there were some cells that were left behind -- his risk of developing non-Hodgkin's lymphoma from hepatitis C went away, right?

A. I disagree.

Q. Let's look at the literature. So let's turn to -- do you have the white binder in front of you?

A. Yes, I do.

Q. Tab 1531.

MS. MOORE: Permission to publish?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. And this is the Taborelli study that the jury saw last week with Dr. Weisenburger, and it is titled Hepatitis B and C Viruses and Risk of non-Hodgkin's Lymphoma: A Case Control Study in Italy. We were about to talk about this right before the break. And you are familiar with this study?

A. Yes, I am.

Q. Okay. And so if we can turn over to page 4 of this study.

MS. MOORE: And if we can go to table 2, Mr. Wolfe, please.

Let's talk about hepatitis C, HCV, that first half of the table.

Great. Thank you.

\\\

BY MS. MOORE

Q. Okay. Dr. Levine, do you agree that Mr. Hardeman would fall under -- and I know it is kind of hard -- you are looking at the actual paper, too, but you will see there is anti-HCV, so that negative. There is a little negative sign next to it -- and that means negative antibody for hepatitis C, correct?

A. Correct.

Q. And then the next one is positive antibody for hepatitis C?

A. Correct.

Q. And then the next category within that is a negative RNA for hepatitis C, correct?

A. Correct.

Q. And that's Mr. Hardeman?

A. That is Mr. Hardeman's status at the time that his diagnosis of lymphoma was made, yes.

Q. Okay. And so I want to stop right there because if you go over and you see the odds ratio in the last column, .98 -- do you see that, Dr. Levine?

A. Yes, I do.

Q. Okay. And what that tells us is that after Mr. Hardeman completed his antiviral therapy and his RNA went to negative for hep C, he no longer was at an increased risk for non-Hodgkin's lymphoma from hepatitis C; isn't that what that

tells us?

A. Yes, statistically the patient would be less likely to develop lymphoma with a negative RNA.

Q. Okay. Let's go to Exhibit 1413, and this is the -- it is in that same binder -- and it is the Nieters study. And the jury heard from Dr. Weisenburger last week. He showed -- he talked about the Nieters study.

THE CLERK: Is this to publish?

MS. MOORE: May I have permission to publish? Thank you.

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. Are you familiar with this study?

A. Yes, I am.

Q. Okay. And do you agree that when a patient -- and this study showed that only patients with active hepatitis C ended up getting non-Hodgkin's lymphoma?

A. No, I disagree.

Q. Okay. Well, do you agree that you can't just look at whether an antibody is present to determine that?

A. Table 4 indicates that people who are anti-HCV positive -- in other words, antibody positive, or HCV RNA positive have an increased risk of diffuse large B-cell lymphoma.

Q. Right. And that is not Mr. Hardeman, correct?

A. No. He is -- that is Mr. Hardeman. He is anti-HCV positive. This says anti-HIV positive or HCV RNA positive. He is anti-HCV positive. So he is on that chart.

Q. But he is RNA negative. So you are including the definition that does not define RNA negative and RNA positive?

A. Well, you are referring to a paper in which that was done. It is either HIV positive antibody or HCV RNA positive. That's what it says.

Q. Dr. Levine, I think you said HIV. Did you mean hep C?

A. I'm sorry. I do that a lot. Forgive me. HCV.

Q. Okay. All right. But, Doctor -- I mean, Mr. Hardeman was not RNA positive?

A. Correct. He was RNA negative.

Q. Okay. So let's go to 1291.

MS. MOORE: Permission to publish?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

THE WITNESS: Forgive me. I don't seem to have -- I have 1271 and then I have 1302. Oh, here it is. Here it is. I'm sorry. Yes.

BY MS. MOORE

Q. Okay. And, Dr. Levine, this is the study by Kawamura. It is viral elimination reduces incidence of malignant lymphoma in patients with hepatitis C?

A. Yes.

Q. And are you familiar with this publication?

A. Yes, I am.

Q. Let's turn over then to page 1039. It's the figure 3 on 1039?

A. Correct.

Q. And the jury saw this with Dr. Weisenburger last week. And this shows on this chart -- and this is following patients at over 15 years; is that right?

A. Not really. The median follow-up on the patients with treatment was 14 -- I'm sorry, without treatment with persistent infection was 14 years. The follow-up with patients with treatment was only 4.5 years. So I disagree that the overall follow-up was 15 years. It was not. It was very different. Much, much longer in those who had not been treated.

Q. Okay. Let's look at what the chart says.

A. Okay.

Q. And the line that is going up, the broken line that is going up, those are people who still have active hepatitis C, correct?

A. Correct.

Q. And then in the people who are sustained virological response, like Mr. Hardeman, after they have gone through that treatment and declared SVR are back at baseline. They are at zero percent, correct?

A. They are.

Q. Okay. All right. So that means that the therapy works, and that would include people who have possibly occult cells?

A. If you follow them long enough. You need to follow them long enough.

Q. The jury will see what that chart says there, 15 years.

So let's go to the next one. Omland. It is 917 in your binder.

MS. MOORE: Permission to publish?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. Dr. Levine, are you familiar with this publication from 2012 Liver Cancer and NHL in Hepatitis C Virus Infected-Patients Results from the Danvir cohort study?

A. Yes, I am.

Q. Okay. Let's go over then to page 2314. And it is the bottom right bracket.

MS. MOORE: If we can pull that up, Mr. Wolfe, please, the non-Hodgkin's lymphoma one.

Thank you.

BY MS. MOORE

Q. And, Dr. Levine, on this graph, does this also show as from the data that once someone becomes RNA negative, that the risk of developing non-Hodgkin's lymphoma goes back to zero?

A. Yes. And this -- yes, and this certainly would include the marginals on lymphomas as well. This is nonspecific, non-Hodgkin's lymphoma.

Q. And it would include those people that even after antiviral therapy may have had some occult cells still in their body?

A. Possibly.

Q. Okay. All right.

MS. MOORE: Let's go to the next publication -- and these are all publications the jury saw last week with Dr. Weisenburger. And that is 918. It is the very next study in your binder.

Permission to publish?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. This is the Su study, and it is just from last November. Do you see that, Dr. Levine?

A. I do.

Q. And it's Early Antiviral Therapy Reduces the Risk of Lymphoma in Patients with Chronic hep C Infection.

Are you familiar with this study?

A. Yes, I am.

Q. Okay. And let's look over at the graph here -- and it is on page 336. And it is figure 2B for non-Hodgkin's lymphoma.

Do you see that?

A. Yes, I do.

Q. Okay. And this is really telling us the same thing, the Omland study -- the one right before it -- told us, that for those who go through the antiviral therapy and receive treatment and go to SVR, that their risk of developing non-Hodgkin's lymphoma from hep C goes down to zero; is that right?

A. No, I disagree. Because as you can tell from the title, what he is really saying is that early antiviral therapy is associated with a decreased risk. Mr. Hardeman had active disease for 39 years. So I don't think this speaks to his case particularly.

Q. Okay. Well, during those 39 years, Mr. Hardeman didn't have any problems from the hepatitis, correct?

A. His body did. He was developing cirrhosis of the liver, but he had no symptoms. And that is very common. That is why it is such a difficult issue clinically.

Q. And you agree that once he was diagnosed with hepatitis C in 2005; that he got the proper treatment and was declared cured?

A. He got the proper treatment, and the doctors declared him "cured."

Q. And this chart here shows us at the bottom -- the bottom axis goes out eight years. Do you see that?

A. I do.

Q. Okay. And when Mr. Hardeman was diagnosed with non-Hodgkin's lymphoma, it had been almost a decade since he had been declared cured of his hep C; isn't that correct?

A. Yes. It forgets the first part of his illness where he was not treated for 39 years, but you are correct.

Q. Well, it is important also, Dr. Levine, not to forget that when you say "39 years," right, that what happened in the middle of that was that he had treatment and he was cured and that the infected cells were killed off, right? It is important not to forget that too?

A. You say that he got treatment in the middle of that, no, he was --

Q. No, no, I'm sorry, Dr. Levine. I didn't mean to imply in the middle. He went 39 years. Then he got treatment.

A. Yes.

Q. So it is important to recognize that fact, that he got treatment. And the purpose of that is to kill off the infected cells.

A. To kill off the virus, the virus.

Q. Okay. Well, and the virus is what -- what infects the cells, right?

A. Yes.

Q. Okay. All right. So let's go back to our graph then on the Su article and -- okay. What this shows us, if you are

treated and -- up there at the top you see the IFN. That is the interferon, right?

A. Correct.

Q. And so if you are treated with interferon, like Mr. Hardeman -- and I think he had two different drugs, right, for his hepatitis C?

A. Yes, he did.

Q. Okay. And that once you are treated, you no longer have the risk of non-Hodgkin's lymphoma, correct?

A. I don't interpret this chart in the same way, but that's fine. That's fine.

Q. Okay. All right. And then let me show you -- this is from a Giannelli article. Are you familiar with the Giannelli study?

A. I am, but would appreciate knowing which tab it was.

Q. Sure. Hold on one second and let me grab this.

This was shown to the jury last week. Let me tell you what number it is. Just a second.

(Whereupon, a brief pause was had.)

THE WITNESS: I see it. 952.

BY MS. MOORE

Q. Did you find it, Dr. Levine?

A. 952.

Q. Yes, 952. Thank you.

MS. MOORE: Permission to publish?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. Okay. This was a publication that Dr. Weisenburger also showed the jury, and we actually have a blowup from it. This is the blowup, Dr. Levine, that the jury saw last week. And you are familiar with this?

A. Yes.

Q. Okay. And what this -- do you agree what this shows us is that after antiviral therapy in someone who has hepatitis C, that you see a dramatic drop, and that their liver enzymes become normal, like Mr. Hardeman?

A. Yes.

Q. And that their RNA, that virus in the blood, also goes to normal, correct?

A. Correct.

Q. And so what Dr. Weisenburger testified to is that this is a good example of what happened to Mr. Hardeman's case. He started out with an elevated -- elevated enzymes and elevated RNA, and then within 12 weeks he dropped down dramatically to baseline. Do you agree with that?

A. That part of the chart is correct, but these patients did not have lymphoma that were being described in this particular study.

Q. Right. This is showing what happens when you actually go

through antiviral therapy for hepatitis C, correct?

A. Yes, correct.

Q. And this is what happened to Mr. Hardeman?

A. Correct.

Q. And the jury was also shown a blowup -- are you familiar with the Zuckerman article -- I know there is two. Let me tell you which one. This is the later one. I think you were asked some questions on your direct examination today regarding the older Zuckerman article; is that right?

A. I'm not sure.

Q. Okay. Well, let's turn to 1599 in your binder.

MS. MOORE: Permission to publish?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. Are you familiar with this publication by Zuckerman in 2001?

A. Yes, I am.

Q. Okay. And this is also talking about the effect of antiviral therapy with --

A. Correct.

Q. -- someone with chronic hep C?

A. Correct.

Q. Okay. I'm going to pull up the chart. That was table 3 -- I have got the blowup here. The jury will remember

that this was also shown by Dr. Weisenburger last week.

And, Dr. Levine, can you see that?

A. Yeah, I can.

Q. Okay. I don't know if the jury can see it. If not, you can look on your paper too. I'm sorry.

A. I will just look on my paper. It's all right.

Q. Sorry. And what this says is that for those patients who had a virologic response -- which is Mr. Hardeman, correct?

A. Correct.

Q. All right.

-- that it actually indicates that -- let me slide through here -- it actually shows that they no longer have an increased risk for non-Hodgkin's lymphoma, correct?

A. Well, that really doesn't say that. It just shows the effect on a specific translocation, 14;18. Whether there was a response to 14;18.

Q. And there was?

A. There was. So of the treated group there were a total of 15. Seven of them remained translocation 14;18 positive, and six of them, there was a loss of that translocation 14;18.

Q. So you would agree with me that the literature shows that once someone obtains sustained virologic response, that their risk of developing non-Hodgkin's lymphoma from the hepatitis C goes away?

A. No, I do not. This translocation 14;18 is not a common

translocation in diffuse large B-cell lymphoma, and this doesn't say anything about the lymphoma going away.

Q. Okay. Let me back up. I was asking it more generally, Dr. Levine. I apologize.

MS. MOORE: We can take it down. Thank you.

BY MS. MOORE

Q. Going through these articles -- the Taborelli, Nieters, Omland, Su, Kawamura -- you agree that the data from those articles tells us that once a patient with hepatitis C -- active hepatitis C goes through antiviral therapy and obtains a sustained virologic response, in other words the active virus it is out of their blood, that the risk for developing non-Hodgkin's lymphoma from hepatitis C goes away?

A. I can't answer it for non-Hodgkin's lymphoma in general. For marginal zone lymphoma what you say is absolutely true. For diffuse large B-cell lymphoma caused by a given mutation, it is not dependent upon active HCV in the blood to get that tumor. It may already have occurred.

Q. Those articles don't say that, do they?

A. Don't say what?

Q. They don't say that it doesn't apply to DLBCL?

A. It talks about non-Hodgkin's lymphoma. And one of the things that I was saying at the beginning is the importance of knowing that non-Hodgkin's lymphoma is a big word and has over 60 different diseases in them, caused by different things,

different illnesses, different clinical illness, different treatment, different prognosis.

Q. Okay. Well, let's look at one that shows us DLBCL -- and this is in the context of hepatitis B -- and I know I said we were done with that, but I just want to show this really quickly. And that is 1302, Dr. Levine.

MS. MOORE: Permission to publish?

MR. STEKLOFF: No objection, Your Honor.

THE COURT: Go ahead.

BY MS. MOORE

Q. This is the Klein/Stern publication that Dr. Weisenburger showed the jury last week. If we could go to page 3, and you see on page 3 it almost looks like forest plots. Do you see that, Dr. Levine?

A. Yes, I do.

MS. MOORE: One more page, Mr. Wolfe. Thank you.

BY MS. MOORE

Q. Okay. And you have --

MS. MOORE: Well, actually I will have you go back. Thank you.

BY MS. MOORE

Q. If we go at the very top of that forest plot, that is overall non-Hodgkin's lymphoma.

A. Yes.

Q. Right?

A. Yes.

Q. And then they break it down to the next one, which is DLBCL. Do you see that?

A. Yes, I do.

Q. And so the odds ratio there with 1. Someone who has -- like Mr. Hardeman goes back to baseline. Do you see that?

A. I do.

Q. Okay. Then if we go to the next page, please, they also break it down between overall NHL and DLBCL. Do you see that?

A. I do.

Q. Okay. And they break it down -- that first one is OBI. Do you see that?

A. Yes, I do.

Q. And that stands for what you have been calling occult B-cell infection, right?

A. Occult hepatitis B infection, correct.

Q. Okay. And on this chart it shows that if you are naturally immune, that you do not have an increased risk of developing DLBCL from hep B, correct?

A. Correct.

Q. And it also tells us that if you are immune via vaccine that you no longer have a risk of developing DLBCL from hepatitis B, correct?

A. Yes. And it also shows that if you have a lack of an immune response, you will have an increased risk of diffuse

large B-cell lymphoma. An immune -- the import of this article is the importance of the immune system in defining how somebody will do with hepatitis B in terms of lymphoma.

Q. Right. And that is important because in Mr. Hardeman's case he never got active hepatitis B after 2005?

A. He was also ten years younger then.

Q. Right. But ten years later he still didn't have it, right?

A. You are correct.

Q. Even under your theory that as you get older, your system is weakened.

A. Yes.

Q. Even when his system is older, he still didn't get it, right?

A. He still didn't get lymphoma.

Q. He still didn't get the hepatitis B back?

A. This is talking -- this graph talks about the risk factors for developing the lymphoma, and it just says that if you don't have a good immune system, you are more likely to get the lymphoma. It doesn't say that you are more likely to get hepatitis B reactivated. That's not what it is looking at.

Q. Right. It is showing us that your risk of developing DLBCL from hepatitis B no longer is increased when you are immune, either by vaccine or naturally, correct?

A. Yes, it does.

Q. Okay. All right. We are almost done, Dr. Levine.

I wanted to go back to our risk factors chart, and I wanted to focus on Roundup. We have talked now about hepatitis B and hepatitis C and Roundup -- and I should put on here this was from Weisenburger, right?

A. I don't know.

Q. Well, you read Dr. Weisenburger's testimony, right?

A. Yes, but do you mean that chart is from him? I'm not sure.

Q. No. I apologize. Let me clarify.

That when we are talking about risk factors for Mr. Hardeman, Dr. Weisenburger testified that he would include Roundup?

A. Yes, he did.

Q. Okay. And I understand your testimony is that you would not include Roundup.

A. That's true.

Q. Okay. So I was just clarifying that this was Dr. Weisenburger only. Age, weight, hep B and hep C, Dr. Weisenburger; and you both said those should be on the list of risk factors, right?

A. I don't know his list. I would agree.

Q. Okay. All right. So let's focus on Roundup for just a few minutes.

You agree, Dr. Levine, that when you are trying to

determine the cause, that you want to consider all the risk factors?

A. Correct.

Q. Okay. And in this situation you did not consider Roundup as a risk factor, right?

A. Correct.

Q. And if the jury finds that Roundup is a risk factor for non-Hodgkin's lymphoma, your list of risk factors would be incomplete?

A. I have a list on mine which is idiopathic, and the idiopathic is something I cannot exclude no matter what.

Q. Right. But your list does not include Roundup, so it would be incomplete, correct?

A. If the jury said that the Roundup was the cause and my list did not have it, then my list would be incomplete as it related to what the jury said, yes.

Q. So you brought up idiopathic, and I just want to touch on that. Are you saying to this jury that Mr. Hardeman's non-Hodgkin's lymphoma was caused by hepatitis B and hepatitis C or are you saying that it is idiopathic; meaning you don't know?

A. I'm saying that the most significant contributory cause is hepatitis C because of those 39 years where a mutation could have occurred. I think the secondary significant cause could be hepatitis B although I don't have enough information about

Mr. Hardeman's hepatitis B infection, per se, to make that Number 1.

And Number 3, under no circumstance can I exclude idiopathic. You can't tell the difference under the microscope. So the most likely cause, C; second most likely cause, B; idiopathic, I cannot exclude. It could easily be idiopathic. That is the most common of all of these in diffuse large B-cell.

Q. So should I -- let me make sure I have got this right.

So for hepatitis B and C, it is your opinion those are most likely causes?

A. Hepatitis C is the most likely cause. Hepatitis B is the second most likely cause.

Q. Okay. Can I just say here most likely causes then?

A. Okay.

Q. Is that okay?

A. Sure.

Q. Okay. And that idiopathic -- what did you say on that?

A. I said I can't exclude idiopathic in anything that has been shown as far as his pathology, lab tests, biopsy.

Q. Okay. And that is because there is no test or marker that tells us that Roundup causes non-Hodgkin's lymphoma; is that right?

A. That's true.

Q. You spoke a lot about smoking cigarettes -- smoking

causing lung cancer earlier. Do you recall that?

A. Yes.

Q. And just like with Roundup, do you agree that there is no test or marker that we can use for smoking to say this person's lung cancer was caused by cigarette smoking?

A. There are certain characteristics of smoking of tobacco-related lung cancer that are quite unique, and I'm not sure that that is true, what you just said.

Q. Well, you agree that smoking causes lung cancer?

A. Some kinds of lung cancer, not all.

Q. And that -- you agree that when you are trying to determine the cause of someone's lung cancer, that you have to consider how much they smoked?

MR. STEKLOFF: Your Honor, I'm objecting under motions in limine.

THE COURT: Sustained.

MS. MOORE: Your Honor, can we have a sidebar?

THE COURT: Sure.

(The following proceedings were heard at the sidebar:)

[redacted]

[redacted]

(Proceedings were heard in the presence of the jury:)

BY MS. MOORE

Q. Dr. Levine, is there any kind of -- can you tell from the pathology whether someone smoked cigarettes when you are trying to determine the cause of someone's lung cancer?

MR. STEKLOFF: Objection, Your Honor.

THE COURT: Sustained.

BY MS. MOORE

Q. Do you agree that when you are trying to determine the cause of someone's cancer, that you have to consider all of the evidence. You can't just say, Well, if there is no test, we don't know?

A. I guess I'm not sure what you are saying. Repeat it

again. Sorry.

Q. No problem. No problem.

When -- I just want to focus on idiopathic.

A. Okay.

Q. Okay. If you know the cause -- or you have a likely cause of someone's cancer, it wouldn't be right to say it is idiopathic; is that correct?

A. If you know what the cause is, it is not right to say idiopathic, but at a certain point you can't -- there is nothing in that idiopathic category that allows you to exclude it. You can't exclude it.

Q. But you would only say something is idiopathic when you don't know the cause, right?

A. Yes.

Q. Okay. And in this case it is your opinion that the cause is either hepatitis B or hepatitis C?

A. And --

MR. STEKLOFF: Objection, Your Honor. This misstates her testimony.

THE COURT: Sustained.

BY MS. MOORE

Q. Your opinion is that the most likely causes are hepatitis B and hepatitis C, correct?

A. In my opinion the most likely contributing factor here is hepatitis C. The second most likely is hepatitis B. But I

can't exclude that this could be idiopathic because under the microscope I can't tell.

Q. We have made some references today to Dr. Weisenburger. And you know Dr. Weisenburger, right?

A. I do.

Q. Okay. And do you consider him to be a good doctor?

A. He is a good pathologist. He is an excellent pathologist. I hired him.

MS. MOORE: Okay. I have no more questions. Thank you, Dr. Levine.

THE WITNESS: Thank you.

THE COURT: Any redirect?

MR. STEKLOFF: Yes, Your Honor. May I please have the ELMO?

REDIRECT EXAMINATION

BY MR. STEKLOFF

Q. Dr. Levine, good afternoon.

A. Good afternoon.

Q. First of all, I had asked you this on direct -- but just to clarify -- did you review Dr. Weisenburger's testimony about all of the hepatitis C studies you were just walked through?

A. Yes, I did.

Q. And did you, in fact, also review those studies?

A. Yes, I did.

Q. Did any of them change the opinions you have been offering

to the jury today?

A. No, not at all.

Q. Okay. So as fast as humanly possible, I just want to briefly touch on the studies. Okay? I'm going to go in reverse order.

This is Exhibit 1599, the Zuckerman study. Do you see that?

A. I do.

Q. Do you see in the title it says, The effect of antiviral therapy on 14;18 translocation and immunoglobulin gene rearrangement in patients with chronic hepatitis C virus infection?

A. I do.

Q. Does that have anything to do with Mr. Hardeman and diffuse large B-cell lymphoma?

A. Not at all.

Q. So did this article change your opinion in any way?

A. Not at all. Has nothing to do with the case under consideration today.

Q. Okay. Let's look at the next one, Giannelli. The title is: Effect of antiviral treatment in patients with chronic HCV infection and T-(14;18) translocation. Do you see that?

A. Yes, I do.

Q. Does that translocation have anything to do with Mr. Hardeman and diffuse large B-cell lymphoma?

A. No. This was not a translocation that he had. These patients did not have lymphoma. He has diffuse large B-cell lymphoma. This doesn't speak to him at all.

Q. Did this change your opinions in any way?

A. No, not at all.

Q. Let's look at the next article, the Su article. The title is: Early antiviral therapy reduces the risk of lymphoma in patients with chronic hepatitis C infection.

Do you see that?

A. I do.

Q. And what -- we have heard that Mr. Hardeman was exposed to hepatitis C in 1966, correct?

A. Yes.

Q. And that he had antiviral therapy starting in 2005, correct?

A. Correct.

Q. So did he have early antiviral therapy?

A. No, he did not. He had 39 years of active HCV infection, which would have allowed mutations to occur.

Q. Did this study change your opinions in any way?

A. Not at all.

Q. Let's look at the next one, the Omland study. Do you recall seeing this study from Dr. Omland and others?

A. I do.

Q. Do you recall being shown one of the graphs here on this

table?

A. Yes.

Could you show me the tab number on that one?

Q. Of course. This is tab 917.

Dr. Levine, tell me when you are ready.

A. Not quite yet. Just one moment.

Q. Okay. No problem.

(Whereupon, a brief pause was had.)

THE WITNESS: Yes, I'm ready.

BY MR. STEKLOFF

Q. You were shown this table here about non-Hodgkin's lymphoma, correct?

A. Yes.

Q. Okay. I want to show you the next page. And what it says here, the author said, Similarly, no models were fitted for non-Hodgkin's lymphoma as only five cases occurred in the HCV RNA positive patients and no cases occurred in HCV RNA negative patients. The results of Gray's test -- that is a statistical test about significance, right?

A. Yes.

Q. -- of the difference in the cumulative incidence of NHL between the two HCV patient groups shown in figure 1 gave a p-value of .09, indicating that our findings could be due to chance.

Do you see that?

A. That's the point. These numbers were not significant statistically. They were not valid statistically. As a clinician, you can't deal with information of that sort. He says These findings could be due to chance alone. And I'm going to have to believe that as a clinician.

Q. So did this article change your opinions in any way?

A. No, it did not.

Q. Let's look at the next one, the Nieters article. Do you recall being shown this article and being shown the title?

A. Yes.

Q. And then you said that you wanted to look at table 4. Do you recall that?

A. Yes.

Q. So let's show table 4. And on table 4 I think you were referring to this column here, anti-HCV or HCV RNA positive, correct?

A. Correct.

Q. So did that group include people who -- some people who had the antibody but not the active virus?

A. Absolutely. That's what it says.

Q. Or there were some people in that group who did, in fact, have the active virus, correct?

A. Correct.

Q. But nonetheless in that group there was an odds ratio of 2.19 that was statistically significant, correct?

A. Correct.

MS. MOORE: Objection. Leading, Your Honor.

THE COURT: Sustained.

BY MR. STEKLOFF

Q. What was the odds ratio, and was it statistically significant?

A. The odds ratio was 2.19. It crossed over 1. In other words, this is statistically significant. There was an increase, a statistical increase, of specific diffuse large B-cell lymphoma among people who had antibody to HCV.

Q. And so did this article change the opinions that you've offered to the jury?

A. No, it did not.

Q. Let's look at the next one, Kawamura. And do you recall being shown this study?

A. Yes.

Q. And then you were shown a table with 15 years. Do you recall that?

A. I do.

Q. And one of the things that you talked about was how long the groups were followed. Do you recall that?

A. Yes.

Q. Okay. So let's look at that.

In this study did the authors write that the observation period was significantly shorter in the Interferon group than

in the non-Interferon group, median 4.5 versus 14 years?

A. Yes. The average time in that study for patients with lymphoma to develop lymphoma was 6.1 years, but the average follow-up was only 4.5; and as I showed early, it takes years and years for this to occur. Four and a half years is not -- it's not a fair comparison.

One group is followed 14 years. You're going to see a lot of truth in there. One group is followed -- the treated group followed only four years. Not enough time to see what the real answer might be.

Q. Okay. So did this article change your opinion in any way?

A. No, it didn't.

Q. And then let's look at the last one, the Taborelli study, the first one you were shown. Do you recall being shown this?

A. I do.

Q. And do you recall being shown this table that Mr. Hardeman would have fit in this group? HCV, he had the core antibody, he was anti-HCV positive but HCV RNA negative?

A. Correct.

Q. And do you see that there were 14 cases in the non-Hodgkin's lymphoma group and 27 cases in the control group?

A. Yes, I do.

Q. And how does that impact your -- whether -- well, first of all, does this study change your opinions in any way?

A. It does not because the numbers are just too small. You

need real numbers to see small results, and those are just too small. Fourteen cases of lymphoma, you can't make a firm conclusion on that.

Q. Okay. So you were asked a lot of questions about these studies. Overall, in any way do you think these studies demonstrate that Mr. Hardeman's non-Hodgkin's lymphoma may not have been caused by hepatitis C?

A. None of them disprove the fact that this lymphoma could easily have been caused by hepatitis C during the 39 years of active infection.

Q. Okay. Now, I want to go to a different -- a slightly different topic, it's related, and show you just a few of Mr. Hardeman's medical records. Okay?

A. Okay.

Q. Now, you were asked questions, a lot of questions, about his antiviral treatment and whether he was cured. Do you recall that?

A. Yes.

Q. Okay.

A. Yes.

Q. And I think you referenced discussions that you relied upon in the medical records between Dr. Ye and Mr. Hardeman; correct?

A. Yes, I did.

Q. And do you remember being shown this exhibit from

February 19th, 2015, from Dr. Ye?

A. Yes.

Q. And I think we showed this on direct, but on cross were you able to discuss again, when you were being asked these questions, this section here on the back page where Dr. Ye wrote (reading):

"We specifically discussed two additional concerns in his case, and then one of those concerns was hepatitis B and hepatitis C reactivation from rituximab" --

That was the medicine to treat his hepatitis B; correct?

A. Correct.

Q. (reading)

-- "and then will monitor both diseases through the treatment."

Correct?

A. Correct.

Q. And so what does -- why did this -- or how did this impact your opinions about whether there may have still been some lingering hepatitis B or C in Mr. Hardeman's blood?

A. For all practical purposes, Dr. Ye believed that he had to be worried about the possibility of latent quiet virus, both hepatitis C and hepatitis B.

He said that the patient was cured, but that's not what he did. And what he did was specifically, which I'm most respectful for, specifically talked to the patient about his

concerns. And his first concern was that there may be reactivation of hepatitis C or B. You can't reactivate a germ unless the germ is in you. You can get a new infection maybe, but you can't reactivate it unless it's there.

And so he's implying here -- I won't say that.

And so he is worried about the fact that there may be latent quiet hepatitis B or C, and he has to be careful about that. And so he's going to monitor the diseases carefully looking at the liver enzymes and so forth, and he's also going to treat the patient for hepatitis B so that it won't, quote, "reactivate." It's not a matter of -- well, so that it won't reactivate.

So, you know, the doctor uses a word "cure." On the other hand, what he's doing here is saying, "I've got to be really careful here. There is such a thing as occult hepatitis B."

MS. MOORE: Objection, Your Honor.

THE WITNESS: Okay.

MS. MOORE: I'm sorry, Dr. Levine.

THE COURT: Overruled.

THE WITNESS: You're right.

BY MR. STEKLOFF:

Q. It was overruled, so you can --

A. Yes -- oh. So he's acting on the knowledge that he has to be concerned about those long-term viral infections that may be occult and that may be reactivated because of the chemo --

because of the immune weakening due to the chemo.

Q. Now, you told us earlier that you reviewed Dr. Ye's testimony; correct?

A. I did.

Q. I mean, based on this, do you have any disagreement with what Dr. Ye said about this in his testimony?

A. No. I'm very respectful of him. He did a very nice job.

Q. Okay. Do you recall also being asked questions on cross-examination about whether Mr. Hardeman was vaccinated for hepatitis B?

A. Yes.

Q. And so I'd like to show you a record. This is Exhibit 1023 at page 860.

MS. MOORE: No objection.

Well, Your Honor, can we have a sidebar?

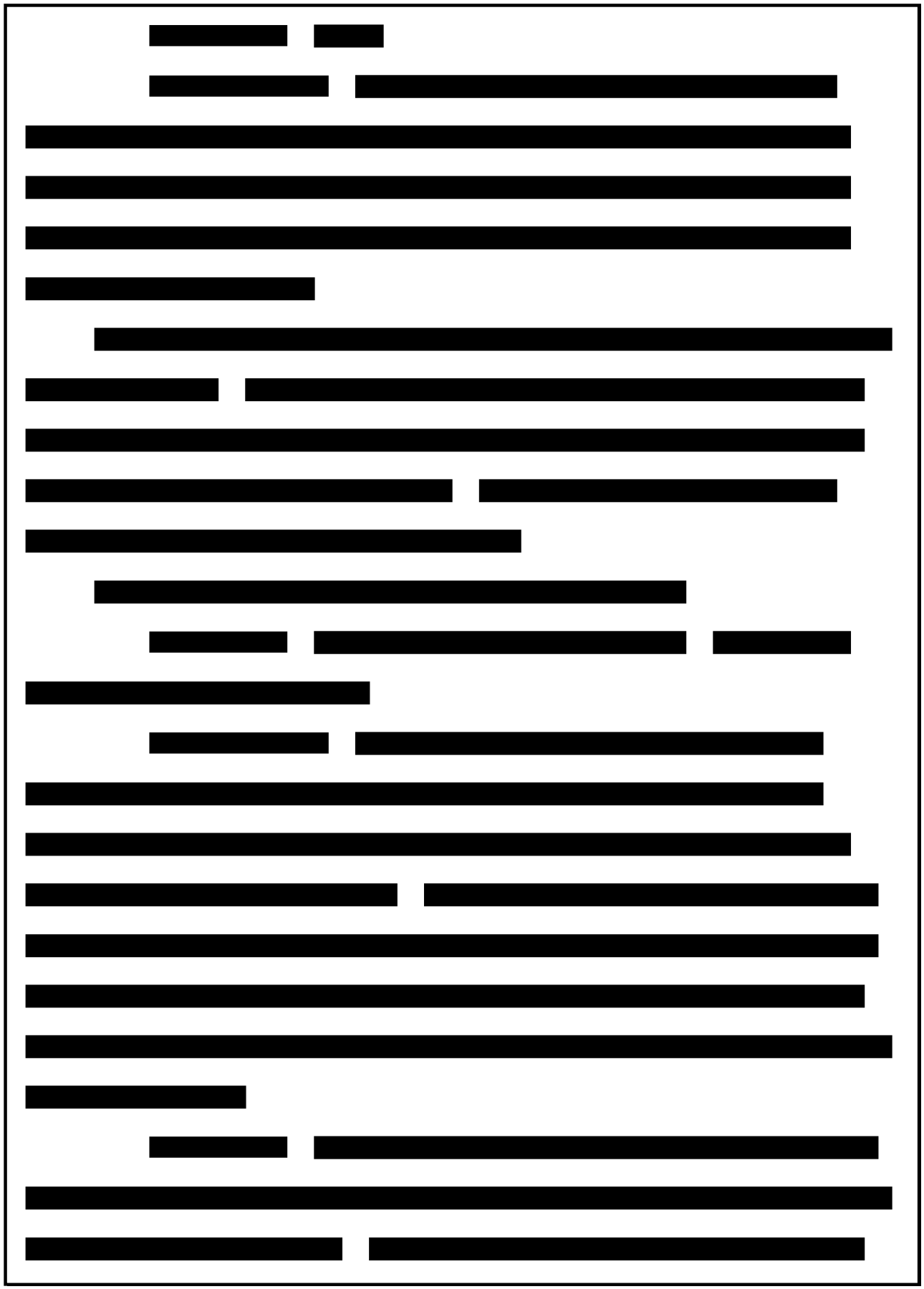
THE COURT: Sure.

(The following proceedings were heard at the sidebar:)

[redacted]

(Pause in proceedings.)

SIDEBAR



[redacted]

(The following proceedings were heard in open court:)

BY MR. STEKLOFF:

Q. Dr. Levine, do you recall being asked questions about whether Mr. Hardeman had been vaccinated for hepatitis B?

A. Yes.

Q. And what is the -- so we've heard about the core antibody; correct?

A. Correct.

Q. Is there something called the surface antibody?

A. Yes.

Q. And what is that?

A. The surface antibody is what the hepatitis B vaccine is generated against. So that's the surface of the virus that attaches to the liver cell and so forth, and the vaccine specifically takes that and puts a phony hepatitis B surface antigen. It puts a phony protein into the vaccine, and your body sees that dead piece of surface hepatitis B and makes an antibody to it because it's seen as foreign.

And so in a patient who's vaccinated, the only abnormality on the blood test is antibody to the surface antigen; but if there's antibody to the core, that means that virus actually -- the virus actually got into that patient. Mr. Hardeman had core antibody, which meant he had been infected. He did not have surface antigen positive so he -- maybe he was vaccinated, I don't know, but if he was, it didn't take because if it had been a good vaccine result, he would have had antibody to the surface, and he didn't. And so his blood test was fully what we expect with somebody who has had hepatitis B infection in the past.

Q. And so have you seen medical records that corroborate that he did not have that surface antibody that he would have had had he been effectively vaccinated?

A. Yes.

Q. Okay. I just want to make a quick timeline.

MR. STEKLOFF: Ms. Moore, do you mind if I use one of your pieces of paper, a clean piece of paper?

MS. MOORE: Sure.

MR. STEKLOFF: We can rip it off afterwards.

MS. MOORE: Sure. That's fine.

MR. STEKLOFF: I'm happy to do it.

Q. Okay. So we have 1966, the first exposure to hepatitis C; correct?

A. By history, yes.

Q. Okay. And then we have 39 years until it's identified in 2005; correct?

A. Correct.

Q. Then he receives the antiviral treatment into 2006; correct?

A. Correct.

Q. And his diagnosis of non-Hodgkin's lymphoma is in 2015; correct?

A. Correct.

MS. MOORE: Your Honor, objection. These are all leading questions.

THE COURT: I'll let you just draw your thing, and then stop asking leading questions.

MR. STEKLOFF: Yes, Your Honor.

Q. Okay. I want you to assume -- let's put aside this entire debate about whether he had occult or hidden hepatitis C or hepatitis B during this time period. Okay? Let's assume that he had no hepatitis B and no hepatitis C, absolutely none. Okay?

A. Yes.

Q. Okay. Does that change your opinion in any way about the most likely cause of his non-Hodgkin's lymphoma?

A. No, it does not. Diffuse large B-cell lymphoma, the defect is a mutation. He had 39 years of active hepatitis C that would have allowed a mutation to occur. He did have a

mutation in his lymphoma. It doesn't matter if he had no hepatitis C or hepatitis B after 2005. He had it for 39 years.

Q. Okay. So this entire debate that we just heard for an hour about whether he had some cells of hepatitis B or hepatitis C from after 2005 and 2006, it doesn't matter at all?

A. It would have mattered if he had marginal zone lymphoma, but he doesn't. He has diffuse large B-cell and so, no, it doesn't matter at all.

Q. Okay. And you were asked on direct, I asked you -- sorry -- or you were asked on cross if there was evidence or data about this; correct?

A. Evidence and data about?

Q. About your -- about what they called your theory of the 39 years.

A. Well, there are all kinds of experiments in the scientific literature that have been shown -- mutations, the hepatitis C has been able -- has been shown to be consistent, has what's called a mutator phenotype that can just cause all these mutations in our own DNA.

Q. And did we show two of those articles on direct?

A. Yes, we did.

Q. Okay. So let's look at this one again. This is the Machida article, and you are one of the authors; correct?

A. Yes.

Q. And in this article you and your authors wrote (reading):

"We demonstrated here that acute and chronic hepatitis C infection caused a 5- to 10-fold increase in mutation frequency in Ig heavy chain, BCL-6, p53, and beta-catenin genes of *in vitro* HCV-infected B cell lines and HCV-associated peripheral blood mononuclear cells, lymphomas, and HCCs."

Correct?

A. Yes.

Q. And how does that, what you demonstrated in this study, relate to diffuse large B-cell lymphoma?

A. These are mutations which are often seen in diffuse large B-cell lymphoma and mutations which Mr. Hardeman had.

Q. Okay. So let's pause for a moment there. I want to come back to that.

Are we going to talk for a moment about the BCL-6 mutation?

A. Yes.

Q. Okay. In Mr. Hardeman?

A. Yes. His pathology report showed a BCL-6 mutation.

Q. Okay. And also did you and your colleagues write (reading):

"These results indicate that HCV induces a mutator phenotype and may transform cells by a hit-and-run mechanism. This finding provides a mechanism of oncogenesis for an RNA virus"?

A. Yes.

Q. And the hit-and-run mechanism, was that what you described this morning for the jury?

A. That's exactly what I described.

Q. And that relates to diffuse large B-cell lymphoma?

A. That relates to diffuse large B-cell lymphoma, which is Mr. Hardeman's lymphoma.

Q. And you and your colleagues, what was the date of this article that you published?

A. 2004.

Q. Okay. Let's look at the next article we showed. Do you recall discussing this article this morning by Dr. Peveling-Oberhag and others?

A. Yes, I do.

Q. And did we show in part this chart here?

A. Yes.

Q. Okay. Does this actually show three different possible mechanisms through which hepatitis C can cause different forms of non-Hodgkin's lymphoma?

A. Yes.

Q. So let's talk first about this top one. Can you explain what that shows to the jury?

A. Yes. That shows what I was showing on my own little chart there, that certain kinds of tumors, marginal zone lymphoma, requires the presence of active, living, activated, active HCV

in order for that tumor to develop and to continue. And so it -- the virus attaches to the lock -- the key attaches to the lock on the B-cell and the -- what happens is ongoing growth, division of those B cells. And if you take away the virus by SVR, as an example, if you decrease it or take it away, that whole thing is going to stop.

But --

Q. You can go to the second one where the HCV looks like it's entering the B-cell lymphoma.

A. Okay. This is more complicated, but basically the virus gets in, causes all kinds of abnormalities based upon what its proteins can do. It can cause problems directly into the DNA by the virus itself or it can do indirectly with other -- other kinds of mechanisms.

Q. And of these first two, is that what you have told the jury occurred in Mr. Hardeman's case?

A. No. No. That's not with Mr. Hardeman.

Q. Okay. So let's look now at the last one. Is this the one that you explained to the jury this morning would apply to Mr. Hardeman's diffuse large B-cell lymphoma?

A. Yes. He had 39 years for one of those mutations to occur, and at that point it doesn't really matter what happens to the HCV. The mutation is there and time will tell whether that will be a true cancer or not. In his case, it was.

Q. In fact, here it shows the HCV entering the cell, but does

it also then show the HCV exiting the cell?

A. Yes. We've shown that B-cell lymphoma cells, diffuse large B-cell lymphomas, for example, can be, quote, "productively infected" by HCV. In other words, the HCV gets into the cell, the HIV [sic] actually divides in that lymphoma cell. The HCV that comes out of that lymphoma cell, if you put it into a test tube with normal B lymphocytes or liver cells that have not been infected, that HCV virus from the lymphoma cell will infect that new cell with hepatitis C.

So we have shown, and others have as well, that HCV can infect the cell, can cause mutations in the cell, can divide in the cell, leave the cell, and go and find -- infect some other cells in the body.

Q. And with this explanation, does the antiviral therapy cure or eliminate that mutation?

A. No. It won't do anything to that mutation.

Q. Okay. And I see here again this mutation BCL-6. Is that what we just looked at in your article?

A. Yes.

Q. And also to be clear, was this article in 2013?

A. Yes.

Q. Okay. So have you reviewed Mr. Hardeman's pathology report?

A. Yes, I have.

Q. And what, if anything, did that report say about whether

Mr. Hardeman had BCL-6 mutations?

A. He did have a mutation of BCL-6.

Q. Now, just to be clear, are you telling the jury that because he had a BCL-6 mutation, you are certain that it was the hepatitis C that caused his non-Hodgkin's lymphoma?

MS. MOORE: Your Honor, objection.

THE COURT: Overruled.

MS. MOORE: Leading.

THE COURT: Overruled.

MS. MOORE: It goes beyond the scope of her testimony.

THE COURT: Let's have a sidebar.

MS. MOORE: Thank you.

THE COURT: Actually, it's probably a good time for our afternoon break. Why don't we take about five minutes. We'll plan on resuming at five minutes to 2:00.

(Proceedings were heard out of the presence of the jury:)

THE COURT: Okay. You're free to step down if you like, but it may be worth you listening to this.

I guess I wanted to pause because I don't understand the objection. They are clearing up -- they're clarifying the very thing that you wanted to make sure was clarified, and you objected to that question, which seems to me runs the risk of leaving a misimpression about BCL-6, precisely the misimpression that you didn't want to leave, yet you're objecting to the question.

So because this may be somewhat important, I wanted to just make sure I understand the nature of your objection to that question.

MS. MOORE: That's fine, Your Honor. And I guess what I heard -- and if I misheard, I apologize -- but what I had heard is that he was asking her about cause.

THE COURT: About what?

MS. MOORE: About cause.

THE COURT: He was clarifying -- he was asking a question that was designed to clarify that you cannot tell from the pathology that hep C is the cause. So I don't understand your objection.

MS. MOORE: He says (reading):

"Just to be clear, are you telling the jury that because he had a BCL-6 mutation, you are certain that it was the hep C that caused his non-Hodgkin's lymphoma?"

That's why I objected.

THE COURT: Right, but she's going to say "no" to that question.

MS. MOORE: I mean, I thought the way he would ask the question, Your Honor, and this was my concern, was that it would be "You cannot tell from the BCL-6 mutation whether it causes..." And I think the way he asked it, that's what I was concerned about. It made it sound like --

THE COURT: Now I understand. So that is a fair

point. That is a fair point.

MR. STEKLOFF: Yes. I was intending to elicit a "no" to my question.

THE COURT: Right. But even --

MR. STEKLOFF: I'm happy to reask it.

MS. MOORE: It implies that there is.

THE COURT: Yes.

MR. STEKLOFF: Okay.

THE COURT: But even with a "no," the way you asked the question is actually not right. I mean, because you said -- you said "Does the pathology make you certain that the hep C caused the non-Hodgkin's lymphoma?" Even if the answer to that is "no," it leaves a misimpression that more likely than not -- the pathology makes you think more likely than not that it caused -- that the hep C caused the non-Hodgkin's lymphoma. So that actually is -- which is why I wanted to take a timeout --

MS. MOORE: Thank you, Your Honor.

THE COURT: -- because I know this is important. So you didn't ask the question fairly, I think.

MR. STEKLOFF: And I want to ask the right question. So what I would propose is: Dr. Levine, you cannot tell from that BCL-6 mutation that hepatitis C was the cause of Mr. Hardeman's non-Hodgkin's lymphoma?

MS. MOORE: And, Your Honor, I would ask that there be

a curative instruction that that question and answer -- that question be struck.

THE COURT: Well, I'll just -- I'll sustain the objection. When the jury comes back, I'll say "The previous question was sustained. Do you want to resume?"

MS. MOORE: Okay. Thank you, Your Honor.

THE COURT: Okay.

THE WITNESS: Can I ask something?

THE COURT: Sure.

THE WITNESS: Could he ask -- I mean, just to get to the truth of this, could he ask: Is the BCL-6 mutation specific to hepatitis C? My answer is no. Doesn't that clarify it?

MS. MOORE: Yeah.

THE COURT: I mean, either the way he proposed it or the way you just proposed it, either one of those I think is appropriate.

MR. STEKLOFF: Okay.

THE COURT: Okay. Anything else?

MS. MOORE: No, Your Honor.

THE COURT: All right.

MS. MOORE: What time are we supposed to be back?

THE COURT: Let's take, you know, about five minutes.

MS. MOORE: Okay. Thank you.

(Recess taken at 1:54 p.m.)

(Proceedings resumed at 2:00 p.m.)

(Proceedings were heard out of the presence of the jury:)

THE COURT: Okay. Bring them in.

(Proceedings were heard in the presence of the jury:)

THE COURT: Okay. You can resume.

And I believe there was an objection pending before the break. That objection is sustained. You can resume.

MR. STEKLOFF: Thank you, Your Honor.

Q. Good afternoon again, Dr. Levine. Just a few more questions.

So I just want to follow-up on that BCL-6 mutation that you were just talking about.

A. Yes.

Q. And is that BCL-6 mutation specific to hepatitis C?

A. No, it is not.

Q. It can occur outside the presence of hepatitis C?

A. It can occur in idiopathic cases, as well it can occur outside of hepatitis C, but it clearly is seen in diffuse large B-cell lymphoma.

Q. Okay. So I want to shift topics on the last topic I want to cover. And do you recall being asked and having this chart created --

A. Yes.

Q. -- and then being asked questions about the fact that you didn't put Roundup on the chart? Do you recall that?

A. I do recall that.

Q. Okay. First of all, going back to this morning, have you ever used Dr. Weisenburger's differential method to determine the cause of one of your patient's non-Hodgkin's lymphoma?

A. No, I haven't.

Q. And now let's talk about Roundup. Did you review all of the published epidemiology regarding Roundup or glyphosate and non-Hodgkin's lymphoma?

A. Yes, I did.

Q. And based on that review, in your opinion is Roundup or glyphosate a cause of non-Hodgkin's lymphoma?

A. No.

Q. Did you provide that opinion in the expert report that you prepared for this case?

A. Yes, I did.

Q. And based on that opinion, is that why you didn't include Roundup as a potential risk factor for Mr. Hardeman?

A. Exactly.

Q. And these opinions that you're offering about Roundup and the fact that you don't believe it is not -- you don't believe it is a cause of non-Hodgkin's lymphoma, do you offer that opinion to the same reasonable degree of medical certainty that you discussed earlier?

A. Could you ask that again?

Q. Sure.

You just told us that you don't believe Roundup is associated with non-Hodgkin's lymphoma; correct?

A. Correct.

Q. Do you offer that opinion just like all the other ones that you've offered to a reasonable degree of medical certainty?

A. Absolutely. To patients, to doctors if it comes up, yes.

MR. STEKLOFF: Okay. I have no further questions, Your Honor.

THE COURT: Okay.

MS. MOORE: Your Honor, just a couple of questions.

THE COURT: Sure.

RECROSS-EXAMINATION

BY MS. MOORE:

Q. Dr. Levine, I just want to clear something up. You were asked some questions about a BCL-6 mutation.

A. Yes.

Q. Do you recall that? Is the BCL-6 mutation specific to hepatitis C?

A. It is not specific to hepatitis C. It is very commonly seen in diffuse large B-cell lymphoma.

Q. In fact, it's one of the most common translocations -- I'm sorry -- most common mutations that you see in DLBCL?

A. Absolutely true, and he had it.

Q. Okay. And so, in other words, you could have a person

who's diagnosed with diffuse large B-cell lymphoma and have the BCL-6 on their pathology and they may not have hepatitis C?

A. Yes. That's why I cannot exclude idiopathic.

MS. MOORE: Okay. Thank you. Those are all my questions.

THE COURT: Okay. You can step down.

THE WITNESS: Thank you very much.

THE COURT: Thank you.

(Witness excused.)

THE COURT: And do you wish to call your next witness?

MR. KILARU: Yes, Your Honor. We call Dr. Daniel Arber, and need to set up briefly.

THE COURT: Sure.

MR. KILARU: Thanks.

(Pause in proceedings.)

MR. KILARU: Your Honor, may I pass these up?

THE COURT: Thank you.

(Pause in proceedings.)

THE CLERK: Please remain standing and raise your right hand.

DANIEL ARBER,

called as a witness for the Defendant, having been duly sworn, testified as follows:

THE WITNESS: Yes.

THE CLERK: Thank you. Please be seated.

And for the record, please state your first and last name and spell both of them.

THE WITNESS: Daniel, D-A-N-I-E-L, Arber, A-R-B-E-R.

THE CLERK: Thank you.

MR. KILARU: Doctor, can I trade binders with you? There's one back there I'll grab too if that's okay. Thank you.

(Pause in proceedings.)

MR. KILARU: Your Honor, we have some slides that we've shown to opposing counsel. There's no objection, so we'd ask to publish those as well?

THE COURT: Sure.

DIRECT EXAMINATION

BY MR. KILARU:

Q. Good afternoon.

A. Hi.

Q. Could you please introduce yourself to the jury and tell them a little bit about yourself?

A. My name is Daniel Arber. I'm a pathologist at the University of Chicago.

Q. And the jury has heard a little bit about this before, but could you tell them in your own words what pathology is?

A. Sure. Pathology in the broadest sense is the study of disease. As a medical specialty, we oversee the running of the laboratories and also any type of tissue biopsy. So any

patient that has a biopsy specimen comes and is reviewed and interpreted by a pathologist, and any type of blood test or urine test or any type of other test that runs through the labs is overseen by a pathologist.

Q. And, Doctor, in your experience as a pathologist, have you ever diagnosed a patient with non-Hodgkin's lymphoma?

A. Yes. I frequently diagnose non-Hodgkin's lymphoma.

Q. Do you have a sense of how many times you've done that?

A. Oh, thousands of times.

Q. Let's start by talking a little bit about your background before we get to your opinions in this case.

A. Okay.

Q. Where did you grow up?

A. I grew up in Texas outside of Houston.

Q. And we heard that you're a doctor. What made you decide you wanted to go to medical school?

A. Well, my father was an engineer and I actually was very good at math, and I struggled more with science but it was more challenging so I thought I would try that. And I really enjoyed medicine, so that's what I chose.

Q. We'll start with this slide here. Could you tell the jury where you went to medical school?

A. I went to medical school at the University of Texas Health Science Center in San Antonio, Texas.

Q. And did you decide when you were there that you wanted to

become a pathologist?

A. I was thinking about it, but I really couldn't decide so I went ahead and did a clinical internship for a year to help give me more time.

Q. And where did you do that internship?

A. I did that in Monroe, Louisiana, at one of the charity hospitals.

Q. Doctor, what did you do during that year at the charity hospital?

A. It was called a rotating internship. So I'd spend months doing internal medicine, surgery, pediatrics, obstetrics, and emergency medicine.

Q. Were you spending that time treating patients?

A. Yes. It was 100 percent taking care of patients.

Q. And, Doctor, what about that internship made you want to go into the field of pathology?

A. Well, I really enjoyed clinical medicine and dealing with patients, but I found that the most interesting patients always had a biopsy or some exotic test, and that you got a really good concentration of very interesting and challenging cases in that -- in the pathology area so I decided to do a residency in that.

Q. And could you tell the jury how pathology helps with diagnosing and treating patients?

A. Sure. So we oversee all laboratory tests, which are

really critical for making a diagnosis, but particularly we interpret all of the biopsy specimens. And so we interpret things as infections or even make diagnoses of cancer and classify them so that the treating physician knows exactly what the diagnosis is, what the prognosis is, so they can determine the appropriate therapy.

Q. And, Doctor, did you pursue training in pathology after you finished that internship?

A. Yes.

Q. Let's go to that. What kind of training did you get?

A. So I did a residency that was combined in anatomic pathology and clinical pathology at the Scott & White Clinic, where anatomic pathology covers the more tissue biopsy and clinical pathology more the blood and lab test work.

Q. And did you find that the clinical work you'd done before was helpful in your further training as a pathologist?

A. Yes. It's very helpful. Most pathologists these days don't do clinical training, but it does help us understand what the need is. When someone does a biopsy, we understand, I think, better what -- what questions are being asked when they submit a specimen.

Q. And, Doctor, after you finished your residency, what was the next step in your career?

A. So I moved to the City of Hope and did a fellowship in hematopathology for two years.

Q. Doctor, what is hematopathology?

A. So it's pathology of the hematopoietic system. So it's looking at diseases or abnormalities of blood, bone marrow, and lymph nodes.

Q. Does that include conditions like lymphoma and non-Hodgkin's lymphoma?

A. Yes, it does.

Q. And, Doctor, we've heard a fair bit about the City of Hope over the last few days. Do you know Dr. Levine and Dr. Weisenburger?

A. I do. I did not overlap with them at City of Hope, but I do know them.

Q. Okay. Doctor, when you were finished with your training, did you get any Board certifications in the field of pathology?

A. Yes. I'm Board certified in anatomic pathology, clinical pathology, and hematology, which in pathology terms is hematopathology.

Q. And could you tell the jury, what does it mean to be Board certified? Why get that credential?

A. Well, first of all, to be Board certified, you have to do an accredited training program and then you have to pass a fairly rigorous examination to be Board certified, and many institutions now require Board certification to be able to have privileges to practice in that hospital.

Q. And, Doctor, as we can see on the slide, it says you have

three Board certifications. Why did you pursue three different Board certifications?

A. Well, the anatomic pathology and clinical pathology are ones that help cover all aspects of pathology; and then if you really want to practice a subspecialty and there's Board certification available, then generally you now get certified in that, and I wanted to practice hematopathology.

Q. Now, Doctor, where did you start your career after your training was complete?

A. I went back to the Scott & White Clinic where I'd done my residency and was on the faculty there for a year and a half.

Q. And where did you go after that?

A. Then I went back to the City of Hope for a staff pathologist position for eight years.

Q. And, Doctor, why did you decide to leave the City of Hope after eight years?

A. Well, City of Hope is really an outstanding institution, but it was a small place and it was a small department of pathology, and I was already the director of hematopathology there. And Stanford offered me a full professor position, and I thought it was just a better opportunity where I'd see more variety of cases and have, I think, opportunity to teach medical students and be involved with residents training, which I couldn't do at City of Hope.

Q. Well, let's talk about your time at Stanford. How did

your career progress once you got there?

A. Well, I was hired as a professor to run the hematology laboratories, which is where the basic blood tests like CBCs are done; and over time I was asked to run all the laboratories, including the anatomic pathology area, and eventually made the vice chair for clinical services.

Q. Now, Doctor, I can see on the slide that it says you're the Ronald F. -- you were the Ronald F. Dorfman Professor in Hematopathology. What does it mean that you had that position?

A. So once you're a full professor, you really can't get promoted again so to honor some faculty, you get named professorships. Dr. Dorfman was a very well-known hematopathologist at Stanford, and so I was very fortunate to get the named professorship in his honor.

Q. And was that professorship different from some of the other endowed professorships on campus?

A. Yes. Most named professorships are named after the person who donated the money, not someone that practices medicine. So it's a real honor to get one that is named after someone in your field.

Q. And you also said that you were the vice chair for clinical services. What did that mean?

A. So it had a number of responsibilities. I held the license for all the laboratories, which is a regulation that a physician has to hold all licenses for laboratories with

hospitals. And I also oversaw all the clinical faculty in the department, which were about 50 or so faculty members.

Q. And, Doctor, did you continue to teach while you were at Stanford?

A. Yes. I taught medical students, residents, and fellows.

Q. And I see there's some teaching awards listed on this slide. Could you tell the jury a little bit about those?

A. So I received the Stanford School of Medicine Teaching Excellence Award, which -- for two years in a row, and that's awarded by the medical students at Stanford. And then the Clinical Pathology Senior Faculty Teaching Award is an award they give each year. The residents in pathology give that one.

Q. Well, Doctor, why did you decide in 2016 to leave Stanford and go back east to Chicago?

A. Well, I really enjoyed working at Stanford, it's a beautiful place and an excellent department, but I was offered a chair position at University of Chicago, which is also an excellent university, and it gave me a chance to not just be over the clinical aspects of the department but the research and education aspects of the department. So I thought I would take that opportunity.

Q. Before we move on, I forgot to ask one thing, which is, did you continue to treat patients and diagnose patients throughout your time at Stanford?

A. Yes. Through my whole career, I have rotated on the

hematopathology service and diagnosed patients on that service.

Q. Well, turning, then, to Chicago, what are your responsibilities as the chair of the Pathology Department?

A. Well, there are a number of administrative responsibilities. I also oversee all the clinical aspects of the department like I did at Stanford, but now I'm over the basic science research component and the education component of the department.

Q. And do you still teach at Chicago?

A. Yes.

Q. How often?

A. I teach medical -- I teach a couple of medical student classes, but I mainly teach residents and fellows now.

Q. And, Doctor, you said a moment ago that you've treated and diagnosed patients throughout your career. Now, at Chicago are -- the patients that you treat and diagnose, are they just patients who come to the hospital in the Chicago system?

A. No, it's not just those. I do rotate on the regular hematopathology service, which are patients at the University of Chicago, and I also get consultation cases from -- mostly from pathologists across the country.

Q. And do you have any knowledge of how those cases end up getting referred to you?

A. Well, some are from people that have attended lectures that I've given or read a book chapter or a paper that I've

written on the topic that they're struggling with, and they'll send the case to me to help them with the diagnosis.

Q. And do they tend to send you the easy cases or the hard cases?

A. They only send the hard cases because pathologists are well trained, and so they -- it's usually something where they have a -- they've gotten to a point that they can't really make a decision about a diagnosis so they send it.

Q. Now, Doctor, a few minutes ago you mentioned something called basic science research, and I think we heard last week that that's the type of research that Dr. Weisenburger does as well. Could you tell the jury what that is?

A. So as the name implies, it goes -- it's more science based. It's not as much as patient-based research, so it includes animal studies, transferring genes to animals to see what happens, looking at cell cultures to see what happens in a petri dish, and that's opposed to more translational research that often is more clinical and directly patient related.

Q. Well, what type of research do you do?

A. Mine is almost entirely clinical and translational, where I -- my focus is on the diagnosis of hematopoietic tumors and determining prognosis based on features that a pathologist will see often under the microscope or doing other testing.

Q. Does your work typically draw from actual patients who are undergoing treatment?

A. Yes. It's almost -- it's all patient sample testing, yes.

Q. Well, let's talk a little bit about some of your research. How much have you published within the field of pathology?

A. I have about 230 peer-reviewed papers, I have nine books, and I have just under 80 book chapters I've written.

Q. And have you served as a reviewer for other people's articles?

A. Oh, yes.

Q. And, Doctor, are there any publications that you're particularly proud of?

A. Well, I did a lot of work with the World Health Organization. So the World Health Organization or WHO writes the classifications of diseases, and so in 2008 and 2016 were the last two editions for hematopoietic tumors, and I wrote many of the chapters for those books and was very actively involved in the 2016 version.

That also resulted in a publication in the journal *Blood* that summarized the classification. And both of those actually had papers that summarized the classification that were I think probably my top publications.

Q. And do you have a sense of whether those two publications are used by doctors in practice?

A. I have a good sense of that. They've been cited thousands of times so that means that when other people are writing papers on topics, they use that as a reference. And so those

papers are very highly referenced because the WHO classification is pretty much universally accepted.

Q. Well, Doctor, let's spend a few minutes to talk about the work that you did in this case in connection with Mr. Hardeman.

A. Okay.

Q. What questions were you trying to answer once you became involved?

A. So I was asked to look at his medical records and his pathology material to determine -- confirm the diagnosis and to see if I had any -- if I saw any features that may suggest the cause of his lymphoma.

Q. And what materials in particular did you review when you were forming your opinions?

A. I did look at Mr. Hardeman's medical record. I received the pathology slides from a number of different specimens and reviewed those.

Q. And, Doctor, what do you mean when you say you looked at the pathology slides?

A. So whenever you have a biopsy, the tissue is processed and slides are cut from it, and I received those original slides as well as the additional ancillary studies that were done to help come to the diagnosis.

Q. So did you have an opportunity to look at Mr. Hardeman's actual tumor?

A. Yes.

Q. And, Doctor, what other materials did you review? Did you have a chance to look at medical records, anything like that?

A. Yes. I had all of his medical records.

Q. And did you have a chance to review any testimony from either his doctors or Mr. Hardeman himself?

A. Yes. I reviewed his -- Mr. Hardeman's deposition and depositions from his treating physicians.

Q. Now, Doctor, when you looked at those -- could you tell the jury when it was that you looked at those pathology slides you mentioned earlier?

A. Well, I think it was in late November, early December.

Q. Okay. Well, did you also have a chance in forming your opinions to look at the reports and conclusions from Dr. Weisenburger?

A. Yes. I have reviewed those.

Q. And do you know when he had a chance to look at the pathology slides?

A. From his testimony, I believe it was a couple of weeks ago.

Q. And you anticipated my next question, which was, did you have a chance to look at the testimony that he provided to the jury last week?

A. Yes.

Q. Okay. Let's spend a minute talking about non-Hodgkin's lymphoma in particular and use your training in pathology to

maybe illuminate that a little bit.

A. Okay.

Q. I'll get to that in a second.

Doctor, what is lymphoma?

A. So lymphoma in the broadest sense is essentially cancer of lymphocytes, and lymphocytes are a subset of the white blood cells you have circulating in your body, and they -- and you can break down lymphoma into two broad groups: One is Hodgkin's disease, which is now called Hodgkin's lymphoma, and the other is non-Hodgkin's lymphoma. And those were separated because we originally thought they were two completely different diseases that were unrelated. Now we know they're both lymphomas arising from lymphocytes.

Non-Hodgkin's lymphoma is broken further down into B-cell and T-cell types, and there are just dozens of subtypes of non-Hodgkin's lymphoma.

Q. And, Doctor, did you bring some slides to help explain the lymphatic system to the jury?

A. Yes.

Q. Let's start with the first one of those. What are we looking at here, Doctor?

A. So this is a sketch of a human, and the green dots represent lymph nodes throughout the body. So lymph nodes are the site where lymphocytes can reside. They circulate in blood but they also reside in lymph nodes. And these are the areas

of your body if you get an infection, you feel a lump where it swells, that's a swollen lymph node.

And the lymphatic system parallels the blood vessel -- the blood system in that it has little tubes or lymphatics that connect these lymph nodes. Blood doesn't pass through those but lymphocytes do, and they circulate throughout the body and also will get into the blood and circulate.

Q. Doctor, you've mentioned the lymphocytes a few times. Do you have a slide to help explain what those are?

A. Yes.

Q. Let's go to that. Can you walk the jury through what we're seeing on the screen here?

A. Sure. There's two main categories of lymphocytes. There's T cells and there's B cells. And T cells are the most common in both your blood and in your tissues, and these are cells that are less targeted. So the whole purpose of lymphocytes -- well, the main purpose is to help fight off when you have an infection or any type of foreign thing enters your body.

T lymphocytes are a little less specific. They're already honed and can attack different infections or antigens and help kill them, but they're not specific to whatever that infection is.

B cells are a lot less numerous in your body but, as I mentioned, I think the majority of lymphomas are of B-cell

lineage. These cells also fight off viruses and bacteria and other foreign things in your body, but it takes a little longer for them to respond because they become very specialized against the antigen or infection that you have.

Q. Now, what happens in these cells when someone gets lymphoma?

A. Well, I'm going to focus mainly on the B cells because that's, I think, relevant here and that's the vast majority of lymphomas.

So the B cells, as they're becoming specialized against an antigen, they reshuffle their DNA. And so every cell in your body has the same DNA, but the DNA gets shuffled to be specific for that cell type. And these cells reshuffle their DNA to make proteins that are directed against the antigen that they are trying to kill, and then they survive and multiply and then go out and kill it all over your body. And that's when you get immunity is when that happens.

So that takes a number of days. So if you get a cold, it takes a number of days before your B cells can get activated and start fighting back, and then it takes a few more days to kill the virus or not get down to a point where you get over your cold.

But if you got that exact virus again, they'd be ready very quickly and fight it off quickly. You may not even realize you're sick.

Q. Well, what happens -- what goes wrong in the case of a patient who has lymphoma?

A. Well, this reshuffling process that makes the B cells very specific just by its nature will result in abnormal reshuffling, which can lead to a lymphoma. The vast majority of times that reshuffling results in a cell that just dies off; but on rare events, it will have a genetic defect that can go on and lead to lymphoma. It doesn't always and you can detect genetic events associated with lymphoma in normal people if you look really, really hard, and presumably those cells just die off, but every once in a while one of them starts dividing and years later you develop lymphoma.

Q. Well, you mentioned years. How long does it take for cancer to develop from one of those mutated cells to something that you can actually diagnose?

A. Well, it certainly varies. Some cancers are more aggressive than others, but you have to remember you're starting with a single cell. That genetic event occurs in one cell, and by the time you have detectable lymphoma in your body, you have millions of cells. So it takes truly years in most patients to get to the point from that one cell to the time that you have clinical lymphoma.

Q. And we've heard that Mr. Hardeman had a specific type of NHL called diffuse large B-cell lymphoma. Could you explain to the jury what that looks like under the microscope?

A. Okay. So diffuse large B-cell lymphoma is the most common lymphoma, and the name really describes it.

So when we look under the microscope, we are trained to know what a normal lymph node looks like. It has a pattern that is very typical. In diffuse large B-cell lymphoma, that pattern is gone and there's a diffuse proliferation of cells instead of nodules that we would expect in a normal lymph node. So that's the diffuse part.

The cells are large so we realize they're bigger than normal looking under the microscope, and then we do studies to tell they're B cells. We can't tell by looking at the cells whether they're B cells or T cells because they look the same under the microscope on a routine slide. So if it's diffuse and they're large and they're B cells, that's diffuse large B-cell lymphoma.

Q. Well, Doctor, what causes -- I think we're done with the slides.

What causes diffuse large B-cell lymphoma to develop?

A. Well, in -- the vast majority of cases are idiopathic, meaning we don't know the cause. There are subsets of cases that do have known causes. The most common are related to immunodeficiency. So patients that have HIV are at risk for -- very high risk for getting lymphoma, patients who have had organ transplants or are taking drugs that make them immunodeficient will have a much higher risk for lymphoma, and

then certain infectious agents increase your risk for lymphoma, both viral and bacterial.

Q. How often is it that you're able to determine a specific cause for a patient's DLBCL?

A. From the pathologist's perspective of looking at the slides, only about 10 percent of the time can we determine a cause of the lymphoma.

Q. So what happens in the other 90 percent of cases?

A. Most are just generally considered to be idiopathic.

Q. Well, we've also heard a few times about this concept called a risk factor. Within the field of pathology, what does that phrase mean to you?

A. So there are certain things that put you at a little bit higher risk of getting lymphoma or, you know, just a number of diseases. There are risk factors for just about all diseases. Some of them are things like age and sex and even race can be risk factors for getting certain diseases because we know some races have disease more commonly than others, but none of them really are specifically defining of the disease.

Q. Well, in those 90 percent of cases, are there risk factors present?

A. Yes.

Q. Well, if there's risk factors present, why aren't you able to determine the cause of the patient's lymphoma?

A. Well, they're usually minor risk factors in that they're

increasing the risk by maybe 20 percent, something like that. That doesn't mean that's the cause of their disease. So one of the risk factors in non-Hodgkin's lymphoma is being a male, but not all males get non-Hodgkin's lymphoma just because of their sex. There are other things going on that can cause you to have disease.

And we're constantly looking for -- looking at the biology of lymphoma and all diseases to try to understand more about them; and if you went in automatically and assigned a risk factor as the cause of a disease, you don't have the opportunity to really discover the real cause if you can find it.

There's certainly you can have inherited causes of disease that may actually be spontaneous where this is the first patient that has it. If you assigned a risk factor of age or sex as the cause, then their other children may not be able to be screened.

Q. I think we're coming close to the end of our time today, but I'd like to just talk, if I could, briefly about methodology, yours and Dr. Weisenburger's.

A. Okay.

Q. Could you walk the jury through the method that you used in reaching your conclusions in this case?

A. So I reviewed the medical record because clinical information is very important for making a diagnosis. We don't

as pathologists make it just blindly by looking at the slides.

Then I reviewed the slides. There's what's called a hematoxylin and eosin stain slide, and that is kind of the type of stain we do for every type of tissue that we get, and that's the starting point for doing an evaluation as a pathologist. And then we look at additional stains, which are usually immunohistochemical studies, which help us.

So I looked at the H and E section, which was suggestive of a diffuse large B-cell lymphoma, but I mentioned I can't tell if it's a B-cell or not by just looking at the microscope. So there were a number of other stains that were done by the pathologist that confirmed that the large cells were B cells and confirmed that diagnosis.

And then there were a variety of other tests that were done that were stains, as well as genetic tests, to determine the prognosis -- prognostic risk group in Mr. Hardeman.

Q. And what did you conclude from looking at those materials?

A. That the -- I agreed with the diagnosis of a diffuse large B-cell lymphoma.

Q. And were you able to determine the cause of Mr. Hardeman's NHL?

A. No. Looking at the slide, it's not possible to determine the cause. There were not features of a immunodeficiency-associated lymphoma. Epstein-Barr viral studies were performed, which is one cause, and they were negative. So I

was not able to determine a cause looking at the slides.

MR. KILARU: Your Honor, at this point I'd ask permission to publish a slide that was shown during opening statements from plaintiff's opening. It's not marked so it would be, I guess, Exhibit 1687 is I think the number we're at.

(Trial Exhibit 1687 marked for identification)

THE COURT: Do you have a copy for me, and have you --

MR. KILARU: I will get a copy of it, yes.

MS. MOORE: Your Honor, it's the differential blowup that we used.

THE COURT: Oh. That's fine.

MR. KILARU: Is that okay?

THE COURT: I think so. Let's make sure there's no objection from them.

Any objection?

MS. MOORE: Oh, no, Your Honor. I apologize.

THE COURT: Thank you.

Go ahead.

MR. KILARU: And, Ms. Melen, can I have the Elmo, please.

Q. Now, Doctor, you said earlier that you had a chance to review the testimony that Dr. Weisenburger provided to the jury?

A. Yes.

Q. And are you familiar with a chart sort of like this that

was used during his testimony?

A. Well, from his testimony, this sounds familiar, yes.

Q. So I think what we're looking at is a chart that lists some risk factors for NHL and then has fields for whether they were Mr. Hardeman's risk factors and a substantial factor. Is that what you're seeing as well?

A. Yes.

Q. Doctor, have you ever used a slide or a chart like this in diagnosing a patient?

A. No.

Q. Have you ever seen any of the doctors you've worked with over the course of your career use a method like this?

A. No.

Q. I think what followed, then, was Dr. Weisenburger going through this chart and filling it out.

MR. KILARU: And if I can publish just a later slide.

MS. MOORE: Your Honor, no objection but just to clarify, this is from opening. This is not what Dr. Weisenburger did.

MR. KILARU: Sure. It's from the opening.

THE COURT: That's fine.

MR. KILARU: So I'm putting up what we'll mark as 16, I think, 88 for identification.

(Trial Exhibit 1688 marked for identification)

\\\

BY MR. KILARU:

Q. Doctor, as you can see on the screen, there's sort of a list -- some risk factors crossed off and then there's a conclusion on the right -- or there's a marking on the right that Roundup was a substantial factor in Mr. Hardeman's NHL. Is that what you're seeing as well?

A. Yes.

Q. And is it your understanding that this is basically the methodology that Dr. Weisenburger used in this case?

A. Yes.

Q. Doctor, have you ever used that methodology in diagnosing a patient within your career as a pathologist?

A. No.

Q. Have you ever seen anyone else you work with use this kind of methodology?

A. No.

Q. And do you believe as someone who's been practicing in pathology for -- how long is it now?

A. 26 years.

Q. -- 26 years, do you believe that this is a valid way of identifying the cause of a patient's NHL as a pathologist?

A. No, I don't.

Q. Why do you say that?

A. Well, it lists a number of risk factors. It ignores some of them like age, sex, and race, all are risk factors; but it's

not -- first of all, you can't just make a list of risk factors and then just mark them off and diagnose with what's left on the list because idiopathic is the most common thing here.

And if you assign a risk factor as the cause of the disease even if it's a weak risk factor, you again lose the opportunity to discover future risk factors that may be very important for the patient.

And if you look at this, things like obesity and viral infections have risk factors of about 1.2, 1.3; and even if you accepted pesticide use, it had some more risk factor. So why would you choose one over the other? These are all relatively weak even if you accept pesticide use as a risk factor.

Q. And, Doctor, just going through this, if you crossed off risk factors that you didn't think applied, would you automatically be able to determine that whatever is left was the thing that caused someone's NHL?

A. No.

Q. And do you think that Dr. Weisenburger's methodology gives adequate consideration to the possibility that Mr. Hardeman's cancer was just idiopathic, that we can't determine the cause?

A. No. Using this methodology, you could never get to idiopathic I don't think.

MR. KILARU: Your Honor, I'm happy to keep going, but --

THE COURT: No. It sounds like this would be a good

time to break for the day.

So, ladies and gentlemen of the jury, let me just give you a quick minute -- let me give you a quick update on where we are.

As I mentioned at the beginning of this trial, from time to time we'll be asking you to deliberate in the middle of the trial on specific questions, and we're getting to the point where we're going to ask you to do that on Phase I, this issue of medical causation that we've been dealing with here.

So what I expect in terms of timing -- sorry to make you sit here and listen to this -- but what I expect in terms of timing is that tomorrow morning we will wrap up with Dr. Arber, and then we will go to closing arguments from the lawyers on the Phase I portion of the case and you will begin your deliberations.

What that means in terms of scheduling and terms of timing is as follows:

As you know, I usually get you out of here at right around 2:30, give or take; but when you -- I want you to start thinking about this now -- when you begin deliberating, and you'll almost certainly begin deliberating tomorrow -- okay? -- when you are deliberating, you can collectively make the decision to stay through the close of business; right? You can stay past 2:30 if you wish to continue your deliberation.

So you might even want to have a little bit of a chat

about that now when you go back there to see if you're interested in going past 2:30 tomorrow.

And then if deliberations go on to Thursday, you are also -- you can also come in and continue your deliberations on Thursday even though that isn't a normal trial day for us.

So I wanted to plant those thoughts in your head right now, but you can plan on hearing closing arguments from the lawyers tomorrow and almost certainly begin your deliberations tomorrow.

With that, remember all my admonitions, and we will see you tomorrow morning. Please try to be here right at -- please try to be in the building well before 8:30 so that we can start right at 8:30 sharp. Thank you.

THE CLERK: All rise.

(Proceedings were heard out of the presence of the jury:)

THE COURT: Okay. You can step down, Dr. Arber.

Okay. So why don't we get back together at 3:00 o'clock and talk about jury instructions and closing arguments and anything else that you-all need to talk about. Okay?

MS. MOORE: Thank you, Your Honor.

MR. STEKLOFF: Thank you, Your Honor.

THE CLERK: Court is in recess.

(Recess taken at 2:38 p.m.)

(Proceedings resumed at 3:01 p.m.)

(Proceedings were heard out of presence of the jury:)

THE COURT: Okay. So let me ask first on the jury instructions, are there any objections to any of the instructions other than causation?

MR. KILARU: Your Honor, we had one suggestion and then one additional instruction that we thought should be given.

THE COURT: Okay.

MR. KILARU: So the suggestion is on Instruction Number 9 -- this is the regulatory agencies one.

THE COURT: Okay.

MR. KILARU: We have two proposals. I think first, given that I think the evidence on both of these fronts has been appropriately limited in how it comes in, our concern is actually saying "other health organizations" may be a little too vague in terms of making clear that what we are talking about here is IARC. So we proposed to change that to, regulatory agencies and IARC have reached conclusions about, because those are the bodies that we have focused on and the bodies we are talking about when we get to this instruction.

THE COURT: Yeah, I mean -- there was a mention of the American Cancer Society today, for example. Any objection to that?

MS. MOORE: Yes, Your Honor. We wouldn't want to single out IARC versus EFSA or EPA or anything else. I mean, we shouldn't just be singling out IARC as one that they

shouldn't reach a conclusion about.

THE COURT: Okay.

MR. KILARU: Just on that, Your Honor, I think our point is that I think it is pretty clear that EFSA, EPA and Health Canada are regulatory agencies. It is not as obvious that IARC fits into this, based on what the jury has heard, this category of other health organizations.

THE COURT: But the bottom line is when they -- whether we word it you are proposing or the way I'm proposing, they are going to know not to defer to IARC. They are going to know not to defer to EPA. They are going to know not to defer to EFSA.

MR. KILARU: The concern is it is not clear that they will with respect to IARC. It is not obvious that this instruction is applying to that. I think the concern is it could lead to the opposite, which is the jury thinks disregard the regulators; but then there is this thing called IARC which is part of the World Health Organization and we can take that for what it is.

THE COURT: Okay. So I assume you might even say -- you might even propose EPA, EFSA and IARC have reached their own conclusions. You shouldn't substitute their judgment for yours.

MR. KILARU: I think that would be fine as well.

MR. STEKLOFF: I have another concern, Your Honor,

which is as phrased "other health organizations," I mean, I don't think this would happen, but it is possible they could think, say, the National Cancer Institute is another "health organization." And we have been talking about the National Cancer Institute so much in the context of AHS. And so I think without being specific, it is potentially problematic.

We have no objection to specifying the regulatory agencies if that is a concern. But I think the phrase "other health organizations" is too ambiguous for the jury, given -- and I would specifically flag the National Cancer Society.

THE COURT: What would be wrong with saying the Environmental Protection Agency, the EFSA, whatever that stands for and the IARC have reached conclusions about glyphosate?

MS. MOORE: Your Honor, I don't think it is necessary. I mean, we could go on and on with defining what this means and what it entails. I mean, I think the Court is going to be very clear in your instructions to the jury that they are not to substitute these conclusions for their own that they draw from the evidence. So I don't think we need to actually identify one versus the other or all or go through the transcript and try to figure out to make sure we have listed everything.

THE COURT: Okay.

MS. MOORE: I think the instruction is sufficient as it is.

THE COURT: I think you could also -- it should

probably say You have heard testimony that, and then whatever phrasing we would use. I think it would be fine to say you have heard testimony that EPA, EFSA and IARC have reached conclusions about glyphosate.

MR. KILARU: That would be fine with us, Your Honor.

THE COURT: Okay. I think that is probably the most appropriate way to do it.

MS. MOORE: So how, Your Honor, would you be changing that then?

THE COURT: You have heard testimony that EPA, EFSA and IARC -- and we will put the -- we will put the full names, then in parentheses the acronyms, have reached conclusions about glyphosate.

MS. MOORE: Okay. So you would just replace "regulatory agencies and other health organizations" with that?

THE COURT: Yeah.

MR. KILARU: I think there might be one more, Your Honor. We can scrub to make sure we are not missing any, but I think ECHA was discussed during --

THE COURT: What is that?

MR. KILARU: I don't know which acronym it stands for, but I know they were talked about in the context. The European Chemical Health Association, I believe. It came up in the Portier deposition.

THE COURT: Well, what is that? Is that a regulatory

agency.

MR. KILARU: Yes, it is.

MS. MOORE: Your Honor, again, this highlights the problem here. I think that if the Court is going to give an instruction to this effect, which I believe that initially we objected to that, when we first saw the original jury instructions, that I don't think it is necessary to keep going through a litany of these. I think what you have here would be sufficient.

MR. KILARU: I think it is four things total based on our review of Dr. Portier's testimony. I don't know that it is an unduly long list. I think there are concerns as Mr. Stekloff contributed with both the just the phrase "health organizations."

MS. MOORE: It is going to cause jury confusion, Your Honor. Because then what are they supposed to give weight to? What are they not supposed to give weight to?

THE COURT: Well, they are not supposed to give weight to the EPA or EFSA or ECHA or IARC. And they are supposed to give weight to the AHS if they decide that it is worth giving weight to.

MS. MOORE: Right. And, again, I think what they are getting at is they are going to say in closing the AHS is part of a governmental study, and so they are going to use this instruction in their favor in that sense.

MR. KILARU: I don't think we are going to tie anything we say about AHS to this instruction, Your Honor. I think this instruction relates to the way in which we present evidence of what the regulators do and what IARC did.

THE COURT: Okay. I think it would be appropriate to list those four, and that is as of now, unless I tell you otherwise, tonight that's what I will do.

You said you had one other thing other than causation?

MR. KILARU: Yes, Your Honor. There is, I think, a pretty standard -- actually just on this instruction one other suggestion. I think this is less important but just wanted to suggest it. In your original instruction there was much more text about IARC and risk versus hazard, and I think we agreed that that doesn't need to happen given the testimony, but it could be appropriate to include something like The question you must answer here is different from the question those organizations have considered, something like that.

THE COURT: I think -- I -- I understand that suggestion, but I think actually in light of this instruction and in light of the limited way that that evidence has come in, that's not necessary. And I would want to refrain from saying something that would further confuse the jury.

MR. KILARU: Okay.

The other instruction, Your Honor, is that there is -- I think pretty standard -- there is a California -- there is a

CACI version 104, and there's a Ninth Circuit model 4.1, just an instruction about how corporations are entitled to the same treatment as individuals. 4.1, the language is: All parties are equal before the law and a corporation is entitled to the same, fair and conscientious consideration by you as any party.

The 104 California instruction is a little bit longer. I but think those are pretty standard in cases involving a corporate defendant and we ask that --

THE COURT: Any objection?

MS. MOORE: Yes, Your Honor. With respect to causation, I don't think that's necessary. If we are talking about liability of the company, I think that that would come into play.

MR. KILARU: It's still relevant given that we are presenting evidence as to causation, and they are a corporation.

THE COURT: The question is whether this corporation's product causes cancer and caused Mr. Hardeman's cancer. I mean, can you -- I understand the point you made.

Can you think of anything -- how -- can you imagine it would create any problems giving this instruction?

MS. MOORE: Well, it may create jury confusion, Your Honor, with respect to the issue about just causation. I mean, I don't think it creates jury confusion when you are talking about a liability instruction. But in this situation

when we have limited it to one question that they are answering on the verdict form, I don't think it makes sense to do that in this case.

THE COURT: I'm just pulling up the Ninth Circuit now, the instruction.

MR. KILARU: I think I might have said this, but it is 4.1, Your Honor.

THE COURT: Okay. I'm pulling these up on the Ninth Circuit website, and it gives you a WordPerfect version.

MR. KILARU: I saw that. I had to find it elsewhere. I haven't used that in a while.

(Whereupon, a brief pause was had.)

THE COURT: Yeah, I think this is fine. This is appropriate to give now, so we will add that.

MR. KILARU: That was all from us other than causation, Your Honor.

THE COURT: Okay. Anything else from the Plaintiffs, putting aside causation for the moment?

MS. MOORE: Your Honor, I think the only thing was I didn't know if we were going to have an instruction about the video depositions and giving them the same weight as someone who was a live witness here. I know you have the What is evidence, Instruction Number 2, and it says the sworn testimony of any witness. I think under the model instructions there is something about video depositions. And so I would have to go

back and pull that. And I can get that for, Your Honor, too.

THE COURT: Well, I have given that to them during trial. I have no problem with kind of repeating it as I give them the instruction about what is evidence.

MS. MOORE: Okay. Thank you, Your Honor.

THE COURT: We should -- so what I can do is just in that Instruction Number 2, What is evidence, I will just say the sworn testimony of any witness. And as I instructed you before, insofar as possible you should consider deposition testimony presented to you in court in lieu of live testimony in the same way as if a witness had been present to testify.

MS. MOORE: That's fine, Your Honor. There is a model instruction. It is 2.4. I just found.

THE COURT: I just read from it.

MS. MOORE: Okay. That's fine.

I think the only remaining issue, Your Honor, would be the causation instruction.

THE COURT: Okay.

All right. On the causation instruction -- oh, I did want to flag one more thing, just to make sure you noticed it. On the credibility instruction, Number 5, Credibility of witnesses, I just wanted to make sure that you noticed that I removed a portion of that instruction from the model on the theory that it didn't seem particularly pertinent to this phase of the trial. It was the part of the model instruction that

talks about how, you know, if you think somebody is lying about one thing you can disbelieve their entire testimony, if you want to; or if you think they are lying about one thing, you can still believe other parts of their testimony, if you want to.

There -- there is a whole -- there is a kind of a series of clunky paragraphs on that topic in this model instruction that I thought I would propose to eliminate, at least for this phase. I don't have superstrong feelings about it, but I just wanted to make sure I flagged for you that I, in fact, eliminated those paragraphs.

MS. MOORE: Okay. Thank you, Your Honor. I have pulled that up. I don't have any objection to your removing those two paragraphs.

MR. KILARU: I think we would be inclined to leave it in, but don't feel strongly about it, Your Honor. I recognize it is a fair amount of text. I do feel that witnesses on both sides have probably been impeached in one way or another. It is fair for the jury to consider that as they go to evaluate the testimony.

THE COURT: Well, my plan walking in was if one side objected and wanted this -- that language in, I would put it back in, even in my view it is not necessary. It is from the model. I don't want to unwittingly deprive somebody of an argument that they might want to make in closing.

MR. KILARU: We would prefer you to leave it in, Your Honor.

THE COURT: Okay. Now, on causation. Here's -- let me try and capture my struggle for you.

On the one hand you have all this language from all these cases that talk about how a multiple causation instruction is going to be very rare, right. And you say normally you give the but-for sentence and you don't give the multiple causation instruction. It is going to be a very rare situation where you do that, okay.

And my concern is that if -- if you are giving it in every case where there are competing risk factors and one side says Risk Factor A caused the medical condition, the cancer, and the other side says Risk Factor B caused the cancer, and then you must give the multiple causation instruction, all of a sudden you are bringing in -- I would think anyway -- a significant percentage of cases where medical causation is at issue.

And so something about that makes me feel uncomfortable, all right. And it makes me wonder, Well, maybe the way that this rule should be interpreted is that you give the multiple causation instruction only in a situation where we know that two things contributed to the harm.

And in a situation where we know that two things contributed to the harm, we have to make sure that the jury understands that just because one thing contributed to the

harm, that doesn't necessarily mean that you conclude that the other thing wasn't a substantial factor.

So two fires are started at the same time and they both combine to burn down the barn, right. Or they both combine into one fire and then the barn is burned down. Even if one fire hadn't started, the other fire would have burned down the barn. And therefore both --

So I suppose that might be a way to interpret the rules' application narrowly. In a way that comports with the general statements that the Courts seem to intone that, you know, this is going to be a rare instruction.

On the other hand, it strikes me as potentially misleading to the jury to not have a multiple causation instruction in this case and to have the but-for sentence. I assume that Monsanto would agree -- let's change the facts of this case a little bit, okay.

Hypothetical: I assume Monsanto would agree that if somebody was negligently responsible for causing Mr. Hardeman's hep C in the '60s, that Mr. Hardeman could sue them for causing his non-Hodgkin's lymphoma, right? Putting aside any statute of limitations issue or whatever, right. But you would agree that he could sue the person who caused his hep C and -- assuming it was negligent -- and prevail on the causation question in a jury trial, right?

MR. KILARU: Right. I think we think the standard

there would be but-for as well, but I think he could bring that suit, yes.

THE COURT: He could bring that suit, and he could establish that hep C was a substantial factor in causing his NHL.

MR. KILARU: Yes. I think if his theory were different than here, which is that it was not hepatitis C. But I think sort of following what I understand --

THE COURT: Right. So you have, in fact, presented evidence from which a jury could conclude that his NHL was caused by hep C, right?

Or let me put it a little bit more precisely. You have presented evidence from which a jury could conclude that hep C was a substantial factor in causing his NHL.

MR. KILARU: Yes. And not Roundup.

THE COURT: Yes, you have also presented substantial evidence that it was not Roundup.

So a jury could conclude that based on the evidence that you have presented in this case. But if the jury concludes that, it doesn't automatically preclude the jury from concluding that Roundup was a substantial factor, I would think.

MR. KILARU: I think that is not correct in this case, Your Honor, at least based on the way the evidence has come in. And that's ultimately what I think our bottom line argument on

this point, because this isn't a case where anyone has said that the hepatitis C could have been caused by both or that at the same time these things were --

THE COURT: Meaning that the NHL could have been caused by --

MR. KILARU: I get it now. There is one NHL, and their expert, Dr. Weisenburger, has said, and I think we have seen the charts and so on, it was Roundup and it was not something else. And our position is basically it wasn't Roundup, and we have presented hepatitis C as an alternative.

But I don't think there is any basis in the record for the jury to say, Well, based on what I have heard, if I believe it was Roundup, I could still believe -- or if I believe it was hepatitis C, I could still believe it was Roundup. Because they have been represented with binary alternatives, one or the other. I don't think in that.

THE COURT: Right.

MR. KILARU: -- in that circumstances --

THE COURT: I suppose you would add that they could have, if they wished, presented expert opinions which said, number one, I believe that the NHL was caused by Roundup and that Roundup was the only substantial factor. But my secondary opinion -- second best choice to use Dr. Levine's concept --

MR. KILARU: Right.

THE COURT: -- is that at a minimum, the Roundup and

the hep C combined to cause his NHL.

And by the way, there would have been -- had they chosen to present such evidence, I assume there would have been scientific support for it. I mean, you disagree that there is scientific support for the idea that Roundup causes NHL, but assuming for the moment that, you know, the jury is allowed to present that. If you have two things that cause cancer, I presume what it means, based on the testimony that has all come in here over the last few days, is that the more -- the more risk factors that are operating on this person, the more genetic mutation and the more likely cancer is to result, right?

And so they could have presumably presented that alternative opinion, and they didn't. And having not presented expert testimony in support of that theory, they should not get the benefit of the instruction. That's your argument.

MR. KILARU: Essentially --

MS. MOORE: Your Honor.

MR. KILARU: Essentially, yes, Your Honor. I think if they try to present that type of sort of combined or, I guess, sort of synergistic cause theory, I don't think this is really germane to your point, I would just say we might have scientific and other validity challenges to that methodology.

And sort of taking that away, because I think that might be an issue that comes up later in other issues, for now I

think that is essentially our argument that all we have is A or not A. And I think in a situation where you have A or not A, there is really no -- we think no basis in California law from departing from I think the general rule, which I think is pretty clear, the general rule that we are in a but-for situation.

THE COURT: But -- but I guess the issue that I'm struggling with is that you seem to be saying that the jury must either -- sort of buy the Plaintiff's experts' theory or the defense experts' theory. Why can't they buy both?

MR. KILARU: Because there has been no evidence that will allow them to buy both. The one side's view of the world was that it was Roundup and not hepatitis C. Dr. Weisenburger crossed it off and said it has nothing to do with my opinion. He was the only case-specific opinion they offered. And certainly no one from our side has said that Roundup and hepatitis C can work together and you can still have Roundup as the cause if hepatitis C were present. I mean, ultimately we have said -- as you know, our main position is that it wasn't Roundup, and that's what we sort of focused on and that's what I think the emphasis will be in closing.

I think we are entitled to present other things so that the jury has other things to consider so we are not just saying it wasn't Roundup. But I don't think that means we are putting in the juror's mind or presenting some valid scientific

evidence that the two things can work together. And that's what the jury would have to think for this -- it was both view. I don't think there is any evidence of that.

THE COURT: What if the jury -- what if the thought -- you know what, I believe Roundup causes -- I have listened to the testimony, and I believe that Roundup causes NHL, general causation. I buy the Plaintiff's argument on general causation. And, you know, I view -- and I think there is a good argument that Roundup caused Mr. Hardeman's cancer, but there is a really strong argument that hep C caused -- was going to cause his cancer anyway. Let's just say he would have gotten it anyway from hep C. He had active hep C for 39 years after all.

So I believe that hep C is the strongest -- was the strongest risk factor, and so I'm going to say that his cancer was caused by hep C.

But they still -- I guess the way -- I guess you can see that I'm struggling with this too. I guess the way to put the question to you is, is there a risk that if you include the but-for sentence that the jury will say -- will think, oh, what this but-for sentence means is that if I think he would have gotten it from hep C anyway, then even if I think he got it from Roundup, I should find for Monsanto. That's my concern.

MR. KILARU: I don't think based on the way you phrased Option Number 2, Your Honor. Because I think the last

sentence you put in there captures that point. But to me the really important point that we need to sort of shelter against the other side is the risk that the jury says could have been either, so therefore -- and I don't know which it was, but it could have been either, therefore, the Plaintiff wins. That's why I think the but-for requirement is so essential.

If I can just -- on the point you made about what if the juror -- this sort of hypothetical juror who thinks maybe it was possible that Roundup was in the mix, but I think hepatitis C was, you know, overwhelmingly the substantial factor here. I think if the juror --

THE COURT: Well, my hypo is a little different. It was my fault because I sort of -- it was pretty convoluted in the way I tried to present it.

MR. KILARU: That's fine.

THE COURT: My hypo is -- okay. So let's go to the actual language of the proposed instruction. Okay?

MR. KILARU: Okay.

THE COURT: Let's look at this sentence that says Conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct. Okay.

The thing I'm worried about here is what if the jury says, Well, I think the Roundup caused his cancer, but it would have -- he would have eventually got the cancer anyway from hep C.

MR. KILARU: I don't think that's what we are arguing, Your Honor, so I don't think that's really a concern about the way the case has come forward. The way we have presented the case to the jury -- and I think the way both sides have presented the case to the jury -- is that the substantial factor is either one thing or the other. And Dr. Weisenburger actually used the term "substantial contributing cause" in his testimony, and he said what that is in this case is Roundup. It is nothing else.

THE COURT: That's what makes this -- this case kind of weird, right? I mean, I would think usually you would have an alternative expert opinion that says, you know, even if you don't think it is the sole cause, the two things combine. I believe, the two things combine to --

MS. MOORE: And, Your Honor, for two things. One, on that sentence that the Court has pointed out that you are worried about conduct is not a substantial factor in causing harm, the same harm would have occurred without the conduct, that is the but-for test. And that has been repudiated under California law for these kind of cases.

And I will just say that Dr. Weisenburger listed the risk factors and included hepatitis C. There is no question that a juror -- and we can -- we will argue our position; they will argue their position. But the evidence is that Dr. Weisenburger considered hepatitis C as a risk factor, just

like Dr. Levine did. Dr. Levine says it is the most likely cause. Dr. Weisenburger says Roundup is the most likely cause. But he also testified that he couldn't just eliminate hepatitis C completely.

So absolutely a juror could say, you know what, I think it is Roundup; also could be hepatitis C. And but if they read this sentence, they are going to find -- they would find for Monsanto, if they are thinking that, Well, if it is also hep C then I can't find for the Plaintiff. But they also might have said, We met our burden of proof. I think it creates jury confusion, and this is the case --

THE COURT: I mean, the problem -- I will say on the issue of jury confusion, I mean, one of the problems with -- when you are looking at Option 2 now, and we are looking at the second paragraph, and one of the problems is that the -- the first sentence and the second sentence seems somewhat at odds with one another, right. And that is a concern that I have with that paragraph. I'm just not 100 percent sure what the solution is.

MS. MOORE: Well, I think the solution is Option 1, Your Honor. Option 1 is very clear. I mean, the first paragraph -- the first paragraph of both, I believe, are identical. But the second paragraph for Option 1 is the one that I think prevents jury confusion in this case. California, for product cases like this, is a substantial factor state.

THE COURT: Well, can I ask you -- what do you think is your best case for the argument for giving this instruction?

MS. MOORE: Option 1, Your Honor. Is that what you are talking about?

THE COURT: Either one.

MS. MOORE: Well, I mean, in this case you have multiple causes that are being presented to the jury. And in the case I pointed out, Your Honor, this morning, the Logacz versus Limansky case, that is what happened in that case. There was a defense expert who presented a causation theory and a Plaintiff's expert that presented a causation theory. And the trial court did not offer the concurring causation instruction and the Court of Appeals reversed on -- and said it was reversible error not to do so in that case.

So in this situation the jury could absolutely find that Roundup and hep C both contributed to his non-Hodgkin's lymphoma, and they can still find for the Plaintiff because Roundup was part of that.

THE COURT: Well, you are using the word "contributed."

MS. MOORE: Okay. Well, substantial factor. I'm sorry, Your Honor.

THE COURT: Because -- I mean, that's important, I think, because what you seem to be suggesting there is that the jury find that even if one of them on their own didn't --

wouldn't have caused the cancer, they both combined to cause the cancer. And I don't think there was anything close to testimony suggesting that, right?

MS. MOORE: I mean, no. Well, Dr. Portier testified -- you will recall the George study, Your Honor, from 2010. And Dr. Portier talked about Roundup is also a promoter not just an initiator. That was the mouse study where they put Roundup on the skin of the mice.

And what they found in that study was that not only was Roundup an initiator of the cancer cells, but it is also a promoter of the cancer cells. So we absolutely have evidence before the jury that if they believe what Dr. Levine said today, which is that the -- I think her word was "accident" -- happened somewhere in the 39-year period where the genetic mutation formed, there is absolutely proof in the case that Roundup could have been a promoter of that genetic mutation that had been caused --

THE COURT: But did Dr. Portier actual offer that opinion? Because I don't think -- I mean, he was talking about it in the context of this one study. But did he ever actually offer an opinion that said, Number 1, I believe that Roundup caused the NHL; but Number 2, even if you believe that hep C caused the NHL, I believe that Roundup or hep C sort of caused an initial genetic mutation that set off a chain reaction, I believe that Roundup contributed to that chain reaction and,

therefore, resulted in Mr. Hardeman getting cancer?

I don't remember any testimony to that effect.

MS. MOORE: I don't think -- well, I don't think he said to that direct of a point, Your Honor. But I don't think he has to. What he offered to the jury was evidence that Roundup has been proven by the science to be an initiator and a promoter. And so that gives us the ability to make that argument in closing arguments that Roundup -- if you believe what the defense says. I'm not saying that that's what we say.

But if you believe what the defense says, that Dr. Levine says that he had this genetic mutation and it did not -- caused by hep C, and it didn't go away with therapy, it stayed in his testimony. But he is also at the same time being exposed to Roundup. And we know from Dr. Portier's testimony that Roundup is also a promoter of precancer and cancer.

And so absolutely we can make that argument in closing and present that to the jury. And so I do think in that situation that it is only right that Option 1 be given versus Option 2.

THE COURT: But you -- I mean, it seems a little strange. I mean, I understand the concept of taking little snippets from different fact witnesses' testimony and then putting together a theory for what happened. But the purpose of expert testimony is to get them up on the stand offering an opinion. And you seem to be saying, Even if you disagree with Dr. Portier's opinion, you can take this little snippet from

his opinion that -- where he commented on a mouse study. And -- the George study was a mouse study, right?

MS. MOORE: Right.

THE COURT: -- and, you know, you can use that to conclude that even if the Defendants are right that hep C caused the genetic mutation that led to the NHL, that -- that the Roundup accelerated that process, isn't that the kind of thing that you need expert testimony to support?

MS. MOORE: Well, I think we have expert testimony that Roundup is a promoter. That is clear, and it is undisputed in this case. As you will recall, they have not brought in one witness to dispute the animal studies in this case.

And so that is the evidence undisputed.

THE COURT: Where is his -- can you show me where his testimony is?

MR. KILARU: Your Honor, while that is happening, can I make a broader point about the George study; is that okay?

THE COURT: Sure.

MR. KILARU: So I think the most fundamental point here is that Dr. Portier wasn't a case-specific expert. He was by definition a general causation expert. And in the context of his testimony, he mentioned that there's this mouse study that says if you paint one chemical on a mouse's skin and then you paint another chemical, it can promote tumor activity.

That has nothing to do and was not in any way tied to hepatitis C. It has nothing to do with the conditions that Mr. Hardeman had. And I know we're not getting into what regulators say, even IARC thinks the George study is not particularly credible and I think discredited it and didn't rely on it in its monograph.

That's sort of more of a side point. I think they also called Dr. Weisenburger; and if they had this belief that the George study -- I mean, Dr. Weisenburger opined on all the science, including general causation. If they had a belief that there was some validity to this theory that George shows that somehow Roundup promotes hepatitis C activity, you would think they would ask him something about that or even talk about the George study at all, but that didn't happen. So I don't think that can be a basis for justifying a jury instruction.

THE COURT: And I'm happy to hear what Portier's testimony said, but I think that you have to be right, particularly given that Portier was just a general causation expert, that they actually -- I mean, this is a discussion about the jury instructions, but it's also a discussion about what can be argued to the jury and what cannot. And it seems to me -- I don't see how they could argue to the jury that the Roundup accelerated the process by which hep C gave Mr. Hardeman cancer.

MR. KILARU: And I think Dr. Weisenburger's testimony, I mean, I have some cites here, but he said on redirect, in talking about hepatitis C (reading):

"I don't believe it was a cause and I don't believe hepatitis B was a cause either for the same or similar reasons."

And they were talking about it. And then later, the last question of the direct was (reading):

"What was the substantial factor in causing Mr. Hardeman's non-Hodgkin's lymphoma?"

And the answer was not Roundup plus hepatitis C, Roundup promoting hepatitis C. It was: It was the Roundup exposure, period.

MS. MOORE: Your Honor, I apologize. We're looking for the right report because it's not in the trial transcript. Sorry.

THE COURT: That's okay. Wait. What's not in the trial transcript?

MS. MOORE: You know, when we had the trial transcripts, it doesn't include what was said in the depositions, and so I have my trial transcript so I can't -- I've got to find the Portier run report.

THE COURT: The Portier what report?

MS. MOORE: What was actually played from Dr. Portier's deposition because the transcript, of course,

that Jo Ann takes down, she's not taking down the deposition testimony itself.

THE COURT: Right. Right. Right. Right.

MS. MOORE: So I have the transcript of the trial but not that.

THE COURT: And we can circle back to that, but why isn't Mr. Kilaru right that, you know, he was a general causation expert? He didn't testify about the interaction between hep C and Roundup at all, much less the interaction between hep C and Roundup as it relates to Mr. Hardeman.

MS. MOORE: And I didn't say he did.

THE COURT: How can you use that -- how can that testimony be the basis for arguing that even if you disagree with us that, you know, Roundup was the initial cause of the cancer, you could find for us by concluding that Roundup accelerated the development of the cancer?

MS. MOORE: Because that's what the George study says. The George study says Roundup is an initiator and a promotor. That's what they showed in the George study. That's what Dr. Portier testified to; and that's about, you know, a promotor as to genetic mutations in the cells. It doesn't have to be specific to hepatitis C, and I wasn't trying to imply that he was because he did not do case-specific opinions.

THE COURT: Okay.

MS. MOORE: But regardless of -- regardless of that,

Your Honor, I mean --

THE COURT: Okay. So let's assume for the purposes of this discussion, and you can point me to the Portier testimony if you want, but let's assume for the purposes of this discussion that I conclude that it would not be appropriate for you to make that argument to the jury because there was not expert testimony to support that argument. Okay?

MS. MOORE: Okay.

THE COURT: So what can you argue to the jury and why is this instruction needed to allow you to do it? I mean, obviously your primary argument to the jury is going to be Roundup causes cancer.

MS. MOORE: Right.

THE COURT: Hep C didn't.

MS. MOORE: Right.

THE COURT: Okay. Now, you are hoping to present an alternative argument to the jury, and we need to talk about -- we need to figure out whether there's a basis in the evidence for you to make that alternative argument to the jury; and then if so, what should the instruction be.

MS. MOORE: Sure.

THE COURT: So what is the alternative argument here?

MS. MOORE: The alternative argument is: You could believe both Dr. Weisenburger and Dr. Levine. You could believe that if you look at all the risk factors that apply to

Mr. Hardeman, which they both agree that hepatitis C is a risk factor that applies, you could believe that Dr. Levine is correct that hepatitis C is a likely cause. You could also believe that Dr. Weisenburger is correct that Roundup is a likely cause. They're not mutually exclusive in that sense.

I mean, obviously our number one argument is what the Court said. Roundup caused his non-Hodgkin's lymphoma. That's our case; right?

But if you believe what the defendant says, which is what happened in the Limansky case, if you believe what the defendant says, that their expert says -- who said "I didn't even consider Roundup in her analysis," but if you agree with her that hep C was the most likely cause, you can also agree with Dr. Weisenburger, and that's why we need this instruction, Your Honor.

MR. KILARU: Your Honor, can I respond on that?

THE COURT: Sure.

MR. KILARU: I think that -- I think what was just described as an argument does not apt this case, and I think it's actually a pretty critical distinction from the case that counsel's mentioned. This -- I'm not going to try to pronounce it. I would guess it's *Logacz*, but I don't know if that's correct.

On page 157 of that decision --

THE COURT: Wait. Hold on. Let me pull it up.

MR. KILARU: Sure.

THE COURT: Give me one second.

MS. MOORE: Which decision?

MR. KILARU: *Logacz*.

THE COURT: Sorry. Wrong folder. Hold on a second.

(Pause in proceedings.)

THE COURT: Here we go.

MR. KILARU: I don't know if you have the Westlaw version or the published version.

THE COURT: Hold on a second.

MR. KILARU: Sure.

(Pause in proceedings.)

MR. KILARU: I have a copy if Your Honor would like, but I'm guessing --

THE COURT: Yeah. Why don't you hand it up to me.

MR. KILARU: Sure.

THE COURT: It's 71 Cal.App. 4th 1149?

MR. KILARU: '49.

THE COURT: Right. I read this last night, but now I need to refresh my memory on it again.

MR. KILARU: So I think if you look at page 6 of what I just handed you, Your Honor, there's a section marked "2. The Trial Court" -- it starts "The Trial Court erroneously refused to give plaintiff's requested instruction."

THE COURT: Yeah.

MR. KILARU: Okay. So the last sentence of that paragraph is I think the key distinction with this case. It says (reading):

"For purposes of this appeal, plaintiffs concede that these other factors" -- which are the ones that the defendants said was the cause -- "may have contributed to Cynthia's death, but that the negligence of the doctor" -- which the jury found was also a cause -- "thus, the principle of concurrent causation was and is a critical part of plaintiff's case."

So I think that puts this more in the bucket of the two fires case where everyone's sort of acknowledging that there are two things going on. And I think the point in those cases of saying multiple causation not but for is that it would allow -- it reveals basically a deficiency in the but-for test because both people could say it was the other person.

But I think the proof here, not to torture an analogy, but the proof here is actually if you had one side saying there was a fire that burned down the house and another side saying there was a stove in the house that ignited, and everyone would -- and I think the testimony here is that both of those things did not happen, it was one or the other -- and in that circumstance, Your Honor, I don't think it would make sense to say the jury can believe both because a jury would have to believe either it was the stove or it was the fire.

And I think that's the case here given what Dr. Weisenburger said. He said it was not hepatitis C. It was Roundup. And Dr. Levine, and I think Dr. Arber will say too, it was not Roundup.

So I think in those circumstances saying the jury could believe both is a little like saying the jury could believe two witnesses who say the exact opposite things on a point of fact. I don't think you would give an instruction about concurrent cause if that was the factual scenario we were talking about.

THE COURT: What -- okay. Let's say the jury believes that hep C would have caused Hardeman's NHL alone. Okay?

MR. KILARU: Okay.

THE COURT: But let's say that the jury also believed that Roundup was a substantial factor in causing his NHL. In other words, let's say they buy the idea -- buy Levine's testimony and they buy Weisenburger's testimony. I mean, why couldn't the jury believe both of those things?

MR. KILARU: Because I think no one has -- our defense has not been even if it was the Roundup, he wouldn't have gotten it anyway. Our defense has been in every argument we have made with the experts and throughout the case has been it was not Roundup; and so I don't think the jury can have, based on the proof they have been presented, those two ideas in their head.

I mean, they're going to be told they have to evaluate the

credibility of the witnesses, but here you literally do have sort of competing views of what happened. So I don't think based on the proof in this case the jury could come to that view.

It would be different perhaps if one of the experts had said, "You know, maybe these were both in the mix," or if Dr. Weisenburger said something like, "I can't rule out hepatitis C," or, "I think hepatitis C may be in the mix but Roundup is clearly more likely." Then I think you could see a world in which a jury could say, "Well, Monsanto might be right that hepatitis C was the more likely cause, but I agree with Dr. Weisenburger that Roundup was the cause."

But here that is just not what we have.

MS. MOORE: But --

MR. KILARU: We have two very different views of the world that have been presented. I think in terms of how we plan to argue it, that would be the case as well.

THE COURT: Why didn't you present testimony from an expert that in the alternative, you know, the two could have combined to cause his NHL?

MS. MOORE: Well, Your Honor, if I could direct the Court's attention to Dr. Weisenburger's testimony, and this is on page 1313 of the transcript, and he was asked a series of questions about hepatitis C and he was asked (reading):

"Hepatitis C just like hepatitis B can cause genetic

mutations; right?"

And he says, "Yes." And then the question was (reading):

"It can cause genetic mutations that ultimately lead to the development of NHL; right?"

And he said, "Yes." And then the question was (reading):

"And so it is possible you can't rule out that in Mr. Hardeman specifically during that 39- or 40-year period he had genetic mutations that were caused by his active hepatitis C; correct?"

And his answer was, "Certainly possible."

And then the question was (reading):

"And so it's certainly possible that the hepatitis C caused genetic mutations in Mr. Hardeman in the 1960s; correct?"

And he says, "It is possible." And then they go on to say the '70s, the '80s, the '80s, and so on.

THE COURT: Yeah, but he never offered expert testimony either that -- I mean, he could have -- what he did testify is, yeah, it's certainly possible but it's very, very unlikely. That was his testimony. "My opinion is that Roundup caused the cancer and that hep C didn't. It was exceedingly unlikely that hep C caused the cancer." That was Weisenburger's testimony.

It seems like he could have said one of a couple things. He could have said, "Look, even if you consider hep C to be a

substantial factor, even if there's evidence to support a conclusion that hep C is a substantial factor, I believe Roundup was also independently a substantial factor and here's why. In other words, here's why I believe even if the jury concluded that hep C participated in causing his cancer, he would have gotten the cancer even if he had not -- from the Roundup even if he had not had hep C." And there's -- he could have testified to that.

Or he could have said, "Even if you don't believe that Roundup didn't cause the cancer on its own, I have -- my secondary opinion is that Roundup and hep C combined to cause the cancer."

And he didn't do either of those things, and now you're saying you want to argue one of those two things to the jury.

MS. MOORE: Well, what I'm saying is that there is testimony by Dr. Weisenburger, which is what Dr. Levine was testifying to today, that there was a genetic mutation. He agrees with Dr. Levine that it's possible that you could have a genetic mutation.

She also testified that she couldn't say with certainty that there was a genetic mutation. That's her theory. There's no actual data or proof with Mr. Hardeman in particular that there's a genetic mutation that still survived the treatment. Okay?

And they both are saying that. The jury heard both of

them say that. So there's -- the jury absolutely could say, "Okay. There's a genetic mutation. They both said that. It's caused by hepatitis C. She says that's what caused the non-Hodgkin's lymphoma. He says it's the Roundup. They both could be right." And that's what happened in the *Limansky* case.

MR. KILARU: But, Your Honor, I think what followed that testimony -- so, yes, Mr. Stekloff asked those questions of Dr. Weisenburger and got him to admit they were mutations, but what followed is Dr. Weisenburger -- or maybe it preceded it, I'm not sure -- but Dr. Weisenburger then said the antiviral treatment killed all of those cells.

I mean, that was the purpose of -- that was what I think counsel was trying to with Dr. Levine on cross today. I mean, that's why Dr. Weisenburger did this whole bit about how sustained virological response -- "bit" is not the right word. I shouldn't have said that, I suppose, but why he talked at length about why sustained virological response eliminates mutations in the cells.

He didn't just say "It will reduce your risk to cancer." He said, "It reduces your risk" -- he says, "If you never had hepatitis C at all." He talked about how all of the cells that would be affected would be killed, and Dr. Levine disagreed with that today with -- the same articles that Dr. Weisenburger talked about were presented to Dr. Levine, and that was the

argument that was being presented to her when she was being cross-examined.

So I don't think that the testimony that counsel pointed to gets them to being able to say it was both because what followed was Dr. Weisenburger saying "That theory doesn't work."

MS. MOORE: Your Honor, the bottom line is under California state law, which applies in this case, the but-for causation has been repudiated in favor of substantial factor for sometime now. I mean, the case is going back over 20 years.

THE COURT: There's a -- that's not correct. I mean, the model instruction includes a but-for sentence, and then it says "In a case where there are" -- and then the law says -- "In a case where there are independent concurrent causes, you dispense with the but-for sentence and you give a multiple causation instruction"; right?

MS. MOORE: But, Your Honor, the jury could absolutely find that these are not independent concurrent -- I guess concurrent, that's redundant, isn't it? They could absolutely find that these causes are not independent. They could hear the evidence and say --

THE COURT: Say the causes combined to cause the cancer? I mean, I just -- I don't think -- I mean, without having elicited an expert opinion about that, I don't see how

you can argue that to the jury.

MS. MOORE: But it's not that one party has to make that argument, Your Honor. In the *Limansky* case, what the Court of Appeals looked at was that there was the plaintiff's expert who made one -- had one opinion and there was the defense expert who made another opinion; and they said because of those multiple causes that were presented to the jury, it was reversible error not to give the multiple causation instruction.

MR. KILARU: Respectfully, Your Honor, I don't think that's what the case says. It says that when you have what I think the jury instruction -- the note to 430 envisions, which is concurrent independent causes, multiple forces operating at the same time and independently -- actually, I'm not even sure that qualifies in *Logacz* because I think in that case it's referring to independent causes.

THE COURT: But here's the thing. I'm looking at *Logacz* and, I mean, I think the key -- you know, I'm going to go back and I'm going to read this decision more carefully during a break and we'll continue this conversation at some point; but, you know, what that case says is for purposes of this appeal, the plaintiffs concede that these factors may have contributed to Cynthia's death, not that they conceded at trial; right?

MR. KILARU: Right, but I think --

THE COURT: And so it sounds like, from the way the court is describing this at least, is that you had one side saying "These factors contributed" and you have the other side saying "These factors contributed."

MR. KILARU: Right, but I think on the next page it clarifies that actually.

THE COURT: Okay.

MR. KILARU: So I think on page 7, if you look at the -- I guess the paragraph with the bold 7.

THE COURT: Okay.

MR. KILARU: It says (reading):

> "Just as in *Hugh v. Candoli*, even if Dr. Limansky established that, as a matter of law, that any one or all of these factors was a cause of Cynthia's death, his negligence could also have been a cause of her death acting in combination with them. Multiple or concurring causes of death do not preclude recovery."

THE COURT: Right.

MR. KILARU: And on that theory the court said you needed to give the multiple causes instruction because the jury could have concluded that multiple things were happening at the same time and working together.

THE COURT: Right.

MR. KILARU: But that is not what we have here, and so I think --

THE COURT: And that gets back to my point -- I mean, I tend to agree with you that that's not what we have here. I think we probably could have had that here. I think the plaintiffs probably could have presented an expert opinion to that effect. I don't know. I'm not the scientist here; but, you know, sort of the understanding I've developed over the course of this case that they probably could have presented such an opinion, but they didn't present that expert opinion.

And so, you know, it seems like they probably would be precluded from arguing that the two things combine to cause Mr. Hardeman's NHL.

But what about -- I mean, it still doesn't quite answer the concern that I have, the primary concern that I have, which is that if they would have thought -- if they thought that he would have gotten it anyway from the hep C, then that is sort of end of the inquiry for them where it shouldn't be because they should still be asking whether Roundup was a substantial factor in causing his cancer.

MR. KILARU: I do think that making that the focus of the inquiry is a little concerning given that the plaintiffs ultimately have the burden of proving that it was Roundup, and we do not have the burden of proving that it was hepatitis C.

THE COURT: Correct.

MR. KILARU: I think to the extent you have that concern, I mean, I think our top-line position would be that

the instruction that should be given is actually the version -- is version two minus the last sentence; but I do think that the last sentence gets, I believe, to the point that you're making.

But I think that it's important to have that but-for language in there under California law because it is a but-for state except in the circumstance where you have these sort of multiple causes working together.

And I would point out -- I don't know if Your Honor has this case, and I can give you a copy of it -- I'm not necessarily saying that if you had this type of opinion offered by an expert, you know, it would automatically justify a multiple causes instruction. But there's this case *Cooper*. It's 239 Cal.App. 4th 555, and it's a case about the multiple causes instruction. And I think in that case what the expert did --

THE COURT: Sorry. What was the --

MR. KILARU: Sorry. It's 239 Cal.App. 4th 555.

THE COURT: *Cooper versus*?

MR. KILARU: *Takeda Pharmaceuticals*. I think it's been cited in the design briefs as well so it covers a lot of issues.

THE COURT: Okay.

MR. KILARU: But in that case the doctor -- the court found that a multiple causation -- or didn't say that there was error in giving a multiple causes instruction because the

expert didn't rule out a different risk factor. So the plaintiff was saying it was negligence, I believe, or design defect, and the defense was saying that smoking somehow played a role into the cause.

And the plaintiff's expert said, "I'm not ruling out smoking. I just think that the design -- the negligence was a greater factor." And that is not what we have here.

So, again, not necessarily committing to what I think should happen in that situation, but here you don't even have that. I mean, that might be a situation where something like what Your Honor is concerned about would be a substantial concern; but I think in this case, based on the way it's been presented and the way it's been argued, there really is no evidentiary basis for the plaintiffs to say that you can believe two experts when the two experts said the opposite of each other and sort of defined their methodology in opposition to each other and where the plaintiffs' expert expressly ruled out and said it was impossible for that to have been a cause because anything -- the theory that we offer for how that could have happened was completely eradicated by this treatment.

MS. MOORE: Your Honor, on the *Limansky* case, it wasn't that anyone offered the testimony that both experts, both the plaintiff and defense experts, could be right. It was that the Court of Appeals -- and this is in that same paragraph that was just read by Monsanto's counsel -- it says that

(reading):

"Even if Dr. *Limansky* establishes as a matter of law that any one or all of these factors were a cause of Cynthia's death" -- and those are what the defense raised -- "his negligence" -- what the plaintiff raised -- "could also have been a cause of her death acting in combination with them."

The plaintiff didn't say they acted in combination with the defense. The defense didn't say they acted in combination with the plaintiff. That's what the court is putting that the jury could make that conclusion when they weighed the evidence of the case. That's why we think that option one is correct under California law.

MR. KILARU: Obviously I don't have the record in that case, Your Honor, but I'd be surprised if Dr. Limansky had said that it was impossible for the other side's theory to be correct and conclusively ruled it out, which I think is what we have here.

THE COURT: Well, neither expert said it was impossible. Well, scratch that. Weisenburger did not say it's impossible that it was hep C.

MR. KILARU: Well, I believe --

MS. MOORE: Correct.

MR. KILARU: -- he was impeached on that point; but I think we when we presented the theory -- I mean, it's exact

thing that was read earlier -- he said it is not the substantial factor.

THE COURT: Yeah.

MR. KILARU: And when he was presented with the theory of how it could have happened, he said that was false because the cells would have been eliminated. He offered that testimony several times.

THE COURT: So -- hold on one second. I'm just looking at your brief.

MR. KILARU: Yes, Your Honor. I think this morning you had asked about cases. We do have some we can point you to, but I'll wait for that.

THE COURT: Okay. Just give me a second.

MR. KILARU: Sure.

(Pause in proceedings.)

THE COURT: See, I'm looking -- I'm on your brief at page 4.

MR. KILARU: Okay.

THE COURT: And this is part of what has me a little bit tied up in knots. I mean, you're talking about the *Xavier* court; right? And you're saying the court in *Xavier* declined to apply the concurrent independent cause exception in a case involving allegations that the defendant's product caused an increased risk of lung cancer because apart from defendant's alleged misconduct, no other independent event or circumstance

was alleged to be a sufficient cause of this harm.

Here there is another independent event or circumstance that the defendant alleges is sufficient to cause this harm; namely, hep C. Right?

MR. KILARU: Yeah. So I think -- I'm sorry.

THE COURT: And then you go on and you talk about how -- you know, you said courts -- you cite *Mays* and you say declining to find concurrent independent causes -- declining to find concurrent independent causes because the plaintiff alleged that harm was brought about by a combination of a doctor and a surgeon's negligence.

I guess what I'm saying to you here is that it seems like the plaintiffs have not presented evidence that it was caused by a combination of the doctor and the surgeon's negligence. They haven't presented any expert opinion that it was the combination of hep C and Roundup; right?

MR. KILARU: Yes.

THE COURT: I know they disagree with that, but I think that's correct. But there has been -- Monsanto has presented evidence of an independent event or circumstance that it alleges is sufficient to cause the harm.

And so in that circumstance why wouldn't we say that even if Monsanto is right, that it's sufficient to cause -- that hep C was sufficient to cause the harm, you don't automatically find in favor of Monsanto based on that? You have to ask

whether Roundup was also a substantial factor.

MR. KILARU: Because I think it goes back to the first point you raised, and I think there's another case that I think is very helpful on that point, but it goes back to the first point you raised because essentially what that means is that whenever the defense doesn't just say it wasn't Roundup and points to something else, that but-for causation is out of the picture, and I think that that would eliminate but-for causation in way too many cases.

THE COURT: That's the problem.

MR. KILARU: And so I think *Vecchione*, and I know Your Honor mentioned potentially some concerns with the case, but I think that's one of the cases that really directly addresses this point. Because in that case -- and I have a copy if Your Honor would like.

THE COURT: No, I have it.

MR. KILARU: In that case, if you look at -- I have the Westlaw version, so I guess it would be page 5, but if you're looking at asterisked pages it would be page 359.

THE COURT: Wait. Hold on.

MR. KILARU: Sure.

(Pause in proceedings.)

THE COURT: Hold on.

(Whereupon, a brief pause was had.)

MR. KILARU: So there is a paragraph that says -- I

think this starts to get at the concern -- The but-for rule, along the rule of finding causation in this state, serves to well to define what is legal causation but fails in the type of situation where several causes concur to bring about an event, and either one of them operating alone could have been sufficient to cause the results.

But then at the end of that paragraph it points out why that case is different. Here there was substantial dispute between the parties, but each contends there was a single cause for the death. Either the prenatal distress resulting in DIC was the cause of death -- I think that was the Plaintiff's position -- excuse me, that was the Defense's position -- or the over-heparinization brought it about. That was the Plaintiff's position.

And I think this is the next line. I don't even think this is the case here, but I think this is an important line.

The Plaintiff expert specifically put the cause as over-heparinization and ruled out DIC as a cause, though he was willing to admit DIC could have been present.

And the Court says the Defendant's experts on the other hand contended the cause was DIC and there was no heparin overdose. Under these circumstances the but-for clause is not improper. And I think because in that circumstance you have two completing causes that are being alleged, and it is really not that different if the defense says it just wasn't the thing

you are saying was the cause.

THE COURT: But the problem is there -- I think the problem with that case is it was disputed whether there was over-heparinization, right, which is an overdose of the drug, as I understand.

MR. KILARU: Yeah, it is a blood thinner, but yes.

THE COURT: And so it was disputed whether there was -- this was an overdose of the drug; is that right?

MR. KILARU: Yes.

THE COURT: Okay. And there was a dispute about whether there was an overdose of the drug. There wouldn't have been a dispute -- if there had been an overdose of the drug, there would not have been a dispute that it was a cause of the harm, right?

MR. KILARU: I'm not sure -- at least based on this paragraph, I'm not sure, Your Honor, because I think here the Court is saying the two sides just presented different theories of causation. I think that is the key point.

One side it was over-heparinization. The other side may have disputed that, but they said -- it seems like they said almost regardless, there was this other thing that caused it, and for that reason it wasn't the over-heparinization. And that I think was the closest analogy to what we have here. I think it is much closer to -- what we have here is much closer to this.

THE COURT: So you think Vecchione is your best case for the proposition that the instructions -- the multiple causation instruction is not appropriate here?

MR. KILARU: I point to three things, Your Honor. That would be one of them. I think the instruction itself -- I don't mean to be circular here -- but I think the notes on the instruction itself say that you apply -- that but-for is well-acknowledged in California, and the circumstance in which you don't apply but-for causation -- or one of the circumstances in which you wouldn't give that supplemental instruction is where you have multiple forces operating at the same time and independently. I don't think that's what we have here based on the proof we have, and there are cases that sort of cite that point; but I don't think they illuminate it beyond what is in the instruction.

THE COURT: But -- and that -- I mean, I get your -- I get the point about Vecchione, but multiple forces operating independently, I mean, we do have evidence in the case of multiple forces operating.

MR. KILARU: Right, but I think --

THE COURT: And we don't have evidence of them operating in combination.

MR. KILARU: Right.

THE COURT: Right?

MR. KILARU: Yes.

THE COURT: But we have evidence that of one force -- that one force caused the cancer. And we have evidence that another force the cancer.

MR. KILARU: I think --

THE COURT: The jury has to consider all of that evidence together.

MR. KILARU: And I think they are not -- this is where it gets a little semantic, but I think the difference is they are not operating based on the proof at the same time. One group is -- we are saying it was the hepatitis C. They are saying it was the Roundup. No one is saying the two things were sort of colliding with each other.

THE COURT: Right.

MR. KILARU: I think the situation where it is more analogous what you are talking about would be, say, in an asbestos case where there are five products at issue, and each Defendant is saying, Well, I mean, there are five products. You can't say it was mine because there were other products at issue; multiple factors operating at the same time concurrently.

But I think it is different from a case like this one where there are two things that are being argued that no one is saying they operated at the same time. We are saying -- you know, they are saying it was Roundup. We are not saying it was Roundup; we are saying it was something else.

MS. MOORE: That was the Limansky case, Your Honor. And that case --

THE COURT: Wait. Wait. Hold on. You said you had three things that you wanted to make sure we focused on.

MR. KILARU: Yes.

THE COURT: One was Vecchione. The other was the notes on the instruction.

MR. KILARU: Yes. And the last was is a case called -- it's an unpublished case so I recognize it has less value for that reason -- but it is a case called *Hudson V Lenz*, and the cite is 2004 Westlaw, 823 492. And in that case there is a discussion of, I think, the concerns that we are talking about here, which is -- I will just read a paragraph, if I could at the end. This is on page star 10. If you have the Westlaw version, it would be on page 8 at the bottom.

Were a concurring cause instruction required -- and I guess I should go back a little bit.

We are aware of no California authorities holding that the jury must be instructed on concurring causes in a medical malpractice case involving only one actor in a contention by the physician that the disease was the sole cause of Plaintiff's damage.

So there was a disease and there was negligent sort of alleged.

And the Court continues: We do not agree that such a

broad application of BAJI 377 -- which I think is the predecessor to what we are talking about here -- to medical malpractice action is appropriate. Were a concurring cause instruction required in such instance, it would be necessary in virtually every case in which the Plaintiff claimed that the medical negligence caused the injury or death, while the defense asserted that the damage was the result of a natural disease process.

So I think it is the essential same point as in the Vecchione case. And we have cited other cases that make this point generally about how, I think, this exception should not swallow the but-for rule. So those are the points we emphasize.

THE COURT: Okay. And then can you think of any other way, you know, before I turn to you and your -- the primary authorities you want me to focus on -- the question, again, is if the jury thinks the evidence was really strong for both.

MR. KILARU: Right.

THE COURT: Really strong for both. And, you know, is there any language that we could use that would make sure that the jury doesn't just call it a day once they have concluded that the evidence was really strong for hep C?

MR. KILARU: I think --

THE COURT: They have to continue to engage in an inquiry about Roundup. That's the basic concern.

MR. KILARU: I think the language you have at the end of two gets to that point, but I guess I would say one broader point, which is that I think based on the way the evidence has come in in this case, if the jury believed that the evidence was strong on both sides, we should win because in this case we have said it was one thing. They have said it was another thing. They have the burden of proof.

So if the jury can't decide between two alternate competing causes that have been proffered that are both strong, that's actually a reason that we should win.

THE COURT: But what you are saying is that -- so you are saying that the second sentence of -- sorry, the second sentence of the second paragraph --

MR. KILARU: Yes.

THE COURT: -- of the second option --

MR. KILARU: Yes, twos all around.

THE COURT: -- sort of gets at this concern. So what if it said -- what if it said, Generally, conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct. However, if you conclude that Mr. Hardeman has proven that his exposure to Roundup was sufficient on its own to cause his NHL, then you should find for Mr. Hardeman, even if you believe that other risk factors were also sufficient to cause NHL on their own.

MR. KILARU: I know we are talking about one word, but

I think we would oppose that, Your Honor, because I think first it would suggest that but-for standard -- which I think should ordinarily apply -- maybe shouldn't apply in this case.

THE COURT: But isn't that the law, that generally the but-for standard does apply?

MR. KILARU: Right, but I think -- sorry.

THE COURT: Except in a situation where you have two independent forces that could each on their own have caused the cancer.

MR. KILARU: Yes. So I think the answer to that is actually -- I think that would be our top-line position; that you actually shouldn't have the second sentence at all because unless you are in -- the second -- you know, twos all the way down -- the second sentence of the second paragraph, because unless you have that type of situation, but-for is the rule.

So I understood this second sentence to be Your Honor trying to address that concept. And I think if we had to put our positions in order, I think based on what I said earlier and based on the proof, I think the instruction should be Number 2; and I think it should end without that conduct, because here there have been two competing things offered. And if the jury is sort of equipoised between those two, that means the Plaintiff has not met their burden.

But I think that to the extent Your Honor believes some extra language is necessary, I don't think the solution would

be to dilute and suggest that but-for doesn't apply. And I think it might be to add additional language, but my concern is that generally to suggest that we are actually farther away from the baseline but-for cause situation. I think we are there.

THE COURT: But -- so what would be an alternative that would -- because the problem with the way I have written it, I think, is that Sentence 1 and Sentence 2 seem to be at odds with one another.

MR. KILARU: I understand that, Your Honor. But I think in some ways the problem with that is the way the evidence has come in in this case because I think what 2 is grappling at is this possibility that the jury could think they were both, and if they are both, then, you know, that doesn't necessarily mean we are off the hook or I suppose it gets maybe at the point that if they think he would have gotten it as a result of hepatitis C, no matter what, they are not going to consider Roundup.

But I think that here, really the jury has been given two competing options. It is A or B. And so I think the first sentence is all that is needed. I think this might have been the initial proposal, but I understand that you continued to think about it. But I think it is A or B based on the evidence, based on the testimony of Dr. Weisenburger. So I don't think any additional language is necessary. I think this

probably comes close to getting it at that point, but I don't think that point is live in this case.

THE COURT: Let me ask you one other quick question here. Hold on.

(A brief pause was had.)

THE COURT: Okay. So let me -- I mean, you know, I wonder if we are dancing on the head of a pin here -- but what if it said Conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct. Okay? That first sentence.

And then what if it then said, With respect to Roundup and hep C, however, if you conclude that either would have caused Hardeman's NHL alone -- if you conclude by a preponderance of the evidence that either would have caused Hardeman's NHL alone, you must find for Hardeman because there can be more than one substantial factor in causing someone's disease.

MR. KILARU: Your Honor, I think that they have -- did you say would have or could have?

THE COURT: Would have.

MR. KILARU: I think -- I don't think -- I'm not sure that that works, Your Honor, for I think the same reasons that we have been talking about here because the jury has been told it is either A or B. And I think if they think it could be either A or B, the Plaintiff shouldn't win in that circumstance because the Plaintiff has to prove in this case based on the

proof that it was Roundup.

I mean, what this instruction does is basically tell the jury, if you can't decide between two risk factors -- I think the concern is it basically tells the jury, If you think there is strong evidence on both sides, then Mr. Hardeman wins. And I don't think that's the way the burden of proof operates in this case especially given that they have been giving sort of competing views of the --

MS. MOORE: But that is ignoring the first paragraph, Your Honor, which is Mr. Hardeman must prove by a preponderance of the evidence that Roundup was a substantial factor in causing his non-Hodgkin's lymphoma. They still have to show -- they still have to find that Roundup was a substantial factor.

I mean, again, I just want to be very clear. Our position is Option 1 is the correct position under California law, but I don't think what Monsanto's attorney just argued right then is accurate because that is taken care of in paragraph 1.

THE COURT: Okay. So what I want to hear from you now is do you have any other argument -- I mean, as of now where we are is that the Plaintiffs are -- may not argue to the jury that the two things combined to cause the cancer because there is not an expert opinion to support that, and there is not really even any scientific evidence to support that.

And so Task Number 1 for you is to talk me out of that.

MS. MOORE: Okay.

THE COURT: And then task Number 2 is to get back to this instruction and figure out if we -- if we can have -- if we should be having some concurrent independent cause-type instruction, as opposed to a concurrent independent cause, which is what you are now arguing.

MS. MOORE: I understand, Your Honor.

As to the first question, I do have Dr. Portier's testimony pulled up now. This appears on line -- I'm sorry, page 156, and it is lines -- let's see -- starting at line 18, and it goes on through page 157.

Dr. Portier was asked about the George study in particular and said: Is that consistent with what you are seeing in the rodent data for glyphosate? And he says, Partially. Obviously it is addressing the question of promotion, which means that you already have these initiated cells. Living can cause mutations to occur. And so it is conceivable that glyphosate, all of these tumor findings we are seeing here are glyphosate promoting out already effects.

And he continues on --

THE COURT: That was his testimony?

MS. MOORE: This is Dr. Portier's testimony.

THE COURT: It is conceivable?

MS. MOORE: Yes.

THE COURT: Okay.

MS. MOORE: And then he continues on, Your Honor. I

can keep going if you want me to, but -- he says: Promoting out already effects. He goes, I don't think it is likely, but it is conceivable that's the case. The initiation promotion study is simply showing you that one system --

THE COURT: Wait. You said -- wait. Sorry. Could you read that one more time?

MS. MOORE: Sure. He goes, I don't think it is likely but it is conceivable that's the case.

THE COURT: What is conceivable that that's the case? Can you refer back to the testimony that he is saying is not likely but conceivable?

MS. MOORE: Yes. That is the initiation -- the question of promotion, Your Honor.

THE COURT: Okay.

MS. MOORE: The very first part of his answer is it is addressing the question of promotion.

THE COURT: So he is saying he doesn't think it is likely that it is promoting?

MS. MOORE: He says it is conceivable that's the case, and he continues. He says: The initiation promotion study --

THE COURT: Wait, wait. You just skipped over something. It is -- okay. Read it again.

MS. MOORE: Sure. Okay. I will start at the very beginning, Your Honor.

THE COURT: Yeah.

MS. MOORE: Okay. Let me back up.

This is the very beginning of his answer, and it starts at 156, line 23. Partially.

Let me read the question because I think that's part -- 156, 18: Well, then let me ask you this question. The George study, this positive finding there, what is that consistent with what you are seeing in the rodent data for glyphosate?

And the answer is: Partially. Obviously it is addressing the question of promotion, which means that you already have these initiated cells. Living -- I don't know why it says living here -- living can cause mutations to occur. And so it is conceivable that glyphosate, all of these tumor findings we are seeing here are glyphosate promoting out already effects. I don't think it's likely but it is conceivable that's the case.

And then he continues: The initiation promotion study is simply showing you that in one system, the skin, glyphosate has this ability to promote out cancer. That is all it really means.

So --

THE COURT: So there is no expert testimony that would support an argument -- I mean, if that's all you have --

MS. MOORE: No, I don't, Your Honor.

THE COURT: Okay.

MS. MOORE: If you continue on to page 157 at line 16,

he is asked: Does it have any influence -- meaning it, the George study -- have any influence on whether or not it could promote a mutation to lead to cancer?

And Dr. Portier's answer is: It certainly increases the chances. That might be the case because now you have evidence to suggest glyphosate can do that. But I would want to see a lot more evidence before I would go there and start thinking about that. There are initiation promotion studies you can do, and he continues on for a while about initiation promotion studies.

THE COURT: Okay. So what you just read me is sort of the opposite of evidence to support the argument that you are proposing to make. I mean, it's an expert who is not willing to offer any sort of opinion remotely close to the argument that you are proposing to make, putting -- even putting aside the fact that it was just general causation testimony and not specific causation and not related to hep C at all.

So if that's your evidence to support your argument that Roundup and hep C combined to cause his cancer, you cannot make that argument at closing.

MS. MOORE: I understand, Your Honor. I would just reserve because that was on the fly, me just searching quickly on the iPad to find those two references. I would want to go back and look at Dr. Portier's testimony.

THE COURT: That's fine. But the ruling now is that

you cannot make that argument. So as you are preparing your closing argument tonight, you cannot make that argument.

MS. MOORE: I understand, Your Honor.

Let me go back to the jury instruction issue I think regardless of the George study and Dr. Portier's testimony on that, that California law is very clear that this is a substantial factor, and that the but-for does not apply here. And that's why I cited the Limansky case, Your Honor.

And I would just point out that in that case what happened at the trial level is that the jury found -- and this was a medical malpractice case --

THE COURT: Is this something -- are you citing to the Court of Appeals' opinion in this case?

MS. MOORE: Yes, Your Honor.

THE COURT: Okay. So where are you describing from?

MS. MOORE: Well, Your Honor, this is at the very beginning the summary of that, and it's -- the first paragraph it starts with This is a medical malpractice case.

THE COURT: Okay.

MS. MOORE: Okay. And if you go -- it is the second-to-the-last sentence in that paragraph. It says: Following a trial during which the trial Court refused to give a jury instruction on concurrent causation, the jury found that while Dr. Limansky was indeed negligent in his care of Cynthia, such negligence was not a cause of her death.

That is the exact worry that we have in this case, Your Honor, that you have pointed out. And that is the jury could absolutely say, you know what, Roundup causes cancer. Roundup cause was a substantial factor in Mr. Hardeman's, but also we think hepatitis C was a substantial factor based on the testimony presented by the Defendant.

THE COURT: And he would have gotten -- he would have gotten cancer from hep C even if Roundup had not been involved.

MS. MOORE: That's right. That's right.

And that's exactly what happened here. It is the same analogy, Your Honor. And what the Court of Appeals said, if you go onto the next paragraph -- because we conclude in that -- in this case, in which causation was the most critical contested issue -- and here, Your Honor, it is the only issue in Phase One -- and in which there was substantial evidence of multiple causes of Cynthia's death, the trial court improperly instructed the jury with respect to concurrent causation, and because such error was clearly prejudicial, we reversed and remand for a new trial.

THE COURT: And that language -- I mean, I was sort of floating to the side of how to limit this concept and limit it only to situations where everybody agrees that the two things caused it, or the two things were operated to cause it, but this -- this language -- and we never know how careful the Courts are being with their language -- but this is -- this

sentence -- this paragraph stands for the proposition that when there is substantial evidence to support both. And so it does -- I will say that it does seem like if that is the rule -- if the rule is that when there is substantial evidence to support two separate causes, you don't give the but-for instruction and you give the multiple -- you give some version --

MS. MOORE: Exactly.

THE COURT: -- version of independent causation, that does seem to be the exception that swallows the rule in some -- to some degree, which is a matter of concern. But that is what the Court seems to be thinking.

Although, one of the things I want to do I want to take a break --

MS. MOORE: Sure.

THE COURT: -- and I want to go back and look at all of the things that you tell me I should really focus on. And so is there anything else other than this case that you want me to really focus on?

MS. MOORE: I just wanted to point out in this particular case -- and this was something, Your Honor, that you highlighted, too, when you go to Section -- it is Number 2, if you flip over, you will see the head note -- it is not a head note. Sorry. It says Number 2, the trial Court irrevocably refused to give the Plaintiff's requested instruction on

concurrent causation.

Do you see that?

THE COURT: I'm sorry. Are you in the standard of -- are you in the same case?

MS. MOORE: Yes, I am, Your Honor. It is after the standard of review. So if you go down, you see where it says Number 2, The trial court erroneously --

THE COURT: Oh, yeah. Okay.

MS. MOORE: And that beginning paragraph there, this was what, you know, they really -- they honed in on. And they said one of the critical issues we resolved by the jury was causation, which, again, this is the only issue here. So it is extremely critical to the Plaintiff, and it would be prejudicial not to have this multiple causation instruction.

And so they listed out initially four different arguments that the Defendant made, that the doctor made in the malpractice case.

Here we heard from Dr. Levine today. She said that -- first -- she said first the primary cause in her opinion was hep C. The secondary cause was hep B. So she gave multiple causes on the stand today.

Then it continues and it says, as the Court pointed out, for purposes of this appeal, Plaintiffs concede that these factors may have contributed to Cynthia's death.

Again, what our position is, Your Honor, it doesn't have

to all come from the Plaintiff. It's what is the evidence that is being presented to the jury. And when they go back to that jury room, the evidence that they have heard in the case is that Roundup can cause cancer, and that Roundup is a substantial factor in causing Mr. Hardeman's cancer. And they have also heard today, hepatitis C and hepatitis B were likely causes of his NHL.

And so to make it one or the other puts the Plaintiff behind the eight-ball, and it is very prejudicial to us. And that's why the multiple causation instructions should apply.

THE COURT: Okay. So anything else you want me to really focus on when I go back for a break right now?

MS. MOORE: No, Your Honor.

THE COURT: Okay. So what I want to do is -- I think -- I mean, obviously you are going to want to get an answer from me soon on this question so you can start working on your closings. So what I would propose to do, if you don't mind, is take like a half an hour break, go back and really focus on these things that you want to make sure that I focus on. And then I will come back, I will ask you -- if I have additional questions, I will ask you. And otherwise I will just let you know what the answer is.

MR. KILARU: Your Honor, before you go, not on the law, but just one suggestion and one -- just on a point you had raised earlier.

THE COURT: Sure.

MR. KILARU: So one suggestion I think on Option 2, which you already have, would be to insert before -- so I guess in the second paragraph of Option 2, after the but-for sentence, one proposal would be to insert something like You have heard evidence about risk factors other than Roundup. And then say If you conclude that, which I think sort of grounds in this idea that there are a couple risk factors potentially circulating around here. That is just a suggestion.

I don't know if Your Honor is still considering this, but just one point on the language you had proposed earlier about -- you said something like, I believe, with respect to Roundup and hepatitis C, If you conclude that either would have caused Mr. Hardeman, I think one concern we have about that phrasing is that if they conclude that hepatitis C would have technically, one of the either, they found that that caused Mr. Hardeman's NHL, and the instruction would tell them to find for Mr. Hardeman in that circumstance. So I think at a minimum, I don't think that phrasing would work for that reason.

THE COURT: I think I understand that, but what I will do is I will come out and give you a chance to pour over language before we --

MR. KILARU: Sure.

MS. MOORE: That would be great, Your Honor.

And the only thing I would add to that is when he refers to risk factors, the testimony in the case is that -- and Dr. Levine admitted this today -- a risk factor is not the same as saying the cause, so I would have some concern there. I don't think when you are talking about multiple causation instruction you could then just say "risk factors."

THE COURT: Well, I mean, that's what -- I think that's actually a good point. And it may argue for -- if we go with some version similar to Option 2, what that might mean is that at the bottom there where I say Then you should find for Mr. Hardeman, even if you believe that other risk factors were also sufficient, it should just say other factors were also sufficient probably, so as to avoid that confusion.

MS. MOORE: I don't know if I would agree to just the word factor, Your Honor, when we are talking about causation, but --

THE COURT: You are saying it should be if you believe that other causes for --

MS. MOORE: Causes, yes. Because risk factor is not the same as a cause.

THE COURT: But factor is -- the center piece of the instruction is factor, substantial factor.

MS. MOORE: Let me look at 431, Your Honor.

I mean, 431 says Cannot avoid responsibility just because some other person, condition or event was also a substantial

factor in causing the Plaintiff's harm.

THE COURT: Yeah. But the problem with that language is that it's -- it's -- that seems to contemplate the type of argument that you haven't made in this case, which is that they combine to -- that's why I'm trying to find something that is more specific to the argument that you can potentially make, subject to my pouring over this material during the break, which is that they are sort of independent causes.

I mean, that's -- it seems to me the only thing you have potentially left yourself room to do is make that type of argument, not make the argument that they have combined to cause his cancer.

MS. MOORE: And I believe that is the Limansky case, Your Honor.

MR. KILARU: Thanks, Your Honor.

THE COURT: Okay. Why don't we plan on coming back at 5:00.

(Recess taken at 4:32 p.m.)

(Proceedings resumed at 5:28 p.m.)

(Proceedings were heard out of the presence of the jury:)

THE COURT: I see it's warmed up in here a little bit. Yeah, our air and heat goes off at 5:00 o'clock. That's ridiculous.

Okay. So I think option one is off the table for all the reasons we discussed. I think it's not appropriate to give an

instruction that would allow them to -- that would allow the jury to conclude that the cause -- in the two things combined to cause the cancer in light of the way the evidence has come in, and the plaintiffs can't argue that.

However, I wanted to give you one more chance to respond to one thing, but I am pretty strongly inclined to give option two with a couple of tweaks. One is to add the word "generally" as I suggested before. The second tweak would be to delete "risk" in the bottom line. So it would just say "other factors were also sufficient to cause his NHL." And then I would add "on their own" to that.

So it would read (reading):

> "Generally, conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct. However, if you conclude that Mr. Hardeman has proven that his exposure to Roundup was sufficient on its own to cause his NHL, then you should find for Mr. Hardeman even if you believe that other factors were also sufficient to cause his NHL on their own."

And I think probably the thing that came pretty close to solidifying this for me was looking back at the illustration in the restatement that came up -- it was cited in a couple of the cases that you cited, so I'm looking at page -- I'm looking at page 379, Section 27 -- right? -- subsection (e), "Alternative Causes."

MR. KILARU: Sorry. Can you -- 379?

THE COURT: Sorry.

MR. KILARU: No, it's fine.

THE COURT: Page 379.

MR. KILARU: Okay.

THE COURT: And it's the section on -- it's the chapter on factual cause, Section 27; right? And then subsection (e) talks about alternative causes. Feel free to pull it up if you want.

MR. KILARU: Yeah.

THE COURT: Yeah, take your time.

(Pause in proceedings.)

MR. KILARU: Is it the second or the third, Your Honor?

THE COURT: The second illustration.

MR. KILARU: Okay.

THE COURT: Oh, which restatement?

MR. KILARU: Yeah.

MS. MOORE: The second, I think.

MR. KILARU: I think you might have cited both, but I could be wrong about that.

THE COURT: Good question. Let me -- hold on one second.

(Pause in proceedings.)

THE COURT: I'm pretty sure this is the third --

MR. KILARU: Okay.

THE COURT: -- but let me just stare at it for a second here.

(Pause in proceedings.)

THE COURT: Yeah, I'm, like, 99 percent sure it's the third.

MR. KILARU: Is this the causal sets piece?

THE COURT: No.

MR. KILARU: Okay. Oh, sorry. I was looking at 26.

(Pause in proceedings.)

MS. MOORE: It's the third, Your Honor.

THE COURT: So there is -- so the subsection right after it, subsection (f), is the paragraph about causal sets.

MR. KILARU: Okay. Got it.

THE COURT: But then subsection (e) is about alternative causes, which is I think the situation we're facing here; right? And there's Illustration Number 2, and -- did you find it?

MR. KILARU: I don't have it. We're trying to pull it up.

THE COURT: Take your time. Take your time.

MR. KILARU: Okay.

(Pause in proceedings.)

MR. KILARU: Your Honor, we'll keep looking, but I don't want to keep you and everyone here.

THE COURT: Well, let me read it to you.

MR. KILARU: Yeah, that would be totally fine.

THE COURT: So subsection (e), it's titled "Alternative Causes."

MR. KILARU: Okay.

THE COURT: And it says that (reading):

"In some cases, a defendant may contend that the acts of another were the cause of the plaintiff's harm and, thus, the defendant's conduct, tortious conduct, was not a cause of the plaintiff's harm." Okay? "Whether that claim implicates the rule in this section depends on whether the other forces" -- here's I think some key language -- "depends on whether the other forces were operating and sufficient to cause the harm contemporaneously with the defendant's tortious conduct." Okay?

MR. KILARU: Uh-huh.

THE COURT: So whether the other forces were operating and sufficient to cause the harm contemporaneously with the defendant's tortious conduct. So as applied here, that would mean the defendant's tortious conduct, or allegedly tortious conduct, is inflicting Roundup upon Mr. Hardeman; right? And the -- but the other force that may have been operating and may have been sufficient to cause the harm was the hepatitis C. Okay?

MR. KILARU: Uh-huh.

THE COURT: And in that sort of situation, the idea is that you instruct the jury on that, you instruct the jury on the alternative independent causes. And the example that's given is, you know, there's -- you know, an infant born with a birth defect and the question is whether the company's drug caused the birth defect or whether a genetic condition caused the birth defect. And one side presents sufficient evidence that the drug caused the birth defect and the other side presents sufficient evidence that the genetic condition caused the birth defect; right? And so the illustration goes on to say (reading):

> "The fact finder must determine if the drug, absent the genetic condition, would have caused the birth defect. The fact finder must also determine if absent the drug, the genetic condition would have caused the birth defect. If the fact finder determines that either the drug or the genetic condition would have, in the absence of the other, caused the birth defect at the same time, then each is a factual cause pursuant to this section."

So, you know, that is -- it seems to me that although the law overall is very muddled in this area, I think the courts are confused and the California courts have not offered a terribly definitive statement on this question. The California courts do look to the restatement, and it seems to me that the

restatement -- that example provided in the restatement kind of highlights why I have this concern about this case and why this type of instruction may well be appropriate in this case.

So that's kind of my tentative view at this point. I want to give you one more chance to address that.

MR. KILARU: Sure. And I understand the concern based on what's here, Your Honor. I guess I would draw attention to the last sentence of that --

THE COURT: Yes.

MR. KILARU: -- which is (reading):

"If the fact finder determines that either the drug or the genetic condition played no role in the birth defect, then the other's causal status is determined under but-for."

THE COURT: But we don't -- yes. So I agree with that.

MR. KILARU: And what I would say on that is as follows:

I know that much of the evidence has focused on the sort of the clash between Roundup and hepatitis C, and I know that that has been really what the experts have talked about more than anything else, but I think we've heard Dr. Levine testify today that in 90 percent of the cases you can't determine a cause. I suspect Dr. -- I actually think Dr. Arber testified to the same thing as well.

So I think the concern about saying that both things are in the mix is that if the jury concludes both are in the mix but ultimately because I can't determine what it is, I think this is a situation where it was neither, this is one of those idiopathic cases where you can't determine the cause, this would still instruct that they should find us liable, and that's why I think but-for has to be the answer here. It's not just because there's A versus B. There's also this possibility that all the experts have discussed about there not being a cause at all or at least the cause being unknown, and that is part of our defense.

THE COURT: But the instruction doesn't say that. I mean, the -- I think idiopathic -- most of the evidence I think established that idiopathic is not actually a factor; right?

MR. KILARU: Right.

THE COURT: It's if you can't identify the factor, then it's idiopathic; right?

MR. KILARU: Right. Then I think that would put you in the last sentence; right?

THE COURT: What?

MR. KILARU: I'm sorry. I didn't mean to cut you off.

THE COURT: No. I think you were making the same point I was making. Go ahead.

MR. KILARU: Okay. I was going to say I think that would put you in the last sentence of this paragraph where I

think it says but-for would apply.

THE COURT: But why -- I don't understand. I'm not sure I -- I'm not sure I understand what you're saying. What is wrong -- in light of what I've said, in light of the fact that the fact finder needs to make a determination about, you know, whether it was this or that or whether they both independently could have done it, what's wrong with (reading):

> "Generally conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct; however, if you conclude that Mr. Hardeman has proven that his exposure to Roundup was sufficient on its own to cause his NHL, then you should find for Mr. Hardeman even if you believe that other factors were also sufficient to cause his NHL on their own" or "also sufficient on their own to cause his NHL"?

I mean, what about that precludes the jury from saying it was idiopathic and, therefore, I'm concluding that Hardeman has not proven that Roundup caused his cancer?

MR. KILARU: Because I think it sort of frames for the jury that, you know, you have two different potential causes, and I know that is what a lot of the discussion has talked about; and I think what that might do -- the danger of that language that I perceive is that if the jury -- if the jury says it's either A or B and I know for sure it was one of them, then I think that language is helpful. But if the jury thinks

it's A or B and, you know, I kind of agree with our doctors and I can't figure out whether it's A or B and so it shouldn't be either, I don't know that this language leaves open the possibility for that juror to still say "Even though I think Roundup could have been sufficient in the abstract, because I can't determine which of the two it is because I think it's more likely to be neither," I think this might still lead them to say Roundup was the cause in that circumstance.

MS. MOORE: Your Honor, I don't think that's what it says, though. It says has -- we still have to prove that his exposure to Roundup was sufficient on its own.

THE COURT: I mean, don't -- let me -- let's back up from the issue of idiopathy --

MS. MOORE: Idiopathic.

THE COURT: Idiopathy?

MS. MOORE: Idiopathy.

THE COURT: -- for just a quick second, and let me ask you this question.

This example that I just read to you -- okay? -- birth defect or genetic abnormality, don't you think the instruction that I'm proposing here would be appropriate for that situation?

MR. KILARU: If they were just the two things, yes, I think that that's what this is getting at, if there's option A or option B and there's nothing else in the mix.

THE COURT: Okay.

MR. KILARU: This is what I think this is sort of envisioning. It's either A or B is I think the example that's being offered here.

THE COURT: But if there were -- if it was A, B, or C, why wouldn't --

MR. KILARU: It's not as much the C point, Your Honor. It's in this example, one side is saying it was absolutely -- I think as I understand the example, one side is saying it was absolutely A --

THE COURT: Right.

MR. KILARU: -- and the other side is saying it was absolutely B.

THE COURT: Right.

MR. KILARU: And so in that circumstance you sort of evaluate A versus B.

THE COURT: Right.

MR. KILARU: I guess the point I'm making is I don't think our argument is just going to be it was hepatitis C. I think we're entitled to argue it wasn't Roundup and the cause may just be unknown.

THE COURT: Right.

MR. KILARU: And I don't think that the way -- I think the concern with this example is it doesn't account for those possibilities. This example is a situation where the only

thing we were coming in and saying is it was hepatitis C.

THE COURT: I don't -- I guess I'm not seeing that because -- I mean, I would certainly be open to tweaking the language to address that concern, but I guess I'm not seeing that concern because what you're saying is -- you know, again, you've got the first paragraph, which says "To win, he has to prove by a preponderance of the evidence that Roundup was a substantial factor."

MR. KILARU: Could I offer a suggestion that I think may get at this?

THE COURT: Yes.

MR. KILARU: Okay. What if we added to the end "If you find that Roundup was not sufficient on its own to cause his NHL, then you must find for Monsanto."

THE COURT: Well, that statement does not seem objectionable in any way. It's just a question of whether it is repetitive of what's already in the instructions.

MS. MOORE: Your Honor, I think it's repetitive from the first sentence in that paragraph.

MR. KILARU: Well, I think that's the -- oh, sorry. Go ahead.

MS. MOORE: Yeah, I just was going to say, Your Honor, I understand --

THE COURT: I'm sorry. I think I see. Let me keep this train of thought.

MS. MOORE: Okay.

THE COURT: I think I see what you're saying. So generally it's not a substantial factor in causing harm if the same harm would have occurred without that conduct; however, if you conclude that Mr. Hardeman has proven that his exposure to Roundup was sufficient on its own to cause NHL, then you should find for Hardeman even if you believe that other factors were also sufficient to cause his NHL on their own. And then you're saying there should be a sentence that says, "However, if you conclude that it was not sufficient on its own, you must find for Monsanto."

MR. KILARU: Yes.

MS. MOORE: And, Your Honor, now we've gone way past what the model instruction is, and I understand the Court's ruling on option one versus option two and I don't want to revisit that. I do want to make sure it's very clear that our position is that -- the plaintiff's position is it should be option one. We're objecting to option two in its entirety. But --

THE COURT: Wait a minute. When you say you're objecting to option two in its entirety, you're not saying that I should just give the standard 430 with the but-for sentence; right?

MS. MOORE: That's correct.

THE COURT: You're saying so surely you would prefer

option two to the standard instruction with the but-for sentence; right?

MS. MOORE: Right. The but-for sentence meaning the conduct is not a substantial factor?

MR. KILARU: The bracketed language.

THE COURT: Yes.

MS. MOORE: That's the sentence that we're objecting to, Your Honor (reading):

"The conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct."

THE COURT: Right.

MS. MOORE: That's what we're objecting to.

THE COURT: And what I've proposed to add is "generally" to that.

MS. MOORE: And I understand the Court's ruling. I just want to note that objection.

THE COURT: Sure.

MS. MOORE: But then to go and to add an additional sentence and another "however," I think that's going to create a lot of jury confusion, Your Honor, because they're going to read this first sentence, the but-for sentence, the conduct, and then you've got "however," and I think the way you've tweaked it explains that -- again, we've objected to it but I understand what you've done here -- but I don't think we then

continue on by adding additional language. I think that's where it's going to get really confusing.

MR. KILARU: Your Honor, could I propose on that, I don't think this will address the objection, but just dropping the howevers? I mean, I think if you drop the howevers, you have a general statement qualified by the word "generally" and then sort of instructions on how to apply that in two circumstances that could be present during deliberations.

THE COURT: And your concern is that it does -- you know, it sort of covers one specific scenario --

MR. KILARU: Right.

THE COURT: -- which is you find it's either sufficient on its own.

MR. KILARU: Right.

THE COURT: But it sort of hasn't targeted the other scenario, which is you find that Roundup is not sufficient on its own.

MR. KILARU: Yeah.

THE COURT: I get that concern. So here's what the ruling is going to be. I'll go back -- I'm going to go back and do some wordsmithing, and if anybody -- you know, and I'll file something tonight; and if anybody wants to file an additional concern about the wordsmithing that hasn't already been raised here --

MS. MOORE: Okay.

THE COURT: -- I mean, you've preserved your objections --

MS. MOORE: Thank you, Your Honor.

THE COURT: -- but if you have an additional wordsmithing concern and you want to file something on that, you're free to do so.

But the instruction that I will put out, I suppose -- you know, I will put it out soon. I will do it -- put it out soon; and I suppose that while I'm drafting it, I reserve the right to change my mind again.

But what I'm going to do, what I'm 99 percent sure I'm going to do is provide option two as I read it to you all just a second ago, including the word "generally" and all that, and then add the concept that Mr. Kilaru was suggesting, and that that will be the causation instruction.

MR. STEKLOFF: And can --

MS. MOORE: And, Your Honor, I'm sorry. So we would just ask that if you're doing that, that you keep that first "however" as you read it to us.

THE COURT: Okay. And I'll wordsmith it --

MS. MOORE: Okay.

THE COURT: I'll wordsmith it to make sure it's not -- it doesn't create undue confusion. I mean, I understand your point that it seems like a "however" is appropriate there, but I'll do some word submitting on it.

MS. MOORE: Right. I think the "however" following the first sentence is appropriate. I'm not so sure that saying "however" the second time is -- I think it's going to raise confusion.

THE COURT: I think the point is that it seems appropriate to call out both concepts, and that's what I will do, and I'll do some wordsmithing to make that work.

MS. MOORE: Okay. We'll look at that. Thank you, Your Honor.

MR. STEKLOFF: And on the current sentence, without the one that we've just proposed adding, can I -- you read this both ways where you put "other factors were also sufficient," I think the "on their own" should come after "sufficient" because it's consistent with the prior line.

THE COURT: Yeah.

MS. MOORE: That's fine, Your Honor.

THE COURT: Okay.

All right. So that's jury instructions.

And then we've covered a major issue in terms of what can be argued and what cannot be argued, and that is, just to repeat, the plaintiffs are not permitted to argue that the two -- that two -- that any combination of factors combined to give Mr. Hardeman his cancer. So that's one ground rule for closing arguments, no combination arguments.

MS. WAGSTAFF: May I go next, Your Honor?

THE COURT: You may, although can I raise one more that's on my mind just before I forget it?

MS. WAGSTAFF: Sure.

THE COURT: This is an issue that I had not focused on until we got to -- until Dr. Mucci's testimony, but Dr. Ritz testified that the numbers in the De Roos 2003 study would have changed if the IARC had classified glyphosate as a probable carcinogen; and if I remember correctly, she testified that the weight that would have been assigned to glyphosate in the De Roos analysis would have been .8 or .9.

That was completely made up. That was -- as far as I can tell, that was completely junk science; and had I sort of understood the lack of basis for that testimony, I would have excluded it.

But after sort of looking carefully at the De Roos study and the explanation of the values that were assigned and how they -- how different values were assigned to different substances or pesticides, I don't see how that it was remotely appropriate for Dr. Ritz to testify to that. And so my tentative view is that, you know, you can't mention that in closing argument.

MS. WAGSTAFF: And I wasn't going to mention that, Your Honor.

THE COURT: Okay.

MS. WAGSTAFF: I will -- I will -- if I intend to talk

about the hierarchical or logistical, it will be for a different reason than that, than Dr. Ritz's testimony.

THE COURT: Okay. So just to be clear, Dr. Ritz's testimony about how the hierarchical regression would have come out if glyphosate had been classified a probable carcinogen by the IARC is off limits. Everybody understand that?

MR. STEKLOFF: I certainly wasn't planning on raising that.

MS. WAGSTAFF: Yeah. I mean, I think the testimony that it would change based on an IARC classification should be allowed, but I don't think that -- I mean, that's right there in the objective language of the --

THE COURT: I don't think so. I think -- I mean, maybe -- I think the problem that you have there is that Dr. Ritz offered, like, a junk opinion on that topic, and so basically you don't have any evidence on that topic.

MS. WAGSTAFF: Well, I have Dr. Mucci, who I asked about it and I showed on the screen. And here's the thing with that study, is that, you know, it's a doubling of the risk fully adjusted study. And so Dr. Mucci is discounting that by saying you look at the hierarchical; right?

THE COURT: Uh-huh.

MS. WAGSTAFF: She's saying don't look at the logistical and the hierarchical isn't a doubling.

THE COURT: Right.

MS. WAGSTAFF: And so what she's doing is she's drawing these thresholds and say "Look at this." And when I asked her about it and I said, "Well, this number was based on this weighted thing," and I walked her through it and I said, "It was given a .3 because of the time that this was done in 2003 or earlier, whenever they did it, IARC hadn't ruled on it." And she said correct. And I said they've ruled on it now. And she said correct.

And when I pushed her, she said she wouldn't know how it would change, but I think I can elicit that at least the circumstances have changed. She admitted that that .3 was a weighting and so, therefore, her discounting of that study was improper --

THE COURT: Well, I --

MS. WAGSTAFF: -- or at least highlight it to the jury.

THE COURT: You know, I mean, maybe it's a question of line drawing because you have no competent testimony that it should have been anything other than .3. I mean, that's the problem. So, you know, I suppose you have evidence that glyphosate -- if the De Roos analysis were done again, glyphosate would not have fit any of the categories in that key; right? That's the only evidence you have, is that glyphosate no longer fits into any of the categories in De Roos' key.

MS. WAGSTAFF: So it would be different. I have --

THE COURT: It might be different.

MS. WAGSTAFF: Uh-huh.

THE COURT: I mean, I -- you know --

MR. STEKLOFF: It might be lower.

THE COURT: Well --

MS. WAGSTAFF: I mean, I have --

THE COURT: -- I don't see how it would be lower.

MS. WAGSTAFF: Right. I mean, I have other things that were testified about it.

THE COURT: It might be the same.

MS. WAGSTAFF: But I will not bring up Ritz when talking about that study.

THE COURT: Well, I mean, I suppose it would be fair -- I mean, I think you have a point that you could say, "Look, Mucci wasn't even willing -- you know, she's" --

MS. WAGSTAFF: Yeah.

THE COURT: -- "focusing on this hierarchical and she's not even willing to acknowledge that it should have changed somehow, somehow, because of -- you know, because of the classification." Maybe that is fair game.

MS. WAGSTAFF: And that's all I was going to do with it, and then I was going to say some other points related to why I think the hierarchical is better or not related to Ritz or anyone, one of them being that the actual author herself

chose to put the logistical numbers in her '05 paper when describing the '03 paper. I think that's fine.

And the second one is that Dr. Weisenburger came here and testified that the logistical numbers were perfectly fine and good to use.

So those three sort of things put together is what I would testify about that.

THE COURT: What would be wrong with saying, you know, she -- you know, that she didn't -- Mucci was unwilling to acknowledge that this might have changed?

MR. STEKLOFF: I don't -- well, I think that's actually not her testimony. So that might be what's wrong is I think she said, "It would have changed. I can't tell you where it falls."

MS. WAGSTAFF: That's fine.

THE COURT: Well, I don't think she said it would have changed. I think she said "I have no idea" because now based on the situation, glyphosate is not in any of these categories.

MR. STEKLOFF: Well, that's fair. But as Your Honor just said, it could have stayed at .3. None of us know. So I think that her testimony -- I think to portray her testimony as somehow being disingenuous or inaccurate is wrong.

THE COURT: Fair enough. But what would be wrong with saying: Look, she relied on this hierarchical but the hierarchical was based on -- was conducted at a time when, you

know, this was a .3 because glyphosate had not been classified by either agency and now it's been classified by IARC as a probable carcinogen; and so, you know, the number that she is focusing on is less reliable now than -- you know, what's wrong with that?

MR. STEKLOFF: Because I don't think that that's factually accurate. I think this is sort of where I've had to draw some lines, say, about BCL-6. I think you would have to say "But the EPA has determined also that it's not carcinogenic and so no one -- as Dr. Mucci said, no one knows where it would be. I think if you completed the story like that, it would not be objectionable. If you only tell half the story, I don't think that that's fine.

THE COURT: Well, I mean, lawyers only tell half the story in closing --

MS. WAGSTAFF: He can argue all he wants.

THE COURT: -- argument all the time.

MS. WAGSTAFF: I think I can --

THE COURT: The point is you can't rely on admissible evidence and you can't be misleading about the evidence.

MR. STEKLOFF: But it's different in this circumstance where had Dr. Ritz not said anything, I agree that she could tell half the story. We are in a different circumstance here because of what Your Honor has identified about Dr. Ritz, and it's that --

THE COURT: Well, you could move to strike that testimony.

MS. WAGSTAFF: And did you even object to it?

MS. MATTHEWS JOHNSON: Yes, I objected to the question.

MS. WAGSTAFF: All right.

MR. STEKLOFF: So I think that the problem of telling -- I agree, lawyers tell half the story. Then it would be my job to get up and tell the other half, but that's different here where it draws attention potentially to something that -- it sort of -- this problem is created because of what you just called junk science.

THE COURT: Well, I mean, you could move to strike Ritz's testimony now. You could move to strike it in the event that she makes a misstatement -- you know, sort of brings it up in her closing. You know, I don't know. But I think that what she is -- the sort of basic thing that she is proposing, which is, you know, the calculation changes, you know, it --

MR. STEKLOFF: Potentially.

THE COURT: -- potentially changes.

MS. WAGSTAFF: And the reason to know how is even more strong for my argument.

THE COURT: Well, I'm not sure how that's the case but, in any event, that's for you to argue, I suppose.

But I think, you know, there can be no direct or indirect

reference to Ritz's testimony about that; and, you know, it's appropriate to say that, you know, that glyphosate doesn't fit into any of these keys anymore.

MS. WAGSTAFF: I mean, I would propose --

THE COURT: You established that in Mucci's cross. That's fine.

MS. WAGSTAFF: Okay.

THE COURT: Okay. And what else?

MS. WAGSTAFF: So just to be clear, though, I can say that when this was done, there was no IARC ruling. Now there's an IARC ruling so it no longer fits in there, and that's what I can say about Mucci's testimony?

THE COURT: I think that's right.

MS. WAGSTAFF: Okay. Something that I would propose is in their opening slides they had failure to warn slides about the doctors. I think that if -- one of their slides said that none of the doctors warned or do warn about it, and I think that that's inappropriate for closing. I think that --

THE COURT: You mean the stuff about just that the doctors never told them --

MS. WAGSTAFF: Yeah.

THE COURT: -- never discussed with Hardeman the fact that glyphosate was a risk factor?

MS. WAGSTAFF: Well, I think their slide actually said something something warned. I can show it to you.

THE COURT: I should have brought my slides up. I don't have them with me.

MS. WAGSTAFF: I think it says specifically -- it was attached to something we filed. Is this it? No, this isn't it. Just one second.

(Pause in proceedings.)

MS. WAGSTAFF: Do you have it in front of you?

MR. STEKLOFF: It's changed a little, but it's that one.

MS. WAGSTAFF: No. There was actual the word "warn."

THE COURT: By the way, we need to talk about the medical records issue; right?

MR. STEKLOFF: I agree.

(Pause in proceedings.)

MS. WAGSTAFF: Yeah. Do the doctors -- there's this -- there's this? It says "Do the cancer doctors," the first one is "Ask about Roundup," "Test for Roundup," "Warn about Roundup"; and I don't think that that's appropriate to be making argument on whether or not the doctors warn about Roundup.

MR. STEKLOFF: I'm not making that argument so I don't need to -- we don't -- I don't think it needs -- I will not make that argument.

THE COURT: Okay. If you're not going to make the argument, therefore, you're not allowed to make the argument.

MR. STEKLOFF: That's fine. I'm not making that argument.

THE COURT: No talk about doctors warning about Roundup.

MR. STEKLOFF: Okay.

MS. WAGSTAFF: One question I would ask. Dr. Mucci gave some testimony elicited on direct about the PPEs, and when she was talking about questionnaires and she kind of went a little bit further than the questionnaire and she started talking about how the thought is that when you wear PPEs, you get less exposure, and she kind of went on and so on and so forth.

And I've got that pulled if you want it, but I just wanted to know if that was going to be one of the arguments, we would want a curative instruction that he used the product pursuant to the label.

MR. STEKLOFF: I'm not arguing that.

MS. WAGSTAFF: Okay.

THE COURT: Okay.

MR. STEKLOFF: I had a few if Ms. Wagstaff was finished.

MS. WAGSTAFF: Yeah. We may ask for a curative instruction on that tomorrow if we go back and reread Dr. Mucci's testimony, but we'll bring that up tomorrow.

THE COURT: Okay. I'll give you my reaction to that

now is that Dr. Ritz and Dr. Mucci both engaged in speculation about what was going on in people's minds when they were filling out this questionnaire, including Dr. Ritz speculating about personal protective equipment.

So, you know, I didn't see anything that sort of crossed the line into raising concerns about whether Hardeman used it as intended, but this topic of using personal protective equipment and how the farmers responded to the questionnaire about that was very much introduced initially by Dr. Ritz in her speculation about what they were thinking and what they were not thinking when they responded to the questionnaire.

MS. WAGSTAFF: So we'll go back and look at that and raise it again tomorrow if we think we need to.

THE COURT: Okay.

MR. STEKLOFF: I should clarify now -- someone said this to me -- on the question of warn, I do think it's relevant that if the oncologists knew that Roundup was a cause, they would tell their patients. I think I can argue that they should stop using Roundup, and I don't want that to be confused with warn.

THE COURT: Right.

MS. WAGSTAFF: So, then, I think if he's going to make that argument, I think that we have a party stipulation that we've already stipulated -- we have an RFA that says Monsanto never warned that Roundup could cause cancer. And so if

they're going to say their doctors, if they had known, they would have warned, and, oh, look, they didn't warn, then I think that one of the reasons we could say is because Monsanto never warned them.

THE COURT: But that begs the question of whether it causes cancer.

MS. WAGSTAFF: Right. So I'm saying that it all -- none of it should come in. I think that it's a complete distraction to what we're doing tomorrow.

THE COURT: Yeah, I understand. I think it's relevant; and, as I've said, I mean, part of why I allowed the stuff in about the mouse study from 1932 or whenever it was was, you know, that --

MS. WAGSTAFF: It's 1985.

THE COURT: I know, sorry.

-- it had some relevance, you know, to this issue. But it is permissible for them to argue in closing the testimony about doctors not warning -- not telling their patients to stop using Roundup.

MR. STEKLOFF: Your Honor, if I can go through my --

THE COURT: It is not permissible to say that Monsanto didn't warn its people -- warn the public and its customers that Roundup causes cancer.

MR. STEKLOFF: Your Honor, I just have a brief list. First, I don't think either of us should say anything about

Phase II. I don't think Phase II -- I'm basing this on the opening. I don't think Phase II should come into play. There should be no talk about what might happen based on their verdict.

THE COURT: Yeah. And I will tell them tomorrow that, you know, they'll be ready to present arguments to you on Phase II when you're done; and then I agree, neither of you should say a word about Phase II either directly or by implication.

MR. STEKLOFF: Okay. My second, Your Honor, is, this is also based on the opening, there was a slide that had company employees and a big question mark that said "live," and I think any argument that we did not present a company witness is inappropriate. It's shifting the burden, and I don't think that that would be appropriate.

MS. WAGSTAFF: I mean, I think that's argument and it goes to sort of the strategy of defending this case. And I think we absolutely, in every case I've ever been involved in, have been able to argue that, that they didn't bring anyone to testify live for you. I think that's completely appropriate in closing argument.

THE COURT: But Donna Farmer doesn't even work there anymore; right?

MS. WAGSTAFF: She does work there.

THE COURT: Oh, she does work there.

MS. WAGSTAFF: So does Bill Reeves. So does Goldstein. So does almost every person we brought on video.

THE COURT: Do you-all have case law on this because my sort of gut is there's nothing wrong with what she did in opening on that. You know, that's not one of the things I called her out on.

You know, Monsanto could bring these people to testify live and they didn't, and they can't force them to come and take the stand. What's wrong with briefly mentioning that?

MR. STEKLOFF: Well, I think it's in any circumstance, even in a nonbifurcated trial, burden shifting because we don't have the burden to bring someone. So I think there's case law on that, but we will have to go find it.

But in this circumstance in a phased trial where we are talking about causation, I'm not -- I mean, what this person could have said where Your Honor has ruled that they can't -- that they're only fact witnesses, they can't present expert testimony, for example, about the extreme dosing and animal studies and other things in Phase -- maybe we revisit this if there's a Phase II; and at the end of Phase II, maybe you say it's appropriate there if we don't bring a company witness. But I'm not even sure -- I mean, I'm not sure how we could have even cabined a company witness' testimony here, and so I think in this trial where we are right now, it's inappropriate and it should not happen tomorrow.

MS. WAGSTAFF: And, Your Honor, I think that they absolutely could have brought company witnesses. And as you know from listening to the trial, one of our themes is sort of looking at the whole picture of evidence, and they didn't produce anyone on toxicology and anyone on mechanism, and I intend to point that out to the jury, whether it's by expert or corporate witness. And they could have brought somebody to talk about this information. Donna Farmer could have come and talked about -- and talked about the animal studies. She absolutely could have.

THE COURT: Well, I don't know. That begs the question whether she was an expert and would have qualified as an expert to do so.

But my ruling as of now on the issue of live witnesses is that I think if you briefly mention it in the way that you did in your opening statement, I think that's fine. That's my sense is that I understand that there's a 403 argument, but I think it's fine. If you have case law to the contrary, go ahead and submit it and I'm happy to look at it and, you know, let you know tomorrow morning.

MR. STEKLOFF: Okay. On Dr. Levine, I think it would be inappropriate to argue anything about her general causation opinions or general causation methodology. I think based on the door opening, I was able to ask a few questions, but I don't think it would be appropriate, for example, to compare,

like, the amount of time Dr. Weisenburger spent talking about general causation with the amount of time Dr. Levine spent on general causation.

THE COURT: Certainly not.

MR. STEKLOFF: Okay.

MS. WAGSTAFF: So just so we're clear on what I intend to do, because I had planned closing before today, I wasn't even considering Levine a general causation witness. So I'm kind of still operating under that assumption because she testified earlier that all of her general causation opinions were coming through Mucci, which I don't think opened the door changed.

I think you let him ask those questions about epidemiology just based on some things that Ms. Moore had asked her. I don't think that you were -- your ruling was, "Oh, now, you're a general causation witness," and that's why we didn't follow up with a bunch of cross on epidemiology. And, furthermore, she didn't testify, even when you did open the door, that she reviewed any animal data or mechanistic data. So that's sort of where I am on that.

THE COURT: Right. But what does that -- I mean --

MS. WAGSTAFF: So I'm not going to --

THE COURT: I mean, I was a little vague about what you were intending to say about her on closing.

MS. WAGSTAFF: So when I talk about -- you know,

obviously there's two sort of sections in closing; right? There's general causation and specific causation. So when I talk about general causation and the testimony that Monsanto brought, I was just going to use Dr. Mucci.

THE COURT: Right.

MS. WAGSTAFF: And I wasn't even going to move her into the classification of general causation because it wasn't my understanding that you were then letting her be a general causation witness. My understanding was you were just letting her say "Yeah, I've read the epidemiology" based on some questions Ms. Moore asked her, but you weren't saying, "Yeah, and so now you're a general causation expert." Because, as you know, we hadn't put her epidemiology opinion through the test.

THE COURT: I mean, I don't have a beef with anything that you just said --

MS. WAGSTAFF: Okay.

THE COURT: -- but I also think it would be appropriate -- you tell me, do you have a beef with anything she just said?

MR. STEKLOFF: No. I think we're going to the same place, which is that I can still argue that Dr. Levine did offer an opinion that Roundup generally does not --

THE COURT: Well, I mean, offer an opinion? I don't know. I think that you can say that she -- I think you can say what she said.

MR. STEKLOFF: Sure. Okay.

THE COURT: I don't think you can say she offered an opinion because she didn't actually offer an opinion in the way that we understand that term --

MR. STEKLOFF: Okay.

THE COURT: -- right?

MR. STEKLOFF: I can use the phrase "Based on her review of the literature does not think," you know, or something.

THE COURT: Yeah, she agrees with Dr. Mucci as she testified. She's reviewed the letter and the literature and she agrees with Dr. Mucci.

MR. STEKLOFF: I think in redirect she was able to go a little bit further, which was to say that independent --

THE COURT: She has reviewed the literature.

MR. STEKLOFF: And independently does not think, not just based on Dr. Mucci, she does not think Roundup causes or is associated with non-Hodgkin's lymphoma.

THE COURT: I mean, I think it is fine to mention the testimony she gave. It was testimony. It was admissible. It was allowed in, but to sort of dress it up as an opinion, right, we have this instruction on experts offering opinions. And I don't think it will -- it would be fair to say that she offered a general causation opinion. She offered a specific causation opinion and in response to questions on

cross-examination or whatever, she offered an opinion on specific causation.

MR. STEKLOFF: I don't think she did. I think if I can reference the testimony that she offered on redirect -- and I will not characterize it as an opinion -- then I'm fine with that.

THE COURT: Yeah. Again, it will be the kind of thing where if you go overboard with it, I will need to cut you off.

MR. STEKLOFF: No problem.

THE COURT: Okay.

MR. STEKLOFF: And then the last one --

MS. WAGSTAFF: Before we leave that topic --

THE COURT: So --

MS. WAGSTAFF: -- I intend to do the reverse and argue that she didn't offer a general causation opinion, because --

THE COURT: Well, I think that would be a real problem because she didn't -- you know --

MS. WAGSTAFF: Or at least if she did, it is only on the epidemiology.

THE COURT: Well, I think it would be fine for you to say she reviewed the epidemiology, but she didn't tell you that she reviewed the animal studies and the cell studies. I think that's fine.

And for the record, your opponent is nodding yes to that.

MS. WAGSTAFF: Yeah. And so taking it one step

further, though, if you put together all of her testimony, what Dr. Levine actually said was she is relying on Dr. Mucci's analysis of the epidemiology. She said that at the beginning of the testimony. I think I can tell the jury that.

And then later Mr. Stekloff said, Have you reviewed the epidemiology?

She said, Yes.

He didn't say, Did you do your own analysis and, you know, all of that kind of stuff.

So I will go back tonight and reread it, and I will make sure I say everything that sort of fits together; but I think her earlier testimony that she is relying on Dr. Mucci's analysis of the epidemiology is sort of the way that her testimony came in.

THE COURT: Well, she relies on it. She agrees with it, and she has done her independent review of the epidemiology. I think it is fair game to say she didn't -- she is not basing -- you know, she is not basing her opinion on animal studies or anything like that. That's certainly fair game.

MS. WAGSTAFF: All right. Well, I thought we just agreed that she wasn't giving a general causation opinion?

THE COURT: Yes.

MS. WAGSTAFF: Okay.

THE COURT: That's correct.

MS. WAGSTAFF: Okay.

MR. STEKLOFF: I think --

THE COURT: Where am I confused? It sounds like --

MS. WAGSTAFF: It gets confusing.

MR. STEKLOFF: I don't think that Ms. Wagstaff should be able to argue that she doesn't -- didn't give a general causation opinion. I similarly don't think I should be able to say she did give a general causation opinion. I think we should both rely on what her testimony was in its totality, and that includes the redirect, which is that she did her own independent review of the epidemiology and based on that review, she does not think that glyphosate or Roundup is caused -- is the cause of non-Hodgkin's lymphoma. That's where we are now based on the cross-examination. And I think anything that characterizes it as something other than that is inaccurate.

MS. WAGSTAFF: The jury doesn't know what general causation is. So, I mean, I will just argue what her testimony is.

THE COURT: That makes me a little bit nervous, but -- you know, I'm not sure how much we can pre-adjudicate this. I think -- all I'm saying is I think it would be inappropriate to say, Look, she got up there and said that she believes -- she reviewed the literature and she believes it is not a risk factor, but she never gave you any explanation why. That would

be totally inappropriate because -- because she was capable of giving an explanation why. She just didn't because that's how the pretrial rulings went down.

MS. WAGSTAFF: Okay.

THE COURT: Does that make sense?

MS. WAGSTAFF: Yeah.

THE COURT: Okay.

MR. STEKLOFF: Doubling of the risk specific to Mr. Hardeman, I think that's off limits in terms of dose response. Again, it is not off limits --

THE COURT: In terms of dose response, yes.

MR. STEKLOFF: Yes.

THE COURT: Yeah.

MS. WAGSTAFF: Well, hang on. Let me just make sure I understand.

In the specific causation when we are saying -- when we are talking about Mr. Hardeman, I'm not to say Because he used it more than two days or ten days, his risk is doubled.

THE COURT: That's correct.

MS. WAGSTAFF: Okay. Yeah, I wasn't going to do that.

THE COURT: The experts were precluded from testifying --

MS. WAGSTAFF: When I talk about the cases, and I'm describing dose response, I can put up there the 2.1, which is a 210 percent increase risk.

THE COURT: I mean --

MS. WAGSTAFF: Talking about the general causation.

THE COURT: General causation, yes.

MS. WAGSTAFF: I'm going to do general causation, and then I am going to do specific causation. So I can actually use those numbers in my general causation?

THE COURT: Yes.

MS. WAGSTAFF: Okay.

MR. STEKLOFF: Then we have two others, and maybe this is sort of just a gray area. But I'm not saying she can't -- of course, she can state what the IARC classification was, and maybe a little bit more, but I think, you know, veering into where we were in opening, in terms of the 18 scientists and France and all of that, I don't think that that -- I think consistent with how you ruled in opening, that we shouldn't cross that territory in closing.

THE COURT: Well, I mean, you know, we have an instruction that you are not supposed to substitute -- you are not to substitute the EPA's judgment for your own or the IARC's judgment for your own. So it seems that it would follow from that, that, you know, you don't cite IARC or EPA in support of your conclusion that it does or does not cause cancer. Right?

MR. STEKLOFF: Yes.

THE COURT: So you agree that you should not be citing the EPA or the European regulators in support of your argument

that it does not cause cancer?

MR. STEKLOFF: I think I can cite the EPA and the European regulators in response, for example, to Dr. Portier's opinions, because that's how it came in. And otherwise I'm fine if neither of us can -- need to -- can -- follow the instruction and not say that they should somehow substitute their judgment for IARC or the regulators.

THE COURT: I mean, the fact that they have reached their conclusion, that has come in.

MR. STEKLOFF: Yeah.

THE COURT: You know, I don't -- I don't -- the question is whether there needs to be, like, a hard-fast gag rule about it or whether, you know, it -- whether it can be mentioned as part of the discussion of the evidence that came in, you know, subject to the limitations that we have already discussed.

MS. WAGSTAFF: Obviously I have an objection with Monsanto talking about the EPA and foreign regulatory decisions and me not being able to talk about IARC. There is sort of a theme that they are developing with their witnesses that there is no evidence, no evidence across the board, no evidence, no evidence.

So I think me being able to at least mention IARC -- I have it in one slide. It is very diluted down. You are going to see it at 7:00 o'clock in the morning. I can take it out if

you don't like it, but I think you will be fine with what I have.

THE COURT: Okay. But it is not just what is in the slides. It is what you say when you put up the slides.

MS. WAGSTAFF: Yeah, I understand that. I can practice in front of you tonight.

THE COURT: Well, I'm comfortable just sort of dealing with IARC and EPA the way we have dealt with it thus far. I mean, in terms of the evidence coming in, it worked out fairly well. The message should be quite clear about -- about closing argument in light of what happened in opening statements.

So, you know, I'm comfortable leaving it that way, but if either side wants to sort of delineate further grounds rules, I'm happy to try that too.

MS. WAGSTAFF: Well, I don't think we presented too much evidence pumping up IARC too much. I wouldn't be surprised if all the jurors don't even know what IARC is.

THE COURT: Well, they will after they get this instruction.

MR. STEKLOFF: The last is just -- it's fine. Okay. I won't even press the other one.

I have a different question about closing, which is -- I know there are no time limits, but I do think that having some time limit for the rebuttal closing is appropriate because otherwise --

THE COURT: Yeah.

MR. STEKLOFF: Normally there are some time limits over closings overall, and a certain part can be apportioned for rebuttal. So I'm hoping there is some guidance of how much time can be used for that.

THE COURT: Well, usually what I do is like a quarter of the time you spent on your initial closing, you can spend on your rebuttal.

MR. STEKLOFF: I would be fine with that.

THE COURT: Any problem with that?

MS. WAGSTAFF: No.

THE COURT: Okay. So if it is an hour in your initial closing argument, it is 15 minutes on rebuttal.

MR. STEKLOFF: And then the last question I have, Your Honor, is earlier it was referenced to potential rebuttal testimony. I don't think in the time remaining -- 20 minutes or so on Dr. Arber -- is going to change the universe of our evidence very much. So I think we should know now if the Plaintiffs are going to argue that there is some sort of rebuttal evidence so we can address if before tomorrow morning.

THE COURT: That's fine.

MS. WAGSTAFF: Well, they have asked me a couple of times about this, and now they are asking in front of you so I guess I should answer.

We have some testimony from Dr. Portier on the third

day -- remember he was in Australia. He did direct, cross, and then the third day was all rebuttal. So we have a couple of sections highlighted out. That is not very much. It is probably less than ten minutes. And we were working on that today as Dr. Levine was testifying.

And so I would like the opportunity to talk to my cocounsel who has been quite busy all day, and I can get to them the cites that we are talking about later tonight. I just don't have it finalized right now, so I don't -- I mean --

THE COURT: Okay.

MS. WAGSTAFF: -- I wasn't prepared to do that.

THE COURT: By 8:00 p.m. tonight.

MS. WAGSTAFF: Okay. That much time, wow.

MR. STEKLOFF: And other than, I think, addressing the medical records, the authentication issue, I don't have anything else, Your Honor.

THE COURT: Well, then, let's talk about that.

MR. KILARU: I think there is a relatively straightforward answer to that, Your Honor, which is 902(11) -- FRE 902(11), talks about certifying domestic records of a regularly conducted activity.

THE COURT: 902 what?

MR. KILARU: 902(11), Your Honor.

It says, The original or a copy of the domestic record that meets the requirements of the Business Records Rule

803(6), as shown by a certification by a custodian or another qualified person that complies with the statute or rule.

And we have -- I think we submitted --

THE COURT: What is the a definition of a domestic record?

MR. KILARU: I believe -- I think it would probably come back up to 803(a)(6) perhaps. I guess it wouldn't go back to 803(a)(6), but --

MS. MOORE: Your Honor, I'm going to -- I don't think medical records come in under this subsection, but I need to double-check.

THE COURT: Well, it's not that they come in. It is about authentication.

MR. KILARU: I think it would count. We can look into this domestic records question. I think this is several arguments we have in favor of letting it come in.

We have affidavits from the custodians of medical records at Kaiser, and on both of these affidavits -- I can provide Your Honor a copy if you like -- they have a box checked that says, The person certifying that the records were prepared by the personnel of the hospital staff, physicians or persons acting under the control of, either in the ordinary course of business at or near the time of the act, commission or event.

THE COURT: Okay.

MR. KILARU: So I think that should get us over the

authentication hurdle.

THE COURT: Okay.

MR. KILARU: Independently, in Rule 901, I believe it is 901(b)(4) -- there is authority for permitting authentication if the appearance, content, substance, internal patterns or other distinctive characteristics of the item, taken together with all the other circumstances, satisfy authenticity.

THE COURT: Okay.

MR. KILARU: I think, as Mr. Stekloff pointed out, these records were discussed on the screen with the medical providers, and so I think there shouldn't be that much debate about that.

THE COURT: Okay.

MR. KILARU: And there is a case, Tate -- actually it involves Kaiser, of all providers -- but *Tate v Kaiser*. It is at 2014 Westlaw 176, 625. It basically talks about both of these provisions, but sort of puts them together and says even if it technically doesn't meet either one, it is close enough. It is a California case. I believe it is from the Northern District, but I'm not 100 percent sure which district in California. I think given the circumstances, given how many of these medical records have come in --

THE COURT: Can you give me the cite again.

MR. KILARU: Sure. 2014 Westlaw, 176, 625, I'm pretty

sure.

THE COURT: Okay.

MR. KILARU: We have looked through the notes on 902, and I don't think there is further definition of domestic records other than to sort of contrast them with foreign records, which I think this clearly isn't.

THE COURT: Okay.

MR. KILARU: So I think that we believe that that should take care of the authentication issue, and at that point we think they can be admitted to the expert.

THE COURT: Okay.

MS. MOORE: Well, Your Honor, there is still the issue of hearsay. Under FRE 703, hearsay is permitted; but that's only to explain that the expert relied upon it. It is not to be admitted for the truth of what is asserted.

And so we would ask for an instruction if the Court was going to allow -- first of all, I don't think it is proper under 902 for them to dump these medical records that they weren't able to get in under the doctor's depositions. And they were there at the doctors' depositions. They had an opportunity to cross-examine all the doctors. They have submitted exhibits at the trial for those doctors. These are additional records that they didn't get in with the doctors, and now they are trying to get them in through an expert. And I don't think that's proper. I don't think that is proper

authentication.

And so we would ask that if the Court was inclined to allow that to come into evidence, that it not -- that there be an instruction -- I mean, I actually need to see what the exhibits are because I don't recall at this point at 6:30 at night, Your Honor, which ones that we are talking about.

THE COURT: I think it was actually relatively inconsequential, but not to say --

MS. MOORE: Yeah, I know. I don't want to spend -- I don't want to waste the Court's time.

THE COURT: No. I'm not saying you can't object to it.

MS. MOORE: If we could -- if you can let me look at it tonight and I can let the defense know.

THE COURT: Well, I mean, the time for looking at the exhibits I think has passed. The question is whether they are admissible under these circumstances, whether they are -- they have been adequately authenticated in the way that Mr. Kilaru has described, and whether -- and whether they can come in through the experts if they have been adequately authenticated. That's really the question.

So do you have anything else to say about that?

MS. MOORE: Yeah, Your Honor. The only other thing is I did object to this when they sent me their exhibit list. And I said that it was improper under hearsay. And I was told, and

I was trying to pull that up -- that they were not going to admit them into evidence, and so I wasn't prepared for that.

I want to try to see if I can -- as you can imagine, we have a lot of e-mails back and forth -- but that was my understanding, Your Honor.

MR. KILARU: I don't believe -- I'm not sure. I don't believe we agreed to that just on the hearsay point. I think if it is authenticated under 902 as a business record, it can come in as a business record. I also think it fits in the medical exception statement, 803(4). I think the authentication objection, it is pretty clear, was not made --

THE COURT: The medical exception statement, was it -- none of those records are reflected as statement by Mr. Hardeman to his treaters, did it?

MR. KILARU: I don't -- well, I think it goes both ways in those records.

THE COURT: I don't think so. I think that statement -- that exception for a statement to a medical provider only goes to a statement by the person who is seeking treatment. I don't think it's from the doctors to the patient.

MR. KILARU: My understanding is different, Your Honor, because I think it is about statements made for medical diagnosis of treatment. And I think the rationale that you have for that rule is that neither side has sort of an incentive to lie in that circumstance. We think it applies

just as well to the doctor's side to the patient's side. I don't think there is anything in the rule that limits it to the declarant being the patient as opposed to the doctor. I also think --

THE COURT: There is nothing in the text of the rule, but I think there is quite of a bit of case law.

MR. KILARU: We can look at that as well. I also think the 803(a)(6) point resolves it as well.

THE COURT: Okay. I will go back and look at that a little bit more, and I will issue a ruling.

What were the exhibit numbers? Does anybody remember?

MR. KILARU: I can get those.

(Whereupon, a brief pause was had.)

MS. RUBENSTEIN: It was Trial Exhibit 1023 at pages 940 and 192.

The other -- the other two that were referenced today are actually already in evidence.

THE COURT: So it was just that one exhibit and those two pages?

MS. RUBENSTEIN: That's right. We have the medical records.

THE COURT: Pages 940 and what?

MS. RUBENSTEIN: 940 and 192, Your Honor.

THE COURT: Okay.

MS. MOORE: Do you have a copy?

MS. RUBENSTEIN: Yep.

THE COURT: In light of the fact that it is down to one exhibit, you want to just glance at it and make sure you really care?

MS. MOORE: I can, Your Honor.

MR. KILARU: Your Honor, do you want these affidavits or --

THE COURT: Sure.

(Whereupon, a brief pause was had.)

MS. MOORE: Your Honor, I do want to look at this because it looks like something has been redacted off of this.

(A brief pause was had.)

MR. KILARU: I want to make an unrelated issue that I don't think should take up too much time.

But we did make our -- Mr. Stekloff made our directed verdict motion the other day. I think, whether it is today or tomorrow morning, I think it would probably behoove us to put some reasons on the record. I don't want to take too much with that, so we can either do that now or later, whatever you prefer. We can do it tomorrow morning very quickly.

THE COURT: Before closings?

MR. KILARU: Yeah. I mean, I think given how much time we spent talking about the jury instructions --

THE COURT: Okay. We can do that before closings if that's necessary, yeah.

MS. WAGSTAFF: And then, Your Honor --

THE COURT: Sorry.

MS. WAGSTAFF: I was going to ask just one follow-up question.

The case will probably go to the jury after lunch. If they choose to go home at 2:30, there is a chance they won't have a verdict. If they do not have a verdict tomorrow, we would do openings on Friday?

THE COURT: Not necessarily.

MS. WAGSTAFF: Okay.

THE COURT: If they come back with a yes verdict in the morning on Wednesday, I will expect you to be ready with your opening statements.

MS. WAGSTAFF: And you would only do it if there was enough time for both parties to do opening or --

THE COURT: Not necessarily.

MS. WAGSTAFF: Okay.

THE COURT: And you should -- I mean, I think you should anticipate that they will go past 2:30. The juries almost always seem to do that. Even when I tell them they have the option to do that, they almost always do, so.

MS. MOORE: Your Honor, on the two pages they just handed me, the one that is marked 1023, page 192, it contains some references that the Court has excluded under a motion in limine, and that has not been redacted. So I would object to

this. This is about eczema, and it's been excluded.

In fact, they stipulated to that being excluded at trial, so I'm not sure of the purpose of getting in page 192, especially as it is unredacted.

Then on page 940, this is one page and it is cut off of a particular office visit. Oh, I see. This is a different version. Okay.

Your Honor, again, I don't think it should come in because it is hearsay and it shouldn't be authenticated with an expert. So that is my objection. I have noted it for the record.

THE COURT: Okay.

MS. MOORE: But I do object to 1023, page 192 for -- because it is excluded under the MIL order.

THE COURT: If you think there is something that needs to be redacted, I --

MR. KILARU: I'm almost certain that this is not the page that we intended. We will figure out which one it is. I think it is one of the ones that was shown to the jury during Mr. Stekloff's direct, so we will figure out what that is.

THE COURT: All right. I will look at that and either issue something tonight or we will straighten it out tomorrow. So I'm planning on being in very early tomorrow to look at slides. So the slides have to be transmitted to us by 7:00 a.m. tomorrow.

MS. MOORE: Okay. Thank you, Your Honor.

MR. KILARU: Thank you.

(Proceedings adjourned at 6:38 p.m.)

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CERTIFICATE OF REPORTERS

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

DATE: Monday, March 11, 2019

Jo Ann Bryce, CSR No. 3321, RMR, CRR, FCRR
U.S. Court Reporter

Marla F. Knox, RPR, CRR
U.S. Court Reporter