UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AZURITY PHARMACEUTICALS, INC.,
Petitioner,
v.
HELSINN HEALTHCARE S.A.,
Patent Owner.

Case IPR2025-00945
Patent No. 8,623,826

DEPOSITION OF ERIC ROELAND, M.D., taken on behalf of Petitioner, at Kimpton Hotel Vintage, 422 Southwest Broadway, Portland, Oregon, commencing at 9:01 a.m., Monday, May 11, 2026, before Marla Sharp, RPR, CLR, CCRR, CA CSR 11924, OR CSR 17-0446, WA CSR 3408.

Azurity Pharmaceuticals, Inc. - EXHIBIT 1067
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A. IPR2025-00947

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I N D E X

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PORTLAND, OREGON
MONDAY, MAY 11, 2026
9:01 A.M.
- - -
ERIC ROELAND,
having been first duly sworn,
was examined and testified as follows:
- - -
THE STENOGRAPHER: Thank you.
Counsel, you may proceed.
- - -
EXAMINATION
BY MR. MILLS:
Q Good morning. Please state your name for the record.
A Eric Roeland.
(Interruption by the stenographer.)
MR. MILLS: Are we back on the record?
THE STENOGRAPHER: (Nodded head.)
BY MR. MILLS:
Q What's your correspondence address?
A My home address is 17285 Tualatin, T-u-a-l-a-t-i-n Street, Lake Oswego, Oregon 97035.
Q Have you ever been deposed before?
A I have.

Q How many times?
A Two prior times.
Q When most recently?
A It would have been last -- last year.
Q What was, in a general sense, the subject matter of that deposition last year?
A It related to chemotherapy-induced nausea and vomiting.
Q Prior to that, when were you -- when was your other deposition?
A A year prior.
Q And at a general level, what was the subject matter of that deposition?
A Again, it was around CINV.
Q Other than the two depositions in the last two years on CINV, you have not otherwise been deposed; is that correct?
A Correct.
Q Just to make sure we're all on the same page about housekeeping and ground rules, I'm going to go through, again, the rules of deposition just to make sure it's fresh in your mind. Is that okay?
A Yes, it is.
Q Okay. So in a normal conversation when we're talking to each other, we often say yes by nodding our

head up and down or say no by shaking our head left and right.

Are we on the same page so far?

A We are.

Q Okay. In a deposition, it's important that your answers be verbal so that the court reporter can record them.

Do you understand that?

A I do.

Q Okay. Perfect. I'm going to do my best not to talk over you or the counsel that's sitting next to you for the court reporter's benefit.

So can you do the same thing?

A I can.

Q Great. We can take breaks whenever you need to. You just need to let us know.

If there is a question pending at the time that you want to take a break, I would ask that you answer the question before we take a break.

Can you agree to that?

A I can as long as I -- yeah, I will do my best. Yes.

Q Okay. If a question's unclear to you, will you let us know that the question's unclear to you?

A I will.

Q Okay. So if you don't tell us that you didn't understand the question, can we fairly assume you think that you understood the question?

A I will try to make sure I understand each question so I can answer it the best I can.

Q And if you have any doubts about understanding, you'll let us know; is that right?

A I will.

Q Okay. At some point during the deposition, it's conceivable that counsel next to you will lodge objections.

Do you understand that unless counsel instructs you not to answer the question, you still need to answer the question?

A I do.

Q Okay. Is there any reason that you cannot provide truthful, accurate testimony today?

A There is not.

Q What did you do to prepare for your deposition today?

MS. RUPERT: Okay. So I'm going to just lodge an objection here.

In your answer, don't disclose any privileged information. You can answer generally, but don't talk about things like discussions with attorneys; otherwise,

you can answer.

THE WITNESS: Yeah. So preparation primarily was -- for this last weekend was just meeting and reviewing the declarations and the available documents.

BY MR. MILLS:

Q So I'm going to follow up to make sure I understand.

Is it correct that all of your preparation for this deposition took place over this past weekend?

A No, that's not correct. I've been working on this for quite some time.

Q Okay. So a moment ago when you were talking about preparation, you were limiting specifically to the preparation you engaged in this past weekend?

A Correct.

Q Okay. So as part of that preparation, you said that you reviewed the declarations; is that correct?

A That is correct.

Q Other than the declarations, is there anything else that you reviewed this past weekend to prepare for your deposition?

MS. RUPERT: So, again, I'm going to object.

You can ask him if he reviewed specific documents. I don't think asking him what he reviewed with his attorneys is an appropriate question. But if

you want to ask him about something specifically, you can answer.

BY MR. MILLS:

Q My question wasn't what you reviewed with the attorneys. My question was what you reviewed.

A Yeah. Primarily, I reviewed just the documents that are available and listed as, you know, things that were -- are relevant to this case.

Q So in preparing for your deposition this last weekend, is it correct that you reviewed all of the documents that are cited in your declarations?

A I didn't review every single document cited in my declarations this last weekend.

Q This last weekend, as you were preparing for your deposition, which documents cited in your declaration did you review?

A Primarily the declarations and the patents.

Q Other than the declarations and the patents, are there any other documents that you reviewed this past weekend to prepare for your deposition?

A The references as described in my declaration. So there are some key references that are all listed in Section 6 of my declaration, the prior art and those particular articles.

Q Go ahead and list those out for me, the ones

that you did review this last weekend.

A So No. 1 is MASCC, M-A-S-C-C, Exhibit 1013; Herrstedt, Exhibit 1010; the 2008 Emend label, Exhibit 1030; the 2003 Emend label, Exhibit 216; the Poli-Bigelli reference, Exhibit 1039; Campos, Exhibit 1023; Herrington, Exhibit 1016; Warr, Exhibit 1034; Hesketh, Exhibit 1037; Schmoll, Exhibit 10 -- or 2073; and Yeo, Exhibit 1048.

Then in part B, we have Hargreaves, Exhibit 1012; Bos, Exhibit 1014; Hoffmann, Exhibit 1011.

I believe that's the list.

Q You also mentioned, in addition to reviewing those documents, that you met with the attorneys to prepare for your deposition, correct?

A Correct.

Q Okay. I'm not asking for the content of what you discussed. Just -- I'm asking questions now about when and for how long.

So go ahead and tell me, before the deposition today, the immediately most preceding meeting that you had with the attorneys to prepare for your deposition.

A So you're talking about this last weekend?

Q Your most recent one before right now.

A Yeah. Yeah. So on Saturday we came -- I came here to this hotel in this room and met with the Paul

Hastings lawyers at 8:30 and then left around 3:30 or 4:00.

And then yesterday, since it was Mother's Day, I came in a little bit later, at 10:00 a.m., and then stayed until, like, 3:30 as well.

Q I'm glad you were able to take a little bit of time off for Mother's Day.

A Yeah.

Q Before -- you mentioned Saturday and Sunday.

So before Saturday and Sunday, was there another session that you had with the attorneys to prepare for your deposition?

A You know, off the top of my head, I've had multiple phone calls with them. The last I can recall was a phone call on Friday before they got on a flight to come this way. They were just checking in.

Q How long was that?

A A couple hours. Yeah.

Q Before that Friday, was there another meeting?

A Yes. As far as each of those dates and times, I'm going to have a harder time recalling all of that.

Q Okay.

A Yeah.

Q If you can't recall the exact dates, just tell me approximately how many times do you think that you

met with counsel before that Friday meeting?
A Roughly speaking, you know, more than 6 times and less than 20, something like that.
Q And if you were to give me your best estimate as to the amount of time for each of those calls, on average?
A On average, our calls were limited to, like, an hour long.
Q I'm going to ask you now about your compensation.
A Okay.
Q So in your declaration, it says that you're compensated at a rate of $600 per hour for your work; is that correct?
A That is correct.
Q Is that the same compensation rate that has applied as you were preparing for the deposition?
A Yes.
Q And is that the same compensation rate that applies for your time during the deposition today?
A Yes.
Q Are there -- what's your best estimate as to the total amount of time that you've spent preparing for your deposition?
A I -- honestly, I don't have an exact time, but

I've spent a lot of time on this and reviewing it and preparing these documents. Yeah.

Q But your best estimate that you've spent at least 10 hours preparing for your deposition?

A That is true, yeah.

Q Would you agree that you spent at least 50 hours preparing for your deposition?

A That sounds about right, yes.

Q Do you think the number's higher than 50?

A In total with, you know, the number of declarations, writing them, editing them, reviewing everything, probably, yes.

Q And right now I'm asking specifically about preparation for the deposition itself.

A Oh, okay. No. No, I did not prepare more than 50 hours.

Q Okay. So you think 50 hours is about the right number for the deposition itself?

A Give or take.

Q But now I'll ask about the declarations.

A Mm-hmm.

Q So -- and we've been using the term "declarations." There's five declarations. There -- correct?

A There are five declarations.

Q Okay. And those five declarations relate to four patents, correct?
A That's my understanding, four patents.
Q Is there a primary difference between your declarations and the -- for the four different patents?
MS. RUPERT: Objection to the form of the question.
THE WITNESS: Maybe you could just help me understand specifically what you're wanting to know.
BY MR. MILLS:
Q Yeah. Would you agree there's a substantial overlap between the declarations for the four different patents?
A There --
MS. RUPERT: Objection to form.
THE WITNESS: There is some information that's shared between all of them, but there's also some unique information presented in each one.
BY MR. MILLS:
Q One of the patents has two different cases associated with it, correct?
A I'm sorry. Could you say that again?
Q Yeah. Let me ask an easier question.
A Mm-hmm.
Q We said that there's five declarations --

A Oh.
Q -- and there's four patents.
A Uh-huh.
Q What -- why is the disparity between the numbers?
MS. RUPERT: Objection to form.
THE WITNESS: You know, I'm -- I'm not a patent lawyer, so I don't know the exact, but I primarily focused on the four claim -- the four patents, yeah.
BY MR. MILLS:
Q Right. Is there any -- for the one patent for which there's two declarations filed, is there anything that stands out to you as being different between your two declarations for that one patent?
A Not that I can recall.
Q You mentioned that there may be some differences for some of the other patents in your declarations.
Can you tell me any differences that stand out to you in your declarations?
MS. RUPERT: Objection to form.
THE WITNESS: Well, the declaration for each patent covers the specifics of each one of those patents.
///

BY MR. MILLS:

Q Because I want to make sure we have a clear transcript today, if I'm asking you a question and we're using one of your declarations, if you think the answer would be different for one of the other declarations, can you let us know?

MS. RUPERT: Objection to form. I don't think that's a fair request.

THE WITNESS: I will say this is pretty overwhelming, the number of declarations and information. So I think I'll constantly be asking to orient to the declaration, and I'll do my best.

BY MR. MILLS:

Q Okay. And that's a good reminder.

Can you tell us what documents you have in front of you?

A Yeah. So today, just to try to keep myself organized, I have the four declarations and the patents that they refer to on top of them as well as a table of contents for each of the declarations, just to try to make sure I answer your questions.

Q You said you have four declarations in front of you.

A Correct.

Q Okay. So you don't have five declarations?

There's four declarations?

A The declarations that I currently have in front of them reference Patent '826, Patent '515, Patent '357, and '297.

Q All right. And you recall that basically there's a declaration submitted twice for the same patent; is that right?

A Yeah. I believe you're referring to -- there's two that kind of refer to '357. Okay.

Q So do you have everything that you need to address the '357 patent in front of you?

MS. RUPERT: Objection to form.

BY MR. MILLS:

Q Sure. I'm just trying to figure out if you're missing a declaration.

A I believe I have everything that I need in front of me.

Q Okay. So you have the four declarations, and those are all the four declarations that you need?

A Correct.

Q Okay. Just want make sure you have everything that you need.

Going back to the question of -- I mean, there's a couple ways we could do the deposition today. We could stay here all seven hours and I can show you

identical phrasing in each declaration and I can ask you the same question four different times.

Or when the language is identical, you know, we could have an understanding that you meant the same thing in the four declarations.

So I guess I'm trying to get some direction from you.

Do you want to go through everything four times? Or when the language is identical in one declaration, do you agree that it means the same thing in your other declaration?

MS. RUPERT: Objection.

Counsel, I don't think that's a fair question for him. You haven't shown him the declarations, and it's very broad.

So I --

MR. MILLS: Yes.

MS. RUPERT: I think this is kind of misleading.

MR. MILLS: So the declarations are all in front of him, and he's just spent 50 hours going through them. And I'm just trying to find out if he wants me to ask him the same exact question four different times about the identical language.

MS. RUPERT: What I think we want is a clear

record.

THE WITNESS: So I need to answer at this point?

I think what I'm most focused on is going to be the question at hand and just making sure that I'm referencing the primary data for that question.

So if that leads to some repetition for clarity, I'm okay with that.

BY MR. MILLS:

Q Is there anything that stands out in your mind right now that, if we were asking for the '826 patent, that you think your identical language in another declaration would mean something different?

MS. RUPERT: Objection to form. There are thousands of pages at issue here.

THE WITNESS: Yes. I've struggled just because there is so much information covered in each of these. So I think we'll just take it as it comes probably is the best way to approach this.

BY MR. MILLS:

Q One of the subjects you address in your declarations is the state of the art, correct?

A Yes, I do cover the state of the art.

Q Is the state of the art different for the four different patents?

A So I think when you're referencing "state of the art," you're describing broadly Section 5 of each of the declarations. Is that what you're referencing?

Q (Indicating.)

A Then my understanding is that those are roughly equivalent throughout, yes.

Q Okay. So at least when we're talking about the state of the art and we're asking questions, do you still want to go through each declaration separately or are you comfortable addressing the state of the art once?

MS. RUPERT: Objection to form.

THE WITNESS: I -- I'm okay given that there is some shared components of the state of the art through all the different declarations.

BY MR. MILLS:

Q Okay. And if at any point I'm asking you something and my question leads you to say -- to think, well, the answer would be different for the other one, please just let us know. Okay?

A Yes. And then I just ask that, as I'm trying to, you know, wade through all of this paperwork, that if I ask you to tell me which one we're talking about, just help me find the primary data.

Q Yes. I will do my best.

Okay. I'd like to talk about your retention in this matter.

So when were you first approached to work in this matter?

MS. RUPERT: And, again, I'd caution you not to reveal any privileged information as part of your answer, for example, the contents of discussions with attorneys. But -- but the "when" is okay.

THE WITNESS: Roughly last -- last year. I don't know exactly when that was, but that's about -- yeah, last year.

BY MR. MILLS:

Q Could you give me maybe a season?

A I -- honestly, I can't recall, but I just know it was last year sometime.

Q Okay. And I'm not asking you what you discussed, but I'm going to ask who approached you.

A Hmm. I can't even recall that one off the top of my head.

Q Okay. Can you tell me the affiliation of the person that first approached you about working on these matters for Helsinn?

A It would have been someone from Paul Hastings.

Q Okay. Prior to speaking with somebody at Paul Hastings about working on these matters, you had not

spoken with anyone else affiliated with Helsinn about these matters; is that correct?

A I have not. I did not speak to anyone from Helsinn.

Q Okay. So that was the period before you were approached.

A Yeah.

Q After you were approached, have you spoken with anyone about these matters other than the Paul Hastings attorneys?

A No, I have not.

Q Okay. And, I guess, I want to try and make sure that we have a good record.

I probably should have also excluded the in-house counsel who's sitting here as well.

A How so?

Q Well, I guess, let me ask you --

A Yeah.

Q -- a predicate question.

A Okay.

Q Was Helsinn's in-house attorney present at your deposition prep meetings?

A There were two lawyers present the last two days, yeah.

Q And one of those is in-house for Helsinn?

A I'm -- the -- so you're asking me a question, and I think the answer is that, you know, they're hired by Helsinn's, so I assume that's the case.

Q Okay. So I'm asking about individuals other than Paul Hastings attorneys.

A Oh. Yeah, no, I've only worked with Paul Hastings attorneys.

Q Okay. So the two attorneys sitting in the room with us right now?

A No. The two attorneys included Melanie --

And remind me of your last name.

MS. RUPERT: Rupert.

THE WITNESS: -- Rupert and Chetan -- his last name starts with a B. I'm sorry. Yeah.

BY MR. MILLS:

Q Okay. Chetan isn't in the room with us right now, but there's a second person from Helsinn in the room with us right now.

When did you meet that individual?

A For the first time today.

Q Okay. So that individual was not present during your deposition preparation?

A No.

Q Okay. And you never discussed the case with that individual at any point prior to today?

A No.
Q Okay. And I think I understood what you meant. But because my question had a "no" in it, "you never," so it probably -- probably what you mean to say is "That's correct."
MS. RUPERT: Objection.
Is there a question pending?
BY MR. MILLS:
Q Yeah. Let me withdraw and ask a new question.
Prior to today, it's correct that you never discussed these cases with the second individual from Helsinn who's sitting here during the deposition today?
A I have never spoken about this case with anyone outside of Melanie and Chetan.
Q Okay. Who is Rudolph Navari?
A Rudolph Navari is a physician and well-known leader in the field of chemotherapy-induced nausea and vomiting.
Q Is it correct that you have collaborated with Rudolph Navari in the past?
A I have.
Q In what manner have you collaborated with Rudolph Navari?
A Primarily with a shared interest in supportive care and chemotherapy-induced nausea and vomiting on

1 some studies and articles.
2 Q Approximately when did you begin collaborating
3 with Rudolph Navari?
4 A I'd say approximately 2013 or '14, something
5 like that.
6 Q What caused you to begin collaborating with
7 Rudolph Navari in 2013 or 2014?
8 A Yeah. So I have dedicated my academic research
9 career to supportive care in cancer, which is -- there's
10 very few experts that have dedicated their academic
11 pursuits to that.
12 And so I had the fortune of meeting him early,
13 as an early faculty member, because of his vast
14 experience in the field of chemotherapy-induced nausea
15 and vomiting.
16 Q How did the two of you meet?
17 A It would have been by chance at a meeting
18 just -- you keep going to meetings, and eventually you
19 run into the same people.
20 Q Had you published on the subject of CINV prior
21 to the collaborating with Rudolph Navari?
22 A I don't remember the exact cadence, but the --
23 you know, meeting him and working on the articles and
24 such would have been kind of related.
25 Q Are you saying that essentially your work on

CINV corresponded in time with your beginning of your collaboration with Dr. Navari?

MS. RUPERT: Objection to the characterization.

THE WITNESS: I guess I don't really understand the question. It's just -- we go to scientific meetings. You run into people. Those spawn queries, questions, and collaborations. So that would have unfolded similarly.

BY MR. MILLS:

Q Have you ever previously worked with Rudolph Navari on a matter for Helsinn?

A No, I have not.

Q Have you ever participated in any Helsinn studies with Dr. Navari sponsored -- sorry. I'm going to withdraw that question and start over.

Have you ever participated in any Helsinn-sponsored studies in collaboration with Dr. Navari?

A Yes, I have in terms of some publications.

Q Can you tell me about those?

A I'm happy to reference them, but, in general, broadly speaking, they're queries around improving the experience of the patient with cancer and receiving chemotherapy and having nausea and vomiting.

Q When did you begin working with Helsinn on this

type of work?

A Early in my career, so after fellowship of just -- this is an area that's been -- I've been dedicated to since my early training.

Q So I want to better understand specifically your relationship with Helsinn.

You said earlier, early in your career. And then I think you said you began collaborating with Dr. Navari in 2013.

A Among others, yeah.

Q So which came first: your collaboration with Dr. Navari or your collaboration with Helsinn?

A I have no idea.

Q Okay. Is there a document that you could look at that would help you to answer the question?

MS. RUPERT: Objection to form.

THE WITNESS: I mean, I can look at my CV and look at publications and the timing of those publications.

BY MR. MILLS:

Q Okay.

A Yeah.

Q Would you like a copy of your CV?

A Sure.

Q So go ahead --

A Oh.
Q -- and take a look at your CV --
A Okay.
Q -- to see if you can answer the question as to when your work for Helsinn began.
A I don't think I would call it work for Helsinn. I would say these are more academic pursuits that may or may not have been sponsored by Helsinn, but I've never been employed by Helsinn. So let's see. If we want to go first to clinical trials.
Q Go ahead and tell us which page you're looking at.
A Okay.
Sorry. Just trying to find the first -- yeah, so the first study that I believe was sponsored by Helsinn, yes, page 10 would have been 2013. That was a study entitled "Anamorelin Hydrochloride in the Treatment of Non-Small Cell Lung Cancer Cachexia: A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase III Study to Evaluate the Safety and Efficacy of Anamorelin Hydrochloride in Patients with Non-Small Cell Lung Cancer," also the known as the ROMANA 1 study.
Followed by, that same year, the ROMANA 3 study, which is:

"Anamorelin in the Treatment of Small Non-Small Cell Lung Cancer Cachexia: An Extension Study."

(Interruption by the stenographer.)

THE WITNESS: -- "Non-Small Cell Lung Cancer Cachexia." Cachexia is c-a-c-h-e-x-i-a.

I'm just going -- looking through here, making sure.

Then there was a research study in 2017 to 2018 of a:

"Fixed-Dose Combination of Netupitant and Palonosetron in the Treatment of Refractory Chemotherapy-Induced Nausea and Vomiting."

And that was a trial that was closed early due to my departure from my institution at the time.

BY MR. MILLS:

Q Are you still on page 10?

A Sorry. That's page 11.

Q Okay.

A Now I'm looking at my publications starting on page 14 and trying to remind myself of when my first publication was.

So I believe my first publication with CINV,

1 that may have been related to Helsinn sponsoring it.
2 I'd have to look at the publication to confirm, but it's
3 No. 19 on page 15, "Roeland" -- or, sorry, No. 20 on
4 page 15:
5 "Roeland, Aapro, and Schwartzberg.
6 Advances in the management of
7 chemotherapy-induced nausea and
8 vomiting: new data from recent and
9 ongoing trials."
10 Q What year is that?
11 A 2015 of October.
12 Q Okay. So that was a mouthful. I want to
13 see --
14 A Yeah.
15 Q -- if we can break that down.
16 So the question that got us originally here --
17 I think there's a lot to discuss. But the question
18 we're first looking at was sort of the beginning of your
19 collaboration with Helsinn.
20 A Mm-hmm.
21 Q So is it correct, based on your review of your
22 CV, that your collaboration with Helsinn began in 2013?
23 A Correct, with regard to supportive care --
24 clinical trial and supportive care focusing on cancer
25 cachexia.

Q Okay. Was there a collaboration with Helsinn other than those many words you just used that included cachexia?

A No. No.

Q Okay. So is it correct to say that your collaboration with Helsinn began in 2013?

A I would -- I would describe it as these are, you know, industry-sponsored studies, and we were a site that opened them. So it was a collaboration amongst Helsinn, my university, and me, yeah.

Q Okay. So you mentioned several dates after that. You mentioned 2017, 2018, and then publications in 2015.

Is there a point where you would say that your collaboration with Helsinn ended after 2013?

MS. RUPERT: Objection to the form.

THE WITNESS: Yeah, I think there's some assumptions here that there's just, like, a constant relationship or -- and that's just not how things unfold in real time.

So, for example, a clinical trial opens, they finish accruing for the study, they close the study.

So it's -- kind of comes and goes as trials are available, as the science changes, opportunities arise, et cetera.

1 BY MR. MILLS:
2 Q Okay. So thank you for that clarification.
3 You mentioned the trial beginning in 2013, and
4 you mentioned a publication in 2015.
5 Were those two related to each other?
6 A No, they were not related.
7 Q Okay. So when did the trial begin that was
8 published in 2015?
9 A So we were -- okay. So, just to be clear,
10 we're talking about the first study, the anamorelin 1
11 study, on page 10, 2013.
12 The ROMANA 1 study, this was a preclinical and
13 early phase clinical trial that informed next steps for
14 their subsequent trials, ROMANAs 2 and 3.
15 I wouldn't, off the top of my head, know when
16 the trials stopped and then when publication occurred.
17 I wasn't involved in those publications associated with
18 that study -- or those studies.
19 (Mr. Bansal entered the proceedings.)
20 THE WITNESS: And then the other study I
21 mentioned in 2017, that was an investigator-initiated
22 study looking at the combination of netupitant and
23 palonosetron for refractory chemotherapy-induced nausea
24 and vomiting.
25 Unfortunately, we were able to get it started,

1 but I didn't complete the study because I had -- I moved
2 from the University of California, San Diego to
3 Massachusetts General Hospital in Boston. So,
4 unfortunately, I had to kind of leave that.
5 And then the publication that I can recall of
6 Roeland and Aapro, Schwartzberg, published in "Clinical
7 Advances of Hematology & Oncology" in 2015, is
8 completely unrelated to the prior clinical trials.
9 BY MR. MILLS:
10 Q Okay. Thank you. So talking -- focusing on
11 that 2015 publication, when did your work on that
12 Helsinn publication begin?
13 A My recollection is that that publication, which
14 I'm happy to review, but I believe that is a -- it was
15 more of a conversation amongst the three of us around
16 CINV and reviewing the data and recent advances.
17 (Brief interruption.)
18 BY MR. MILLS:
19 Q Okay. My question is about the timing. So you
20 told us a little bit about what that publication is.
21 You said it was a conversation among the three of you.
22 I'm just trying to figure out -- you say it published in
23 2015.
24 So when did it begin?
25 A At the earliest, it would have occurred about a

1 year before, but probably pretty darn close to its
2 publication time.
3 Q Okay. And then going back to the studies on
4 page 10 of your CV, ROMANA 1 and 2, you said those began
5 in 2013.
6 How long did that collaboration last?
7 A I suspect that they ended fairly soon
8 thereafter because I don't have dates -- you know,
9 normally I list the ending date. So I -- currently it
10 just says 2013. So I would assume that it started and
11 ended in that same year.
12 Q So other than ROMANA 1 and 2 and then your
13 publication No. 20 and the 2017-2018 fixed-dose study,
14 so those three things that you mentioned, are there
15 other collaborations that you've had with Helsinn over
16 the years?
17 MS. RUPERT: And, again, objection to form.
18 THE WITNESS: Yes. There are. I actually
19 can't recall every single time that they may or may not
20 have sponsored a study.
21 So I'd have to go through each of the
22 publications and look at whether or not they were a
23 sponsor of a study, which is pretty darn standard for
24 research in cancer cachexia -- or cancer and supportive
25 care in cancer.

But the general topics discussed would have been supportive care in cancer. The process would always be scientifically robust and peer-reviewed and published.

BY MR. MILLS:

Q So you were talking about Helsinn sponsoring the publications.

Is there some way we can tell by looking at your CV which of your academic work is supported by Helsinn and which is not?

A That level of detail is not in a curriculum vitae. That level of detail would be expressed for -- by each article where it describes the funding mechanism for each article.

Q Okay. You do mention Helsinn in your CV several times, correct?

A Sorry. Can you be more clear? Like, be more specific? We just named several of those examples.

Q Right. So you named it for the ROMANA 1 and 3 studies, correct?

A Correct.

Q And then you named it for the Akynzeo study?

A Akynzeo study, which, sadly, never got off the ground due to my departure from UC San Diego.

Q Okay. Your CV doesn't name Helsinn as a

sponsor of any of your other work; is that correct?

A I don't think that that's actually the way we do -- write our CVs.

So what I think you might be suggesting is that I would have listed a sponsor for every single publication, which is not how your CV is written.

Q Is there any collaboration that you've had with Helsinn that you haven't listed in your CV?

MS. RUPERT: Objection to form.

THE WITNESS: I'm happy to review every publication and look at who sponsored each one, but, off the top of my head, I'm not going to be able to tell you every single sponsor of every study.

BY MR. MILLS:

Q What about clinical trials?

A The clinical trials are -- that I have participated in are listed, and the sponsor is cited for the clinical trials but not necessarily for the publications.

Q What date did you prepare the copy of your CV that you submitted?

A As described here on the first page of my curriculum vitae, date prepared was January 30th, 2026.

Q And as of January 30th, 2026, is your CV a complete and accurate representation of all of the

clinical trials that you participated in?

A Yes, as up to January 30th, 2026.

Q Other than the aborted Akynzeo trial at UC San Diego, have you participated in any other Akynzeo clinical trials?

A I cannot recall any specific clinical trials for Akynzeo.

Q Have you heard of the MyRisk clinical trial?

A I have.

Q What's the MyRisk clinical trial?

A So going to my publications, No. -- No. 114 describes a publication by Molassis et al. entitled "Personalised antiemetic prophylaxis with NEPA for patients at high risk of chemotherapy-induced nausea and vomiting receiving moderately emetogenic chemotherapy: results from the randomised, multinational, MyRisk trial," published in February of 2026 in the "Annals of Oncology."

Q And who's the sponsor to the MyRisk trial?

A The sponsor of that study is Helsinn.

Q Did you participate in that?

A I was not a site for the clinical trial. I participated as a key opinion leader in the development of the clinical trial as well as the publication.

Q Were you compensated for that work?

1 A No.
2 Q I want to go back to the ROMANA 1 and 3 trials.
3 A Okay.
4 Q You mentioned that you weren't involved in the
5 publication of those trials, correct?
6 A Correct.
7 Q Also be fair to say that you weren't involved
8 in designing of those studies?
9 MS. RUPERT: Objection to form.
10 THE WITNESS: Correct. So those studies have
11 been designed when I was a new faculty member opening up
12 supportive care studies at the University of California,
13 San Diego.
14 BY MR. MILLS:
15 Q Okay. Have you ever designed a clinical trial?
16 A Yes, I have.
17 Q When was the first time that you designed a
18 clinical trial?
19 A You're taking me back here. Hold on a second.
20 I think my first grant was probably a local grant.
21 Yeah, I think it would be on page 13 of my CV,
22 a:
23 "Single-center, Prospective
24 Expansion Study Evaluating Advanced Care
25 Planning Discussions Utilizing a Novel

Approach as Performed by a Palliative Care Pharmacist."

So that was a American Cancer Society-sponsored study.

Q Was that an CINV study?

A No. And it's an advanced care planning study. So that's not CINV.

Q Okay. Have you ever designed a clinical study for CINV?

A So I have looked -- I have helped design analyses of available data with -- in collaboration with other CINV key opinion leaders.

And then, as you pointed out, I was involved with the MyRisk study in developing the question and approach to that study.

Q When you say you analyzed available data -- my question was whether you'd ever designed a study. And you said you've analyzed available data.

Can you tell me whether those are the same thing or different?

A I think you're -- the term "study" is very broad. So we have prospective studies. Prospective studies include observational studies. Prospective studies include interventional studies.

And then we have retrospective studies where

we're looking at available data, published data, and analyzing that data to inform, you know, question -- scientific questions around the previously published data.

Q Okay. So is it correct that your involvement in designing clinical studies is limited to designing retrospective studies of existing data?

MS. RUPERT: Objection to form.

THE WITNESS: No, that is not true.

BY MR. MILLS:

Q Okay. Can you explain the difference between what you said and what I said?

A I think what I hear you saying is you're trying to say that I do one -- one type of study or not.

And my career has spanned all these types of research, which is why it's hard for me to answer exactly what I was doing at every single moment.

But -- yeah, so I have designed prospective observational studies. I have designed prospective interventional studies. I have been involved with retrospective analyses, as is described in my CV.

Q Okay. So I'd like to focus on, I think, what you called a "prospective interventional study."

A Okay.

Q Can you tell us what that is?

A Yes. So, in general, a prospective interventional study, there's multiple designs.

But, in general, you're looking at an intervention and comparing it, usually, to another intervention and -- to measure a difference. It's usually driven by a hypothesis.

There's a statistical analysis of that. The results are then analyzed. And then hopefully you get it published in a journal.

Q When did you first design a interventional study?

A Interventional. Hmm. It would have been early in my career at UC San Diego. And I'm happy to go through my CV and identify that for you if that's important.

Q That would be helpful.

A I think it would go back to that same study in advanced care planning where we were assessing a novel intervention to explore the values and preferences of patients at the end of life. So that would have been 2013.

Q Have you ever designed an interventional study for CINV?

A I helped design the MyRisk study.

Q When did that work begin?

A I don't recall, but it's been many, many years. It's been in the works for a while.

And that intervention is really an assessment of individual risk factors for CINV and so those at high risk of CINV versus those at low risk and kind of changing our approach to how to prevent nausea and vomiting.

And that study took a long time to get up and running and accrued for.

Q I want to see if we can get a good estimate. The first world event I'm going to mention is COVID.

Do you remember if your work on MyRisk predated COVID or started after COVID?

A Most likely, it predated COVID.

Q Okay. And COVID was about March 2020?

A Sure.

Q Okay. And then MyRisk published in the fall of 2025?

A No. It finally got published here recently -- what did I say? It finally was in print in the "Annals of Oncology" in February of 2026. And I'm listed as the fifth author.

Q Okay. And I do have a little bit of a question.

Okay. So your CV's dated January 2026. That

1 study you said was published in February 2026.
2 It made it onto your CV because you knew it was
3 coming out?
4 A Yeah. So the way things get published -- so
5 they're initially accepted, then they're printed online,
6 and then -- then they eventually land in print. So I
7 must have known that that was the case there.
8 Q Okay. So we said at least since March 2020,
9 you've been working on the MyRisk trial with Helsinn; is
10 that correct?
11 A That sounds about right.
12 Q So I know this is hard to remember anything
13 pre-COVID. But let's see if you can -- do you remember?
14 Was it maybe a year before COVID or two years? Any --
15 your best estimate.
16 A I wouldn't be able to estimate. I'm sorry.
17 Q Okay. All right. So you would agree for the
18 last six years or so, you have -- you've been
19 collaborating with Helsinn on the MyRisk trial for this
20 NEPA, correct?
21 MS. RUPERT: Objection to form.
22 THE WITNESS: I would say that it was an
23 ongoing project that I would intermittently -- all the
24 investigators would come and speak about the study.
25 But I was not actively accruing for that study.

I was not a site for that study and so primarily got reengaged once the data were available for us to analyze.

BY MR. MILLS:

Q Right. You -- I think you identified MyRisk as the interventional study that you helped to plan.

A Yeah. So, you know, from conception -- first of all, from question to the conception, the design, opening the different sites, accruing, getting the data, analyzing the data -- I mean, this took many, many, many years.

Was I involved in every single piece of those -- that -- those steps? No, I wasn't.

Q What steps were you involved in?

A In the conceptual design, the question, and then, near the end, analyzing the results, the data, and the publication.

Q Okay. So we've mentioned MyRisk as an interventional study that you had a role in designing that related to CINV.

Other than that, is there any other study that you -- an interventional study that you helped design for CINV?

A Off the top of my head just because my career has spanded -- spanned so many different symptoms, I

1 just can't name it off the top of my head. But that's
2 the best I can recall.
3 Q Okay. And you do have your CV in front of you.
4 So if it would help you to look through it, I'd be happy
5 to let you take a look if you think that there's
6 something else.
7 A Okay. I'm happy to look through every single
8 piece of this if that's what you would like me to do.
9 Again, you want me to just name anything with
10 CINV?
11 Q So the question's specifically about
12 interventional studies that you designed for CINV.
13 A Okay. So there's a publication that I was
14 involved with on No. 39 led by Schwartzberg, Roeland.
15 That was:
16 "Phase III study of intravenous
17 NEPA, a novel fixed antiemetic
18 combination of fosnetupitant and
19 palonosetron in patients receiving
20 highly emetogenic chemotherapy."
21 I was not involved in design of that study, but
22 I was involved in the interpretation and the results of
23 that study.
24 Q Okay. If we can pause, I want to ask you some
25 questions about that.

1 So that NEPA, N-E-P-A, that's Helsinn's
2 product, correct?
3 A NEPA refers to the combination of netupitant
4 and palonosetron. And that was Helsinn's product.
5 Q Okay. So when we were talking earlier about
6 studies, Helsinn studies that you participated in, this
7 publication No. 39 references one of those?
8 A It's a publication. When you ask if I
9 participated in the clinical trial, I was not a site for
10 their clinical trial. I was not actively enrolling.
11 So I think that's where you -- there might be
12 some misunderstanding because sometimes you are involved
13 actively in recruiting the patients, and then sometimes
14 you can be involved in just looking at the data, putting
15 it into context and understanding the significance of
16 the findings.
17 Q Okay. So in addition to your collaborations as
18 a site director for studies sponsored by Helsinn, you
19 also have publications in which you were involved in --
20 where Helsinn is using you to interpret the data for
21 publications; is that correct?
22 MS. RUPERT: Objection to the form of the
23 question.
24 THE WITNESS: No, I wouldn't say that at all.
25 I would say that it is industry standard for drug

1 companies to sponsor a study, usually have a novel
2 intervention, and have experts in the field involved in
3 not only accruing for the study, designing the study,
4 but also understanding the findings of the study.
5 So, to me, I don't really understand your
6 point.
7 BY MR. MILLS:
8 Q I'm not making a point.
9 A Oh.
10 Q I'm just asking you questions, right.
11 So we've talked about ways that you've
12 collaborated with Helsinn where you were -- where
13 there's a site that's a clinical trial that you're in
14 charge of and Helsinn is sponsoring it.
15 That's one category we talked about, correct?
16 A Yeah.
17 Q Okay. So this other category is where Helsinn
18 has a study, and you come in to help interpret the data.
19 Is that the second category?
20 A It can be one of them, yes.
21 Q Okay. And in your particular situation, you've
22 pointed to this study that was published in 2018 as
23 another collaboration that you had with Helsinn; is that
24 correct?
25 MS. RUPERT: Objection to form.

1 THE WITNESS: This is another collaboration,
2 correct.
3 BY MR. MILLS:
4 Q Okay. And this one is published in 2018.
5 When did it begin, your collaboration with
6 them?
7 A Again, speaking to 2018, I can't tell you
8 exactly when that collaboration began.
9 Q Okay. So I'm just trying to understand a
10 timeline.
11 So we talked earlier about trials in 2013, 2014
12 in collaboration with Helsinn.
13 You remember that?
14 A When you're speaking about ROMANA 1 and -- and
15 3? Okay.
16 Q Yeah. And now we have some in 2017, 2018 time
17 frame, correct?
18 A We do.
19 Q Okay. And you also had one in 2015, correct,
20 that publication No. 20?
21 A You're referencing "Advances in management of
22 chemotherapy-induced nausea and vomiting" published in
23 2015.
24 Q Right. Okay. And then in 2020 -- or at least
25 by 2020, you were also collaborating with Helsinn on the

MyRisk study, correct?

A Approximately.

Q Okay. So, you know, although maybe some years there's more work going on than others, it's fair to say that your collaboration with Helsinn has extended, you know, over the past decade; is that fair?

MS. RUPERT: Objection to form.

THE WITNESS: I think, as a key opinion leader in supportive care in cancer, I have worked with one of the very few companies in the space of supportive care since being a new faculty member in San Diego, yes.

BY MR. MILLS:

Q And just to make sure we know who we're talking about, right, so since the time you were a new faculty member, you've collaborated with Helsinn over the past decade in their supportive cancer care research; is that correct?

A It -- correct.

Q Okay. And then we also talked about Dr. Navari.

That time period has essentially been coextensive with your collaboration with Dr. Navari; is that correct?

MS. RUPERT: Objection to form.

THE WITNESS: I don't know if "extensive" is

the right term. We have collaborated on projects together, and I see him at meetings. Yeah.

BY MR. MILLS:

Q Would you say that you've collaborated -- so I asked if it was coextensive, and you said you weren't sure.

Would you say that you've collaborated more with Dr. Navari than with Helsinn?

MS. RUPERT: Objection to form.

THE WITNESS: I can't really say one is more than the other. It's not something I've really noted.

BY MR. MILLS:

Q Okay. All right. So now I'm going back to my original question.

We were trying to think about studies that you helped design for CINV. You pointed to a 2018 study, but you said you didn't design it.

So what I'm trying to figure out is what's the -- is there a -- what's the earliest study that you helped design -- and we're talking about interventional studies -- for CINV?

A Well, the earliest one would have been the -- the Akynzeo study of the -- in 2017 exploring the use of netupitant in combination with palo, or Akynzeo, in the treatment of refractory chemotherapy-induced nausea and

vomiting. That is a study that I independently designed. It was an investigator-initiated trial.

Q Okay. So the earliest interventional study that you designed for CINV is the one that ended up being aborted because you moved facilities, correct?

A Correct.

Q And that took place in 2017?

A Correct.

Q Okay. Great. Thank you.

I do want to just ask a couple more questions about sort of what we've been talking about here. You mentioned Schwartzberg several times as a coauthor.

Can you tell us who Schwartzberg is?

A Lee Schwartzberg is another key opinion leader in CINV.

Q Okay. And how did you begin collaborating with Lee Schwartzberg?

A Again, I'm not going to be able to recall a specific time, date, place, but this would be someone that I would have met at a meeting and shared similar interests.

Again, a very -- not a very big group of people that are dedicating their research to supportive care in cancer.

Q In your view, is Lee Schwartzberg a person of

ordinary skill in the art for these cases?

MS. RUPERT: Objection to form. Calls for legal conclusion.

THE WITNESS: In general, I would say, Lee Schwarzberg is a recognized leader in the CINV space, yeah.

BY MR. MILLS:

Q So is being a recognized leader in CINV -- do you think that makes Lee Schwartzberg not a person of ordinary skill in the art?

MS. RUPERT: Objection to form, calls for a legal conclusion.

THE WITNESS: I would say -- you're asking me what a person of ordinary skill in the art -- how do you define that?

BY MR. MILLS:

Q Well, I think you've given a definition in your declarations, correct?

A Yeah. I'm happy to read that if you want me to.

Q Okay. And you can look at it if you want to. Or if you remember it, that's fine too.

A Again, there's just so much information packed into all this that I have to keep referring back to some of my definitions just so we're all being really clear.

Q Sure. Do you know where that is in your declaration?
A I don't.
Q Okay.
A Level of skill. I think Section 4.
So when I look at my declaration for '826, Section 4, level of ordinary skill, page 10, paragraph 25.
Q Yeah. So if you can just read that to yourself, and then after you've read that, let us know when you're ready.
A Okay.
Q So using your definition of a person of ordinary skill in the art, do you agree that Lee Schwartzberg is a person of ordinary skill in the art?
MS. RUPERT: Objection to form, calls for a legal conclusion, outside the scope of his report.
THE WITNESS: Yes, I would say he is.
BY MR. MILLS:
Q Okay. Now, I think Lee Schwartzberg has some initials after his name.
A He's a physician.
Q Okay. He has an MD?
A Correct.

1 Q Do you know what field his MD is in?
2 A Medical -- well, he's an -- he's a medical
3 oncologist. Are you asking me where did he get his
4 medical degree?
5 Q Not where, but are there different types of
6 MDs, or is an MD an MD?
7 MS. RUPERT: Objection to form.
8 THE WITNESS: There are different medical
9 degrees. There's MD, there's DO, there's MBBS.
10 BY MR. MILLS:
11 Q Say the last one again.
12 A MBBS. There's PhDs. And we can go on and on
13 here.
14 Q So in your POSA definition, you reference an
15 advanced degree as an MD.
16 Do you recall that?
17 A More specifically in my definition, I describe
18 a POSA as someone who's actively involved in oncology
19 with supportive care in cancer. So someone who's
20 engaged in patient care.
21 Q Do you see the words "MD" in your definition?
22 A In the definition, I see multiple advanced
23 degrees: PhD, MD, MS, MSN, DNP, or equivalent.
24 Q Okay. So when we're talking about the MD, are
25 there different kinds of MDs that someone would need in

order to study that definition? So --

MS. RUPERT: Okay. Objection.

BY MR. MILLS:

Q -- let -- let me tell you what I'm trying to get at. The phrasing there is a little bit awkward. It says something like "an advanced degree in supportive oncology" or something like that.

Do you see what I'm talking about?

A The POSA would have an advanced degree in a relevant field such as an example of supportive care in cancer or at least three years of experience in the treatment of nausea and vomiting with supportive care medications and patients with cancer undergoing chemotherapy.

Q Right. So it's that -- an advanced degree in supportive care and a -- e.g., an MD.

Is there -- I just want to know, is there a particular MD that we need to look for when we're looking at someone's CV? Does it needs to say MD, in supportive care or if they have an "MD in supportive care"? Or if they have an MD, is that what we're looking for so far as the education?

MS. RUPERT: Objection to form.

THE WITNESS: So an MD is a -- or an equivalent is obtained after completing medical school. And then

1 that's followed by an internship, and then residency,
2 and then a fellowship.
3 So in my opinion, someone engaged, a POSA would
4 have completed training to be caring for patients living
5 with cancer. So, you know, that can happen as soon as
6 you start taking care of patients, which, clinically,
7 you are starting to take care of patients in your intern
8 year.
9 Q Okay. So I want to focus first just on the MD
10 portion. So if I'm looking at an individual and trying
11 to understand if they're a POSA, so far as the degree,
12 if they have an MD from an accredited medical school,
13 that portion is satisfied; is that correct?
14 A That's one of the degrees that you could have,
15 correct.
16 Q Right. But I --
17 MS. RUPERT: I just want to interrupt for --
18 we've been going an hour and 15. Can we have a break
19 soon?
20 MR. MILLS: Would you like to take a break?
21 MS. RUPERT: Is that okay?
22 THE WITNESS: Sure.
23 MS. RUPERT: Okay.
24 MR. MILLS: Yeah. Thank you for answering the
25 question before we took the break.

1 MS. RUPERT: I jumped in.
2 (Recess taken from 10:15 a.m.
3 to 10:28 a.m.)
4 BY MR. MILLS:
5 Q Welcome back, Dr. Roeland.
6 A Thank you.
7 Q During the break, did you have any discussions
8 with counsel that related in any way to your testimony?
9 A No. I peed and needed a little break.
10 Q Okay. That's fine.
11 A Yeah.
12 Q Great. Can you take a look at page 14 of your
13 declaration -- sorry -- paragraph 14?
14 A Paragraph 14 of which declaration?
15 Q Well, go ahead and just tell us which one that
16 you're in, and then you can let us know if it --
17 MR. BANSAL: Do you want to hand us a copy of
18 his declaration?
19 THE WITNESS: I'm looking at declaration '826.
20 And then, sorry, where did you want me to go?
21 BY MR. MILLS:
22 Q Paragraph 14.
23 A Paragraph 14 on page 10 -- oh, page 5. Sorry.
24 Q Okay. Yes.
25 A Yeah.

Q Go ahead and read that paragraph 14 to yourself. And let me know when you're done.
A Okay.
Q All right. Can you go ahead and look at your other declarations and let me know if there's any difference in that paragraph between the four of them?
A So now I'm looking at '515 and going to paragraph 14.
Now I'm going to '357. And I'm looking at paragraph 14.
And then to declaration '297, paragraph 14.
(Interruption by the stenographer.)
THE WITNESS: Fourteen.
All right.
BY MR. MILLS:
Q So having compared those paragraphs in all four declarations, have you satisfied yourself that that particular subparagraph is identical across the four of them?
A Yes. It appears identical across all four declarations.
Q Okay. In that paragraph 14 of your declarations, you provide a list of companies for which you've served in a consulting/advisory role. Do you see that?

A Yes, I do.
Q And having reviewed that list of pharmaceutical companies, I noticed Helsinn is not listed there. Do you see that?
A I do see that.
Q Have you ever served on an advisory board for Helsinn?
A I have.
Q Okay. So is that perhaps something that should be corrected in your declaration --
A Yes. It's a simple --
Q -- in paragraph 14?
A -- simple error.
Q Right.
A Yeah.
Q Okay. Great. And can you tell me about that work on advisory boards for Helsinn?
A I cannot recall because it's been so long, but I do know that I have participated on an advisory board for Helsinn.
Q Could you tell me anything about the time frame?
A I can't recall.
Q Okay. So at some point within the years that you've collaborated with them since 2013, you served on

at least one advisory board for Helsinn, correct?
A That sounds about right.
Q I want to go back to what we were discussing earlier when you were talking about the ROMANA studies. You used a term that's a little bit hard for me to pronounce, but I think you called it "cachexia."
A Cachexia.
Q Cachexia. Okay. So can you just tell us what cachexia is?
A Sure. Cachexia is a hypermetabolic weight-loss syndrome associated with decreased quality of life, fatigue, muscle wasting treatment-related toxicity and decreased survival.
Q And sometimes it's colloquially called "wasting disease"; is that correct?
A Yeah. Inappropriately, yes.
Q Okay. I'll try not to be inappropriate.
A Okay.
Q I'm -- but -- okay. And then I also want to ask you about -- you had an Alliance study in 2015 with Dr. Navari.
Do you remember that one?
A Yeah. So the Alliance is one of the four national comprehensive collaborative research groups sponsored by the National Cancer Institute.

1 And I was involved with the Alliance starting
2 in my fellowship where I served on the committee for --
3 the symptom intervention committee.
4 And one of our clinical trials was -- early on,
5 there was a trial sponsored through the Alliance looking
6 at the role of olanzapine in the management of patients
7 who are experiencing nausea and vomiting.
8 Q And this is a study that you participated with
9 in collaboration with Dr. Navari, correct?
10 A There were multiple people, but Dr. Navari was
11 one of them.
12 Q And in your listing in your CV, he's the one
13 identified as the PI, correct?
14 A Here, let me just try to find it on my CV here.
15 It's been a while. That was a national one.
16 So on page 7, "2015" at the top there.
17 "Alliance A221301: Olanzapine for the Prevention of
18 Chemotherapy-Induced Nausea and Vomiting in Patients
19 Receiving Highly Emetogenic Chemotherapy: A Randomized,
20 Double-Blind, Placebo-Controlled Trial" sponsored by the
21 NCI.
22 And I served as a site principal investigator,
23 and Dr. Navari was the principal investigator.
24 Q So were you collaborating with Dr. Navari as
25 sort of adjunct in this study?

A So, in general, when we're looking at cooperative group studies, it's quite a process for this to go from conception to completion, but you need a champion within the cooperative group, who was Dr. Navari.

And then you have Alliance-affiliated institutions. And then at each of those institutions, you find another key stakeholder who wants to open up that study.

I was interested in olanzapine's potential role for highly emetogenic chemotherapy. And so I was involved as the site PI for that study as well as a member of the symptom intervention committee for the Alliance.

Q Okay. In your CV, in this entry on page 7, you provide a brief narrative description below the NCT number and the PI name; is that correct?

A I do.

Q Okay. Did you draft this?

A Did I write that paragraph?

Q Yeah.

A Yes, I did.

Q Okay. Could you just read us that paragraph?

A Sure.

"Olanzapine is a second-generation

1 antipsychotic with dopamine and
2 serotonin (D2, 5HT2A, 5HT2C, and 5HT3)
3 neurotransmitter activity, including
4 receptors in the nausea/vomiting
5 pathway. The study evaluated the
6 combination of olanzapine versus placebo
7 with standard chemotherapy-induced
8 nausea and vomiting prophylaxis in
9 patients receiving highly emetogenic
10 chemotherapy. Results demonstrated that
11 adding olanzapine improved
12 chemotherapy-induced nausea and vomiting
13 complete response without severe side
14 effects (New England Journal of
15 Medicine, 2016). Olanzapine is now part
16 of all evidence-based guidelines for
17 CINV prophylaxis."
18 Q Okay. Is there anything you need to add to
19 that description there, or is it still good?
20 A It's -- I read the words on the page there.
21 Q Okay. Great. So we've talked a little bit
22 about the word "nausea" and the word "vomiting." You've
23 mentioned them a couple of times.
24 And I just want to ask you about -- in your
25 declaration, you talk about subjective measurements in

trials and objective measurements in trials.

Do you know what I'm talking about when I say that?

A Just because there are so many declarations, could you point me to where you're talking about that?

Q Yeah. I can look for it.

Just while I'm looking for it, off the top of your head, do you have a recollection as to objective measurements of CINV in clinical trials, in your experience?

A Just because I want to make sure I answer these questions as thoroughly and truthfully as possible, I'd like to go to the -- where it was in the declaration.

Q Okay. I think I found one. I'm looking at paragraph 46.

A Which declaration is that?

Q So I'm in the '826 patent, but I think they may be identical. You can let us know if there's a difference.

And, in particular, there's a list of bullet points. And in the fifth bullet point, I'm seeing the language:

"Nausea is an inherently subjective adverse event and is difficult to quantify from patient to patient."

1 Do you see that language?
2 A So I'm on page 26 of the '826 declaration. I
3 see paragraph 46.
4 "In November of 2009, developing
5 treatments for CINV in general, and for
6 chemotherapy-induced nausea in
7 particular, was a highly complicated and
8 unpredictable art for a multitude of
9 reasons, including..."
10 The first bullet point is:
11 "CINV clinical trials used a vetted
12 primary endpoint of 'complete response'
13 to establish efficacy."
14 Second bullet point:
15 "CINV's etiology and pathophysiology
16 were not well understood."
17 The next one is:
18 "CINV treatments had mechanisms of
19 action that were not well understood."
20 The fourth one:
21 "High failure rate of NK-1 receptor
22 antagonists, especially in treating
23 nausea in the delayed phase."
24 And then the last bullet point:
25 "Nausea is inherently subjective" --

"is an" -- I'm sorry. "Nausea is an inherently subjective adverse event and is difficult to quantify from patient to patient."

Q Okay. So that fifth bullet point, that's the one I was asking you about, right?

A Yeah, I believe so.

Q Okay. So you see that fifth bullet point.

Can you go ahead and take a moment to check your other declarations to see if they're different on the topic of nausea being "an inherently subjectively adverse event that is difficult to quantify from patient to patient"?

A Sure. So now I'm going to look at declaration '515. Sorry. There's just so much paper.

Section 5. Section 4B. Section 4.

Sorry. So now I'm in '515. I'm at Section 4. I do not see -- oh, hold on.

Sorry. I'm having to orient myself a little bit. I'm not seeing it right here. Forty-six.

I'm sorry. Can you point me in the right direction for Patent '515, which paragraph you're referring to?

Q So I just have it in the '826 patent declaration, paragraph 46.

You're not able to find that in the other declarations?

A Forty --

Q The heading is "State of CINV Treatments."

A Ah, yes. Here it is on page 26B.

Q Okay. What's the paragraph number?

A Paragraph 46 again.

Q Okay. So it's the same paragraph number in -- does it have a fifth bullet point that's identical to the other one?

A Yeah. The fifth bullet point says:

"Nausea is inherently" -- "is an inherently subjective adverse event and is difficult to quantify from patient to patient."

Q Okay. Do you want to look at the others to see if you said something different about nausea in there, or are you satisfied that your opinion on the inherently subjective nature of nausea is consistent across the four of them?

A Just to make sure I didn't have any inconsistencies -- so on Patent '357, again, paragraph 46 on page 26, it states again:

"Nausea is an inherently subjective adverse event and is difficult to

1 quantify from patient to patient."
2 And then for Patent '297, paragraph 46 is
3 located on page 26. And the fifth bullet point reads:
4 "Nausea is an inherently subjective
5 adverse event and is difficult to
6 quantify from patient to patient."
7 Q Okay. So with respect to that opinion, they're
8 all the same, you would agree?
9 A They are the same.
10 Q Okay. Great. So nausea, you're saying, is a
11 subjective thing.
12 In contrast for CINV, based on your experience,
13 there's also objective variables that can be measured;
14 is that correct?
15 A No, that's not what I'm saying. There are
16 measures to quantify both the experience of vomiting
17 and -- as well as the experience of nausea.
18 Q Okay. And which of those measures are
19 objective?
20 A So for vomiting more specifically, we have
21 vetted measures that include the number of times someone
22 vomits or retches as well as the number of times they're
23 using their breakthrough antiemetics is something that
24 we measure.
25 The experience for nausea has been vetted

through parent reports, which include -- are then quantified by different measures which include visual analog scales as well as some other vetted measures called patient reported outcomes, which, if you want, I can list some of those.

Q Okay. So what are the objective measures in the studies?

A I think what -- I'm trying to understand your question.

So we have -- we have different measures. There's quantitative measures as well as qualitative measures. And for symptoms broadly, we have a whole science around patient-reported outcomes. And we use those to measure the patient experience. That's a way of quantifying that experience.

Q Right. So your declaration talked about nausea being something that's inherently subjective, right?

A I think what I was trying to get at when I say that is that nausea is reported by the patient in their lived experience. It's not something that you can measure, say, across the room.

Someone can be having horrible nausea or low-grade nausea, but you wouldn't be able to measure it visually.

Q Right. So when you use the term "objective

1 measurements," you gave the examples of actual vomiting
2 or retching and also the use of rescue therapy.
3 Those are things that somebody across the room
4 can measure themselves.
5 Is that what you're saying is an objective
6 measurement?
7 A It's one of the measures that we use, yes.
8 Q Okay. And then in contrast to that, nausea is
9 something that's reported by the patients themselves
10 based on their lived experience, and that's why they're
11 called "subjective measurements"?
12 A That is true. That is true.
13 Q Okay. Great. Let's take a look at
14 paragraph 51 of your declaration.
15 A So, again, which declaration are we referring
16 to?
17 Q Well, I'm looking in the '826 patent.
18 A Okay.
19 Q If you think there's a difference, you're
20 welcome to look at the others and see if there's a
21 difference, but...
22 A I can't -- I can't remember --
23 Q Yeah.
24 A -- all of them. Sorry.
25 So I'm happy to speak to one declaration at a

time and the paragraph that you're pointing at.

Q Yeah. So in paragraph 51, there's a reproduction of Table IV. Do you see that?

A I do see a Table IV.

Q Okay. And you've added some color coding to that?

A I can't see the colors on my page because --

Q Oh.

A -- it's all black-and-white.

Q Okay. Do you remember at some point looking at it with color coding on it?

A Yes. At some point, I'm sure.

Q Okay. And --

MS. RUPERT: Do you have a copy with color coding on it?

MR. MILLS: I don't have -- no, I don't have color-printed exhibits.

BY MR. MILLS:

Q When you made your declaration, did you add the color yourself or is that something perhaps you asked somebody else to do for you?

MS. RUPERT: Okay. So I'm going to object as calling for privileged communications with counsel. I'm going to instruct the witness not to answer that question.

MR. MILLS: Okay.
BY MR. MILLS:
Q So, Dr. Roeland, did you personally add color coding to your declaration at any point?
A I can't recall if I did or not just because --
MS. RUPERT: Yeah, and don't disclose communications with counsel.
THE WITNESS: -- I can't remember.
BY MR. MILLS:
Q Okay. You do see in paragraph 51 that there's some -- even though it's black-and-white, there's some terms that have been highlighted in some fashion; is that correct?
A There are terms that have been highlighted.
Q Okay. Do you recall causing or intending for those terms to be highlighted?
A I cannot recall.
Q Okay. So I guess what I'm trying to get at is: As you sit here right now, are you -- you're suspecting or wondering whether I added those things? Or is that a concern that you have?
A No. In terms of you highlighting these things? Well, I'm sitting in front of a black-and-white printed document, so I don't think -- I mean, I just met you, so hopefully you didn't --

Q Right.
A -- have a gray highlighter.
Q Yeah. So I'll represent to you that I printed it out as I received it with --
A Okay.
Q -- the highlighting, you know, from Helsinn.
Does that --
MS. RUPERT: I'm just going to object to the characterization because this isn't the highlighting that was in his report, the color highlighting.
MR. MILLS: So it's completely incorrect, Counsel.
First of all, if you need to make an objection, make an objection. These are speaking objections, which in some jurisdictions in district court might be okay. But here in an IPR, they're inappropriate.
I've been pretty patient with you in the past, but I just want to make it clear you shouldn't be making speaking objections.
I printed out the document exactly as it came to me. It is black-and-white printing, right. So I'll represent to you I haven't made any alterations to the document. It's as I received it.
BY MR. MILLS:
Q So my question to you is: Do you -- as you sit

here now, do you recall that this section of the document had -- it refers to highlights in the beginning of paragraph 51. Do you see that?

A So paragraph 51 states:

"Below, I have copied Table IV from the 2009 review article, which summarized [sic] the various efficacy endpoints that were used in aprepitant's Phase III trials, and denote the single-component endpoints with blue highlights and the composite end points with green highlights."

Q Okay. So I'm going to ask you about what's meant there.

So in that sentence that you wrote in paragraph 51 of your declaration, are you purporting to tell us that Table IV, when copied from the 2009 review article, already had blue and green highlights in it or that those were used in your declaration to denote certain things?

A My understanding of the use of highlights in this setting was to add clarity to the points I was making.

Q Okay. So that's something that you added or somebody added on your behalf that you approved; is that

fair?

MS. RUPERT: Again, don't reveal communications with counsel.

THE WITNESS: I -- I don't recall.

BY MR. MILLS:

Q Okay. So you don't have any recollection, as you sit here today, anything about the blue highlights and green highlights that are referenced in paragraph 51?

MS. RUPERT: Objection to the form of the question. Mischaracterizes.

THE WITNESS: I don't recall.

BY MR. MILLS:

Q Okay. You can see that there are certain terms that have sort of a black-and-white highlighting on them now.

And I apologize. You can't tell which ones are blue and which ones are green. That wasn't intentional here, but...

A Mm-hmm.

Q So at the very top, on the left-hand side there's an endpoint that says "No emesis." Do you see that?

A "No emesis" is the first endpoint, yep.

Q Okay. And definition, the first two words say

"No vomiting." Do you see that?
A I do see that.
Q Okay. So this is one of the objective measures that you were talking about a minute ago, correct?
A It is.
Q Okay. And then the very second endpoint says "No rescue therapy." Do you see that?
A Well, above on that definition, it says:
"No vomiting" like "(including oral expulsion of stomach contents), retching or dry heaves (an attempt to vomit that is not productive of stomach contents) regardless of use of rescue medicines."
So I think that that is important to recognize that no emesis is not restricted just to no vomiting, but someone who could be having retching or dry heaves, that would be part of the definition.
And then underneath that, we see "No rescue therapy," which is defined as:
"No use of medication to treat established nausea or emesis."
Q Okay. So I want to address each of those things. I just want to do it one at a time.
So, first, on the "No emesis" endpoint -- you know which one I'm talking about?

A Correct.
Q Okay. So the no emesis endpoint is an objective measure, correct?
A It is a objective measure.
Q Okay. Now, asking about the "No rescue therapy" endpoint.
That also is an objective measure, correct?
A It's a measure that we quantify as a vetted endpoint in CINV trials.
Q So, earlier, we were talking about objective and subjective measures, and you gave rescue therapy as an example of an objective measure.
So I'm trying to understand if you're saying that this rescue therapy endpoint is not an objective measure.
MS. RUPERT: Objection. Is there a question?
THE WITNESS: Whether or not someone takes a medicine for nausea or vomiting is something that's quantified and is objective.
BY MR. MILLS:
Q Okay. So in this Table IV, the endpoint of "No rescue therapy" is an objective measure, correct?
A Correct.
Q And the objective measure is that there's no use of medication to treat established nausea or emesis,

1 correct?
2 A Correct.
3 Q Okay. Further down there's an endpoint that
4 says "Complete response." Do you see that?
5 A I do see "Complete response."
6 Q And the definition for "Complete response" is:
7 "No emesis (or no vomiting) and no
8 rescue therapy."
9 Do you see that?
10 A I do see that.
11 Q In "Complete response" definition where it says
12 "no rescue therapy," do you agree that that that refers
13 to the endpoint up above that says "No rescue therapy"?
14 A Yes, I agree that it says "No emesis" or "No
15 vomiting" and "No rescue therapy" and that "No rescue
16 therapy" would be referring to:
17 "No use of medication to treat established
18 nausea or emesis."
19 Q Okay. So that complete response incorporates
20 the definitions for both the objective "No emesis" and
21 "No rescue therapy endpoints," correct?
22 A Yes.
23 Q Thank you. You see the endpoint that says
24 "Complete protection"?
25 A I do.

Q So that one says, as its definition:
"No emesis (or no vomiting), no rescue therapy, no significant nausea."
Correct?
A That is correct.
Q So "Complete protection" also incorporates both the "No emesis" and the "No rescue therapy" endpoint definitions given in Table IV, correct?
A Correct.
Q And in addition to that, it has an additional requirement of no significant nausea, correct?
A It does have that.
Q Okay. Great. Thank you. We were talking earlier about your experience in your education. We got a little bit sidetracked just because we're having such an interesting discussion. So I do want to return to that.
Your undergraduate degree -- I assume you were premed; is that correct?
A That is correct.
Q Okay. So in addition to the premed coursework, you also obtained a degree in Spanish language and literature; is that correct?
A That is correct.
Q Okay. Is it correct that you are not a

biochemist?
A That is correct.
Q Is it correct that you are not a pharmacologist?
A That is correct.
Q Is it correct that you are not an attorney?
A That is true.
Q Is it correct that you do not have a PhD?
A That is true.
Q Is it correct that you are not a pharmaceutical scientist?
A I am not a pharmaceutical scientist.
Q Is it correct that you are not a statistician?
A I am not a statistician.
Q So I want to go back to initials. We were talking about initials earlier, and there were the initials of -- we talked about MD. There's another set of initials called "FACP." Do you know what that means?
A Usually a "F" stands for "fellow" or -- and it's then referring to a status of fellow of an academy.
Q Okay. And do you know what FACP -- which academic that refers to?
A Most likely the American College of Physicians, at least in my world.
Q Okay. And if I tell you that that's an initial

1 that follows Lee Schwartzberg's name, does that help you
2 tell me if that's what FACP stands for?
3 MS. RUPERT: Objection to form.
4 THE WITNESS: I can't assume what fellow he's
5 part of, but the American College of Physicians is an
6 organization for internal medicine.
7 BY MR. MILLS:
8 Q Okay. What about the appellation after
9 someone's name of "PharmD"? Do you understand what that
10 stands for?
11 A PharmD would indicate they've done an
12 additional degree in developed -- or received a
13 doctorate degree in pharmacology or the study of
14 pharmacology.
15 Q Okay. What about the initials "CRNP"? And
16 perhaps it's "CRNP-OCN."
17 A I'm so sorry. I don't know all of those, but
18 I'm -- I would have to guess.
19 Q Okay. Your title is MD, correct?
20 A That is correct.
21 Q And in addition to being an MD, you also have,
22 I think, two board certifications. Is that correct?
23 A That's incorrect. Oh, board certifications?
24 Help me understand what your question is.
25 Q Are you a board-certified oncologist?

A I am.
Q Okay. And who certifies you as a board-certified oncologist?
A The American Board of Internal Medicine.
Q And when were you certified by them as a medical oncologist?
A In January of 2013.
Q Okay. Now, I have a question in your declaration in paragraph 10. Go ahead and look at paragraph 10.
A So, again, we're going to '826?
Q That's where I'm looking, but if you think your qualifications might be different in the different declarations, please do check.
A So paragraph 10 on page 4?
Q Yes. Do you see that you have a statement there about certifications from the American Board of Internal Medicine?
A Correct.
Q That's the board you mentioned just a moment ago, correct?
A Not -- so, yes, the American Board of Internal medicine is the credentialing board for internal medicine and its subspecialties. So I had my initial training in internal medicine. That was my internship

1 and residency.
2 Then I did a fellowship in hospice and
3 palliative medicine, followed by another one in
4 hematology-oncology.
5 Q Okay. And so you have two board
6 certifications; is that correct?
7 A No. Over my career, I've had three:
8 internal medicine, hospice and palliative medicine,
9 and -- as well as medical oncology.
10 Q Okay. And the internal medicine is kind of the
11 umbrella term?
12 A You have to do internal medicine training first
13 to then subspecialize. And so it is, you know, entry
14 into the subspecializing as well as the group that would
15 maintain the license for the general internal medicine
16 as well as the sub -- the medicine subspecialties.
17 Q Okay. So your subspecialty in medical oncology
18 was certified in paragraph 10, it says, beginning in
19 2014. Do you see that?
20 A I do see that on the page.
21 Q Okay. And is that -- is that accurate?
22 A It should have been -- I think it's 2013.
23 Q Do you want to check your other declarations
24 and see if they say something different?
25 A So for Patent --

1 (Interruption by the stenographer.)
2 THE WITNESS: For Patent '357, page 4,
3 paragraph 10, for "Medical Oncology," it says "(2014 to
4 present)."
5 And for Patent '297, paragraph 10, for "Medical
6 Oncology," it says "(2014 to present)." And for Patent
7 '515, page 4, paragraph 10, it says "Medical Oncology
8 (2014 to present)."
9 BY MR. MILLS:
10 Q Okay. So either your CV or the declaration is,
11 perhaps, a typo?
12 A Yeah. It would be an unintentional typo.
13 Q Okay. And one of the reasons -- I'm just
14 trying to clarify and make sure I understand.
15 When I looked on your OHSU website, it also
16 said "2014."
17 A I'm so sorry. I can't explain everything other
18 than I can walk you through my training.
19 So I got my medical degree from the University
20 of Colorado in June of 2005. That was followed by an
21 internship year at the University of California,
22 San Diego, which went from July 2005 to June 2006.
23 That was followed by two years of internal
24 medicine training at the University of California,
25 San Diego, from July 2006 to June 2008.

1 Then I did a fellowship in hospice and
2 palliative medicine at the San Diego hospice and the
3 Institute for Palliative Medicine between July 2008 and
4 June 2009.
5 That was directly followed by a fellowship in
6 hematology-oncology from July 2009 to June 2012 at the
7 University of California, San Diego.
8 As far as my board certifications, they don't
9 align specifically with the moment you finish your
10 training because you get to study for them and then take
11 them at a later date.
12 Q Okay. So do you know, sitting here right now,
13 whether the 2013 date or the 2014 date is the accurate
14 date?
15 A I can't -- I can't recall.
16 Q Okay.
17 A I mean, it's a long time ago. And, quite
18 honestly, it really doesn't matter.
19 Q Okay. So you are confident, though, that it
20 was either in 2013 or 2014 that you were first certified
21 as a medical oncologist; is that correct?
22 A Correct, and that I was practicing medical
23 oncology from July 2009 to June 2012.
24 Q Okay. Great. Now, we talked about your
25 specialty in supportive care. We talked about your

1 fellowship and your certification in medical oncology in
2 2013 or 2014. And we talked about some of the things
3 you're not, right.
4 You're not a lawyer, thank goodness, right?
5 A Yeah, thank goodness.
6 Q Okay. And we talked about that you're not a
7 pharmacologist.
8 Are you a pharmacokineticist?
9 A I am not a formally trained pharmacokineticist.
10 Q Have you ever personally performed experiments
11 that measured receptor occupancy?
12 A I have never done a specific study of receptor
13 occupancy -- performing the experiments.
14 Q Okay. Have you ever personally performed
15 experiments measuring binding affinity to receptors?
16 A I have never personally performed an experiment
17 measuring binding affinity.
18 Q Have you ever performed an experiment measuring
19 blood-brain barrier penetration?
20 A I have never personally performed an experiment
21 measuring blood-brain barrier penetration.
22 Q Have you ever personally performed an
23 experience -- an experiment measuring drug clearance?
24 A I have never personally performed an experiment
25 measuring drug clearance.

Q Have you ever personally performed an experiment measuring volume of distribution?

A That --

MS. RUPERT: Objection to form.

THE WITNESS: I have never personally performed an experiment measuring drug clearance.

BY MR. MILLS:

Q And now the same question for volume of distribution.

Have you ever personally performed an experiment measuring volume of distribution?

MS. RUPERT: Objection to form.

THE WITNESS: I have never performed -- or I've never led an experiment personally for measuring volume of distribution.

BY MR. MILLS:

Q Have you ever personally performed an experiment measuring absorption rate?

A I have not personally performed an experiment measuring absorption rate.

Q Have you ever personally performed an experiment measuring drug half-life?

A Yeah, off the top of my head, I have not performed personal experiments quantifying drug levels for half-life.

Q Have you ever personally performed experiments doing PET imaging?

A I have personally not performed experiments looking at PET imaging.

Q Okay. I want to go back to Dr. Navari. He's mentioned in paragraph 22 of your declaration.

Do you see his name there?

A So for declaration '826 on page 9, paragraph 22, I see the words "Dr. Navari."

Q Okay. And just go ahead and look at paragraph 2 [sic] in your other declarations and evaluate whether your discussion in the four declarations is the same in that paragraph.

A So the '826 states:

"I have reviewed Dr. Navari's declaration and the opinions set forth therein. I have incorporated several portions of his declaration as they were relevant to my analysis and the opinions I have set forth in this declaration."

Now I'm going to turn to '515. And Section 3, paragraph 22 on page 9:

"I have reviewed Dr. Navari's declaration and the opinions set forth therein. I have incorporated several

portions of his declaration as they were relevant to my analysis and the opinions I have set forth in this declaration."

Q So those are the same?

A Those are the same.

Q Okay. And just -- you don't have to read it again. I don't want to make your mouth too dry.

But just look at other ones and tell me if there's any differences.

A So now I'm looking at patent '357, Section 22. That looks the same. And then declaration '297, paragraph 22 on page 9. And that is the same.

Q Okay. Thank you. In paragraph 22 of your declarations, when you say that you incorporated several portions of Dr. Navari's declaration into your own, which portions of your declarations, as they sit in front of you, came from Dr. Navari?

A I would be unable to tell you exactly which portions because I significantly reviewed and edited and added and whatnot, so I wouldn't be able to tell you.

Q Okay. It sounds like you have some things in mind of changes that you made, starting from the Navari declaration.

So tell me off the top of your head what it is that you added or revised.

1 MS. RUPERT: Objection to form.
2 THE WITNESS: Yeah, I don't think, off the top
3 of my head -- just given the length of these documents
4 and the amount of time, it would be hard for me to go
5 through this now and point line by line what was added,
6 what was edited.
7 All I can say is I spent a lot of time
8 reviewing, vetting all the language to the best of my
9 ability in preparing the document.
10 BY MR. MILLS:
11 Q Can you tell me any portion of your
12 declaration -- your declarations, as they sit in front
13 of you, that the things that you added to what began
14 with Dr. Navari's declaration?
15 MS. RUPERT: Objection to form.
16 THE WITNESS: All I can speak to is that I
17 thoroughly reviewed, edited, crafted this document to
18 reflect my own opinions and experience.
19 BY MR. MILLS:
20 Q So, as you sit here right now, there's not a
21 single thing you can tell me, you know, "This portion of
22 the declaration, I know that is the part that I added"?
23 MS. RUPERT: Objection to the characterization.
24 THE WITNESS: I'm happy to read the whole
25 document, but I'm not going to guess as to what -- the

editing history of this entire document.
BY MR. MILLS:
Q And I -- we clearly don't have time for you to read the whole thing right now. You just spent 50 hours reading over the weekend, right? It's a big haul.
But, as you sit here right now, after that 50 hours of studying the declarations over the weekend, there's nothing that stands out to you as something that you recall your contribution to the declarations separate and apart from what originated with Dr. Navari?
MS. RUPERT: Objection. Asked and answered.
THE WITNESS: I can speak to that I personally reviewed every line of this declaration, all four declarations. It was overwhelming. There was just a lot of information.
But the facts are the facts around the topics, and that's all I can speak to.
BY MR. MILLS:
Q Okay. And I understand being overwhelmed by it. I had to wade through it as well.
A Mm-hmm.
Q And the board will have to wade through it as well.
A Mm-hmm.
Q But, as you sit here right now, there's not any

1 particular thing you can point to and say, "I know that
2 was my contribution separate and apart from Dr. Navari"?
3 MS. RUPERT: Objection to the characterization.
4 THE WITNESS: I can speak to the fact that I
5 know I significantly contributed and -- to the document
6 and edited it based on my own experience,
7 interpretation. Yeah.
8 BY MR. MILLS:
9 Q There's just no example that you want to point
10 to that you say, "I know that was my contribution"?
11 A I think I've answered that question already.
12 Q So you don't have anything to identify for me?
13 MS. RUPERT: Counsel, if you have a copy of the
14 Navari declaration, you could give it to him.
15 THE WITNESS: I'm happy to do a line-by-line
16 comparison if that's what you're looking for.
17 BY MR. MILLS:
18 Q So -- and I'm trying to make this easier for
19 you. Of course, there's no way we can do a line-by-line
20 comparison in the amount of time that we have.
21 But just as you sit here right now, there's not
22 a single example that you want to point to as your
23 unique contribution to the declaration?
24 MS. RUPERT: Objection. Mischaracterizes.
25 THE WITNESS: I think I can speak to the whole

1 document that I would never have agreed to this document
2 being finalized without personally vetting every portion
3 of it.
4 BY MR. MILLS:
5 Q So -- and I do have a question related to that.
6 So it sounds like you're telling me that you were not
7 relying on Dr. Navari for any of these opinions in the
8 declarations; is that fair?
9 MS. RUPERT: Objection to form.
10 THE WITNESS: No. As I stated, I think --
11 let's -- let's go back to those words.
12 I reviewed his declaration and the opinions set
13 forth therein, and I incorporated several portions of
14 his declaration as they were relevant to my own analysis
15 and opinions. So that answers your question.
16 BY MR. MILLS:
17 Q And the answer is that you're not relying on
18 Dr. Navari for any of the opinions in your declarations;
19 is that correct?
20 A I think what we can agree to is that when
21 Dr. Navari describes a medical fact or a result that is
22 a fact, that we would -- I would use that same fact in
23 my analysis.
24 Q So I understand that there's some overlap. I'm
25 just trying to understand whose opinions, right, are

being evaluated here.

So what -- I'm trying to understand whether at some point you're relying on Dr. Navari.

You're saying, "Well, Dr. Navari said, so that must be correct," without independently verifying it for yourself?

A Yeah. You clearly don't know me very well because I would never do that. I have my own opinions, experience. And although Dr. Navari is a recognized leader in this field, he has strengths and weaknesses, and I have strengths and weaknesses.

So this document reflects my own assessment, and there's parts with Dr. Navari that I'm going to agree with and parts that I don't agree with.

Q And regardless of whether there may be places where there's overlap between what Dr. Navari said and what you've said, you're comfortable saying you're not relying on Dr. Navari for any of the opinions in your declaration, they're your own; is that correct?

A I'm going to go back to the declaration, paragraph 22. There are pieces that -- opinions set forth by Dr. Navari. And there are portions that I reviewed and edited appropriately.

Q Right. So I understand that the starting point was his declaration.

My question's really a different question.

Are you deferring to Dr. Navari on any point in your declaration?

A So very clearly -- I don't know how else to say this -- I have my own opinions. I am my own expert. And so I am not deferring to Dr. Navari.

Q Okay. Perfect.

And just related to that, is there some additional expertise that Dr. Navari has that you don't have for which, in reaching your opinions, you're relying on some expertise that Dr. Navari has that you don't?

MS. RUPERT: Objection to form.

THE WITNESS: Off the top of my head, I am unaware of Dr. Navari's training and his expertise.

But what I can bring to the table that is unique is I'm one of 4 percent of medical oncologists in the country who are dual trained in hospice and palliative medicine as well as medical oncology and, of those, probably less than half a percent that did hospice and palliative medicine before doing their oncology career.

So I think that that is my own unique contribution and perspective here.

///

BY MR. MILLS:

Q Okay. So because of your dual training, you have a -- you can provide a unique perspective on the subject matter that your average medical oncologist wouldn't have? Is that what you're saying?

MS. RUPERT: Objection to form.

THE WITNESS: I think it speaks to a unique training and a commitment to understanding supportive care.

BY MR. MILLS:

Q All right. So that dual training that you have, that's the perspective that you applied in providing your opinions in this case, correct?

MS. RUPERT: Objection to the characterization. Misstates testimony.

THE WITNESS: Well, I think what you're asking is: Are the opinions coming from me and my lived experience? And so that is who I am, yes.

BY MR. MILLS:

Q Okay. And it's that unique experience as someone who's dual trained in both palliative care and medical oncology, correct?

MS. RUPERT: Objection to the form of the question. This has become very confusing.

MR. MILLS: Counsel, please don't engage in

speaking objections.

MS. RUPERT: He's entitled to a fair question.

MR. MILLS: He's not entitled to speaking objections and coaching. You need to follow the rules just like everyone else.

MS. RUPERT: I'm not doing --

BY MR. MILLS:

Q Would you like me to --

MS. RUPERT: -- speaking objections and coaching.

BY MR. MILLS:

Q Would you like me to ask the question again?

A Yeah. You kind of lost me here. I don't really understand what's going on.

Q So you said there's a very small group of people that are dual trained in both palliative care and medical oncology, correct?

A That is true, because the people were in the supportive care space without saying -- having a dedicated fellowship until -- I can't remember when it first started, but early 2000s.

Q So it's a relatively small group of people. You qualified with that dual training, correct?

A Correct.

Q And that's the perspective with that dual

1 training that you brought to your opinions in this case,
2 correct?
3 MS. RUPERT: Objection to the characterization.
4 Misstates report.
5 THE WITNESS: I don't know how else to say it,
6 but, yes, I have a unique perspective and training. But
7 it's all based off of my lived experience.
8 BY MR. MILLS:
9 Q Are you good to keep going, or would you like
10 another break?
11 A I think I need a break.
12 MR. MILLS: Okay. Let's go ahead. Off the
13 record.
14 (Recess taken from 11:28 a.m.
15 to 11:41 a.m.)
16 BY MR. MILLS:
17 Q Welcome back, Dr. Roeland.
18 A Thank you.
19 Q Did you have any communications with counsel
20 during the break that related in any way to your
21 testimony?
22 A No. I just got a glass of water, went to the
23 bathroom, got some rest.
24 Q Okay. We're going to play a little bit more of
25 the "who is" game. I'm going to ask you some names and

see if these are people that you know.
The first person is Fabio Trento.
A I recognize his name from the patent only. It's listed in front of me, but I do not know Fabio Trento.
Q Do you know anything about Fabio Trento?
A No, I do not.
Q Did you ever communicate with Fabio Trento in regards to this case in any manner?
A No, I did not.
Q And do you know anything about Fabio Trento's education or training as of November 2009?
A I do not know anything about Fabio Trento.
Q Who is Sergio Cantoreggi?
A I have no idea. He's listed on the patents sitting in front of me, but I do not know Sergio Cantoreggi.
Q Did you ever communicate with Sergio Cantoreggi as part of your work on this case?
A No, I did not.
Q Did you ever investigate the training or qualifications of Sergio Cantoreggi as part of reaching your opinions in this case?
A No, I did not.
Q Who's Roberta Cannella?

A Again, I see a name listed on the patent, but I do not know who that is.

Q So it's correct that you never spoke with Roberta Cannella as part of reaching your opinions in this case?

A That is correct.

Q You also never investigated the training or qualifications of Roberta Cannella in November 2009 as part of providing your opinions in this case, correct?

A Yeah, I do not know anything about Roberta Cannella.

Q And the same is true of Daniele Bonadeo?

A I don't know anything about Daniele Bonadeo.

Q And you also never spoke with Daniele Bonadeo as part of providing your opinions in this case, correct?

A Correct. I have never discussed anything with Daniele Bonadeo.

Q Great. Thank you. I also noticed in your declaration there's no section that's titled "Legal Standards."

Can you check your table of contents and confirm for me that I am correct?

A So you're -- sorry. Say that again.

Q There's no section of your declaration that

1 says "Legal Standards," "Here are the legal standards I
2 was given to apply to this case."
3 A As far as a section entitled "Legal
4 Standards" -- I'm not a lawyer, so -- I don't think I
5 have that in here, no.
6 Q Are there any legal standards that you were
7 given to apply in -- for your opinions in this case?
8 MS. RUPERT: So I'm going to object to that as
9 calling for disclosure of attorney-client
10 communications. And I don't think that's an appropriate
11 question here.
12 BY MR. MILLS:
13 Q So let me ask a new question.
14 So my question is specifically if there is any
15 legal standard that you were given to apply in this case
16 that you relied upon for your opinions in the case.
17 MS. RUPERT: That's the same question. And
18 that calls for disclosure of attorney-client-privileged
19 communications. That's not an appropriate question.
20 It's calling for privileged information.
21 MR. MILLS: So register your objection.
22 MS. RUPERT: Yeah.
23 And I instruct you not to answer.
24 BY MR. MILLS:
25 Q Okay. Are you following counsel's

1 instructions?
2 A Yes, I am.
3 Q Okay. So I'm entitled to know if you're
4 relying on counsel as a basis for your opinions, even if
5 it's legal standards that have been provided to you.
6 So I'm not trying to get at the specific
7 communications that you have. It's customary in a
8 declaration for them to say, "These are the legal
9 standards that I'm applying."
10 Is there anything you can point me to in your
11 declaration that tells me the legal standards that were
12 given to you by counsel to apply in this case?
13 MS. RUPERT: Objection to the form of the
14 question. Assumes facts not in evidence.
15 Could you rephrase? Because you're assuming a
16 privileged communication as part of your question. So
17 can you just rephrase that and make it clean?
18 MR. MILLS: So I'm not assuming any privileged
19 communications because it's -- there's no privilege. If
20 you're giving him legal standards to apply in the case
21 that he's relying on for his opinions, those aren't
22 privileged.
23 MS. RUPERT: You're calling for a privileged
24 communication. I think you can ask him what's in his
25 report, and that's fine. Your questions about "Does

this appear in your report?" that's fine.

MR. MILLS: So that was my question.

BY MR. MILLS:

Q Is there something you can point me to in your declaration that provides legal standards that you were given to rely on for applying in this case?

MS. RUPERT: The problem is the last part, "legal standards that you were given to apply to this case." That assumes --

BY MR. MILLS:

Q Okay. So I'll withdraw the question and ask a new question.

Is there anything you can point me to in your declaration that provides legal standards that you rely on for your opinions in this case?

A So I think, as you're quite aware, I'm not a lawyer. So I'm not sure what you're getting at.

Q Well -- yeah. So there's no disclosure in your declaration of any legal standards that you are applying; is that correct?

A I'm struggling to understand what you're trying to say here.

So, you know, if you're describing legal standards as just the formatting of this document and the certain words that were used, like, "objective

1 indicia" or "nexus" or things like that, those are
2 included in this document.
3 Q So were you provided -- let me withdraw and
4 start a new question.
5 In your declaration, is there a recitation of
6 the legal standards for objective indicia?
7 A Section 9 is entitled "Objective Indicia."
8 Q And is "objective indicia" a term that you use
9 as part of your practice in palliative care and medical
10 oncology?
11 A I am not a lawyer.
12 Q Right. My question is about in your practice
13 in palliative care and medical oncology, is "objective
14 indicia" a term that you use in your field of expertise?
15 A Medical oncology and palliative care are not
16 law.
17 Q I understand that.
18 So I'm -- the answer seems self-apparent to me.
19 I just want to make sure that we agree.
20 So that "Objective Indicia" section, that's a
21 term that you understand is a legal term that is --
22 doesn't have a medical oncology or palliative care
23 meaning; is that fair?
24 A I can say that the term "Objective Indicia" is
25 not something that we use in medical oncology or

1 palliative care.
2 Q Okay. So can you identify for me in your
3 declaration where it explains the legal meaning of
4 "Objective Indicia"?
5 A I can point you in the location on page 175 and
6 read to you what it says with regard to the "Objective
7 Indicia."
8 But if you're asking me to opine about the
9 meaning of legal terms, I'm not a lawyer.
10 Q Is it correct to say, because you are providing
11 testimony from the perspective of a dual-trained
12 palliative care and medical oncology specialist and not
13 from the perspective of a lawyer, you don't have an
14 understanding as to which legal principles apply to the
15 concept of objective indicia?
16 MS. RUPERT: Objection to the form of the
17 question and misstates prior testimony.
18 THE WITNESS: I'm here today speaking as a
19 clinician, clinician-researcher, in the space of
20 supportive care in cancer.
21 BY MR. MILLS:
22 Q Do you know one way or the other whether your
23 declaration section that's titled "Objective Indicia" is
24 responsive to the legal standards for objective indicia?
25 A Again, I'll say I'm not a lawyer.

Q And because you're a lawyer [sic], you don't know one way or the other whether the section that's titled "Objective Indicia" is responsive to the legal standards for objective indicia; is that fair?

MS. RUPERT: Objection to the characterization.

You just said "because you're a lawyer."

BY MR. MILLS:

Q So I'll withdraw the question and start over.

Because you are not a lawyer, you do not know one way or the other whether the section in your declarations that is titled "Objective Indicia" is responsive to the legal standards for objective indicia, correct?

A I -- again, I am not a lawyer, so -- that's all. That's what I'm going to say.

Q What I mean --

A We're kind of going over this over and over again. How can I help you?

Q Well, I need to know whether you have an understanding as to whether the testimony that you're giving under the heading of "objective indicia" -- whether that's responsive to the actual legal standards for objective indicia.

I mean, let me try and make this easier.

The title "Objective Indicia" did not come from

your oncology background, correct? Fair?

A That is fair.

Q So you seem to be telling me, "I'm not a lawyer. I'm an oncologist," which that's also fair, right? We agree on that?

A That is true.

Q Right. So you really just don't know one way or the other what those things have to do with the legal standards; is that fair?

MS. RUPERT: Objection to the characterization.

THE WITNESS: I can speak to what's in my report and -- but I am not a lawyer. I don't know how else to say that.

BY MR. MILLS:

Q Right. So I understand you're not a lawyer. But you're telling us that you don't have any understanding as to what the legal standards are for objective indicia; is that correct?

A If you were to ask me all the points required for objective indicia with regard to legal terms, I cannot answer that.

Q All right. Thank you. I want to ask you about some more people.

We struck out on the inventors. You don't know any of the inventors. You didn't speak to them. You

1 don't know anything about their qualifications.
2 Do you know a person named Dawn, D-a-w-n, last
3 name Dolan, D-o-l-a-n?
4 A Off the top of my head, I do not know that
5 person.
6 Q Okay. Do you know a person named
7 Howard Levine?
8 A Off the top of my head, I do not know that
9 person.
10 Q Do you know a person named Beth Eaby-Sandy?
11 A I do not know that person.
12 Q I'd like to ask you more about your
13 declaration. So let's go to paragraph 33 of your
14 declaration.
15 A So, again, we're talking about '826?
16 Q So I'm in the '826. So when you get to
17 paragraph 33, go ahead and read it to yourself. And to
18 spare you the dry mouth, we won't make you read it out
19 loud right now.
20 Let me know when you've finished reading that
21 paragraph 33 to yourself.
22 A Okay.
23 Q Now go ahead and, again, without reading it out
24 loud but reading it to yourself, compare that
25 paragraph 33 to the paragraphs in your other

1 declarations, and let me know if there are any
2 differences.
3 A So '515 appears to be the same.
4 For '357, paragraph 33 on page 14 going on to
5 page 15 looks the same.
6 And then for '297, on page 14 and 15, that
7 looks the same.
8 Q Okay. Great. Thank you. I'm going to ask you
9 now about the second sentence in paragraph 3 [sic] of
10 your declarations where it says:
11 "This distinction between nausea and
12 vomiting is important because, as I
13 discuss later in this declaration (see
14 Section V.B), in November 2009, no such
15 treatment existed to treat both nausea
16 and vomiting."
17 Do you see -- did I read that correctly?
18 A I see that sentence.
19 Q And then the following sentence says:
20 "While the standard of care 'triple
21 therapy' regimen (i.e., a combination of
22 a corticosteroid (dexamethasone), a
23 5-HT3 receptor antagonist, and
24 aprepitant, further explained below in
25 Section V.B.3) was effective in

1 preventing vomiting after chemotherapy
2 administration, it failed to provide
3 meaningful control of nausea, including
4 delayed nausea (i.e., nausea occurring
5 24 to 120 hours after the administration
6 of chemotherapy)."
7 Did I read that sentence correctly?
8 A Yes, you did.
9 Q Okay. So, Dr. Roeland, I've spent quite a bit
10 of time in your declaration trying to understand it and
11 trying to understand -- you know, anytime somebody
12 drafts a declaration, there's times where they might --
13 maybe they could have been more artful in exactly what
14 they said versus what they intended.
15 And we went through a couple of times today
16 where you found, you know, something that -- the way
17 that it was written isn't exactly as you intended it.
18 So, for instance, the advisory board discussion
19 omitted Helsinn from the list. There's a little bit of
20 confusion about whether you were board-certified in 2013
21 or 2014. In the scheme of things, those are pretty
22 small matters.
23 But what I've really been puzzling about in
24 your declaration is there's places all over your
25 declaration where you make the point, which seems to be

1 a central theme in your declaration, that you're not
2 convinced that the triple therapy is more efficacious
3 for treating nausea than the standard therapy, at least
4 as demonstrated by a statistically significant result in
5 a study.
6 So there's places in your declaration where you
7 say that, and there's many places where you say that.
8 Here, in particular, when I read these words literally,
9 you seem to be saying that there is no efficacy for
10 either the triple therapy or the standard therapy for
11 treating nausea.
12 And I -- I think this is just a circumstance
13 where, you know, the language maybe wasn't crafted as
14 artfully as you intended.
15 So -- but my question to you is: Is it your
16 opinion, based on your expertise and qualifications,
17 that in November 2009, no treatment existed to treat
18 both nausea and vomiting?
19 MS. RUPERT: Objection to the form of the
20 question.
21 THE WITNESS: So I think this paragraph is
22 specifically addressing our clinical trials to date.
23 So the primary endpoint for our CINV trials in
24 November 2009 consistently used a complete response as
25 the primary endpoint was a -- which was a measure of no

1 emesis and no use of rescue therapy, which does not
2 include the second phenomena of nausea. That sometimes
3 is included as a secondary endpoint.
4 And as of November 2009, we did not have any
5 medication that had demonstrated an improvement in both
6 vomiting and nausea across the acute and delayed phases
7 that showed a statistically meaningful impact on both
8 vomiting and nausea.
9 BY MR. MILLS:
10 Q You said "improvement."
11 Improvement as compared to what?
12 A So improvement is always compared to baseline
13 or to the standard therapy.
14 Q Okay. And in this case, the standard therapy
15 was the combination of the 5-HT3 receptor antagonist and
16 dexamethasone, correct?
17 A Well, it doesn't say, you know, in general,
18 we're talking about -- so as of November 2009 with --
19 while we were studying the impact of NK-1 receptor
20 antagonists, they would have been compared to the
21 standard therapy, which at the time would have included
22 a 5-HT3 receptor antagonist and a steroid.
23 Q Okay. So in the context of paragraph 33, the
24 standard therapy to which it was compared was 5-HT3
25 receptor antagonists in combination with dexamethasone;

is that correct?

A I think it's overly broad. We'd have to actually talk about which study we're -- we're thinking about.

Q In what aspect is that statement overly broad? You think it's a different corticosteroid?

A Well, so each study would define which 5-HT3 receptor antagonist they're using, the dosing, as well as the interval as well as the steroid. So there is a little bit of devil in the details.

Q So you mentioned that there may be a couple different iterations of the standard therapy.

Is that what you're saying?

MS. RUPERT: Objection to form.

THE WITNESS: Well, I think what you're asking is what is standard therapy, which would have been defined at the time by national guidelines and would have taken into account the setting.

So was this highly emetogenic chemotherapy? Was this moderate emetogenic chemotherapy? Or --

(Interruption by the stenographer.)

THE WITNESS: Oh.

Highly emetogenic chemotherapy, moderately emetogenic therapy, or low emetogenic chemotherapy.

And then those guidelines identify drugs with

1 evidence available in that setting and support
2 guideline-concordant care based on best evidence.
3 BY MR. MILLS:
4 Q And take a look at paragraph 47 of your
5 declaration. The very last sentence of that paragraph,
6 you provide a discussion of standard therapy.
7 Why don't you go ahead and read that sentence
8 out for us.
9 A Sorry. Which --
10 Q Paragraph 47.
11 A Oh. Thirty-seven or 47?
12 Q Forty-seven.
13 A Forty-seven. So -- sorry -- what portion of
14 that?
15 Q Very last sentence.
16 A So "prior to the use of 'triple
17 therapy' for treating CINV,
18 clinician used 'standard therapy'
19 for treatment of CINV, which was a
20 two-drug regimen involving a
21 corticosteroid (mainly
22 dexamethasone) and a 5-HT3 receptor
23 antagonist."
24 Q And so when you're talking about standard
25 therapy, is this the meaning of standard therapy that

you have in mind?

A Broadly speaking, yes. But if we're ever looking at a clinical trial, though, I'd like to make sure I understand what the standard therapy was evaluated in that study.

Q All right. And here, in particular, you put the words "standard therapy" in quotes, right?

A Yes, I did. It's in quotes.

Q And that's sort of to distinguish it from triple therapy, which you also put in quotes, correct?

A Triple therapy.

Q In that same sentence.

A Oh, yeah --

Q Yeah.

A -- in that same sentence, correct.

Q Okay. And in the sentence before, that's where you give us the description of the triple therapy in quotes.

Do you see that, the sentence that begins "This combination was referred to as 'triple therapy'"?

A I do see that sentence.

Q Okay. So the difference between the standard therapy and the triple therapy is the addition of the NK-1 receptor antagonist aprepitant; is that correct?

A Correct.

1 Q So now I'm asking about the standard therapy.
2 That's the two-component system, as you've described it
3 in paragraph 47.
4 Is it your opinion, based on your expertise and
5 qualifications, that in November 2009, a person of
6 ordinary skill in the art believed that this "standard
7 therapy" lacked any efficacy for treating nausea in CINV
8 patients?
9 MS. RUPERT: Objection to the form.
10 THE WITNESS: I'm trying to get at your
11 question. I want to answer it the best I can.
12 So you're asking me to put myself in a position
13 of someone in 2009 and asking if they felt that the
14 combination of 5-HT3 and dexamethasone did not improve
15 the experience of nausea?
16 BY MR. MILLS:
17 Q Lacks all efficacy for treating nausea. There
18 is no such treatment for treating both nausea and
19 vomiting in November 2009.
20 Is that what you mean? Is that what you mean
21 to say?
22 MS. RUPERT: Objection to form.
23 THE WITNESS: I can tell you that there was
24 incremental benefits in terms of controlling both
25 vomiting and nausea spanning decades with a use

1 initially of dexamethasone, then metoclopramide. These
2 were all incremental benefits.
3 BY MR. MILLS:
4 Q You can take a look at paragraph 59 of your
5 declaration.
6 The last sentence of that paragraph, go ahead
7 and read that one out loud for us.
8 A So for declaration '826, page 34, under
9 "Corticosteroids"? Is that the one you're talking
10 about?
11 Q So paragraph 59 --
12 A Oh.
13 Q -- page 34 of your declaration.
14 A 5-HT3 receptor antagonists.
15 (Interruption by the stenographer.)
16 THE WITNESS: 5-HT3 receptor antagonists.
17 "As of November 2009" --
18 BY MR. MILLS:
19 Q Oh, we might be in a different place. The last
20 sentence of the paragraph 59 starts "However, clinical
21 studies."
22 A Fifty-nine. Oh.
23 "However, clinical studies have also
24 demonstrated that dexamethasone was significantly
25 superior to placebo in terms of the percentage of

1 patients free of delayed vomiting or moderate to severe
2 nausea.
3 Q Okay. So, I mean, this is where I'm telling
4 you I was having a problem reading your declaration is
5 because I see where you're very forthright telling us,
6 "We have treatments for nausea. There's things" --
7 "more things we want to do. But there are treatments
8 that we give for nausea and vomiting. It helps a
9 certain set of people, not everyone. But it is treating
10 nausea -- both nausea and vomiting, and we call it the
11 'standard therapy.'"
12 Did I understand that part of your testimony
13 correctly?
14 MS. RUPERT: Objection to form.
15 THE WITNESS: I think we can agree that at the
16 time that the tool that was available in the prevention
17 of chemotherapy-induced nausea and vomiting was a
18 combination of a 5-HT3 receptor antagonist and a
19 corticosteroid and that the corticosteroid had some
20 impact on nausea.
21 I'd also like to point out, though, that as we
22 are taking care of patients, we're going to continually
23 try to improve that experience, that just because we
24 have a tool now, we're hoping that we continue to
25 improve it so that, when any of us get cancer, that

1 experience can be improved.
2 BY MR. MILLS:
3 Q Right. And I understood that point completely,
4 right. So you care about your patient. You're not
5 satisfied. You want -- you want more. You want
6 something better.
7 But there's places in your declaration that
8 make it seem like you're saying there was no treatment.
9 You used the words "no such treatment." There was
10 nothing that treated both of them.
11 And when I read everything together in context,
12 I think, "He can't have meant that. He must have meant"
13 that you weren't convinced that the triple therapy was
14 better than the standard therapy.
15 But it doesn't mean there's no treatment. It's
16 just that there -- you didn't have something that you
17 were convinced was better.
18 And I just want to make sure that we're not --
19 you know, we're not perpetuating, like, fake news kind
20 of antivax type of stuff where we -- where we're saying
21 that there was no treatment when there clearly was a
22 treatment, that you were in search of a better
23 treatment.
24 A So --
25 MS. RUPERT: Is there a question?

1 And I'm going to object to the form of the
2 question. It mischaracterizes his testimony.
3 And I'm not even sure what the question is.
4 THE WITNESS: So, you know, I can speak to in
5 2009 what we had available to treat nausea broadly,
6 corticosteroids was one of them, which is limited by all
7 sorts of reasons.
8 And they have multiple side effects including
9 insomnia, anxiety, infections, hyperglycemia, drug
10 interactions.
11 So, yes, we may have had one tool that was
12 very, very old. Other tools that we would have had
13 available include some of the antiemetics such as
14 prochlorperazine, metoclopramide, and others.
15 And those were used kind of as needed in that
16 setting.
17 BY MR. MILLS:
18 Q And, in fact, in your declaration, you even
19 talk about adding olanzapine as a -- in addition to the
20 triple combination, making it a quadruple combination.
21 A That particular combination was not
22 standardized until a study in 2016. But there was early
23 signals of the use of olanzapine before that.
24 Q Right. So -- and I'm not trying to put words
25 in your mouth.

1 I understand that you were not satisfied
2 with -- I'll use the word "armamentarium" -- I don't
3 know if you use that for where you're treating symptoms
4 as opposed to chemotherapy or something.
5 But you weren't satisfied with the quiver of
6 arrows that you had. You wanted more.
7 But you'll agree with me that there were
8 treatments, including standard therapy, that were given
9 to patients as treatments for both nausea and vomiting
10 in November 2009, correct?
11 MS. RUPERT: Objection to form.
12 Mischaracterizes.
13 THE WITNESS: No. So I think that is a little
14 overly broad in that it's not quite as simple as that.
15 So we had medicines that we know targeted
16 vomiting, and we had medicines that we know was more
17 targeting nausea, but those were very limited.
18 And despite the medicines that we had
19 available, there was some overwhelming challenge of
20 patients still having nausea, especially in the delayed
21 phase.
22 So that was a big problem.
23 BY MR. MILLS:
24 Q So you keep wanting to pivot back to saying
25 that they're very limited.

1 But your statement in your declaration -- and
2 there's many more. I have them highlighted in red --
3 A I'm sure you do.
4 Q -- because it jumped out as a red flag to me.
5 A Yeah.
6 Q And I don't think you meant to say that.
7 And so what I'm trying to do is I'm just -- I'm
8 trying to get you to make your record clear as to what
9 your opinions really are and what they're not, and -- as
10 to whether you're saying there really was no treatment
11 that existed to treat both nausea and vomiting in
12 November 2009.
13 MS. RUPERT: Objection to the form. Asked and
14 answered repeatedly at this point.
15 THE WITNESS: I -- I'm sorry if you misread it
16 that way. That was not the intent.
17 BY MR. MILLS:
18 Q Okay.
19 A The intent is that there were limited options
20 that neither you nor your loved ones -- you would want
21 them to receive that during that time for treatment
22 because we needed to do better. Nausea and vomiting,
23 especially nausea, remained a major challenge.
24 And these are people having nausea at home,
25 away from the clinic with limited tools to keep that

1 under control.
2 Q So I need to follow up on that answer. There's
3 a couple things you said in there, right? But one of
4 them is you said that somebody that cares about a
5 patient wouldn't want them to receive that.
6 So are you saying that the alternative would be
7 that they receive nothing?
8 A No. I would never indicate that.
9 Q I understand you to be saying, "They wouldn't
10 want us to stop there," right?
11 "They want" -- "they want more. They want
12 something better. But there is a treatment. It's the
13 standard of care treatment. And we're on the lookout to
14 improve it even more."
15 Is that what you're saying?
16 A I think we can agree that we're always trying
17 to strive for better treatments for the -- for people
18 living with cancer.
19 Q Right. In addition to always striving for
20 better treatments, there was a recognition, and it was,
21 in fact, the standard of care to provide the standard
22 therapy, that dual therapy, for treatment of both nausea
23 and vomiting.
24 Do you agree?
25 A I agree with that statement.

1 Q Thank you. I want to ask you -- I need to find
2 where this is. Let's look at paragraph 102 of your
3 declaration.
4 All right. And this is one where you have to
5 turn the page because there's some charts here.
6 And you're a numbers guy, and you're trying to
7 be very precise. And I appreciate that. So I want to
8 talk a little bit about the numbers here.
9 One of the points you make in your declaration
10 is that the different iterations of table 2 from these
11 different references all refer to the same data; is that
12 correct?
13 A Yes. So on page 64 we have the Emend label
14 from 2008, which is Exhibit 1030. We have a 2003 Emend
15 label, which is Exhibit 216, and then a reference by
16 Poli-Bigelli, and that's Exhibit 1039.
17 Q Okay. And I'm -- I think these questions are
18 going to be easy. And I'll even -- if it's helpful for
19 you, I'll give you a piece of paper and a pen. You
20 don't have to use them; but if you want use them, you
21 can use them.
22 Okay. So I just want to make sure we
23 understand the numbers and we're in agreement on those.
24 So when I'm looking at table 2, the N value for
25 the aprepitant regimen is 261 patients.

Am I correct so far?

A So aprepitant regimen, 261 patients. That's what it says.

Q Okay. In the table, they're giving us percentages; is that correct?

A Proportions is -- but yes --

Q Okay.

A -- percentages, proportions.

Q So I just -- I want to be able to translate those percentages or proportions into patients, because you're very patient focused. And I agree that's wonderful.

So when we're looking at 49 percent of 261 patients, that's about 127 patients; is that right?

A I can't do the math in my head. But if you want me to get a calculator out, I'm happy to --

Q Yeah.

A -- get a calculator.

Q So I've given you paper if you want to do it there. Or if -- you know, 49 percent's about 50 percent, so it's about half. So if you want to just give me your best estimate as to what you think 49 percent of 260 --

MS. RUPERT: Counsel, he's not here to do math, and he asked for a calculator. Do you have one for him?

BY MR. MILLS:
Q Do you have your phone with you?
A I do.
Q If you'd like to -- I don't mind if you use the calculator on your phone. Just don't phone a friend. And I'm not trying to trip you up here on the calculations. I just want to make sure we're all in agreement.
A So 49 percent of 261 is 127.89.
Q Okay. So can you write either 127 or 128, depending on which number you prefer, next to that "49 percent" in the exhibit?
A (Complied with request.)
Q Okay. And which number did you write?
A 128.
Q Okay. That's perfectly fine.
So the data tables are telling us that 128 of the 261 patients had no nausea overall, correct?
A In the aprepitant group, 49 patients in the overall phase reported no nausea, that is correct.
Q All right. And you said "49 patients," but you meant 49 percent --
A Forty-nine percent, yeah.
Q -- which is 128 patients, correct?
A Forty-nine percent. You're correct.

Q Okay. And when it says "no nausea overall," that means from days one to five, they never reported having any nausea; is that correct?

A So my understanding is the overall period is from 0 to 120 hours.

Q And that's what "overall" means in this table, correct?

A Yes.

Q Okay. So you would agree that, for those 127 patients, their nausea was controlled, correct?

MS. RUPERT: Objection to the form of the question.

THE WITNESS: I would say they did not report nausea in the overall phase.

BY MR. MILLS:

Q Okay. So at least as far as we could measure it, their nausea was controlled for those 128 patients, correct?

MS. RUPERT: Objection to the form of the question.

THE WITNESS: As stated, 128 patients in the overall phase did not have -- report nausea --

BY MR. MILLS:

Q Okay.

A -- or no nausea.

Q Right. And when your patients report that there's no nausea, at that point, do you conclude that their nausea has been controlled?

A Are you asking me if -- do I trust my patients when they say they don't have nausea?

Q Well, I understand you say in your declaration that sometimes they underreport.

But you can't read their minds, right. And so you have to kind of just go off of what they say.

I mean, is that fair?

A It is fair. But, yes, you know, unfortunately, as when I am in the role of the prescribing medical oncologist, patients frequently underreport nausea directly to me for fear that I will reduce the dose, stop the dose. And we've studied that as well.

But there are 128 patients in this table that report no nausea in the overall phase.

Q Right. So for those 128 patients, they're reporting that their nausea's under control; is that correct?

A They're reporting no nausea.

Q And is that different from them reporting that their nausea's under control?

MS. RUPERT: Objection to form.

THE WITNESS: There's -- yeah, we get very

nuanced in the measure of nausea. There's different parameters. No nausea is one of them.

BY MR. MILLS:

Q Now, the 53 percent for the delayed phase, can you tell me the number of patients in the aprepitant regimen that report no nausea in the delayed phase?

A 138.33.

Q Great. Can you write -- you can pick 138 or --

A Sure.

Q -- whatever whole number -- whatever integer you think is appropriate. Just tell us which one.

A 138.

Q Okay. And for those 138 patients, you'll agree that table 2 is telling us that those patients are reporting that, during the delayed phase, their nausea was controlled, correct?

MS. RUPERT: Objection to form of the question.

THE WITNESS: I am -- you know, just doing simple math, 53 percent of 261 is 138, as reported -- no nausea in the delayed phase as reported on the 2008 Emend label.

BY MR. MILLS:

Q All right. And that 53 percent is a majority of the patients in that regimen, correct?

MS. RUPERT: Objection to the form.

1 THE WITNESS: It's greater than 50, sure.
2 BY MR. MILLS:
3 Q By definition, that satisfies majority.
4 Can we agree?
5 A Well, it depends on how you define "majority."
6 Q Well, you -- perhaps a supermajority.
7 But, I guess, if I'm just asking about a simple
8 majority, you would agree with me?
9 A Yeah, I would -- I look at it, though, as a
10 clinician, very, very differently, which is -- so
11 roughly half of patients in the delayed phase reported
12 no nausea, but that means there's another half that did
13 report nausea.
14 Q Nearly. Nearly.
15 A No -- not -- yeah.
16 Q Right.
17 A So I think you're focusing on the part that are
18 doing well, but, clinically, the challenge for me are
19 the patients that are not doing well.
20 Q Right.
21 A Because they're going to require that I'm
22 calling them, that I'm educating them, that I'm bringing
23 them in for hydration, that I'm delaying their
24 treatment, that I'm admitting them to the hospital.
25 So though I appreciate your optimism in that

setting, I see it more as a glass half empty because there's still a -- almost half of patients still experiencing nausea in that setting.

Q And I appreciate your commitment to your patients.

Let me phrase it this way. For those 138 patients that are coming to you and telling you that they have -- let me start with the 128.

For those 128 patients that are coming and telling you that they have no nausea, are you prescribing additional interventions to treat nausea?

MS. RUPERT: Objection to the form of the question. Mischaracterizes testimony and document.

THE WITNESS: So one key thing to understand in this setting is that you wouldn't ever stop providing the antiemetics.

So if they're reporting no nausea in that setting, we're going to continue to provide antiemetics moving forward. And that experience can change over time.

BY MR. MILLS:

Q Right.

A Yeah.

Q So for the other people for whom they have some nausea, you might consider additional treatment; is that

fair?

MS. RUPERT: Objection to the form of the question.

A We always want -- you know, try to improve the patient experience. So if they were reporting any nausea or if they didn't and then developed nausea later on, we would want to try to improve that experience.

Q Right. So you listed several options. So one of those was olanzapine in a quadruple therapy. There were some other options.

Can you remind me what those were?

A There's many, many options, you know.

Q And don't leave that page yet because I do -- but there are many options, right. So for the people who -- they are reporting significant nausea, you know, you're going to be considering additional options.

But for the 128 patients who are reporting no nausea, for those people, you're going to continue giving them the treatment that they've been given; is that fair?

MS. RUPERT: Objection to form.

THE WITNESS: So --

MS. RUPERT: Or just -- mischaracterizes testimony, vague.

///

BY MR. MILLS:

Q Let me withdraw the question because I know we want to get to lunch. I just want to finish off the numbers here.

Okay. So underneath the 53 percent, there's a 71 percent for no significant nausea in the first five days, and then 73 percent for no significance nausea in the delayed phase.

Am I understanding those -- the meaning of those numbers first?

A You are.

Q Okay. Now, can you go ahead and give me the number of patients that corresponds to each of those and write it -- go ahead and write it into the declaration?

A So for overall, 71 percent of 261 is 185. And 73 percent of 261 is 190.

MR. MILLS: Okay. Great. Thank you.

Would you like to take a break for lunch now?

MS. RUPERT: We can keep going.

THE WITNESS: Yeah, I think we're okay.

MS. RUPERT: Yeah.

MR. MILLS: You're okay. I thought the knock was that they were wanting lunch. Okay.

MS. RUPERT: Yeah.

MR. MILLS: Great.

1 BY MR. MILLS:
2 Q In your declaration, you discuss the rate at
3 which triple therapy addressed emesis in CINV patients.
4 Do you recall that?
5 MS. RUPERT: Objection to form.
6 THE WITNESS: Can you point me into a specific
7 direction, please?
8 BY MR. MILLS:
9 Q Yeah. I'm looking for it. And while I look
10 for it, is there anything that comes to mind for you
11 about the ability of triple therapy to control emesis in
12 CINV patients?
13 MS. RUPERT: Objection. Vague.
14 THE WITNESS: There's -- I have lots of
15 thoughts around that. I think I just need you to be a
16 little more specific.
17 BY MR. MILLS:
18 Q All right. Let's look at paragraph 72 of your
19 declaration. We get to rotate it back, and we'll try
20 our best not to make anyone dizzy.
21 Do you see in the first sentence of
22 paragraph 72 you say:
23 "As of November 2009, the triple
24 therapy had largely solved the problem
25 of chemotherapy-induced vomiting

(emesis)"?

A I do see that.

Q Okay. And there, where you use the term "triple therapy," that's the same triple therapy we've been referring to throughout the deposition today, correct?

MS. RUPERT: Objection. Vague.

THE WITNESS: So, broadly speaking, triple therapy with regard to chemotherapy-induced nausea and vomiting is indicating a combination of an NK-1 receptor antagonist, 5-HT3 receptor antagonist, and a corticosteroid.

BY MR. MILLS:

Q Okay. And it's your opinion that triple therapy had largely solved the problem of chemotherapy-induced vomiting as of November 2009, correct?

A So, again, I think we have to put this in context. And you're missing kind of the larger context or oversimplifying.

But we were -- we're best at controlling the vomiting experience of patients compared to nausea at that time.

And we had improved that quite a bit with the addition of the combination. But there were still

1 patient populations, individual patients who still,
2 sadly, suffered from the issue.
3 But when you're looking at it from, like, a
4 context of the CINV history, we had done a pretty darn
5 good job by 2009 of controlling chemotherapy-induced
6 vomiting.
7 Q And you used the word "largely solved," right,
8 in your declaration?
9 A Largely solved. Again, always room for
10 improvement, but there, I'm sure, are examples where
11 that was not the case. But largely, yes.
12 Q Right. Let's take a look at paragraph 38 of
13 your declaration.
14 While you're turning there, I should ask you.
15 Your statement about largely solving
16 chemotherapy-induced vomiting by November 2009, does
17 that aspect of the state of the art -- does that differ
18 for the different patents or that's something that's
19 constant for all four -- all five cases?
20 A Help me understand the question. So --
21 Q Remember there's five cases, four different
22 patents?
23 A Yes.
24 Q But we're talking about the state of the art.
25 Is this something that differs for one of them

1 versus the other? Or this is the same answer?
2 A I can speak to -- overall, across all patents.
3 Well, actually, it's just -- it's so broad.
4 We'd have to go through each one and look at each one.
5 I'm sorry.
6 Q Okay. All right. Let's take a look at
7 paragraph 38 of your declaration. I'm looking at the
8 first full sentence, which comes after a bunch of
9 citations, where it says:
10 "While 5-HT3 receptor antagonists
11 combined with dexamethasone had achieved
12 approximately 70% control of acute
13 emesis by the early 2000s..."
14 I'm going to pause there. We'll come back to
15 the second half of the sentence in a moment.
16 Okay. So can you tell me what that first part
17 of that sentence that I just read -- first of all, did I
18 read it correctly?
19 A You did read it correctly.
20 Q Okay. So can you tell me what that means,
21 where it says that:
22 "5-HT3 receptor antagonists combined
23 with dexamethasone had achieved
24 approximately 70% control of acute
25 emesis by the early 2000s"?

1 A So, first, we're referencing Exhibit 2081.
2 Just to remind myself what that is -- it's an article
3 written by Dr. Jordan, "Chemotherapy-induced nausea and
4 vomiting: current and new standards in the antiemetic
5 prophylaxis and treatment," published in 2005.
6 So breaking this down a bit, "5-HT3 receptor
7 antagonists combined with dexamethasone."
8 So our dual therapy had achieved approximately
9 70 percent control of acute emesis. And "acute" here
10 would be a time period of less than 24 hours from the
11 initiation of cytotoxic chemotherapy.
12 Q Okay. So the "acute emesis" refers to within
13 the first 24 hours; is that correct?
14 A Correct.
15 Q What does "70% control" refer to?
16 A "70 percent control," again, it's
17 approximately, would be referring, especially when we're
18 thinking about the time, largely referring to complete
19 response, which is defined in most studies as the
20 primary aim of no vomiting and no use of rescue
21 medicines.
22 Q Where does the 70 percent come from? And --
23 A It's -- it's a citation. So it's from
24 Dr. Jordan's article, Exhibit 2081.
25 Q Right. So I guess what I'm trying to get at is

1 the 70 percent telling us that 70 percent of the
2 patients achieve that measure? Or is it telling us, you
3 know, one patient was only protected 70 percent of the
4 time?
5 MS. RUPERT: Objection to form.
6 Do you -- do you have the exhibit?
7 MR. MILLS: I don't have it right now, but
8 first, I want to just understand what he means when he's
9 pointing to it in his declaration.
10 THE WITNESS: I think it's pretty clear that
11 I'm saying approximately 70 percent had control of their
12 vomiting within the acute phase.
13 The context is critical here because we're
14 talking about vomiting versus nausea, which are two
15 different symptoms and really trying to understand how
16 good were we at that in 2009 in controlling vomiting
17 versus how good are we at it in controlling nausea.
18 BY MR. MILLS:
19 Q Right. And it -- my first question really is
20 pretty straightforward and simple. Like you said, I
21 just -- I want to make sure we're on the same page. And
22 I appreciate you being patient with me.
23 So when it says "70% control," it means that
24 70 percent of the patients satisfied the measure; is
25 that correct?

1 MS. RUPERT: Objection to form.
2 THE WITNESS: Yeah, I -- so 70 percent of
3 patients didn't have a episode of vomiting or need of
4 rescue medicines within the first 24 hours of receiving
5 chemotherapy.
6 BY MR. MILLS:
7 Q Thank you. Now, in the latter half of the
8 sentence, it talks about 40 percent of patients with
9 symptoms in the delayed phase. Do you see that?
10 A I do see that.
11 Q Okay. So I just want to make sure that I
12 understand the math correctly. So what they're telling
13 us is that in the acute phase, 70 percent are not having
14 symptoms, and in the delayed phase, 60 percent are not
15 having symptoms because 40 percent are; is that correct?
16 MS. RUPERT: Objection to form.
17 THE WITNESS: Sorry. I think you're confusing
18 me a little bit. Taking a simple sentence -- let's see.
19 So 40 percent of patients still experienced delayed
20 emesis is what it says.
21 BY MR. MILLS:
22 Q Right. And so if 40 percent of patients
23 experienced symptoms in the delayed phase, you agree
24 that 60 percent of patients did not report experiencing
25 symptoms in the delayed phase, correct?

MS. RUPERT: Objection to form. Vague.

THE WITNESS: Yeah. So it -- yeah, I mean, the -- 100 minus 40 is 60.

But I think one of the pieces that's not well captured in this particular sentence that you want me to focus on is how dangerous that is because in the acute phase, people are -- had just received their medicines. We know that they got in them. They're going home.

But in the delayed phase, you're at home by yourself, and so any percentage is really unacceptable, quite honestly.

But there are patients, then, that aren't going to be able to control those at home, who then end up calling us, coming into the clinic, going to the emergency department, et cetera.

BY MR. MILLS:

Q Okay. So I -- and I -- of course, I don't mean to minimize at all in any way the experience of the patients or your desire to help your patients, which is admirable.

I just want to make sure that I understand what you're talking about here is during the acute phase, there's 70 percent control, and during the delayed phase, there's 60 percent control.

Do I have the numbers correct?

1 MS. RUPERT: Objection to form.
2 THE WITNESS: Around a very specific -- you
3 know, looking at emesis alone.
4 BY MR. MILLS:
5 Q Okay. Thank you.
6 But it says "still experienced symptoms in the
7 delayed phase" -- right? And then it says "with delayed
8 nausea being particularly problematic" in that
9 40 percent.
10 A I'm happy to go to the original citation and
11 tell you exactly what it was.
12 But the overall gist of -- and the point that
13 I'm trying to say here is that delayed nausea remained
14 highly problematic and particularly challenging.
15 And I can tell you, as a clinician, I have lots
16 of patients that would rather just vomit and get it over
17 with than experience even low-grade nausea over multiple
18 days.
19 So it's unfair for us to compare the experience
20 of vomiting versus the experience of nausea and say that
21 one is more important than the other because, you know,
22 some people are afraid of vomiting. They'd rather have
23 pain than vomit out of control.
24 So I think overall what is -- what the point
25 here is that we're describing what is happening at that

time and that there was clear opportunity to improve beyond that.

Q Right. And thank you for that. I just want to make sure what you say in your declaration, there's 70 percent control during the acute phase, and it says that only 40 percent of patients still experience symptoms in the delayed phase, correct?

MS. RUPERT: Objection to form. Vague.

THE WITNESS: So I'm using a citation by Dr. Jordan. I didn't make up those numbers. Those came from that. And you're reading the sentence correctly.

MR. MILLS: Great. Thank you.

Are you ready for lunch or you want to keep going?

MS. RUPERT: I think --

Are you ready for lunch?

THE WITNESS: Yeah.

MS. RUPERT: Okay.

MR. MILLS: Okay. Great.

(The luncheon recess was taken from 12:43 p.m. to 1:24 p.m.)

MR. MILLS: On the record.

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EXAMINATION

(resumed)

BY MR. MILLS:

Q Welcome back. How was lunch?

A It was a dry sandwich, yeah.

Q We can try and do better some other time. There used to be a place called Mother's, but I don't know if it survived -- it's really good -- down in Portland.

A I haven't heard of it, yeah.

Q Yeah. Okay. I want to get some nomenclature down.

Do you know what Cinvatti is? C-i-n-v-a-t-t-i.

A I don't know what Cinvatti is. Cinvanti, C-i-n-v-a-n-t-i. It's not, you know, something covered in the declarations, but it's a drug for CINV.

Q Okay. What are the active ingredients in that?

A It is a formulation of aprepitant.

Q Okay. Great. I want to ask you about the materials that you reviewed in preparing your declarations.

So earlier we talked about your process of preparing for the deposition.

You remember telling me that it was about

50 hours to prepare for the deposition today? Do you remember that?

A Yeah. Roughly, yep.

Q Okay. So now I want to talk about the declaration process. And what I know so far is you said that you were approached sometime last year about these cases.

You recall that?

A I do.

Q Okay. Do you recall approximately when you began working on these cases?

A Honestly, I have to tell you that it's been a crazy year, so I really don't recall much from the last year, yeah.

Q Okay. Do you have an estimate as to how much time you spent working on the case from the time that you were hired until the time that you assigned the final declarations?

A I can't pin that down exactly. That's been going on for a while, so...

Q Do you think that it was at least as much time as you spent preparing for the deposition today?

A Given the volume and level of detail, I would suspect something similar.

Q Okay. So your best estimate is it was also

about 50 hours to prepare the declarations; is that fair?

A I --

MS. RUPERT: Objection to form.

THE WITNESS: I can't give an approximate, but enough that I felt, more importantly, not the number of hours, but just that the facts were there in the reports and that I was trying to do my best to inform the board of what was going on.

BY MR. MILLS:

Q Are you reasonably confident you spent more than ten hours preparing your declarations?

A Yes.

Q Are you reasonably confident you spent at least 50 hours?

A I'm so sorry, but I -- I didn't, like, have a timer sitting next to me or anything. And this is, of course, in between all the other things I'm doing with my work. So I'm not going to be able to give you, like, a definitive amount of time. Sorry.

Q And at some point you did bill by the hour; is that correct?

A I do bill by the hour, and I would say I should probably be better at keeping track of my time. It's just not how I am wired. So I would fail as a lawyer,

for sure.

Q And I understand not having the exact number --

A Yeah.

Q -- in mind.

But you were reasonably confident at least 10 hours, or you were reasonably confident at least 15 hours preparing for declarations?

A It was a lot of time. So, yeah, definitely more than 15 hours, fair.

Q What about 20? Was it at least 20 hours?

A It's in the ballpark of 20, something like that, more. I don't know.

Q Okay. What was your first step that you engaged in in preparing your opinions for this case?

MS. RUPERT: And, again, I'd caution you not to reveal the substance of attorney-client communications. Otherwise, you can answer.

THE WITNESS: So I remember having a phone call and talking about --

MS. RUPERT: No substance of communications.

THE WITNESS: Yeah.

-- you know, CINV. And that's an area I feel is important and relevant. I don't know what else -- what else -- kind of vague, yeah.

///

BY MR. MILLS:

Q So after you had a phone call, at some point you were retained, correct?

A Correct.

Q And then once you were retained, you began your work at some point; isn't that correct?

A Correct.

Q Okay. What's the first thing that you reviewed as part of your work?

A I reviewed many things. So I think most important was just really orienting myself to the time of November 2009, because a lot's changed since then.

So different articles. As I previously stated, you know, we looked at -- well, just lots of material. I mean, I have all the listed materials here in the back.

That's why I'm having a hard time just simply answering this question because there was a lot of stuff.

Just really trying to make sure I understood the question, the issue at hand, and what the general understanding was in November of 2009.

Q When you said you have a list here, tell us what you're referring to.

A So, I mean, I'm looking at appendix A of the

declaration. And this is a list of all the different exhibits. Yeah.

Q Do you have an understanding as to whether appendix A in your declarations are identical or whether they differ depending on the patent?

A I'm happy to compare them. I didn't review it line by line whether or not they're exactly the same, but I'm happy to do that if you want me to.

Q Feel free to take a look.

But also just, while you're doing that, tell me off the top of your head, was there anything that you thought was different about what you reviewed for one patent versus the other?

A Well, the context of each patent, obviously there's different descriptions of the claims and -- yeah.

But I see for declaration '515, we have exhibit numbers going all the way out to 2103, which is the same number, at least. For patent '357, we see the same thing going out to 2103, same author.

And for declaration '297, the same, the exhibits go out to 2103. So without going line by line for each one, I would say they're roughly the same.

Q And let me follow up on that.

You were talking about the largest numbered

exhibit, 2103.

But you would agree with me that it's not that consecutively that table lists every exhibit from 1, you know, to 2103, that there are some gaps in places; is that fair?

A There may be some differences across the different declarations. I think we can agree to that.

Q Well, and -- so my original question was about that, differences between the declarations.

And, as I understand it, you've done a look at that, and you don't see any differences between the exhibits listed for the different declarations; is that correct?

A The only way for me to answer that is to go line by line through the exhibits. If that's something you want me to do, I'm happy to do that.

Q Right. And understanding that you haven't gone line from line, but you did a -- sort of a look, a glance, there's nothing that popped out at you on that glance as being different between the four declarations; is that fair?

MS. RUPERT: Objection to form.

THE WITNESS: Yeah, we can speak to rough glances, that rough glances give you that, just an approximate, yeah.

BY MR. MILLS:

Q Okay. My other question was a little bit different, and that's that you mentioned the last exhibit number, which is 2103, and the first exhibit number's 1001?

A Mm-hmm.

Q And so this question's about in between there, it's -- you know, there are some numbers that are not consecutive with one another in a given list.

Do you agree with me on that?

A So what I hear you saying is, for example, it goes from, like, 2077 to 2088 as the next listed one?

Q Exactly.

A Yes, I can agree that there are numbered gaps between the different exhibits.

Q Okay. So my question now is whether, in performing your analysis, you reviewed any other exhibits that are not included in that list.

A As I can recall, everything I've reviewed is listed here to the best -- because this, again, was a lot of -- a lot of things, yeah.

Q Thank you. Now, one of the exhibits that's listed in your appendix A is Exhibit 1009; is that correct?

A Exhibit A, 1009, is an -- yeah, the expert

report of Dr. Peroutka.

Q And as you understand it, who is Dr. Peroutka?

A He is an expert on the other side.

Q Okay. Did you receive the complete Peroutka declaration when you were preparing your declarations?

MS. RUPERT: Objection to form.

THE WITNESS: I'm assuming it was complete. But, as I understood, it was the complete declaration, and I reviewed it.

BY MR. MILLS:

Q Did you review Dr. Peroutka's declaration, Exhibit 1009, in its entirety?

A I read through the entire document. That said, I cannot recite every single line. I cannot recall every single line. I wish I had a photographic memory, but I don't.

Q And would you agree that you had an adequate opportunity to comment on every portion of Dr. Peroutka's declaration that you chose to comment on?

MS. RUPERT: Objection to form.

THE WITNESS: It's -- I mean, it's a really general statement. It's hard for me to say that for sure.

I'm sure if I looked at it again today, I would see something or -- you know, just as you pointed out in

my own declarations, I missed a word here or there. I mean, to err is human, yes.

BY MR. MILLS:

Q But at least so far as the review that you've completed to date, after reviewing Dr. Peroutka's declaration, your declarations that you submitted contain all of the opinions that you have about his declaration; is that correct?

MS. RUPERT: Objection to form, vague.

THE WITNESS: I think it -- you know, it's, at the time, my best attempt at doing as much as I could.

Is it complete? I don't know. Can I -- I can always develop my own independent thoughts and observations as I'm going through anything, right.

So I may have additional thoughts that weren't captured in my report.

BY MR. MILLS:

Q Right now?

A Well, it depend -- again, that's a very general question. Do I have independent thoughts right now? Yes, I do have independent thoughts right now.

Q But do you have additional opinions about Dr. Peroutka's declaration that you held back that you didn't include in your declarations when you submitted them?

MS. RUPERT: Objection to form.

THE WITNESS: I would never willingly not include something. So it was just my best effort to just review his and state the facts.

BY MR. MILLS:

Q And -- and I don't want you to talk about the content of any communications with counsel.

My question is: Were you denied access to any case materials that you wanted to look at as part of providing your opinions in this case?

MS. RUPERT: And you can answer that "yes" or "no" or "I don't know" or "I don't recall."

THE WITNESS: I can't recall any time where I didn't receive something that I thought would be helpful.

BY MR. MILLS:

Q Do you know what the prosecution history is for the patents?

MS. RUPERT: Objection to form.

THE WITNESS: I know that that exists, but, again, I'm not a lawyer, and I'm not going to be able to comment on to what those all mean.

BY MR. MILLS:

Q Did you review the prosecution histories of the patents prior to signing your declaration?

1 MS. RUPERT: Objection to form.
2 THE WITNESS: So you're asking me as a
3 clinician if I reviewed the prosecution history of
4 patents. I don't remember reviewing the prosecution
5 history, but I know that it exists.
6 My -- I was more focused on reviewing the
7 patent in front of me and trying to put that within the
8 context of this case.
9 Q Okay. Do you know what OncLive is?
10 A Yes, I do know what it is.
11 Q Did I pronounce it correctly?
12 A You did, yeah.
13 Q Okay. What is -- and I think it's called
14 OncLive Peer Exchange, O-n-c-L-i-v-e, OncLive; is that
15 correct?
16 A I believe so, yep.
17 Q Okay. And what is OncLive Peer Exchange?
18 A As I recall, it was a forum for experts to
19 discuss and talk about clinically relevant topics in
20 oncology. Usually, you select a key opinion leader or
21 several to discuss, maybe, topics or educational
22 opportunities.
23 Q And you have, in fact, participated in OncLive
24 Peer Exchange in the past, correct?
25 A I have. I can't recall the exact date, but I

1 know I have.
2 Q Have you done it more than once, or was it one
3 occasion?
4 A I think it was at least twice.
5 Q Okay. Do you happen to recall anything about
6 the timing for either one of those?
7 A I'll tell you, with two kids at home and a
8 full-time job, I'm having a hard time recalling what I
9 had for breakfast yesterday, yeah.
10 Q Okay. Do you recall anything about the people
11 who were on the panel with you when you appeared at
12 OncLive?
13 A I don't remember, no.
14 Q Okay. So what I have now here is a video from
15 OncLive. So right now I'm just displaying the
16 panelists.
17 Okay. So looking at the panelists on the far
18 left side as you view it, there's a good-looking fellow
19 there in the video.
20 Can you tell us --
21 A Super handsome guy.
22 Q -- who that is?
23 MS. RUPERT: Object to the relevance of this.
24 MR. MILLS: Okay. Well, right now these are
25 foundational questions.

BY MR. MILLS:

Q Okay. So tell me again. Who is on the far left as you look at the video?

MS. RUPERT: And I also want to lodge a hearsay objection to this line of questioning.

THE WITNESS: So I'm looking at a screen. It says "OncLive Peer Exchange." On the far left is me.

BY MR. MILLS:

Q Okay. Perfect. And then in the middle of the panel, do you recognize that individual?

A In the middle is Lee Schwartzberg.

Q Okay. We talked about him earlier?

A Yes.

Q Then between you and Lee, there's another individual.

Do you recall that individual?

A I'm so sorry. I don't recall.

Q Okay. And then on the right-hand side of our screen, there's two more experts on the panel. Do you recall who either -- any of those are?

A I don't recall, no.

Q Okay. So I'm going to play some of the video. And as we do that, I think at the bottom of the screen they tell us who's talking.

And so one of the questions I'll be -- is, you

1 know: Are they identifying the people correctly as far
2 as you remember it?
3 So -- okay.
4 MS. RUPERT: Counsel, do you have a copy of
5 this for us?
6 MR. MILLS: Right now, I just have it right
7 here.
8 MS. RUPERT: Because I don't even know if this
9 is proper evidence.
10 MR. MILLS: Yeah.
11 MS. RUPERT: I've never in my life seen a video
12 shown to a witness the first time in the middle of a
13 deposition.
14 So I'm going to object to even the inclusion of
15 this evidence.
16 MR. MILLS: Okay.
17 MS. RUPERT: I don't think it's appropriate.
18 MR. MILLS: So your objection is noted. Thank
19 you. And you can have a standing objection.
20 MS. RUPERT: I'll make my objections when I see
21 fit. Thank you.
22 (Video recording played.)
23 DR. SCHWARTZBERG: ...drugs that we
24 use and how we approach highly
25 emetogenic chemotherapy, moderately

emetogenic chemotherapy. So we already mentioned there's several classes of drugs. And first cornerstone of therapy were the serotonin antagonists and a specific subtype of serotonin, 5-HT3, and we have receptor antagonists there.

(Video playback stopped.)

BY MR. MILLS:

Q Okay. So the identification of the speaker there was Lee Schwartzberg; is that correct?

A Lee was talking, yes.

MS. RUPERT: Counsel, do you have a date on this video?

MR. MILLS: So, yes, but I will -- rather than me saying it, we'll ask a question of the witness.

BY MR. MILLS:

Q Do you see on the Web page the date at the top?

MS. RUPERT: Counsel, the witness has never seen this before. This is completely inappropriate.

THE WITNESS: So I will say I very much want to answer your questions. If you want to give me time to go review the video, I'm happy to do so.

BY MR. MILLS:

Q All right. So, I mean, we're --

A And --

Q -- reviewing it. We'll review it right now.

MS. RUPERT: No. Objection.

BY MR. MILLS:

Q So --

MS. RUPERT: You don't -- I don't know if this is a whole video. I don't know if this is an edited video. This could be an AI video, for all we know.

MR. MILLS: So --

MS. RUPERT: This is not appropriate.

MR. MILLS: Okay. So, Counsel, your speaking objections are what are inappropriate. You can't keep doing that.

MS. RUPERT: I can --

MR. MILLS: You know that that's --

MS. RUPERT: -- when you're --

MR. MILLS: You know --

MS. RUPERT: -- trying to --

MR. MILLS: -- that's not allowed.

MS. RUPERT: -- manipulate my witness.

MR. MILLS: I'm not manipulating the witness. Okay.

You cannot do this. You're coaching the witness. It's inappropriate. Make your objections. When your objection -- it's a single word. That's how it works. Those are the rules.

MS. RUPERT: No.
MR. MILLS: And you can --
MS. RUPERT: How it works --
MR. MILLS: -- be sanctioned.
MS. RUPERT: -- is that you can't --
MR. MILLS: Counsel, you can be sanctioned.
MS. RUPERT: -- bring up a video that --
MR. MILLS: You can be sanctioned.
MS. RUPERT: -- no one has seen before --
(Interruption by the reporter.)
MS. RUPERT: No. How it works is you can't bring up a video that could be inauthentic, for all we know, for the first time in a deposition and show it to a witness. This is hearsay, and this is not appropriate. I've asked you for a copy. You haven't given me one.
MR. MILLS: Are you done with your objection?
MS. RUPERT: (Indicating.)
MR. MILLS: Okay. So he's testified that he appeared on the panel. I'm showing him the materials.
If he thinks that it's inauthentic or doctored, then he can testify about that. Okay. That's what we're doing. Okay.
MS. RUPERT: Again, standing objection.
///

BY MR. MILLS:
Q So my -- my next question --
MS. RUPERT: This is not appropriate.
BY MR. MILLS:
Q -- is above the video do you see a date --
A Sorry. One thing I can say is I recall the event. I cannot recall every single thing that I said. I cannot speak to whether or not this has been edited in any way.
I mean, this is a long time ago. I feel a little bit blindsided by the showing of this video.
Q Okay. Dr. Roeland, can you see the date "July 17th, 2017," above the video?
A I can see a date there. Again, I think we all know, on the Web, you can't always just trust blindly when a date is stated.
MS. RUPERT: Okay. And, just for the record, I want to make clear because we don't have a video, counsel is holding his laptop in front of the witness. We don't know what has been altered here.
Again, this is inappropriate. Could be hearsay. It might not even be authentic evidence.
MR. MILLS: Okay -- so you've registered --
MS. RUPERT: So I want the record to reflect that.

MR. MILLS: You've registered your objections. It's inappropriate for you to be making the speaking objections. Okay.

BY MR. MILLS:

Q Okay. So July 17th, 2017, we heard from Lee Schwartzberg. I'm now going to -- there's going to be a second speaker. And I want to see if --

A I think -- I think I've already stated that I don't know who the other speakers are. So you showing me the video and then -- is not -- and I'm not sure what the point is here.

Q Okay. So I'm going to go ahead and play the next portion of the video.

(Video recording played.)

DR. SCHWARTZBERG: So, Dawn, can you tell us a little bit about where we are with that and how we got there?

DR. DOLAN: Sure. So we're lucky enough to have a handful of 5-HT3 antagonist --

BY MR. MILLS:

Q So I'm just going to pause it there.

Can you see on the screen it says Dawn, D-a-w-n, last name Dolan, D-o-l-a-n? Do you see that?

A I agree that you can read off the screen

"Dawn Dolan."

Q Okay. And "Dawn Dolan" on the screen refers to the person that's sitting next to you in the video; is that correct?

A Again, it's on video that I'm sitting next to this person. Do I remember that that was Dawn Dolan or what we talked about? I don't.

Q Okay. Thank you.

(Video recording played.)

DR. DOLAN: And we now can separate them out into the first-generation, second-generation 5-HT3 antagonists.

So the first generations being the ondansetron, dolasetron, granisetron oral. And then the second generations being our newer agents, palonosetron and the subcutaneous granisetron.

So some very unique differences. You know, those early first generations typically have a shorter half-life.

Pretty good for preventing acute nausea, but not so great in the delayed phase is what we're finding and probably not adding a whole lot of value in giving those drugs in the delayed phase.

1 But our newer agents, the
2 palonosetron and subcu granisetron, you
3 know, not only do they have a much
4 longer half-life, but they definitely
5 have some distinct differences that set
6 them apart with regards to receptor
7 binding that make them, you know, more
8 potent. They definitely have higher
9 efficacy rates compared to the
10 first-generation 5H --
11 (Video playback stopped.)
12 BY MR. MILLS:
13 Q Okay. So I'm pausing it at 1 minute,
14 40 seconds.
15 Can you tell me in the video what your head is
16 doing right there as Dawn Dolan is speaking? Is it
17 correct that your head is nodding up and down?
18 MS. RUPERT: All right. Objection.
19 Again, whatever Dawn Dolan said is hearsay.
20 This is completely inappropriate. And, again, we don't
21 know that this is even authentic.
22 THE WITNESS: Oh, I was not paying attention to
23 my head.
24 BY MR. MILLS:
25 Q Okay.

A Sorry.

Q I'm going to rewind it just a little bit, and I just want you to watch your head and see if you can see your head nodding up and down in agreement as Dawn is speaking.

MS. RUPERT: Same objections.

(Video recording played.)

DR. DOLAN: -- that make them, you know, more potent. They definitely have higher efficacy rates compared to the first-generation 5-HT3 antagonists.

(Video playback stopped.)

BY MR. MILLS:

Q Okay. So did you see your head nodding up and down in agreement as she was speaking just there?

A I see my head moving. And that could have been for many, many reasons. Maybe -- what if someone off camera is saying something to me? We had some directors around telling us what to do.

So I can't speak to what my head movement was doing in supposed 2017 on a -- you know, my overall goal of participating in something like this is really to help educate my colleagues and my patients.

So this kind of line-by-line interrogation isn't, obviously, why I would have done something like

that.

Q So I can show it to you again if it would be helpful to back it up.

But you would agree with me that it looks like your head is nodding up and down in agreement as she's speaking at just that particular moment, correct?

MS. RUPERT: Objection. Asked and answered.

THE WITNESS: I'm just -- yeah, do you want to talk about degrees of head movement?

(Video recording played.)

DR. SCHWARTZBERG: What -- do you use palonosetron --

(Video recording stopped.)

THE WITNESS: What if I have a resting tremor? There's a lot of other things that could be going on here. I think there's just a lot of assumptions.

So what I'm feeling like is you're trying to drive home a point that you have but not necessarily what I would have participated in this for, which is just a discussion around CINV, educating my colleagues who largely ignore CINV, and try to get the information out to the public.

BY MR. MILLS:

Q So is it your testimony that when Dawn Dolan was speaking and your head was nodding up and down, that

that was the result of a tremor?

A I think we can agree that it's your interpretation of what I was doing at that point. I don't recall what I was doing at that point.

Q Okay. But you can see with your eyes that your head is moving up and down repeatedly as if nodding in agreement?

A I wouldn't --

MS. RUPERT: Objection. Asked and answered.

THE WITNESS: I definitely would not say it was repeatedly up and down emphatically.

(Video recording played.)

DR. DOLAN: -- 5-HT3 antagonists.

DR. SCHWARTZBERG: What -- do you use palonosetron --

DR. DOLAN: Yes.

DR. SCHWARTZBERG: -- based on that?

DR. DOLAN: Yes. We are exclusively using palonosetron right now.

DR. SCHWARTZBERG: And you give that at -- when?

DR. DOLAN: Thirty minutes prior to chemotherapy.

DR. SCHWARTZBERG: And one dose for the entire period because of the

1 receptor binding and the half-life?
2 DR. DOLAN: Usually one dose. What
3 we're --
4 (Video playback stopped.)
5 BY MR. MILLS:
6 Q Okay. So that's still Dawn speaking; is that
7 correct?
8 A Yeah. I can also just kind of go back to this,
9 when I'm thinking out loud or thinking in my head like I
10 am right now, I'm moving my head in the same way you are
11 when you're listening to me.
12 So moving your head could also be a sign that
13 you're listening to somebody.
14 Q Okay. So you would agree, as -- we backed it
15 up to watch it again.
16 You would agree that, as she's speaking, you're
17 nodding your head up and down; is that correct?
18 MS. RUPERT: Objection. Asked and answered.
19 THE WITNESS: I think what I'm really trying to
20 show that -- is that I'm listening.
21 BY MR. MILLS:
22 Q Do you recall, as you sit here today,
23 contradicting Dawn Dolan as she spoke during that panel
24 that you sat on with her back in 2017?
25 MS. RUPERT: Objection. Form.

THE WITNESS: I think I've already spoken that I don't recall this event other -- outside of just I was there.

BY MR. MILLS:

Q Okay. So you do agree that you were there, correct?

A I recall being at an OncLive event and talking about CINV, yes.

Q Okay. So now I'm at the 11:20 mark in the video. And I want to hear what Lee Schwartzberg has to say and your reaction to it.

A Hold on.

MS. RUPERT: Wait. Counsel, hold on.

(Video recording played.)

DR. SCHWARTZBERG: ...different. But I think it's interesting. We could have a healthy debate on using palonosetron in MEC -- in HEC but not MEC because, actually, the data supports, in doublet therapy, that that's where you see the advantage of palo over the first generations. And there may not be as much advantage of palo when you add the NK --

(Video playback stopped.)

MS. RUPERT: Okay. So, Counsel, you just said "11:20," which means you've skipped a good 10 minutes of this video.

And I want to object because you're showing him snippets taken out of context to a video that we don't even have authenticated.

MR. MILLS: So your objection's registered. Please don't interrupt my question.

BY MR. MILLS:

Q So my question is that -- those words that were just read on the video, you recognize Lee Schwartzberg's voice as he was making that comment there; is that correct?

MS. RUPERT: Same objection.

THE WITNESS: I think what I would really like to do is see the video in its entirety to understand the context and the specifics of what was discussed.

This kind of, like, sound bite that you're trying to get, that has me concerned because I think we're missing the entirety of what the point of this was.

BY MR. MILLS:

Q So can you confirm whether that was Lee Schwartzberg that was talking a moment ago in the portion of the video we just listened to?

A Could you play it again, please?
(Video recording played.)
DR. SCHWARTZBERG: ...setron which is a -- well, a little different. But I think it's interesting. We could have a healthy debate on using palonosetron in MEC -- in HEC but not MEC because, actually, the data supports, in doublet therapy, that that's where you see the advantage of palo over the first generations. And there may not be as much advantage of palo when you add the NK-1.
(Video playback stopped.)
MR. MILLS: Okay.
MS. RUPERT: Same objections to this video.
BY MR. MILLS:
Q So you would agree that's Lee Schwartzberg's voice that's speaking those words?
A I -- that is, on the video, Lee Schwartzberg.
Q Okay. And at the time he's speaking those words, you're present in the video with him; is that correct?
MS. RUPERT: Same objection to the video.
THE WITNESS: I am physically present in the

same room as Lee Schwartzberg while he's talking words. That is true.

BY MR. MILLS:

Q And you're within hearing of those words at that time, correct?

A Yes, I would be in hearing distance.

Q Okay. And then can you just go ahead and read the URL at the top of what we're looking at?

A OncLive.com\view\role-of-5-ht3-receptor-antagonists-in-treating-CINV.

Q Thank you. All right. So now I have a -- one more URL. If you can read that one.

MS. RUPERT: Just for the record, I'm sitting here. I'm not seeing any of this.

I don't know if you just went to a different Web page. If the URL's different, I assume you did. What are you showing the witness right now because I can't see it?

MR. MILLS: So, Counsel, here's the URL.

MS. RUPERT: Is this the same Web page? Why did the URL change? I'm asking you.

MR. MILLS: So I'll read this URL. It's OncLive.com/view/5-ht3-nk1-receptor. -- sorry --
-antagonists-combinations-for-CINV.

MS. RUPERT: So now you're looking at a

different Web page that we haven't seen before.
BY MR. MILLS:
Q Can you read the URL, please?
MS. RUPERT: Is that correct? Counsel, just -- so you're not going to tell me if you've switched up the Web pages that I can't see?
BY MR. MILLS:
Q There's a question pending to the witness so that the witness can tell you what the URL is.
MS. RUPERT: This is completely inappropriate and manipulative, and we can move for sanctions too.
MR. MILLS: You need to stop making speaking objections. You can lodge your objections, and then the witness can answer the questions as to the URL.
MS. RUPERT: And you need to stop presenting evidence this way because it's inappropriate.
MR. MILLS: It's not inappropriate.
BY MR. MILLS:
Q Can you please go ahead and read the URL?
A So you're asking me to read the URL of a Web page?
Q Yes.
A Okay. Onc, o-n-c, live, l-i-v-e, .com\view\5-5h -- no, sorry -- 5-ht3-nk1-receptor-antagonist-combinations-for, f-o-r, -cinv.

Q Thank you. And you would agree that -- well, let me withdraw that question and start over.

So on this Web page it also says "July 17th, 2017," correct?

MS. RUPERT: Objection. Hearsay.

THE WITNESS: I agree that on this Web page, it says "Videos July 17th, 2017."

BY MR. MILLS:

Q Thank you. Okay. So I'm going to play the video so that you can see who's speaking now, and I'm going to ask you to watch for the identification of the speaker.

MS. RUPERT: And, Counsel, are you starting at the beginning of the video?

(Video recording playing.)

DR. LEVINE: Prior to availability of the combination, we were using oral aprepitant.

DR. SCHWARTZBERG: Oh, you were?

DR. LEVINE: And we're using the TriPEX and explaining to the patient how "You won't get sick by taking it," magically, they take their drugs. We have very, very little patient, you know, failure on that end. They would

take the medication and do well.

When we looked at the new NK-1 -- again, we were a naloxi [ph] practice for 12 years, at least, since I've been there. We looked at inefficacy among the NK-1 -- the new NK-1 drugs. They're all the same, pretty much. I didn't see much of a difference. You could tease out differences depending on how you do any study. But the reality is they all worked.

So efficacy, in our eyes, was never an issue among the choices. Safety also, similar safety profiles, little differences here and there, but --

(Video playback stopped.)

MS. RUPERT: Okay. Since counsel refused to answer my question, I want the record to reflect that he did not start the video at the beginning.

MR. MILLS: So that was beginning at 1 minute and 6 seconds and continuing on until 2 minutes and 5 seconds.

BY MR. MILLS:

Q Okay. So do you recognize the speaker?

A I don't.

Q Okay. There we go.

Can you see the identification in the still image of the speaker is Howard Levine, PharmD?

A Yeah, you are reading from the screen "Howard Levine, PharmD."

Q Okay. And it's identifying him as the speaker at that moment, correct?

MS. RUPERT: Objection. Hearsay.

THE WITNESS: I believe so, yes.

MR. MILLS: Okay. Thank you. Okay.

So, Counsel, you asked when we're playing from. So now I'm beginning at 4:22 in the video.

MS. RUPERT: So we've skipped 2 minutes?

BY MR. MILLS:

Q All right. And at this point the speaker is identified as the lady who is next to Dr. Levine, and she's identified as Beth Eaby-Sandy; is that correct?

A The screen reads "Beth Eaby," E-a-b-y, "-Sandy," S-a-n-d-y, "CRNP-OCN."

Q And at this point there's two people in the -- in the image; is that correct?

A There are two people in -- on your screen, yes.

Q Okay. And one of them is -- was identified as Mark Levine [sic]?

MS. RUPERT: Objection. Hearsay.

1 THE WITNESS: Say it again.
2 BY MR. MILLS:
3 Q And one of them was a male who was identified
4 as Dr. Levine; is that correct?
5 MS. RUPERT: Objection. Hearsay.
6 THE WITNESS: Yeah, the last -- whoever I read
7 off last is sitting on the left.
8 BY MR. MILLS:
9 Q And now it's referring to a woman named Beth
10 Eaby-Sandy, correct?
11 A It does say that.
12 Q Okay. Thank you. This is starting at 4:22.
13 (Video recording played.)
14 MS. EABY-SANDY: And they said her
15 plan requires a step approach. So I
16 called the plan, and I said they wanted
17 her to fail aprepitant or fosaprepitant
18 and ondansetron before approving. I
19 said, "Can we go to the NCCN guideline
20 website together and see that either
21 option is approved? It is not a
22 stepwise approach."
23 And they did not budge on it. They
24 said, "This is our" -- "the way we're
25 doing this as a managed care

organization." They said, "This is our stepwise approach. So this person must fail ondansetron and either aprepitant or fosaprepitant before we would approve either rolapitant or the netupitant palonosetron."

DR. SCHWARTZBERG: So, to be clear, that doesn't make medical sense, and it's --

MS. EABY-SANDY: I asked --

DR. SCHWARTZBERG: -- it's really just --

MS. EABY-SANDY: We went --

DR. SCHWARTZBERG: -- an arbitrary decision.

MS. EABY-SANDY: -- together to the NCCN guideline website --

DR. SCHWARTZBERG: Right.

MS. EABY-SANDY: -- and pulled it up. And I said, you know, "These are options. There's not a one fail this is better than at all. These are options that you have that work equally." So --

(Video playback stopped.)

MR. MILLS: Okay.

MS. RUPERT: And -- okay. Objection. Hearsay.

1 There is no testimony going into the record
2 that is being spoken by someone years ago who is not in
3 this room, and I want to make that very clear for the
4 record.
5 BY MR. MILLS:
6 Q Okay. So there's two people speaking there on
7 the panel in your presence.
8 There was a female that was Beth Eaby-Sandy,
9 and then there's Dr. Schwartz responding to her --
10 Schwartzberg responding to her; is that correct?
11 A I don't recall who responded. But
12 Dr. Schwartzberg is sitting in the center, and then the
13 other two people are sitting to his side.
14 Q Okay. And I'm just -- I'm going to rewind it a
15 little bit to 5 so that you can satisfy yourself that
16 it's Dr. Schwartzberg that's responding to
17 Beth Eaby-Sandy. Okay. So this is starting at 5
18 minutes.
19 (Video recording played.)
20 DR. SCHWARTZBERG: -- sense and
21 it's --
22 MS. EABY-SANDY: I --
23 DR. SCHWARTZBERG: -- and it's
24 really just an arbitrary --
25 MS. EABY-SANDY: We went together --

(Video playback stopped.)
BY MR. MILLS:
Q Okay. So --
MS. RUPERT: Objection. Hearsay.
BY MR. MILLS:
Q -- the man speaking is Dr. Schwartzberg; is that correct?
MS. RUPERT: Objection to the form of the question.
THE WITNESS: There's two people speaking. And Dr. Schwartzberg is trying to speak to her, and she's speaking back.
BY MR. MILLS:
Q Okay. Thank you. Okay. And that all occurred in your presence during the OncLive Peer Exchange, correct?
MS. RUPERT: Objection to form.
THE WITNESS: I was physically present, as you've pointed out.
BY MR. MILLS:
Q Okay. So now this is --
(Video recording played.)
DR. ROELAND: It's interesting that we have --
(Video recording stopped.)

BY MR. MILLS:
Q Okay. So this is starting at 5:35 in the video. And now there's two people in the frame again.
One of those people is you, correct?
A Yes. I'm on the left side.
Q Okay. And then the other person is Dawn Dolan, who was speaking earlier in the video we listened to, correct?
A As I was reminded today. I didn't remember Dawn.
Q Okay. And in this video that we're about to watch, you -- I accidentally clicked "play" a little bit -- you heard your voice, correct? So you're speaking at this point of the video, correct?
A I did hear my voice.
Q Okay.
(Video recording played.)
DR. ROELAND: -- such an IV focus, based on reimbursement, when we know the efficacy is equal.
(Video playback stopped.)
BY MR. MILLS:
Q Okay. So those words that came out just now, those are words that you used in this video, correct?
MS. RUPERT: Objection to the form of the

1 question. Also, it seems like this was just a snippet.
2 This is, again, inappropriate. And he's asked to watch
3 the whole video.
4 I would ask that you let him watch the whole
5 video before you ask him questions.
6 THE WITNESS: So the challenge with all of this
7 is that I really want to do a good job and answer your
8 questions, but all I'm really doing is answering sound
9 bites.
10 So I'm not getting the full context of what's
11 being discussed. And I really can't speak to the
12 nuances of all of this.
13 So one thing that needs to be very clear,
14 especially for the board, is that we have broad
15 categories of antiemetics.
16 And within those, we, as clinicians, can choose
17 one over another based on its pharmacokinetic and
18 dynamic properties, especially when we're thinking about
19 specific clinical situations that a patient is
20 experiencing.
21 BY MR. MILLS:
22 Q So my question is specifically very limited.
23 I just want to know if the person speaking in
24 this portion of the video, if that's you who's speaking
25 and your voice. I'll play it one more time so that you

can answer that question.

A I think -- I believe I --

(Video recording played.)

DR. ROELAND: ...focused based on reimbursement when we know the efficacy is equal.

(Video playback stopped.)

MR. MILLS: Okay.

MS. RUPERT: You were going to say something and he cut you off with the video. You can finish your answer.

BY MR. MILLS:

Q Can we answer the question? That's you speaking, correct?

A Can you please play it again?

(Video recording played.)

DR. ROELAND: ...interesting that we have been such an IV-focused based on reimbursement when we know the efficacy is equal.

(Video playback stopped.)

MS. RUPERT: Same objections.

BY MR. MILLS:

Q Okay. That's you speaking, correct?

A That is me speaking.

MR. MILLS: Okay. Thank you. No further questions.

MS. RUPERT: You're done?

MR. MILLS: Yes.

MS. RUPERT: With the deposition?

MR. MILLS: Yes. We're off the record.

(Recess taken from 2:06 p.m.
to 2:55 p.m.)

MS. RUPERT: Back on the record.

We have no further questions for this witness at this time.

Sir, you're free to go.

MR. MILLS: Can I ask one housekeeping thing? Are you okay if we mark the page that he wrote on?

MS. RUPERT: The page that he wrote in --

MR. MILLS: It's of his declaration. There was one page he wrote on. I just want to mark that one page.

MS. RUPERT: Oh, where you asked him to write?

MR. MILLS: Yep. Is that okay?

MS. RUPERT: I think that's fine. Yeah, that's fine.

MR. MILLS: So we'll go on the record. We're marking that page as 1066. And we're off the record.

///

(Exhibit 1066 was marked for identification by the reporter.)

THE STENOGRAPHER: Can I get orders for the transcript?

Do you want regular two-week delivery, Mr. Mills?

MR. MILLS: We should check with my people. I think it may be close to that, but we may want to expedite a little bit.

THE STENOGRAPHER: And do you need a rough draft?

MR. MILLS: Yes, we'll take a rough.

THE STENOGRAPHER: And for you, Ms. Rupert?

MS. RUPERT: I'll let this -- this guy --

MR. BANSAL: We don't need a copy.

- - -

(The deposition concluded at 2:56 p.m.)

WITNESS CERTIFICATION

DEPONENT: ERIC ROELAND, M.D.
CASE: AZURITY PHARMACEUTICALS, INC. vs. HELSINN HEALTHCARE S.A.
DEPOSITION DATE: MAY 11, 2026

I, ERIC ROELAND, M.D., having appeared for my deposition on May 11, 2026, hereby certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

IN WITNESS WHEREOF, I have hereunto subscribed my name this _____ day of _____ 201___, at _____, _____.
(city) (state)

_____
ERIC ROELAND, M.D.

1 DEPONENT'S CHANGES OR CORRECTIONS

2 Note: If you are adding to your testimony, print the exact words you want to add. If you are deleting from
3 your testimony, print the exact words you want to delete. Specify with "Add" or "Delete" and sign this
4 form.

5

6 DEPONENT: ERIC ROELAND, M.D.

7 CASE: AZURITY PHARMACEUTICALS, INC. vs.

8 HELSINN HEALTHCARE S.A.

9 DEPOSITION DATE: MAY 11, 2026

10 PAGE LINE CHANGE/ADD/DELETE

11 ____ ____ _____

12 ____ ____ _____

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19 ____ ____ _____

20 ____ ____ _____

21 ____ ____ _____

22 ____ ____ _____

23 ____ ____ _____

24 ____ ____ _____

25 Deponent's Signature _____ Date_____

CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

CASE: AZURITY PHARMACEUTICALS, INC. vs. HELSINN HEALTHCARE S.A.

DEPOSITION DATE: MAY 11, 2026

JOB NUMBER: J14724125

I, Marla Sharp, certified stenographic reporter licensed in California, Oregon, and Washington, hereby certify that the foregoing deposition of ERIC ROELAND, M.D., was taken remotely before me on May 11, 2026; that the witness was remotely duly sworn by me; that all of the testimony, colloquy, and objections made were recorded stenographically by me and thereafter transcribed, said transcript being a true copy of my shorthand notes thereof; that review of the transcript was neither requested nor waived before completion of the deposition; ( ) that the witness has failed or refused to approve the transcript; and that I am neither financially interested in the action nor a relative or employee of any attorney of any party.

In witness whereof, I have subscribed my name and signature this date, May 20, 2026.

_____
Marla Sharp, RPR, CLR, CCRR
CA CSR 11924, OR CSR 17-0446, WA CSR 3408