UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE ANDREW J. GUILFORD, JUDGE PRESIDING

HSINGCHING HSU,	)	
	)	
Plaintiff,	)	
Vs.	)	**No. SACV15-0865-AG**
PUMA BIOTECHNOLOGY, ET AL,	)	
Defendants.	)	

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL, DAY 2

SANTA ANA, CALIFORNIA

WEDNESDAY, JANUARY 16, 2019

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A P P E A R A N C E S

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EXHIBITS:

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SANTA ANA, CALIFORNIA; WEDNESDAY, JANUARY 16, 2019; 8:05 A.M.

THE CLERK: All rise.

(Open court - jury present)

THE COURT: All right. Welcome back, everyone. Thank you for being here fairly promptly on this rainy day. We have a lot of people ready to go. I'm going to begin by reading those brief introductory jury instructions.

I just wanted to say the court is in a bit of disarray, and I actually need to talk to Lisa, Miriam, and Melissa about pay. We may be coming to a point -- Lisa, we need to talk on folks not getting paid and mortgages not getting met. And I'm doing my best to make sure it doesn't affect this trial.

So we do have that bit of uncertainty. It's just interesting. You're in a federal facility right now, and everyone is wondering where we're going, where the paycheck may or may not be.

All right. With that, I'm prepared to begin with the preliminary instructions here, and here we go.

Members of the jury, you are now the jury in this case. It is my duty to instruct you on the law. It is your duty to find the facts from all the evidence in this case. To those facts you will apply the law as I give it to you.

You must follow the law as I give it to you whether

you agree with it or not, and you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means you must decide the case solely on the evidence before you. You will recall that you took an oath yesterday to do exactly that.

At the end of the trial, I will give you final instructions. It is the final instructions that will govern your duties. Please do not read into these instructions or anything I may say or do that I have an opinion regarding the evidence or what your verdict should be.

Let me say these instructions as well as the instructions that I give at the end of the case will be given to you when you deliberate. You may take notes on these instructions, but you'll have them when you deliberate. So keep that in mind.

The party that brings a lawsuit is called the plaintiff. In this case the lead plaintiff is a pension fund that invested in Puma common stock. Plaintiff Norfolk Pension Fund brings this lawsuit as a class representative, which means it is bringing the lawsuit for itself and on behalf of all investors who bought shares of Puma common stock during the period July 22, 2014, and May 29, 2015, which will be referred to as the class period.

Unless I distinguish them, I will refer to Norfolk Pension Fund and the class collectively as plaintiffs.

The parties against whom this suit is brought are called defendants. In this action the defendants are Puma Biotechnology, Inc., and Alan Auerbach, each of whom will be referred to as defendants throughout the trial.

When a party has the burden of proving any claim by a preponderance of the evidence, it means you must be persuaded by the evidence that the claim is more probably true than not true. You should base your decision on all of the evidence regardless of which party presented it.

The evidence you are to consider in deciding what the facts are consists of: one, the sworn testimony of any witness; two, the exhibits that are admitted into evidence; three, any facts to which the lawyers have agreed; and four, any facts that I may instruct you to accept as proved.

In reaching your verdict, you may consider only the testimony and exhibits received into evidence. Certain things are not evidence and you may not consider them in deciding what the facts are.

I will list them for you:

One, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they may say in their opening statements, closing arguments, and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of

them controls.

Two, questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by the Court's ruling on it.

Three, testimony that is excluded or stricken or that you are instructed to disregard is not evidence and must not be considered.

In addition, some evidence may be received only for a limited purpose. When I instruct you to consider certain evidence only for a limited purpose, you must do so and you may not consider that evidence for any other purpose.

Anything you may see or hear when the court was not in session is not evidence. You are to decide the case solely on evidence received at the trial.

Some evidence may be admitted only for a limited purpose. When I instruct you that an item of evidence has been admitted only for a limited purpose, you must consider it only for that limited purpose and not for any other purpose.

Evidence may be direct or circumstantial. Direct evidence is direct proof of a fact such as testimony by a witness about what that witness personally saw or heard or did.

Circumstantial evidence is proof of one or more facts from which you could find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how much weight to give to any evidence.

There are rules of evidence that control what can be received into evidence. When a lawyer asks a question or offers an exhibit into evidence and a lawyer on the other side thinks that it is not permitted by the rules of evidence, that lawyer may object.

If I overrule the objection, the question may be answered or the exhibit received. If I sustain the objection, the question cannot be answered and the exhibit cannot be received.

Whenever I sustain an objection to a question, you must ignore the question and must not guess what the answer might have been.

Sometimes I may order that the evidence be stricken from the record and that you disregard or ignore that evidence. That means when you are deciding the case, you must not consider the stricken evidence for any purpose.

Let me stop for a moment and say something about receiving exhibits into evidence. We have identified quite a few exhibits. Sometimes I see jurors taking notes, which you

are allowed to do. The moment I receive an exhibit into evidence, it means you will have it with you when you deliberate.

So when someone moves Exhibit 28 and there's no objection and Exhibit 28 is in evidence, take all the notes you want, but you'll also have it back there with you. Sometimes I see jurors vigorously taking notes maybe not realizing they will have that document when they deliberate.

Also, I'll say to you and counsel, when I strike evidence, sometimes I just might grant the motion to strike without an extensive discussion with the jury about what that means. If you think I need to remind them of the instruction I just read or be more specific about what is stricken and what isn't stricken, it's up to you to speak up and tell me.

Sometimes it's obvious what I'm striking, so I may not give further detail on that. My statement to the attorneys is if they think more is needed, let me know and I certainly will provide it.

All right. Credibility of witnesses. In deciding the facts in this case, you have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says or part of it or none of it.

In considering the testimony of any witness, you may take into account: one, the opportunity and ability of the witness to see or hear or know the things testified to;

two, the witness's memory; three, the witness's manner while testifying; four, the witness's interest in the outcome of the case, if any; five, the witness's bias or prejudice, if any; six, whether other evidence contradicted the witness's testimony; seven, the reasonableness of the witness's testimony in light of all the other evidence; and eight, any other factors that bear on believability.

Sometimes a witness may say something that is not consistent with something else he or she said. Sometimes different witnesses will give different versions of what happened. People often forget things or make mistakes in what they remember. Also, two people may see the same event but remember it differently.

You may consider these differences, but do not decide that the testimony is untrue just because it differs from other testimony. However, if you decide that a witness has deliberately testified untruthfully about something important, you may choose not to believe anything that witness said.

On the other hand, if you think the witness testified untruthfully about some things but told the truth about others, you may accept the part you think is true and ignore the rest.

The weight of the evidence as to a fact does not depend on the number of witnesses who testify. What is

important is how believable the witnesses were and how much weight you think their testimony deserves.

I will now say a few words about your conduct as jurors. This is similar to the instruction I read yesterday, so if it sounds similar, it's because it is. First, keep an open mind throughout the trial and do not decide what the verdict should be until you and your fellow jurors have completed your deliberations at the end of the case.

Second, because you must decide this case based only on the evidence received in the case and on my instructions as to the law that applies, you must not be exposed to any other information about the case or to the issues it involves during the course of your jury duty.

Thus, until the end of the case or unless I tell you otherwise, do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it.

This includes discussing the case in person, in writing, by phone or electronic means, via e-mail, text messaging, or any internet chat room, blog, website, or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media.

This applies to communicating with your fellow jurors until I give you the case for deliberation at the end.

It applies to communicating with everyone else including your family members, your employer, the media or press, and the people involved in the trial, although you may notify your family and your employer that you have been seated as a juror in the case and how long you expect it to last.

If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and report the contact to the Court.

Because you will receive all the evidence and legal arguments you properly may consider to return a verdict, do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it, although I have no information that there will be news reports about this case.

Do not do any research such as consulting dictionaries, searching the internet, or using other reference materials, and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in the case, and do not use internet programs or other devices to search for or view any place discussed during the trial.

Also, do not do any research about the case, the law, or the people involved, including the parties, the witnesses, or the lawyers, until you have been excused as

jurors.

If you happen to read or hear something touching on the case in the media, turn away and report it to me as soon as possible. These rules protect each party's right to have their case decided only on evidence that has been presented here in court.

Witnesses here in court take an oath to tell the truth. The accuracy of their testimony is tested through the trial process. If you do any research or investigation outside the courtroom or gain information through improper communications, then your verdict may be influenced by inaccurate, incomplete, or misleading information that has not been tested by the trial process.

Each of the parties is entitled to a fair trial by an impartial jury. If you decide the case based on information not presented in the case, you will have denied the parties a fair trial.

Remember, you have taken an oath to follow the rules, and it is very important that you follow these rules. A juror who violates these restrictions jeopardizes the fairness of the proceedings and a mistrial could result that would require the entire process to start over.

If any juror is exposed to any outside information, please notify the Court immediately. I urge you to pay close attention to the trial testimony as it is given.

During deliberations you will not have a transcript of the trial. If you wish, you may take notes to help you remember the evidence. If you do take notes, please keep them to yourself until you go to the jury room to decide the case. Do not let note-taking interfere or distract you.

When you leave, your notes should be left in the jury room. No one will read your notes. Whether or not you take notes, you should rely on your own memory of the evidence. Notes are only to assist your memory. You should not be overly influenced by your notes or those of other jurors.

From time to time during the trial, it may be necessary for me to talk to the attorneys out of the hearing of the jury either by having a conference right outside this door when the jury remains present in the courtroom or by calling a recess. Please understand that while you are waiting, we are working.

The purpose of these conferences is not to keep relevant information from you but to decide how certain evidence is to be treated under the rules of evidence and to avoid confusion and error. Of course, we will do what we can to keep the number and length of these conferences to a minimum.

I may not always grant an attorney's request for a conference. Do not consider my granting or denying a request

for a conference as any indication of my opinion of the case or what your verdict should be.

Trials proceed in the following way. First, each side may make an opening statement, which we did yesterday. An opening statement is not evidence. It is simply an outline to help you understand what that party expects the evidence will show. A party is not required to make an opening statement.

Plaintiffs will then present evidence, and counsel for the defendants may cross-examine. Then the defendants may present evidence, and counsel for the plaintiffs may cross-examine.

After the evidence has been presented, I will instruct you on the law that applies to the case and the attorneys will make closing argument. After that, you will go to the jury room to deliberate your verdict.

All right. That concludes the preliminary instruction, and we are ready to begin with evidence.

The plaintiff will call their first witness.

MR. FORGE: Thank you, Your Honor. The plaintiffs call Dr. Kerin Adelson.

Your Honor, with your permission may I approach with the witness binders?

THE COURT: Yes, you may. Thank you.

Kerin Adelson, Plaintiffs' witness, sworn

THE CLERK: If you will please state and spell your first and last name.

THE WITNESS: My first name is Kerin, K-e-r-i-n. My last name is Adelson, A-d-e-l-s-o-n.

DIRECT EXAMINATION

BY MR. FORGE:

Q. Good morning, Dr. Adelson.

A. Good morning.

Q. Dr. Adelson, where do you live?

A. I live in New Haven, Connecticut.

Q. Can you please explain to the jury what it is you do for a living?

A. Yes. I'm a medical oncologist at the Yale University School of Medicine and the Yale Cancer Center. I am a breast cancer oncologist, so I treat exclusively breast cancer, which I have been doing ever since I completed my fellowship training.

Then I also work as the chief quality officer for the Cancer Center and the cancer hospital.

Q. Let's break that down. In terms of being the chief quality officer, what does that mean in terms of your weekly responsibilities?

A. Yeah. It means I have oversight for the quality of patient care all across the cancer hospital, so for patient safety, for patient experience, for making sure that we are

meeting and exceeding all national guidelines, and for continuously improving the quality of care that we deliver to our patients.

Q. Do you still treat real patients?

A. Absolutely. Yeah.

Q. Approximately how many patients a week do you see?

A. Probably about 15, maybe a little bit more.

Q. Do you also teach in connection with your treatment of the patients?

A. Yes. So when I see patients in my breast cancer practice, I work with oncology fellows. These are already doctors but who are developing a specialization of hematology and oncology.

They work with me in my practice and see patients along with me and learn how to give the very best evidence-based treatments to our breast cancer patients.

And then when I attend on the inpatient service, which I do about six weeks a year, I care for all solid-tumor patients at that time. And I work with residents who are also physicians but earlier in their training, and they are, you know, learning how to provide really internal medicine care.

Q. Now, when you see your patients, are these, generally speaking, one-off encounters, or is it an ongoing relationship?

A. No. The reason I actually decided to go in to specialize in breast cancer is because you have very deep experiences with patients while they're going through their treatment and then can actually follow them for many, many years to come because many patients are cured of their disease.

Q. And how does your typical doctor/patient relationship begin?

A. So often a patient comes to me -- there's different routes, but often their breast cancer is diagnosed by mammography or screening. And from the screening, if they see a suspicious mass and do a biopsy which in fact shows breast cancer, the patient's primary care doctor or gynecologist will refer the patient to a breast surgeon.

When they refer the patient to the breast surgeon and into our breast center, they will usually see myself and the breast surgeon on the same day. Sometimes I'll see the patient shortly after the breast surgeon sees the patient.

Q. Do you also occasionally work on clinical trials?

A. I work intensively on clinical trials. I am currently the director of our breast cancer research program and the director of breast cancer medical oncology. So I oversee all of the clinical trials that we have open to our patients.

In the last year we actually were able to put an extra 59 percent -- we've doubled our clinical trial

enrollment -- by a really careful look to make sure we were opening trials that fit the needs of our patients.

Q. Approximately how many clinical trials have you worked on?

A. Honestly, it's probably more than I can count because trials open and close. When they hit their accrual, they close. Probably in my years in practice it's, you know, 50 to 100, maybe more. Yeah.

Q. Could you please give the jurors an overview of what a typical clinical trial entails?

A. There's different kinds of clinical trials, and they're described based on the phase of treatment as a trial leads to FDA drug approval. So phase I or early-stage trials I don't usually work on. Those are testing the safety of a new drug, but they don't really look at the efficacy of the drug.

Phase II trials are trials that explore the idea that a drug may increase the outcomes or may improve outcomes for patients. So I've actually lead a national multi-centered phase II trial looking at a combination of drugs in breast cancer.

And then phase III trials are for when the drug is closer to approval and they give it to a very, very large number of patients with the goal of showing that patients either have a higher cure rate or that, if they have metastatic disease, which is incurable, that they can go

longer without their cancer growing.

Q. In the phase III trials, do they typically measure -- you used the terms efficacy and safety. Do they typically measure both?

A. Yes.

Q. And could you please explain to the jurors in lay terms what efficacy and safety mean?

A. So to prove a drug is better than the standard of care, you need to have one group of patients who receive the very best standard of care that has been proven until that day. Then you need to give the group of patients that is matched, so very similar patients, similar risk breast cancer, similar biology, you need to give the standard of care treatment plus something new.

If the drug is effective and they're able to demonstrate efficacy of the drug, that the patients in the group getting something new do better than the patients in the other group, that's called a positive clinical trial.

And sometimes -- so it can be hard to explain to a patient why they receive a placebo. What I always say to patients is that if every time we had the suspicion that a drug might work and we gave it to you without a randomized placebo-controlled trial, you would be carrying around a suitcase full of drugs to take every day that ultimately were proven not to work.

Q. How about the safety side of the equation?
A. Uh-huh. So safety has to do with acutely what side effects patients have. So, you know, in the oncology world a lot of our drugs have a lot of side effects and toxicity, things like nausea, vomiting, mouth sores, hair loss -- everything you've heard about chemotherapy but other side effects, too.

So patients can get damage to their heart, and then there are serious long-term side effects that often are not seen in the first phase of a clinical trial because they occur years later. That can be things like secondary malignancies or secondary cancers that are due to the treatments that the patients got.

And again, damage to the heart and, you know, other long-term problems.

Q. Why is it important to test both the efficacy and safety of --
A. Because, you know, everything in medicine is a weight between risk and benefit. Certainly for very, very large benefits, patients might be willing to tolerate more side effects or more toxicity with the goal of a very substantial increase in their chance of living for a longer time or being cured of their disease.

But when the benefit is smaller for different treatments and the likelihood that they're going to do well

even without the treatments, they're going to not be as willing to experience serious toxicities, because in that case the risk can outweigh the benefit.

Q. Throughout your career have you engaged in research activities?

A. Yes.

Q. Can you provide us just an overview of those?

A. Yeah. So, you know, I participate in standard clinical trials, which again are cooperative group studies that are literally open all over the world often looking at whether new drugs will help patients.

But I also am really interested in improving what we call patient-centered care. So I currently have a research project that's looking at how to develop a shared decision-making tool for patients with early-stage breast cancer. It's based on the idea that oncologists have been trained really to only think about efficacy.

So even when a treatment for an individual patient might only have a one-percent difference, a tiny difference in efficacy but a really big difference in toxicity or what we call treatment burden, the number of times they have to come to the infusion center and get a babysitter and pay for parking and spend, you know, their own money on treatment and increase the risk of bankruptcy and all of these things, we don't do a good job describing that to patients. And they're

often surprised and upset as they go through treatment and see the effect it really has on their life.

So I just finished what we call a qualitative study, which was really a study where we interviewed patients and their caregivers about what they wished they had known when they went into their treatments, and going forward what we could do to better address those needs.

Then we're going to take that information and put it together to actually build an electronic tool that both the doctors and the patients would use and that the patient could actually log in from home and see the likelihood that different treatments would benefit them and how much they would actually benefit them and then what it would mean for them to get the treatment. What are the side effects?

I always say, you know, numbness and tingling means something different for the marathon runner than it does for the violinist, right? For the violinist it could ruin their whole career.

So patients really need to understand that not all toxicities are the same and make a personalized interpretation of what they're willing to go through.

Q. How long have you been at Yale?

A. Four and a half, four and three-quarters years, something like that.

Q. I don't want to go through in painful detail, but let's

back up and give us an overview of your education. Where did you go for your undergraduate degree?

A. University of California at Santa Cruz.

Q. What was your major there?

A. American literature.

Q. And from Santa Cruz what was the next stage in your --

A. So I worked as a journalist in documentary film for about three years and did some investigative journalism. And then I actually decided that I no longer wanted to be calling people who weren't interested in talking and trying to push them to go on the record.

I wanted people to come with me, come to me with a problem that they needed help with, and I decided that being a doctor would allow that kind of relationship. So then I went back to Columbia University and I did all the pre-med classes that I hadn't done as an undergrad.

Q. Where did you go after Columbia?

A. Then I went to Yale for medical school.

Q. How long was that?

A. Four years.

Q. And what did that entail? Both classroom and practical?

A. Yes. So, you know, you do -- actually they've changed it lately. Back when I did it, we did two years of basic science in the classroom and then another two years rotating through most of the different medical specialties before we

actually chose a specialty.

Q. What was the next step in your career after medical school?

A. So then I did internship and residency in internal medicine at the Mt. Sinai School of Medicine in New York. That was three years.

Q. What after Mt. Sinai?

A. And then I went and I did a fellowship in hematology. I actually did a year of research in both breast cancer and leukemia. Then I went to Columbia University School of Medicine for a fellowship in hematology oncology, which was another three years.

Q. After what point in your career did you start focusing on breast cancer?

A. So that in that year of research I did before I started my fellowship, I became very committed to treating women with breast cancer and studying breast cancer. So actually even when I started my fellowship, I really had a focus in breast cancer.

And while most fellows just did half a year or a year of the breast cancer clinic that we had, I continued that clinic for all three years. I actually did a lot of extra.

Q. So after your fellowship ended, what was the next stage for you?

A. So then I went back to Mt. Sinai School of Medicine as an academic breast cancer oncologist.
Q. How long did you practice there?
A. About seven and a half years.
Q. Could you give us a sense of how many patients you saw --
A. Yeah.
Q. -- on an everyday basis?
A. So I was very busy. I saw probably 23 breast cancer patients a day, three and a half days a week. And then the remainder of my time was spent sometimes just following up on issues that patients were having but also doing administrative work with quality and the electronic health record.
Q. You mentioned earlier that these are ongoing relationships. Could you describe to us a little bit more the nature of the relationship in terms of is it purely clinical and scientific?
A. It's both. It's all of the above. And, you know, it's really a privilege to take care of women with breast cancer. They're incredibly motivated to do everything they can to make sure that their disease doesn't come back.

So when I first meet a patient, I have to explain to them a little bit about the scientific literature and the likelihood of benefit that they're going to get from any

different treatment and the likelihood of toxicity. And I have to be able to do that in language that they understand.

It is the most painful, traumatic period often in a woman's life because they're really facing their mortality. Many of them have young children or small children. I've had patients who care for, you know, disabled children or husbands who, you know, they're terrified will not be able to really get by without them if they were to die.

So we develop a really special bond during that period. Often actually I have patients who do make it through and who probably don't need to continue seeing me past five or ten years, and they keep coming.

I still have patients actually who travel to New Haven from New York because I think the bond is so intense and I think they're just afraid to let go of the follow-up. It gives them security and the feeling that they're doing okay.

Q. To what extent do quality-of-life issues play in the treatment plans that you have for your patients?

A. So I will say across the board for all oncologists, not enough. We really have not done a good job paying attention to what we actually put our patients through.

So I really try to do everything I can to let my patients understand what they're signing up for and that if there's one treatment that's a lot harder than another, that

they really understand what the absolute difference in benefit the harder treatment will be, because sometimes it's not -- the difference in efficacy is not enough to justify how much more we put them through.

MR. FORGE: Your Honor, may I approach to put a demonstrative board on the easel?

THE COURT: Yes.

MR. FORGE: Can everyone see that?

THE WITNESS: Am I supposed to get up?

BY MR. FORGE:

Q. If you can reach without standing up --

A. I don't think so, not too well.

Q. Dr. Adelson, I'm going to ask you to kind of walk us through -- first of all, let me just ask you: The phrase standard of care, what does that phrase mean to you?

A. So standard of care is the sort of universally accepted treatment that a patient with a specific disease scenario should receive.

For the most part, whether you're getting treatment in California or New York, the standard of care in first world countries is generally about the same with some regional variation based on which academic centers have developed which treatments in which regions, but basically the same idea.

Q. Okay. And just to orient you for timing wise, the frame

of reference for all the questions I'm going to ask you about standard of care and other issues should be the frame of reference from July 2014 to June of 2015. So when I'm asking you about standard of care, please keep that time frame in mind. Okay?

A. Yes.

Q. Now, in the upper left-hand corner of that board, it refers to HER-2 positive breast cancer.

A. Uh-huh.

Q. What is HER-2 positive breast cancer?

A. So HER-2 is a growth factor that is expressed on about 20 percent of breast cancer cells. Back before I did my training, patients with HER-2 positive breast cancers had a much worse prognosis. The cancer cells grew rapidly. They metastasized early, and it was a very bad kind of breast cancer to have.

But in about 2004 the drug Herceptin -- the generic name of that is trastuzumab -- was approved in the curative setting for patients with HER-2 positive breast cancer. Literally to this day Herceptin is the single best drug ever approved in breast cancer.

So when you add Herceptin to chemotherapy, it reduces the risk of recurrence by 50 percent, so a huge benefit added on top of chemotherapy. And in and of itself, Herceptin actually has very, very little toxicity.

So when I think about drugs, that's a home run. Right? It's a drug that dramatically improves benefit without improving -- without worsening suffering.

Q. Dr. Adelson, before we proceed with the rest of the board, let me just ask you: How did you get involved in this case?

A. So there is a company that I think connects lawyers to doctors called the expert institute. Somehow they found me, and that's how you found me.

Q. Do you testify strictly for plaintiffs?

A. No.

Q. When is the last time you testified in court?

A. I actually have only testified once before, and it was about a month ago, and it was a defense case.

Q. Approximately how many times have you served as an expert in a case?

A. Probably about 20.

Q. In terms of your compensation, how long have you been working on this case?

A. I -- it feels like about two years.

Q. And approximately how much money have you been paid throughout those two years?

A. So I've been paid a lot of money. This case has been many, many hours of work that we've logged in. So I believe it's $55,000.

Q. Do you -- are you paid on an hourly basis?
A. Yes.
Q. And how much is the hourly rate?
A. So when I first started working on this case, my hourly rate was $600. Now it's $700.
Q. How about for testifying in court such as today?
A. When I first started on this case, it was 6,000, and I have -- it has gone up to 8,000.
Q. Now, is your compensation tied in any way, shape, or form to the outcome of this case?
A. No.
Q. Is it tied in any way to specific opinions you must give?
A. No.
Q. Is it influenced in any way by the -- is your -- are your opinions influenced in any way by your compensation?
A. No.
Q. Now, Dr. Adelson, you've told us what HER-2 positive breast cancer is. Could you please explain, keeping that time frame in mind, what the standard of care for HER-2 positive breast cancer was in that 2014-2015 time frame?
A. Yeah. So the standard of care was for patients to receive chemotherapy along with Herceptin for a few months, followed by Herceptin alone until a year. When that chemotherapy was given, it could either be before surgery to

shrink the cancer, which is called neoadjuvant treatment, or it could be given after surgery, after the cancer was removed, which is called adjuvant treatment.

What the studies have shown is patients' outcomes are equal whether you give the chemotherapy before or after surgery.

Q. So referring to our board there, we have the neoadjuvant category. We have the adjuvant category. And you mentioned surgery. Explain to the jurors what that stage of treatment involves.

A. Uh-huh. So there's different kinds of surgery that you can do for breast cancer. If the tumor is small enough that you can just remove the area of the tumor and a little more, that's called a partial mastectomy or a lumpectomy.

Patients who undergo that also generally undergo something called a sentinel lymph node dissection where they remove the nodes that drain the breast and see whether or not the cancer cells have spread to those lymph nodes.

Then for women who have a lumpectomy, they must get breast radiation, which at this time was generally -- it could either have been seven weeks of treatment, and then there was a new regimen that was a shorter period that was just coming into play in 2015.

Women who require a mastectomy, so they have to remove the whole breast, often undergo reconstruction, and

that process can be relatively intense. So there's different ways to do breast reconstruction. You can use the patient's own tissue and actually remove some of the fat from the abdomen and move it up and they actually -- it's pretty amazing. They recreate a breast out of tissue from the abdomen.

For women who are too thin or who are getting treated at an institution that doesn't have the plastic surgery expertise to do the flaps, they end up getting something called a tissue expander.

The tissue expander is like an implant, but it slowly stretches the skin. And they go back multiple times to see their plastic surgeon to stretch the skin. Then ultimately they require a second surgery to put in the permanent implant.

Q. Could you walk us through, Dr. Adelson, the side effects of these different phases of treatment?

A. So when a patient is going through any chemotherapy, so, say, neoadjuvant chemotherapy, all of the regimens for HER-2 positive breast cancer will make them lose their hair. Nausea and vomiting is very common, although we have good drugs to try to prevent that that are often successful.

They can get bony pain and pain in their joints from medicine that we give them to boost their white blood cells. They can develop very low white blood cell counts,

which puts them at risk for infection and at times can land a patient in the hospital.

They can get diarrhea. They can get constipation. They can get neuropathy or numbness and tingling in their hands and feet which can be permanent if the treatment isn't stopped when a patient is developing that. The list is quite extensive. You know, I could go on.

Q. And then for surgery -- and when you're explaining the side effects, if you could, as you just mentioned, perhaps explain the side effect and the quality-of-life impact from the side effect.

A. Uh-huh. So patients going through chemo have a variable impact on their quality of life. So some are unable to work and some are able to work. They tend to experience a lot of fatigue. Then they spend a lot of time coming and going to the hospital.

So, you know, we really demand a lot from them in terms of spending time coming to the cancer center, parking, paying for parking. You know, again, walking from the garage into the cancer center when they may not be feeling fully up to their norm.

So it -- I don't want to call it a lost three months because people -- or four months -- because patients are sometimes able to do their usual activities, but many can't.

Q. What about in the surgery phase? What is the impact physically and on quality of life?

A. Yeah. So particularly for patients who get a mastectomy, they have drains that they go home with for a couple weeks that are draining extra fluid from the breast. They can have pain in the area of the surgery. Sometimes that pain can sort of go down the arm and into the armpit where the lymph nodes were removed.

They can numbness and tingling because -- different numbness and tingling because the nerves get cut. When they have tissue expanders, they feel almost like a band is around their chest and tightening because they're literally pulling the tissue out.

Q. And then the adjuvant stage, again back in the 2014-2015 time frame?

A. So if the chemotherapy is given adjuvantly, it's all the same side effects that I just talked about in the neoadjuvant setting, but then in the adjuvant setting, when they're done -- in a -- whether a patient got the chemo before surgery or after surgery, when the chemo is over, they often need additional treatments.

So about two-thirds of breast cancers are estrogen receptor positive, so those patients need estrogen-blocking therapy. Young women will often end up in menopause from the chemotherapy alone. And if not from the chemotherapy, from

medicine we give them to shut down their ovaries, which is very important to block the effects of estrogen on the cancer cells, which is like food for the cancer cells.

For a woman, a premature menopause is loaded with other symptoms like decrease in sex drive, decrease in libido, vaginal dryness, weight gain, anxiety, sleep disturbance. And so, you know, that can contribute to really a lot of the trauma that a patient goes through, and that continues to last. And that will start in the adjuvant period.

For patients who are HER-2 positive, they continue receiving their Herceptin after the chemo stops until they've had an entire year of Herceptin. And they may be getting radiation during that same time period. So you will get women who are on Herceptin getting radiation and taking hormone-blocking therapy all together. That, you know, again can really change somebody's sense of well-being.

Q. How long does the hormone modification treatment last?

A. Yeah. That's a moving target. In 2015 it lasted five years. It lasts longer today.

Q. What are the expenses associated with these different phases?

A. Uh-huh. So as we've really had a crisis in healthcare in this country, patients are responsible for more and more of the percentage -- more and more percentage of their own

care.

I'm sure that anybody here has experienced that, that when they go to fill a prescription, it seems much more expensive than it may have felt 15 or 20 years ago. That's because the insurance pays less and patients have higher out-of-pocket.

For drugs that tend to be administered in the hospital, after patients meet their deductible, there's usually less individual patient responsibility, although it varies by insurance plans.

For prescription drugs, patients tend to be responsible for about 20 percent of the cost of the prescription drugs. And as our drugs have literally increased at an exponential rate, some many, many new approved drugs are 10,000, even 15,000 a month.

So patients will actually be responsible for over $2,000 a month, which is, as you know, more than many people earn.

Q. What kind of impact have you seen those types of expenses have on patients?

A. So the most important thing is actually to ask the patient, because most oncologists don't and just don't think about it. Not -- they're not vindictive. It just has not occurred to them.

There's become increasing awareness that patients

who are paying for more and more of their own care, cancer patients, are more than twice as likely to go through bankruptcy as a general person in the population. They're not -- they're much more likely to not be able to pay their rent or their mortgage payment, to have to skimp on food and groceries, to spend through their inheritance they were hoping to leave for their children, and to spend savings.

I actually had a patient recently, she had to sell her house because she could not afford the tax payments because she was spending all of her money, and this is a patient who had Medicare, government insurance. She was spending all of her money on co-pays for her prescriptions.

Q. Are you familiar with the phrase financial toxicity?

A. Yes.

Q. Is that a phrase that you use on a regular basis?

A. Yes.

Q. Does that phrase refer to those types of burdens that you just described?

A. Yes.

Q. Now, you mentioned earlier, you gave a percentage or a fraction. You said that the estrogen-receptor positive patient population is about two-thirds?

A. Yes.

Q. How about HER-2 positive? I apologize if I didn't ask you before, but what percentage of breast cancer patients are

HER-2 positive?

A. About 20 percent.

Q. Are you familiar with the ExteNET study on HER-2 positive patients?

A. Yes.

Q. Before we get into the ExteNET study, if you could please take us through a bit of a technical lesson on the terms that are on that board. The first one is DFS or disease-free survival rate.

A. So I'd like to say to the jury, please do not be intimidated by these terms. The concepts behind them are relatively simple. And if I do a good job communicating, you should be able to understand all of it. But they're statistical terms that we use in oncology.

THE COURT: Excuse me.

I think she needs to be responding to questions, not providing comments. Go ahead.

MR. FORGE: Okay, Your Honor.

THE WITNESS: Okay. I hear you.

So disease-free survival is the percent of patients who are treated in a study who remain free of cancer. The disease-free survival in a study doesn't just include the number of patients who develop metastatic disease, which is incurable. It also includes the percentage of patients who develop new cancers.

So as a benefit, it's not as powerful as overall survival, which is the number of patients who actually do not die of their cancer. But because overall survival takes so long to see in clinical trials, clinical trialists have picked this disease-free survival end point as a surrogate for overall survival.

BY MR. FORGE:

Q. So in terms of HER-2 positive patients and the ExteNET study specifically, is there a distinction between a local recurrence of cancer and a distant recurrence?

A. Yes. So metastases-free survival is the percentage of patients who do not develop an incurable metastatic recurrence. So it's important to point out that breast cancer that's confined to the breast and the lymph nodes is curable. But if microscopic cells travel either through the lymphatic channels or through the blood vessels to another organ and actually take seed and grow in that other organ, that becomes incurable breast cancer or stage IV metastatic breast cancer.

So when we think about patients, the most important thing as a clinician is that they don't develop metastases. It's a metastases-free survival. We worry a little bit less about local recurrences or new breast cancers because those patients are followed so closely that those we can potentially catch and cure. So...

Q. Next term on there is absolute benefit. Could you explain what that represents?

A. Yes. So absolute benefit is the absolute number of patients in a specific risk category who will benefit from the treatment being studied. We can also talk about absolute benefit for the individual patient.

So if we say that a treatment reduces the risk of recurrence by 50 percent, that sounds great. But that 50 percent has to be applied to the patient's risk to begin with. So if the patient has a 90 percent risk of recurrence based on how aggressive their disease is and the number of lymph nodes involved, and I reduce that 90 percent by half, the patient gets a 45 percent benefit, right? It's half of 90. That's a huge benefit.

But if the patient is likely to do well anyway, either because their disease is lower risk or because they're going to receive excellent treatments -- say a patient has a five percent risk of recurrence, I can still reduce that by 50 percent. But the absolute benefit for that patient is only two and a half percent.

So absolute benefit is the thing that's actually most important for each individual patient.

Q. The next term is HR or hazard ratio. Could you please explain what that means?

A. So hazard ratio is a comparison of how patients do or

how many patients do not have a recurrence or die of their disease in a group that received an intervention compared to the group that received the standard of care.

So if the hazard ratio is 80 percent, that means that the group that got a new treatment have 80 percent of the risk compared to the standard-of-care population. So that 80 percent risk represents a 20 percent reduction in risk.

Q. Okay. And those categories, those terms are all under how good a drug is in terms of the side effects beneath how bad is it. The first one is AEs or adverse events.

A. So adverse events in a clinical trial setting are a graded form of side effects. So we have standard definitions for what the different grades of nausea or vomiting or diarrhea or neuropathy are. And that's very important because when you're comparing different treatments, you want to be speaking essentially the same language when you're comparing the toxicities.

Q. I apologize, Dr. Adelson. I think I skipped the last one in the how good is it, the Kaplan-Meier curves. Are you familiar with what those are?

A. Yes. So Kaplan-Meier curves are really a representation of the hazard ratio, and it shows -- essentially it's a graph that shows the entire population of patients over time. And every time a patient has a recurrence or dies, depending on

what the outcome of the study is, you'll see that the Kaplan-Meier curve starts to drop off.

And when we compare different treatments, what we want to see is that the group that got the new treatment drop off less and, you know, more patients go without having that bad end point than in the group that got the standard of care.

Q. Okay. Now, shifting back to the side effects, the one listed on there is grade-three diarrhea. Can you explain what that is?

A. So grade-three diarrhea is about seven bowel movements a day. It can, you know, have cramping. It can lead to electrolyte disturbances where the salts in the blood get messed up because it's all coming out of the body in diarrhea. They can have dehydration. Some can actually end up hospitalized.

Q. Are there medicines, antidiarrheal medications?

A. Yes.

Q. Do those medications to treat side effects have side effects of their own?

A. Yes. So all medications have side effects. As one might expect, the side effects of the antidiarrheal are the opposite of diarrhea. So essentially the side effects are constipation, bloating, abdominal pain, some nausea which potentially comes from decreased motility in the GI tract.

Q. In terms of quality of life, have your patients expressed concerns about both diarrhea and constipation?
A. Yes.
Q. And in terms of impact on their lives, is there a big disparity between the two?
A. No. I think actually sometimes constipation can be even more distressing. Patients will get admitted to the hospital. They can get admitted with either, but with constipation they actually can have almost a blockage in the bowel where, you know, they can't eat and they're vomiting, you know, a lot of bloating, real abdominal pain and discomfort. That's the extreme. You know, otherwise it can just be comfortable.
Q. Is constipation one of the side effects of Imodium?
A. Yes.
Q. Is the scientific name for that loperamide?
A. Yes.
Q. Now let's talk about the ExteNET results. Are you familiar with the ExteNET results as presented at the ASCO conference in 2015?
A. Yes.
Q. Let's take a look at the abstracts first.
MR. FORGE: Your Honor, I would move into evidence -- I don't believe there's any objection to Exhibit 503.
THE COURT: Just a moment.

THE WITNESS: I don't think I have 503, but I'm sure I'd remember.

MR. FORGE: I apologize. It might be 798. We have different versions.

THE WITNESS: I have 798.

MR. FORGE. Okay.

THE COURT: All right. Hold on.

THE WITNESS: There's nothing under that.

THE COURT: Just a moment.

What exhibit are you moving in?

MR. FORGE: 798, Your Honor.

THE COURT: Any objection?

THE WITNESS: Is that the abstract?

MR. FORGE: Yes.

THE WITNESS: Okay.

MS. JOHNSON: This is the wrong version. There's a -- there's no objection to the abstract, but we have an objection to the e-mail that's at the top.

THE COURT: All right. You object?

MS. JOHNSON: Yes, Your Honor.

THE COURT: Response?

MR. FORGE: Your Honor, there's no question regarding the authenticity of this document. The terms -- the numbers set forth within it are all --

THE COURT: All right. Let me ask this: Should I

be looking in the witness book or in one of the 16 other books?

MR. FORGE: The witness book is probably the quickest way to access it, Your Honor.

THE COURT: Let's focus here. That answers question. I'll look in the witness book.

All right. The objection is foundation; is that correct?

MS. JOHNSON: It's 803 as well. This is an e-mail among bankers that are not present here in the trial, as well as foundation. Again, the abstract --

THE COURT: All right. For now the objection is sustained. Lay a foundation if the defense wants a foundation.

MR. FORGE: Your Honor, we can use the same figures from Exhibit 503.

THE COURT: Do you move Exhibit 503?

MR. FORGE: Yes, Your Honor.

THE COURT: Any objection?

MS. JOHNSON: No, Your Honor.

THE COURT: Okay. 503 is admitted.

(Exhibit 503 received.)

MR. FORGE: If we can put 503 on the screen. That way Dr. Adelson will be able to see the numbers and we can focus in on them.

BY MR. FORGE:

Q. Before we get into 503, the last term on that board, Dr. Adelson, is the dropouts into AEs. What does that represent?

A. That represents the percentage of patients in each group, so the group getting the standard of care and the group getting the new treatment, who stop taking the study drug because of side effects or who stop actually participating in the study because of side effects.

Q. Okay. So now if you could focus on the screen -- and the jurors can see screens at both ends of the jury box. We'll go to the second page of Exhibit 503.

Focusing on that table, what actual absolute benefit did the abstract reveal for the IDFS population?

A. 2.3 percent.

Q. And that's determined -- that's the difference between what two figures?

A. The difference between the disease-free survival in the patients who received the standard of care versus the disease-free survival in patients who received neratinib.

Q. What is the corresponding hazard ratio for that population?

A. 67 percent.

Q. Is that the only population with that 67 percent hazard ratio?

A. The only population in this abstract, yes.
Q. Yes. If you look up above that table, we can focus in really the first line of that second page.
A. I don't --
Q. Okay. We're going to focus in on the first line of the second page. And what did that abstract reveal in terms of the grade-three diarrhea rate?
A. 40 percent of patients had grade-three diarrhea.
Q. Okay. Now, if you could, please, turn to Exhibit 176 in your binder.

MR. FORGE: Your Honor, I would move Exhibit 176 --

THE COURT: Any objection to 176?

MS. JOHNSON: No objection.

THE COURT: 176 is admitted.

Proceed.

(Exhibit 176 received.)

BY MR. FORGE:
Q. Dr. Adelson, when -- after an abstract for a conference such as ASCO, is there a presentation of the results?
A. Yes. So the -- you know, some presentations get actually oral presentations where the -- the doctor or the investigator who led the study gets up in front of a large audience and goes through slides. Some studies just get posters.
Q. Now, if you could, please, turn to page 17 of

Exhibit 176.

A. I'm trying to find it. Okay.

Q. And we're going to focus in on the diarrhea section all the way through the fifth bullet point.

A. Okay.

Q. So if we can zoom in on that. In the ASCO presentation, what did it reveal in terms of the discontinuation rate due to diarrhea?

A. It was nearly 17 percent, 16.8.

Q. And you see beneath there it says grade-three diarrhea can be reduced to 0 to 17 percent with intensive loperamide prophylaxis. Do you see that?

A. Yes.

Q. Is that the same thing as the Imodium we were discussing earlier?

A. Yes.

Q. With the constipation side effect?

A. Yes.

Q. Now, are there typically Q&A sessions after presentations at a conference?

A. Yes.

MR. FORGE: Your Honor, at this time I would move into evidence Exhibit 639, which is a transcript, and Exhibit 741, which is the audio of the ExteNET presentation.

THE COURT: Any objection?

MS. JOHNSON: No, Your Honor.

THE COURT: 639 and 741 are admitted.

(Exhibits 639 and 741 received.)

MR. FORGE: If we could turn, please, to page 6 of Exhibit 639. And if we have the audio cued up for the part beginning with Dr. Vogl, so it would be going from lines 14 through 25. Could you please play that.

(Audiotape recording played)

BY MR. FORGE:

Q. Dr. Adelson, I saw you smile a bit when Dr. Vogl was speaking. Do you know who Dr. Vogl is?

A. Yeah. So Dr. Vogl is an oncologist from New York who attends all breast cancer conferences. He has actually sort of become famous for his brilliant questions. Now, at the San Antonio breast conference, which is the biggest conference, they actually have an expression where when somebody presents and he asks a question, they'll say: Congratulations. You've been Vogl'd.

Q. Now, this particular question that Dr. Vogl asks was how many people are still taking -- how many people actually finished a year of the stuff. Dr. Chan responded, 61 percent.

How -- what percent does that leave that did not complete a full year of treatment of neratinib?

A. 39 percent.

Q. Now if you could, please, turn to Exhibit 124. You're going to look at the last page of the exhibit.

MR. FORGE: And, Your Honor, I would move Exhibit 124 into evidence.

THE COURT: Any objection?

MS. JOHNSON: No, Your Honor.

THE COURT: 124 is admitted.

(Exhibit 124 received.)

MR. FORGE: It's a lengthy exhibit, and the last page has tables on it. So page 266.

BY MR. FORGE:

Q. Just let me know when you've gotten there, Dr. Adelson.

A. Okay. Yes.

Q. And if you look, I think it's, five lines down, the adverse events leading to discontinuation. What does Exhibit 124 reveal as to the percentage of patients for whom the adverse events led to a discontinuation?

A. 27.6.

MR. FORGE: Your Honor, may I approach with another demonstrative?

THE COURT: Yes.

MR. FORGE: Actually, before we get to that demonstrative, if we can go back to Exhibit 176, please.

BY MR. FORGE:

Q. If you could turn to page 10. In the meantime I'm going

to try to straighten out that exhibit.

Does that page of the ASCO presentation depict the Kaplan-Meier curves from the ExteNET study?

A. Yes.

Q. If we could, please, focus in on the -- first of all, do those curves last beyond two years?

A. No.

MR. FORGE: If we could focus in on the end of those curves.

BY MR. FORGE:

Q. Do the curves appear to be separating at the end of two years?

A. No.

Q. Now, Dr. Adelson, if you could --

MR. FORGE: And just for the record, this is plaintiffs' demonstrative number two. The first board we had on there was plaintiffs' demonstrative number one.

BY MR. FORGE:

Q. If you could focus on the board to your left, Dr. Adelson, in the left column we're going to -- are figures that the jury is going to be hearing about in the case, and in the right column are the figures that we've just gone over that were revealed at ASCO.

If all you knew about a drug was the absolute benefit that it delivered, everything else equal, and you

were choosing between drug A which had an absolute benefit of four to five percent, and drug B which had an absolute benefit of 2.3 percent, which would you choose?

A. Drug A, of course.

Q. If all you knew -- if all you knew about a drug were its Kaplan-Meier curves, its KM curves, and drug A had Kaplan-Meier curves that were separating at two years and continuing to separate through years three and four, whereas drug B Kaplan-Meier curves were not separating at two years where they end, which drug would you choose?

A. Drug A, because that would imply that the drug was going to offer more benefit over time as patients were followed for longer.

Q. And the third row is the grade-three diarrhea rate. If drug A had a 29 to 30 percent grade-three diarrhea rate and drug B had a 39.9 percent diarrhea rate, all else being equal, which drug would you choose?

A. Drug A, because it has a lower rate of diarrhea.

Q. And the fourth row, for the dropouts due to adverse events, for drug A, five to ten percent; for drug B, 27.6 percent overall, 16.8 percent due to diarrhea alone, which drug would be the drug of choice?

A. Drug A.

Q. Are any of these close calls?

A. No.

Q. And then how about -- I asked you each of these individually. How about if the two drugs had those collective results? So drug A had all of those results in its column versus drug B with all the results in its column, is the choice even more disparate?

A. Yes. So drug A has a better risk-benefit ratio than drug B.

Q. Now --

A. I should say benefit-risk ratio with benefit in the numerator.

Q. As revealed to ASCO in that right column and based on your practice in that June 2015 time frame, if neratinib had been available in June 2015, approximately what percentage of your breast cancer patients would it have been appropriate to consider prescribing neratinib?

A. So based on the analysis that was published, when you look at the groups that actually benefited from neratinib, it was a small benefit, but it was pronounced much more in patients who were lymph-node positive and estrogen-receptor positive.

So if I do the math and I say about 25 percent of breast cancers are lymph-node positive, 20 percent are HER-2 positive, and about 66 percent are also ER positive, that comes out to be three percent of breast cancer patients, or I think .33 exactly.

Q. 3.4 percent?
A. 3.3. Yeah, 3.3 percent.
MR. FORGE: Thank you, Dr. Adelson. I have nothing further.
THE WITNESS: Thank you.
THE COURT: Cross-examination.
MS. JOHNSON: Take a moment to get the cross binders up to the witness.
THE COURT: So we have two binders for this witness?
MR. CLUBOK: No, Your Honor.
MS. JOHNSON: We have one. They had one.
THE COURT: That means we have two binders for this witness?
MS. JOHNSON: Yes, Your Honor.
THE COURT: All right, folks.
MS. JOHNSON: May I approach, Your Honor?
THE COURT: Yes.
May I ask, in the plaintiffs' binder, how many of the exhibits did we actually use out of how many? What percentage since we're under percentages?
MR. FORGE: Your Honor, I can count those up.
THE COURT: I'm just saying, we are getting a lot of binders. I'm concerned about the efficiency of how multiple binders and multiple exhibits can lead to confusion.

I'd just suggest that, boy, in the binders we should be closing in on my 80 percent rule, and I don't even think we're doing that on the binders. So it's kind of strange.

Proceed.

MR. FORGE: Thank you, Your Honor.

MS. JOHNSON: Thank you, Your Honor.

CROSS-EXAMINATION

BY MS. JOHNSON:

Q. Good morning, Dr. Adelson.

A. Good morning.

Q. You are here as a breast cancer oncologist, right?

A. Correct.

Q. You're not a statistician?

A. No.

Q. And you're not an expert in regulatory approval of drugs?

A. No.

Q. And you've never advised the FDA on whether to approve a drug?

A. No.

Q. You've never worked for the FDA yourself?

A. No.

Q. You've never advised pharmaceutical companies on the process for getting FDA approval for a drug?

A. No.
Q. You're not an expert on securities disclosures?
A. No.
Q. And you're certainly not an expert on securities disclosures made on conference calls to investors?
A. No.
Q. And looking at the chart, which I would be happy to put back up if you still have the demonstrative.
MS. JOHNSON: Can I use your own demonstrative?
MR. FORGE: Sure.
BY MS. JOHNSON:
Q. I'll put it back up.
A. Okay.
Q. Looking at your chart there, is it correct to say you haven't engaged in any methodology to determine whether in this case the CEO of Puma said anything during the conference call that -- whether it meets the standard for disclosures to investors, right?
A. I don't -- no. I don't even know the criteria for that. But I have read his transcript and have read the claims that they made about efficacy of the drug.
Q. Right. But you haven't engaged in any methodology to compare those to what he was obligated to disclose under the securities laws, right?
A. I don't know the securities laws.

Q. You testified that you're being paid here for your testimony. You were contacted by the plaintiffs' lawyers a couple of years ago to start work on this case?
A. Yes.
Q. And you are -- you were being paid an hourly rate for your work to review materials, right?
A. Yes.
Q. $700 an hour, I think you said?
A. It was 600 for the majority of the time I worked on it.
Q. And then it increased to 700?
A. Yes.
Q. And you're being paid here today a daily rate for your testimony that is now $8,000 a day?
A. Yes.
Q. Do you get paid for that work separately from your work as a practicing breast cancer oncologist?
A. Yes.
Q. And as a doctor, with that hat on, it's not your practice to read press releases from pharmaceutical companies, right?
A. Actually, the -- you can't avoid the press releases. They come through Medscape and everything into my e-mail. So I do hear press releases about new drugs.
Q. But in this case it's certainly the case that you did not read Puma's press release at the time it came out in July

of 2014, right?
A. I don't recall reading it.
Q. Instead, you read the press release in this case with your testifying expert hat on, correct?
A. Correct.
Q. And you didn't dial in to the conference call on July 22nd --
A. No.
Q. -- as part of your regular work?
A. No.
Q. You read the transcript and listened to the audio as part of your testifying work?
A. I didn't -- I read the transcript. I did not listen to the audio.
Q. Okay. You read the transcript. Where did you first learn about neratinib as a practicing oncologist?
MR. FORGE: Your Honor, I'm going to object. Motion in limine number four.
MS. JOHNSON: Where she learned about the drug is not --
THE COURT: You know, the problem with all the motions in limine, as I stated, sometimes they become relevant in another context.
I'm going to overrule the objection and simply tell the witness to briefly answer that question, as briefly as

possible.

THE WITNESS: I first heard about neratinib at the San Antonio breast conference about six months after the initial ASCO presentation.

BY MS. JOHNSON:

Q. Okay. You didn't learn about neratinib from reading a press release. But instead as a practicing oncologist, you learned about it from a major medical meeting?

A. Correct.

Q. And that meeting was the San Antonio breast cancer symposium about six months after the ASCO conference where neratinib was first presented?

A. Correct.

Q. In preparation for your testimony here today, you prepared two expert reports; is that right?

A. Yes.

Q. And you were required to list the authorities and materials that you read and relied on in preparing those expert reports, right?

A. Right.

Q. And those materials included the June 1st ASCO presentation -- we saw it a moment ago -- that was presented on neratinib at ASCO, right?

A. Right. Yes.

Q. And those materials did not include -- you can tell me

if this is your memory, but those materials did not include the investor presentation made by Mr. Auerbach also on June 1st after the ASCO panel presentation; is that right?

A. So I believe I read the press release of a phone call that he had, but I don't think there was an actual presentation that I read.

Q. Okay. So you haven't seen or reviewed the actual materials that he presented later in the day on June 1st to investors; is that right?

A. I believe that's right.

Q. And you never reviewed the ASCO data with your doctor hat on, but instead you've now reviewed it as a testifying expert, right?

A. I always have my doctor hat on.

Q. Do you recall being deposed in this case?

A. Yes.

Q. And you were asked questions and you gave your answers, and they were transcribed?

A. Yes.

Q. And you took an oath to tell the truth on that deposition the same as you've taken it here today?

A. Yes.

Q. Would you turn in your binder to -- there's a tab marked deposition.

A. Yes.

Q. Would you turn to page 63 and focus on lines 23 to 25, going on to the next page, page 64, line 1. Do you see that?
A. Sorry. So I'm looking at page 61 -- where am I looking again?
Q. There are four pages on a page.
A. Yep.
Q. And 63 is the upper right-hand box.
A. Okay. Yep.
Q. Line 23?
A. Uh-huh.
Q. Down to page 64, which is right under it, line 1. Do you see that?
A. Yes.

MS. JOHNSON: Your Honor, may I play the clip?

THE COURT: Any objection?

MR. FORGE: No, Your Honor.

THE COURT: You may.

MS. JOHNSON: Thank you.

Clip 14.

(Portion of videotape recording played)

BY MS. JOHNSON:
Q. Were you asked that question and you gave that answer?
A. I suppose I did.
Q. Thank you. Would you agree that there's been tremendous success in treating breast cancer to date?

A. Yes.
Q. And over 80 percent of patients are cured based on the standard of care that existed before neratinib came on the scene, right?
A. Yes.
Q. Wouldn't you agree that because there's been such success, there's a relatively small amount of patients left to treat that aren't already treated by the existing standard of care before neratinib?
A. I think what you mean is that there is a relatively smaller number of patients left to help because most patients are going to do well without additional treatment. Yes, that's true.
Q. Right.

But in a perfect world in the field of breast cancer oncology, the goal should be to reduce cancer recurrence to as close to zero as possible; wouldn't you agree?
A. Again, it's a risk-balance ratio, so of course we want to cure as many people as we can. But we also need to minimize the toxicities people have. And the issue of overtreatment is acutely profound in the field right now and being talked about all the time.
Q. Yeah. And you testified earlier that patients should be educated about the different treatments and side effects so

that they can make an educated decision?
A. Absolutely.
Q. But if there's a company working to develop a treatment that will give patients the option of what to talk about, that would be a good thing; wouldn't you agree?
A. Yes.
Q. So neratinib was being studied in order to treat that relatively small group of patients that don't respond well to the existing standard of care, right?
A. Yes.
Q. All right. Let's talk about the ExteNET trial. You in your report -- what you testified earlier is that you want to be precise with patients about what the absolute benefit is so that they can make an informed decision, right?
A. Correct.
Q. In your report -- and you can turn to it if you like. It's the tab called report, expert report -- at page 20 --
A. Yes.
Q. -- there in the middle you give an illustration, and you say: Assume a hundred of my patients take neratinib. Slightly more than two them might benefit in terms of living longer before the cancer recurs than without treatment.
Do you see that?
A. Yes.
Q. But slightly more than two of them might benefit is not

correct, right?
A. Slightly more than two will benefit. We corrected that.
Q. When you were deposed --
A. Yes.
Q. -- you talked about correcting that?
A. Yes.
Q. So it's precise -- it's -- the right way to say it is that every patient who takes neratinib has a potential to benefit?
A. Not exactly, because the ExteNET trial was disproportionately weighted to higher-risk patients than the general HER-2 positive population because they changed the eligibility criteria for the trial and only included node-positive patients.
Q. Later in the study, right?
A. Yes.
Q. But statistically speaking -- I'm talking about the actual ExteNET trial. Statistically speaking for those patients who were in the trial, every patient who took neratinib in the trial had the potential to benefit, correct?
A. If -- no, because when you actually look at the subgroup analyses, the patients who were ER negative did not benefit, and the patients who were node negative looked like they didn't benefit.
But on average in the ExteNET population, which was

enriched for higher-risk patients, the absolute benefit was 2.3 percent.

Q. So you brought up a good point of different subgroups or subpopulations within the ExteNET trial, right?

A. Correct.

Q. And some of those subgroups and subpopulations benefited more than the 2.3 percent overall, correct?

A. Correct.

Q. Before we get to that, I wanted to ask you, you mentioned --

THE COURT: Hold on. Anytime you wish to break, feel free. We usually break 90 minutes into it. But if you're making a point, proceed.

MS. JOHNSON: Okay. I'll finish the one question.

BY MS. JOHNSON:

Q. You mentioned chemotherapy earlier and all of the somewhat terrible side effects that chemotherapy can have. Nevertheless, you would agree that chemotherapy would be worth considering if it had an absolute benefit of even about three percent, right?

A. So back in the days when we had very little available to treat breast cancer patients and there were no genomic assays available to personalize care, the standard accepted amount in the field for chemo to be considered was an absolute benefit of three percent.

Now we have much, much better ways to actually quantify an individual patient's risk and benefit, and patients decide that for themselves. I don't say that if you're going to have a three percent benefit, you should do it. I say it might give you a three percent benefit. Is that worth it to you?

Q. But back when chemotherapy was being developed, it was worth doing even if there was an absolute difference of three percent, right?

A. I think it -- again it depended on the individual patient.

Q. So let's look at your deposition on page 109 starting at line 18, going to page 110, line 6.

MS. JOHNSON: I'd like to play the clip.

THE COURT: Any objection?

MR. FORGE: No, Your Honor.

THE COURT: You may.

MS. JOHNSON: Clip 58.

(Videotape recording played)

BY MS. JOHNSON:

Q. Were you asked that question and you gave that answer under oath?

A. Yes.

MS. JOHNSON: We can take a break.

THE COURT: Okay. Let's take a break, folks, and

let's come back in 15 minutes, which will be at 9:55.

Thank you. Remember, don't discuss the case. Don't research the case. Keep an open mind. See you in 15 minutes.

THE CLERK: All rise.

(Recess taken from 9:40 a.m. until 9:54 a.m.)

THE COURT: Let's go on the record quickly.

Good news for some. I just got an e-mail from Washington that says Center Director John Cook and Chief Judge Sydney Thomas have agreed to postpone the mid-winter Ninth Circuit meeting now set for January 28th through 30th.

So that is postponed, so I am available for jury deliberations during that time.

With that, I will issue an order on the timed trial, now realizing there's a little more flexibility arising from that.

Go ahead.

THE CLERK: All rise.

(Open court - jury present)

THE COURT: Continue.

BY MS. JOHNSON:

Q. Dr. Adelson --

A. Yes.

Q. -- would you turn now to Exhibit 102 in your binder. Exhibit 102 is a copy of the July 22nd, 2014, press release.

MS. JOHNSON: I would move to admit 102 into evidence.

MR. FORGE: No objection.

THE COURT: 102 is admitted.

(Exhibit 102 received)

BY MS. JOHNSON:

Q. This, Dr. Adelson, is a copy of the press release that you reviewed not at the time it came out but rather in connection with your work here today, right?

A. Yes.

Q. And in this press release Puma announces topline results for the ExteNET trial. You see there in the first paragraph, right?

A. Does this say topline? I'm not seeing that word.

Q. We can quickly read it. Puma Biotechnology, a development-stage biopharmaceutical company, announced --

A. Got it.

Q. -- topline results --

A. Yes.

Q. -- great. And the second paragraph identifies the number of patients enrolled as 2,821 patients in 41 countries with early-stage HER-2 positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab, right?

A. Correct.

Q. And that's the name for Herceptin?
A. Yes.
Q. And then in the third paragraph, the press release announces the results. It says the primary end point of the trial was disease-free survival, DFS. The results of the trial demonstrated that treatment with neratinib resulted in a 33 percent improvement in disease-free survival versus placebo.
A. Yes.
Q. Do you see that?
A. Yes.
Q. The hazard ratio .67, and statistically significant p-value of .0046, right?
A. Yes.
Q. It's not your testimony here today that anything in this press release was untrue, correct?
A. Correct.
Q. You talked a lot earlier about the standard of care in breast cancer treatment, right?
A. Yes.
Q. You recall that testimony? And you said that a standard of care is a universally accepted treatment that a patient should expect to receive irrespective of where they are?
A. Assuming that they are healthy enough to tolerate it.
Q. And you also testified that a positive clinical trial

occurs if a new treatment did better than the standard of care, right?

A. Yes. I think, however, it's important to point out the difference between statistically significant and clinically significant. I know you will have statisticians who can do that. But sometimes trials are statistically significant. The difference between the groups is real, but they're not clinically significant because the amount of benefit is so small.

Q. And you're not here as a statistician to talk about statistically significant, right?

A. No.

Q. You participate on tumor boards --

THE COURT: Just a moment. Just one moment, please.

(Record read)

THE COURT: Which means wrong. Let me just say when you have a negative precedent, you're not here, followed by a cross-examination statement such as right or correct, the answer always comes out no, confirming the precedent.

In the statement, it's negating the right or correct. Okay?

MS. JOHNSON: I appreciate that.

THE COURT: Sorry. It's just a small point. On appeal I want to make it clear -- if there were such an

appeal. Go ahead.

MS. JOHNSON: I appreciate that. I'll do better.

BY MS. JOHNSON:

Q. So you participate on a tumor board at Yale as part of your breast cancer oncology job at Yale, right?

A. Yes.

Q. And the tumor board is a group of surgeons and oncologists and radiologists who get together and discuss complicated cases, right?

A. Correct.

Q. And when your colleagues get together as a group for the most complicated cases that come to the tumor board, you believe that the result reached is the appropriate standard of care for that particular patient, right?

A. Yes.

Q. In at least some cases the collective wisdom of this tumor board that you sit on has been to consider neratinib as part of the appropriate standard of care, right?

MR. FORGE: Objection, Your Honor. This is in-limine number four.

THE COURT: Okay. We're going to have to take a moment. I do not have each motion in limine memorized.

MR. FORGE: Understand, Your Honor.

THE COURT: I need to go back and check it out. Just a moment.

(Pause in proceedings)

THE COURT: All right. May I say your motion in limine is ten pages long. Can you direct me to where in that motion in limine this issue is covered that we now have before us?

MR. FORGE: Your Honor, if we could do this at sidebar. It's hard to direct it without --

THE COURT: No. You're going to have to try, then. If not, I'll just look and try and decide myself.

MR. FORGE: If I -- I don't have the in-limine in front of me, Your Honor, but --

THE COURT: I'm sorry. If you're going to make an objection on the in limines, you need to have them in front of you, especially when you give me ten pages and I need to compare whether those ten pages go to the question that was just asked. So I'll decide without your assistance telling me where. Just a moment.

Okay. I understand your objection. I believe you need to direct me to pages -- page 3 particularly of document 515. Okay. I'm understanding. You did not provide a date in your question. Is it after the class period?

MS. JOHNSON: It is.

THE COURT: Okay.

MS. JOHNSON: But can I -- may I respond to the objection?

THE COURT: Briefly.

MS. JOHNSON: The witness testified --

THE COURT: Don't restate. We went over this in such detail on the motions in limine, and I made my ruling and I need to stick with it. Go ahead.

MS. JOHNSON: The witness testified that a positive clinical trial result has a relationship to the standard of care. These questions are about her work with respect to the standard of care, not affecting the topic of the motion in limine.

THE COURT: Okay. The objection is sustained. I understand. That's my ruling.

MS. JOHNSON: Your Honor, can I make a proffer?

THE COURT: I don't know what you mean by make a proffer. Maybe at a break you may.

MS. JOHNSON: It would have to be at a break, yes.

All right. Thank you, Your Honor.

BY MS. JOHNSON:

Q. You are familiar with Dr. Richard Schwab in this matter?

A. Yes.

Q. He's an expert retained by the defendants in this case?

A. Yes.

Q. You're familiar with his work in this case?

A. Yes.

Q. And as a practicing doctor, you talked a little bit

about your practice. And in Dr. Schwab's practice, he treats about four times as many patients as you treat currently; is that correct?

A. Correct.

MR. FORGE: Objection, Your Honor. Foundation.

THE COURT: Sustained as to foundation.

BY MS. JOHNSON:

Q. Do you agree that he has had the occasion to actually talk with and work with many more patients who might qualify for consideration of neratinib?

THE COURT: Vague. I don't know what many more means.

MR. FORGE: I would say, Your Honor --

THE COURT: Hold on. I -- do you have something else to say?

MR. FORGE: Yes. Also foundation and also in-limine four.

THE COURT: Sustained as to foundation.

Well, I'll just say sustained.

BY MS. JOHNSON:

Q. In your work in this case, did you review Dr. Schwab's work as a treating practicing physician?

A. Yes.

Q. And did you have the opportunity to compare his work and the frequency with which he sees patients to your work and

the frequency with which you see patients?

MR. FORGE: Objection, Your Honor. Still foundation and hearsay.

THE COURT: Overruled. She's asking the foundational question and that is appropriate, particularly for this expert. Overruled.

THE WITNESS: So --

THE COURT: You can answer. Did you have the opportunity to compare?

THE WITNESS: Yes.

THE COURT: Next question.

BY MS. JOHNSON:

Q. And isn't it the case that Dr. Schwab treats about four times as many patients as you treat?

MR. FORGE: Again, Your Honor, I'm going to object to foundation and hearsay.

THE COURT: This is an expert witness.

Overruled.

THE WITNESS: Currently he treats more patients than me, but I do believe I'm a little bit older than him and I was extremely busy as an academic oncologist for many years. So I cannot say that he has treated more HER-2 positive patients than I have.

BY MS. JOHNSON:

Q. Just because Dr. Schwab is treating about four times as

many patients as you are, he has had occasion to actually talk to and work with many more patients who qualify for consideration of neratinib than you have, correct?

MR. FORGE: Again, Your Honor, I'll say vague as to to time. And I think once that is clarified, I would have a motion in limine number four objection.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MS. JOHNSON:

Q. Thank you.

Let's turn back to the chart that we have been discussing. You call drug B on the right -- you notate drug B on the right, then you list certain attributes of that drug, right?

A. Yes.

Q. But 2.3 percent and the DFS difference of 91.6 versus 93.9 were not the only statistics disclosed in the ASCO abstract that we looked at and the ASCO conference, right?

A. Right.

Q. It's fair to say that there were different subgroups and subpopulations within the ExteNET trial in addition to the overall entire population of patients as a whole, right?

A. Right.

Q. Yes?

A. Yes.

Q. And, in fact, in your demonstrative earlier you pointed out one of those subgroups. You called it ER positive?
A. Yes.
Q. And that is the subgroup that means estrogen-receptor positive patients?
A. Yes.
Q. And that's the same thing. Sometimes it's referred to as hormone-receptor positive patients?
A. They're not exactly the same, but -- so you could be estrogen negative and progesterone positive and still be called hormone positive.
Q. In the ExteNET study there was a subgroup called hormone-receptor positive, right?
A. Right.
Q. And the data for that subgroup which you said was 66 percent of all HER-2 positive patients was higher than 2.3 percent, correct?
A. Yes.
Q. And you believe there was about a 4.4 percent absolute DFS benefit for the subgroup that you called out on your demonstrative, correct?
A. Correct -- enriched again for node-positive patients, who are inherently higher risk.
Q. The node-negative or positive subgroups were tested in the ExteNET trial as well, right?

A. Right.
Q. And would you say that a four percent absolute DFS benefit is more than a marginal benefit?
A. Yes.
Q. There's another cut of the data in the ExteNET trial for what's called centrally confirmed HER-2 positive patients, right?
A. Right.
Q. And doctors can confirm whether a patient actually has the HER-2 gene mutation by testing either in the doctor's office or in a central lab?
A. No. You only have access to central testing when you're participating in a clinical trial, not in everyday practice.
Q. Great clarification. So in the clinical trial patients can be confirmed either by their doctor or, because it's a clinical trial, by this centralized lab, right?
A. It depends on the trial. Some trials require central confirmation and some do not.
Q. And the ExteNET trial did not, correct?
A. You know, honestly I don't remember. I know they had a centrally confirmed, but I don't remember if it was a requirement.
Q. You do recall that the results of the centrally confirmed patient population were presented in the ASCO presentation?

A. Yes.
Q. Let's look at that. Again, it's Exhibit 176. Let's look first at slide 14. Again, this is the ExteNET data actually presented at the ASCO conference on June 1, 2015, and this is the subgroup that we just talked about by hormone-receptor positive on the left and hormone-receptor negative on the right, correct?
A. Correct.
Q. And the difference there on -- by hormone-receptor positive, the numbers are 91.2 and 95.4. Do you agree with me?
A. Yes.
Q. For a difference of 4.2 percent, right?
A. Correct.
Q. And then in the centrally confirmed population which is on the next slide, on slide 15, on the right is the graph for centrally confirmed, and the difference is 90.6 to 94.7. Do you see that?
A. Yes.
Q. For a 4.1 percent difference?
A. Yes.
Q. And you would agree again that a 4.1 percent difference is more than a marginal benefit?
A. Yes.
Q. And by the way, centrally confirmed testing, is that

sometimes called the fish test?

A. No.

Q. Is it -- depends by lab?

A. No. So there are criteria for how you define HER-2 positivity. So the first thing they do is they paint an antibody. This is done at a local lab or central lab. They basically paint an antibody equal and opposite to the HER-2 receptor on.

If it lights up with strong intensity or it is called three plus, that's automatically considered positive by immunohistochemistry, which is the name of that. If it comes back two plus, which is more borderline, that's when they run the fish.

The fish is a method where they actually look at gene sequencing. Those are done standard at every lab that is certified to do HER-2. It doesn't have to be central. The issue about a central lab is it's really irrelevant for clinical practice because I am limited to the population that is tested at my local lab, as is every oncologist in the country, because a central HER-2 lab that they use in the study is not available in everyday practice.

Q. For everyday practice, correct. For these -- for these big clinical trials, that's where you would use this centralized testing in order to confirm whether a patient actually has the HER-2 positive gene?

A. No. So when you interpret the data, you know, interpreting the data based on the local lab is much more in line with the real-world population and what would be happening in your practice, because a central lab is something that only happens in the strict guidelines of the study.

So to extrapolate for the centrally tested population is again a population that would not have been picked up in real practice -- potentially, you know, bigger or smaller, depending on the difference.

Q. But in the ExteNET trial, this centrally confirmed population was done in order to centralize the identification of the patients as HER-2 positive in the ExteNET study, right?

MR. FORGE: Objection, Your Honor. Foundation.

THE WITNESS: So in the ExteNET study --

THE COURT: Hold on. There was an objection.

THE WITNESS: Sorry.

THE COURT: Response?

MS. JOHNSON: I could ask the foundation question.

THE COURT: Please do. Ask some foundational questions.

BY MS. JOHNSON:

Q. You've studied the ExteNET data in the course of doing this work, correct?

A. Yes.
Q. And you've studied the subpopulations including the centrally confirmed subpopulation, right?
A. Right. But the overall data they reported was not the overall benefit that they reported. The primary end point was not in the centrally confirmed HER-2 population. It was in the overall locally confirmed HER-2 population. That's the important difference I'm trying to get at.
BY MS. JOHNSON:
Q. The 2.3 percent meaning?
A. Yes.
Q. And then within that there was a centrally confirmed population which is the 4.2 percent -- 4.1 percent that we're looking at, correct?
A. Correct.
Q. Did you also have an opportunity to look at the centrally confirmed hormone-receptor positive population, putting these two together?
A. You know, I cannot remember, but I would be happy to look if you show it to me.
Q. Okay. Great. Would you turn to Exhibit 886.
MS. JOHNSON: I would move 886 into evidence.
THE COURT: Any objection?
MR. FORGE: No, Your Honor.
THE COURT: 886 is admitted.

(Exhibit 886 received.)

BY MS. JOHNSON:

Q. So 886 is the Puma Biotechnology 2015 ASCO analyst meeting. This is the meeting I asked you about whether you attended on the evening of the June 1st ASCO conference, and you said you did not attend, correct?

A. Correct.

Q. And you didn't find this presentation in the list of materials that you looked at. Is it the case that you have not looked at this document?

A. Right. It does not look like something I've seen before.

Q. Okay. This document which is now in evidence is a presentation that is labeled 1 June 2015, presented by Puma at an analyst meeting. If you'll turn to slide eight, there is a depiction of what is denominated HR-positive patients, meaning hormone-receptor positive, that subgroup that we've been talking about, centrally confirmed in the population. And the difference is 88.4 percent to 97 percent.

Do you see that?

A. Yes.

Q. So what that means is the placebo arm ended up at 88.4 percent for this particular subpopulation, right?

A. Yes.

Q. And the neratinib arm for the people who took neratinib

ended up at 97 percent disease-free survival at two years, right?

A. Yes.

Q. And that's an 8.6 percent absolute DFS difference; is that correct?

A. Yes, for a population of patients that you would never see in the real world.

Q. You would never see hormone-receptor positive patients that have been confirmed as actually being HER-2 positive?

A. Not centrally confirmed. It's different. So local labs include -- there's a lot of borderline cases in defining HER-2 positivity. Those borderline cases are less likely to benefit from HER-2 targeted drugs.

But in the real world those borderline patients make it into the trials and make it into the real world of the patients who will receive the drug. So this is essentially enriched for the percentage of patients who are most HER-2 driven by the central confirmation and are most likely to benefit.

Q. So for those patients who are highest risk and most likely to benefit, they get up to 97 percent?

A. I didn't say highest risk. The highest HER-2.

Q. Highest HER-2?

A. Yes.

Q. Thank you for the clarification. For the patients with

the highest HER-2 and hormone-receptor positive who are most likely to benefit from neratinib, they get up to 97 percent disease-free survival rate at two years, right?

A. Can you close the box, because I've never seen this. I just want to look at the number of patients that actually fit this and whether it was significant. So it was statistically significant.

Q. And the reason you say that is the p-value --

A. The p-value is less than --

Q. -- is less than .001, meaning that the result is highly statistically significant, right?

A. Correct. But the other thing that you have to point out is the number of patients who fit into these arms. And you can see that the number of patients is about 380 in each group, which shows you what a small percentage of the overall study population actually met this criteria.

Q. Other drugs have been FDA approved based on patient populations much less than this; wouldn't you agree?

A. Less than 300?

Q. Per arm?

A. Not commonly and not in a phase III adjuvant study.

Q. So you have characterized the benefit of Herceptin which you've described as, you know, the standard of care, right?

A. Correct.

Q. You've characterized the absolute benefit of Herceptin

as a dramatic benefit; is that fair?
A. Yes.
Q. And that benefit was eight to ten percent overall?
A. Yes.
Q. And by the way, I wanted to ask you about the patient population of HER-2 positive. In your testimony here today, you said only 20 percent of breast cancer patients are HER-2 positive, right?
A. 20 to 25 percent, yeah.
Q. 20 to 25. There is literature that says 25 to 30 percent; isn't that correct?
A. I think there's literature that is all over the board, and it has to do with how you define HER-2 positivity, which has evolved over time as well.
Q. And in your testimony by deposition, you indicated it was 25 to 30 percent as well; didn't you?
A. Maybe so.
Q. Okay. It can be a range?
A. It's a range.
Q. It's a range from 20 percent to 30 percent depending on how you define HER-2 positive?
A. All right.
Q. Then let's talk about the Kaplan-Meier curve. This is one, I guess. We can just look at what's up here. But let's look at the primary end point, which is 176 again, because

what you've listed here next is KM curves not separating at two years where they end.

I wanted to look at that Kaplan-Meier curve for the primary end point, which is slide 10. And notice that at 12 months, the difference is 2.2 percent. Would you agree with me, 95.6?

A. You're showing it here.

Q. To 97.8?

A. Yes.

Q. That's 2.2 percent difference. And at three years it's 91.6 and 93.9 of course, which is a difference of 2.3 percent, right?

A. It's a difference of .1, which is in the range of the margin of any statistical error. The difference between 2.2 ask 2.3 does not classify as a widening curve.

Q. Certainly the curves are not narrowing, correct?

A. Correct.

Q. And it's fair to say that from 2.2 to 2.3, putting aside statistical significance, is a wider difference, correct?

A. I think it's really the same. It -- you absolutely cannot say that is a trend towards an improving curve. You know, you would be laughed out of the room if you tried to say that in the scientific world.

It's a -- you're talking about a 0.1 difference. That is just not a number that anybody can count on.

Q. But we can all agree that the curves are not narrowing, correct?
A. Correct.
Q. So are you aware of the data that Puma had available to it in July of 2014?
A. I don't know how far out they had followed patients at that point off the top of my head, no.
Q. Are you aware that the trial was started in 2009?
A. Yes.
Q. And that by 2013-14, there had been many patients on the trial for more than two years at that point?
MR. FORGE: Objection, Your Honor. Vague as to many.
THE COURT: Overruled.
THE WITNESS: Again, I don't know how many, you know, had gone beyond the two years at that point. Again, the analysis was limited to two years as the end point, so I don't even know if they had really done the analysis beyond that. It's not in anything I've read.
BY MS. JOHNSON:
Q. So you don't know what analysis Puma had done internally to look at that data that was available beyond the two-year point, correct?
A. Correct.
Q. And you have not seen in this case any analysis of that

data that was available to Puma as of the July 2014 time period, right?

A. Right.

Q. You indicated that you reviewed plaintiffs' other experts, the statisticians, Dr. Jewell and Dr. Lavin, you reviewed their work, right?

A. I did.

Q. And you did not see an analysis of the curves based on data that Puma had available to it as of July 2014 to see what it showed, right?

A. I don't remember honestly the details of the statistical transcripts and exactly what they had looked at. But off the top of my head, no, I don't remember analysis beyond the two years.

Q. And you are limiting your opinion about these curves just to the June 2015 time period, right?

A. Right.

Q. You are not taking into account anything that you have learned between that date and today, right?

A. Right.

Q. You are not taking into account other studies that you've seen, other ExteNET data that you've seen, correct?

A. Correct.

Q. You are only saying I'm going to stop my analysis based on what was printed in this June 2015 period, right?

A. Right.
Q. Yet you testified earlier that you got into breast cancer work because of the opportunity to follow patients for many, many years, correct?
A. Correct.
Q. So it's important in the real world with your doctor hat, if I can use that phrase again, to follow patients for many, many years, correct?
A. Correct.
Q. And so only for purposes of this analysis do you stop looking at the data and cut it off and look at the curves at just two years, right?
A. Right.
Q. You've heard -- you've -- let's talk about safety, which is your next line there on your chart. You have certainly reviewed the Herceptin label, correct?
A. Correct.
Q. And it's fair to say that a label is what provides the prescribing information to the physician about how a prescription medication is supposed to be used?
A. Correct.
Q. And it's also fair to say that a label includes information on side effects?
A. Yes.
Q. And who makes Herceptin?

A. Genentech.
Q. And you're a consultant for Genentech, right?
A. Yes. Not -- not exactly a consultant. I've done advisory boards where I have spoken for them.
Q. And you've received grants?
A. Yes, research funding.
Q. You've received research funding from Genentech?
A. Yes, but totally unrelated to any drugs.
Q. And you didn't -- I checked your expert report. You didn't happen to disclose that you were an advisor for Genentech or that you received grant funding for clinical research from Genentech?
A. I may not have had any grant funding when I first started working on this.
Q. Let's look at the date of your expert report.
A. Uh-huh.
Q. The first one is there in your binder. It's the end of 2018; is that correct?
A. Yep. Can I ask you a question? Was I required to disclose in my expert report? This is not the same thing as publishing a manuscript, just to --
THE COURT: Actually you need to ask the next question.
MS. JOHNSON: Right.

BY MS. JOHNSON:
Q. So requirement or not, it does not appear in your expert report that you are an advisor or consultant for Genentech, right?
A. Again, I haven't been an advisor for Genentech. I've received research funding, and I have spoken at their conferences on shared decision making, not anything to do with their drugs or drug approval.
Q. Okay. Would you turn to tab B in your binder.
A. (Witness complies.)
Q. Did you speak on a panel called differentiating among the CDK4/6 inhibitors in the management of metastatic breast cancer?
A. Yes. This was a CME, and they don't even tell you when you do these CMEs. It's separate from the pharma company, so I actually didn't even know who provided the funding. CMEs are considered objective educational conferences.
Q. And you were a panelist at that conference?
A. Yes.
Q. If you would just turn to the second page.
A. Uh-huh.
Q. Did you not disclose the following relevant financial relationships, colon, served as an advisor or consultant for Genentech?
A. Yes. So they give you -- you have to select a box, and

I wanted to be fully transparent. So because Genentech had invited me to talk about shared decision making, which is exactly the only thing I spoke about, it didn't fit the exact boxes. So I went -- I erred on the side of just saying advisor. But I'm not an advisor. I just wanted to disclose that I had received payment for giving a talk at Genentech.

Q. You had received payment for giving the talk at Genentech?

A. Yeah.

Q. And you also checked the box for received grants for clinical research from Genentech?

A. Yes. That is, again, the shared decision-making research.

Q. Right. And again, Genentech is the maker of Herceptin?

A. Yes.

Q. You have, of course, looked at the Herceptin warning label?

A. Yes.

Q. And you have noticed that right up front, there's a black box warning?

A. Black box warning for cardiac toxicity?

Q. Correct. Yes. Good.

A. I assume that's what you're getting at.

Q. Good memory.

A. Okay.

Q. Are you aware that a black box warning typically appears on a prescription drug label when it is designed to call attention to serious or life-threatening risks?
A. Yes.
Q. Let's turn to the Herceptin warning label. It's at tab 984. In the course of your work, you have reviewed the Herceptin warning labels?
A. Not in recent years. You know, I've been using the drug for so long. But when it first came out, yes.
Q. Is this Exhibit 984 a copy of one of those Herceptin FDA labels?
A. Yes.
MS. JOHNSON: I would move Exhibit 984 into evidence.
MR. FORGE: No objection, Your Honor.
THE COURT: 984 is admitted.
(Exhibit 984 received.)
MS. JOHNSON: Let's put up the first page.
BY MS. JOHNSON:
Q. So that warning label that I talked about with this black box that indicates life-threatening risk for Herceptin says, Warning: Cardiomyopathy, infusion reaction, embryofetal toxicity, and pulmonary toxicity; right?
A. Yes.
THE COURT: I'm sorry. Excuse me. This concerns

984?

MS. JOHNSON: Yes, Your Honor.

THE COURT: I'm looking at page 18 of the exhibit list. I don't see 984.

MS. JOHNSON: We'll check on that, Your Honor.

THE COURT: Okay. It's just -- you know, we have the duty of making sure the jury gets to see the exhibits, and it's things like this that cause me a little bit of concern. I don't have a place at this moment to mark exhibits admitted or any of that, through no fault of the Court or the courtroom deputy.

So follow up and see what the problem is. When there's a huge bunch of documents and we don't keep current track of it or we don't have a list that allows us to easily keep track of it, problems arise.

984 is admitted. Please look into the situation that my exhibit list is incomplete.

Go ahead.

MS. JOHNSON: Will do, Your Honor. Thank you.

BY MS. JOHNSON:

Q. Dr. Adelson, cardiomyopathy listed in the black box is a disease of the heart muscle that makes it harder to pump blood?

A. Yes.

Q. Is that fair? And cardiomyopathy can lead to congestive

heart failure?
A. Yes.
Q. Infusion reaction, that refers to the fact that Herceptin is an IV administered drug, right?
A. Yes. It's -- well, they're describing an allergic reaction.
Q. Right. So there can be allergic reactions to intravenous infusion, meaning the IV, right?
A. There can be allergic reactions to any drug.
Q. But particularly ones that are administered by IV, there can be an infusion reaction, correct?
A. I don't know if that's any more common than reactions to oral drugs. But, yes, absolutely. Anything that is infused into a patient can potentially cause an allergic reaction.
Q. And pulmonary toxicity means damage to the lungs basically, right?
A. Yes.
Q. And neratinib does not cause any of these adverse events like cardiomyopathy, congestive heart failure, infusion reactions, et cetera, that are listed on this label?
A. So I actually would have to look at the early phase I studies in neratinib to see if it had no cardiac toxicity, but I don't remember off the top of my head any cardio toxicity reported disproportionately in the neratinib population of ExteNET.

Q. In fact, after reviewing all of the ExteNET data, you concluded that there was no indication that neratinib causes any long-term adverse side effects, correct?
A. No. Neratinib hasn't been around long enough to know if it has long-term toxicity. It's too new a drug. So I would not say that.
THE COURT: You had a negative followed by correct, and actually I don't know what her no means.
MS. JOHNSON: Okay.
BY MS. JOHNSON:
Q. Was there any indication -- was there any indication in the ExteNET data that you reviewed that there were long-term adverse side effects?
A. It's totally inappropriate to discuss long-term side effects from a study that stopped reporting at two years. Long-term side effects can happen much later.
Q. But the good news is that if you were talking to a patient about neratinib, you would not have to warn her of long-term negative side effects associated with the use of neratinib, correct?
A. I would say that we don't know yet what the long-term potential toxicities are because it's a very new drug.
Q. But you would not say when you're doing your list of pros and cons about the drug, you wouldn't add any long-term side effects, correct?

A. Correct.
Q. Let's talk briefly about diarrhea.
A. Okay.
Q. Not -- neratinib is a tyrosine kinase inhibitor, right?
A. Tyrosine, right.
Q. Known as TKI?
A. Yes.
Q. Especially to people like me.
And before you had heard of neratinib, you knew that diarrhea was a side effect of TKIs, right?
A. Yes.
Q. And there are a huge number of TKIs that are FDA approved, right?
A. Yes.
Q. And for those drugs that got FDA approval, it's known that the incidences of grade-three diarrhea ranges up to about 50 percent, correct?
A. It depends on which TKIs. Some have much more what we call GI, gastrointestinal, toxicity than others.
Q. And the range runs up to about 50 percent; isn't that true?
A. Yes. I would -- I would say overall diarrhea is usually about 50 percent. Grade-three off the top of my head I don't know because I'm so focused on breast cancer at this point. A lot of TKIs are used in other malignancies. There's only

one other TKI that we use in breast cancer, which has a lower rate of diarrhea.

Q. But for grade-three diarrhea, the evidence shows that for TKIs grade-three diarrhea ranges up to about 50 percent, correct?

A. So I really off the top of my head don't know that for all TKIs. I would have to look that up.

Q. Okay. Let's just turn to your deposition at page 116.

A. What number?

Q. It's just marked deposition, page 116. We'll start at line 21, through page 117, line 13. Do you see that?

A. Yeah.

MS. JOHNSON: Your Honor, may I play the clip?

THE COURT: Any objection?

MR. FORGE: No, Your Honor.

THE COURT: Yes, you may.

MS. JOHNSON: Clip 26.

(Videotape recording played)

BY MS. JOHNSON:

Q. Were you asked those questions and you gave those answers?

A. Yeah. I didn't come up with the 50 percent. The person who asked the question did.

Q. So isn't it also the case in ExteNET that the median cumulative duration of diarrhea was about five days?

A. So I think that was reported in one of the manuscripts that came after this period. But the initial thing that I remember is that it usually resolved by the end of the first month.

Q. And that is information that if you're a treating physician, your patients would certainly want to know, correct?

A. Correct.

Q. Both the duration, the median duration of diarrhea and the dissipation after a month, correct?

A. Correct.

Q. And that would be the kind of information you would share with your patients as a treating physician, right?

A. Yes.

Q. To be clear, that five-day median grade-three diarrhea duration was without the loperamide prophylaxis, right?

A. So patients in ExteNET were allowed to receive loperamide. They just weren't started on it prophylactically. So I think that's really important to point out. It's not that they didn't have any antidiarrheals. It's just that the treating physicians were encouraged to manage the diarrhea at the time in which a patient had a symptom as opposed to all patients just being started on prophylactic antidiarrheals.

Q. But you don't personally know whether any of the doctors

in the ExteNET study actually prescribed loperamide after the onset of diarrhea symptoms, right?

A. Well, the ExteNET protocol stated that they should use antidiarrheals. So you would have had to have a whole lot of investigators who did not follow the protocol when their patients had diarrhea for them not to have received loperamide in the ExteNET trial.

Q. But --

A. It was in the protocol.

Q. Thank you.

But you personally don't know what their practice was with regard to loperamide, correct?

A. No, but I know that doctors don't like to see their patients suffering. So if a patient is having bad diarrhea, usually they try to offer them something.

THE COURT: Another negative followed by the word correct.

MS. JOHNSON: Got to work on that.

BY MS. JOHNSON:

Q. Finally, dropout rates is the last line in your chart. When you testified, you said your definition of a dropout rate was a patient stopped taking the drug because of side effects or stopped participating in the study because of side effects. I just wanted to clarify. You're not making a distinction in your testimony about what -- whether the

dropout rate means discontinue the drug or withdraw from the study, correct?

A. So patients can drop out of a study for a multitude of reasons, and the dropout rate in the neratinib arm was 39 percent. It was, I think, about 17 percent in the placebo arm. Of those 39 percent who dropped out in the neratinib arm, 27 percent had dropped out due to side effects.

The remaining 12 percent we don't know why they dropped out. Maybe they had just had it, or they didn't accurately, you know, characterize the side effects. But the dropout rate was much higher in the neratinib arm than in the placebo arm.

Q. We looked at Exhibit 124 in your previous testimony where you noted that 27.6 number. Can we look at that again?

A. Sure.

Q. It's at page 266. Do you see that? That's what we looked at earlier?

A. Uh-huh. I'm on page 266 -- oh, wait. I'm in the wrong place. I'm in my deposition. Where am I suppose to go?

Q. The exhibit binder --

A. I got it. I'll just look at the screen. Okay.

Q. Great. So the number 27.6 that we talked about earlier, that is adverse events leading to discontinuation, correct?

A. Correct.

Q. That means discontinuation of treatment on drug?

A. Yes.
Q. That does not mean one way or the other whether they dropped out of the study, right?
A. Right.
Q. Okay. Finally, you talked about the cost --
THE COURT: Just one moment. Do you know there's a clear-all button? You see where it says clear all? Hit it right there. Boom.
THE WITNESS: Thank you.
THE COURT: Good. Go ahead.
BY MS. JOHNSON:
Q. You talked about the cost of drugs being an important factor in whether patients will accept a treatment, right?
A. Yes.
Q. Isn't it the case -- and then you talked about a crisis in healthcare and that insurance ends up paying less and less, right?
A. Yes.
Q. Isn't it true that neratinib is likely to be covered by insurance?
MR. FORGE: Objection, Your Honor. Beyond the scope of the opinion offered. It's also in-limine number four.
THE COURT: Also what?
MR. FORGE: In-limine number four.

THE COURT: Overruled.

THE WITNESS: So a percentage of neratinib is likely to be covered from insurance. Most prescription plans cover 80 percent. So if the -- so if neratinib costs 10,500 a month, the insurance will pay a little over 8,000 and the patient could be on the line for 2,000 a month.

BY MS. JOHNSON:

Q. Are you aware that Puma has a policy that it will cover the entire cost of neratinib for patients who can't afford it?

A. I think they have a --

MR. FORGE: Your Honor --

THE COURT: Yes.

MR. FORGE: Same in-limine number four --

THE COURT: Didn't she -- I thought you asked her questions about cost; didn't you?

MR. FORGE: Not as pertains to neratinib. I just asked about --

THE COURT: The objection is overruled. Thank you.

THE WITNESS: So we're talking about today or in 2015?

BY MS. JOHNSON:

Q. We're talking about in general, any time period. Are you aware of Puma's policy to make sure that any patient who gets -- who wants to take neratinib does not lose the

opportunity to take that drug based on inability to pay?
A. So I am not aware of the details of that policy. I will say that in my experience with compassionate-use programs from pharmaceutical companies, the patients have to qualify by having an income level that is low enough to allow, I think, the pharmaceutical company to make up the difference. I would imagine this, like all other co-pay assistance programs, likely does have a financial limit.
Q. But again, you're not aware of Puma's policy with regard to covering that kind of cost, correct?
A. Correct.
MS. JOHNSON: Thank you. No further questions.
THE COURT: Thank you.
Redirect.

REDIRECT EXAMINATION

BY MR. FORGE:
Q. Doctor, Ms. Johnson asked you a number of questions about subpopulations, but she didn't ask you about the subpopulation for distant disease-free survival. Are you familiar with that term, distant disease-free survival?
A. Yes.
Q. What does distant disease-free survival represent?
A. That is the percentage of patients who do not develop a distant metastasis. It's distant metastasis that lead people to die from their cancers, so that is the most relevant end

point when you're talking about curing cancer or dying from cancer.

Q. And did the ExteNET study reveal a statistically significant benefit in distant disease-free survival from neratinib?

A. No, it did not.

MR. FORGE: Nothing further.

THE COURT: Recross.

RECROSS-EXAMINATION

BY MS. JOHNSON:

Q. Very briefly, Dr. Adelson. You did not take into account in your review of neratinib for this case any later information that came out about -- that may have or may not have come out about neratinib's impact on brain metastasis; did you?

A. No.

MS. JOHNSON: Thank you.

MR. FORGE: No further questions, Your Honor.

May the witness be excused?

THE COURT: Yes. I will excuse the witness.

Thank, you, Doctor.

Plaintiff will call its next witness.

MR. FORGE: Thank you, Your Honor.

Your Honor, may I approach just to --

THE COURT: Yes, you may.

MR. COUGHLIN: Your Honor, plaintiffs call as their next witness Dr. Nicholas Jewell.

I'm going to refer to every exhibit in that binder, Your Honor.

THE COURT: Good for you.

Nicholas Jewell, Plaintiff's witness, sworn

THE CLERK: If you will please state and spell your first and last name.

THE WITNESS: Nicholas, N-i-c-h-o-l-a-s. Last name is Jewell, J-e-w-e-l-l.

THE CLERK: Thank you.

DIRECT EXAMINATION

BY MR. COUGHLIN:

Q. Good morning, Doctor.

A. Good morning.

Q. You're a biostatistician; is that correct?

A. Yes.

Q. Can you tell us what a biostatistician is?

A. A biostatistician works on data arising from medical or public health studies and designs and analyzes the data from such studies.

Q. And how do you become a biostatistician?

A. Usually by training in the quantitative sciences in some form and then with practical experience in working on applications.

Q. And do you have both those?
A. Yes.
Q. And can you give us a little of your educational background?
A. Yes. My undergraduate degree was in applied mathematics from the University of Edinburgh, followed by a Ph.D. in mathematics also from the University of Edinburgh. Then post-doctoral experience in biostatistics at the University of California Berkeley, Stanford University, and the University of Edinburgh before taking a faculty position.
Q. A faculty position at Berkeley?
A. No. My first faculty position was at Princeton University on the east coast. And then I moved to the University of California Berkeley.
Q. And when was that?
A. I returned to Berkeley in 1981. So I -- I have been there for close to 40 years.
Q. And what are some of the positions you've held at Berkeley?
A. Well, primarily I've served as a professor of biostatistics through that entire period, but for a term I worked in the office of the chancellor as the vice provost for the Berkeley campus. Then I worked as vice provost for the whole University of California system, which has now ten campuses.

Q. Okay. I see that you've been elected to the National Academy of Medicine. What's that about?

A. The National Academy of Medicine is probably preeminent recognition of people doing medical research and clinical work in the United States. It is reserved for a few people each year who are elected to the National Academy of Medicine.

It's unusual for someone like me as a biostatistician because I'm not a clinician. I think there are about maybe ten to a dozen biostatisticians currently in the National Academy of Medicine.

Q. Okay. And you've been hired as an expert before; is that right?

A. Yes.

Q. And about how many matters?

A. I probably provided testimony in somewhere between 40 or 50 litigation cases.

Q. And is that -- is that for both plaintiffs and defendants?

A. Yes. I've worked for both plaintiffs and for defendants, and I've worked for pharmaceutical companies on occasion.

Q. Have the parties in those actions almost challenged your opinions almost uniformly in almost every action?

A. There's certainly a substantial number I've been

challenged in, yes.
Q. Right. Has anybody ever excluded your testimony?
A. In those 40 or 50 cases, maybe on about three, maybe two or three part of my testimony was excluded by a judge. In one case it was excluded entirely. Ironically that was a case where one judge accepted the testimony and in one court and another judge excluded it in another court for the same testimony.
Q. Is that analysis that you did, is that the same analysis that you undertook in this case?
A. No. Those cases involved much more complex biostatistical work where I was analyzing or reanalyzing clinical trial data, which I did not do in this case.
Q. You accepted data and analyzed the data as presented; is that correct?
A. In this case, yes.
Q. Okay. And you're here to explain some of the terms that are at issue in this case; is that right?
A. Yes, if you ask me.
Q. Okay. I'll try to get there as soon as I can.
So about how long have you been working on this case?
A. I would say it's probably about two years.
Q. And your rate is?
A. $700 per hour for consulting.

Q. So I think it's a little over $100,000 that you've been paid in this case?
A. Well, I've never actually added it up, but it sounds about right.
Q. I added it up. It's expensive, right?
A. Yeah. I tried to do a good job.
Q. Okay.
At any time during this engagement, did we ask you to reach any certain conclusion?
A. No.
Q. Okay. Would you do -- have you ever done that? Would you do that?
A. No. That would be unethical.
Q. Okay. So let's turn to what you did do in this case and why you did it.
If we could take a look at demonstrative number three.
Dr. Jewell, could you explain -- and this is just to help the jury to look as you explain what you intend to talk about here in this case as we move forward. If we could first start with -- let's start and talk about some of the things here like the p-value, the hazard rates, the Kaplan-Meier curves. And what do you intend to offer there?
A. Well, I'm absolutely happy to try and explain briefly in layman terms what these terms mean because they're complex

and technical.

The p-value, for example, is a measure of evidence that there is a difference between two treatment groups. And if it's a small value, that says you're unlikely to accept that there is no difference between patients receiving alternative treatments.

Q. And that was -- that was used in the ExteNET trial that is at issue here, right?

A. That's correct. We've heard a few statements about p-values already.

Q. And it's a common value that's used in these clinical trial; is that right?

MR. CLUBOK: Objection, Your Honor. Leading.

THE COURT: Pull your microphone over to you. Make sure -- it's a long cord. Pull it all the way over to you. It's a long cord.

The objection is leading. I'm going to allow it.

Will you be offering this witness as an expert?

MR. COUGHLIN: Yes.

THE COURT: I'm going to allow it at this point as an expert. I won't allow all leading questions to proceed, but I will allow this one.

BY MR. COUGHLIN:

Q. Was the p-value used here as an analysis in the ExteNET trial?

A. Yes.
Q. Okay. Let's talk about hazard rates. Could you tell us what those are?
A. Hazard rates measure the rate at which events happen. In this case, we're talking about reoccurrences of cancer or death. It measures the rate at which this happens during the time of follow-up, how quickly people in the population suffer these events.

You usually would compute a hazard rate for each of the two treatment groups, in this case a neratinib group and a control or placebo group, and compare the rates at which the events occur.

BY MR. COUGHLIN:
Q. Was that done in this case?
A. Yes.
Q. Okay. Let's talk about the next value. Can you talk about Kaplan-Meier curves and tell us what those are?
A. Well, as others have said, Kaplan-Meier curves -- and we've been looking at a few of them in this case -- they measure over time the fraction of patients in a treatment group who suffer the event -- in this case a cancer reoccurrence or death.

That fraction necessarily has to -- sorry. The Kaplan-Meier actually measures the fraction who don't suffer the event. That fraction necessarily has to decline over

time because eventually a few people have the event. So the percentage of the original group who have had the -- who haven't had the event starts to go down over time.

Q. And something that's not listed up there is the -- and what is the delta between the Kaplan-Meier curves called?

A. Well, it is specific at the end point of the trial. In this case, two years, two plus years. It's the absolute difference in risk.

Q. Okay. And now there's two terms that I don't think we've heard so far. That is number needed to treat. Could you tell us what that is?

A. Yes. The number needed to treat is a way of translating that difference, that absolute difference in a risk in a way that's more understandable to physicians. So it measures on average the number of people who need to receive treatment, the new treatment, in order to see one person benefit as compared to the standard of care or control group.

Q. And do the Kaplan-Meier curves have anything to do with the number needed to treat?

A. Yes. It's a direct -- you can calculate the number needed to treat directly from the Kaplan-Meier curves.

Q. So here we have an absolute value or delta of 2.3 percent at the end of the study. How would you figure out the number needed to treat?

A. The number needed to treat is then just simply one

divided by 2.3 percent. So it's around 43 or 44.
Q. Okay. And now the next term there, we see a number needed to harm. Do you see that?
A. I do.
Q. And what does that mean?
A. The number needed to harm is the same kind of concept but now referring to adverse effects or safety events. It measures on average the number of patients who need to be treated with the new drug in order for one more adverse event to occur than would have under the standard of care or control arm.
Q. And how is this number arrived at? What figures go into this number, number needed to harm?
A. Well, it's the same really as the number needed to treat. It's just one over the difference in the fraction of people who have the adverse event in the treatment group minus the fraction of people who have the adverse event in the placebo or control group.
Q. Okay. Next, did you analyze the data in the ExteNET trial?
A. I did not analyze the data, but I looked at the results of the trial. I did not actually do any reanalysis. I've never actually had access to the original ExteNET data, but I did analyze the reporting of the results.
Q. Okay. And let's take a look at a few more terms.

What's a randomized clinical trial, if you would?

A. A randomized clinical trial just refers to recruiting eligible patients to a study and randomly choosing which patient gets the new treatment and which person gets the standard of care or control, or placebo in this case, treatment.

So that decision is not made by the patient. It's not made by the physician. It's not made by the study investigator. It's made randomly usually by a statistician who provides a random code for providing which treatment gets -- which patient gets which treatment.

Q. Once a clinical trial ends -- and ExteNET was such a thing, a phase III clinical trial. Once a clinical trial ends, what happens then?

A. Well, usually when a trial ends and they're moving towards an analysis of the data, the data would be locked at that point, meaning that no subsequent changes can be made without due cause.

Then the data would be analyzed. The data would be analyzed and unblinded so that the statisticians analyzing the data then will know for the first time who got which treatment and then calculate the various concepts we've discussed such as the Kaplan-Meier curves.

Q. And something that was discussed earlier but you haven't discussed, what DFS means. What does that mean?

A. DFS is just an outcome. It just means during a period of follow-up, in this case two years, the event being looked at is did you have a reoccurrence or die during that period. That would be an event.

If you didn't have invasive reoccurrence and didn't die, then you would have survived the two years disease free and survived. So that's referred to as disease-free survival.

Q. Let's take a look at Exhibit 129.

MR. COUGHLIN: I'd move for its admission, Your Honor. I don't think there's any objection.

THE COURT: Without objection, 129 is admitted.

(Exhibit 129 received.)

MS. SMITH: No objection.

BY MR. COUGHLIN:

Q. So you reviewed this document; is that correct, Doctor?

A. I did.

Q. Okay. And it says in reference to attachments up at the top, it says -- the e-mail that covers it says it's the SAP. What is a SAP?

A. The SAP is a word that refers to the statistical analysis plan. This is a document prepared when the trial is being designed and before the data is collected and analyzed.

Q. Why is this document prepared before the trial?

A. Well, one of the reasons -- first of all, it sets out a

list of instructions and definitions about eligibility and the way data is going to be reported and measured and various instructions. It's also important that the intent of how the data will be measured, captured, and analyzed is not changed once people start seeing the data, because that opens the door to data manipulation.

And we don't want to have data manipulated once you start seeing results, changing the definition, or making any alteration to the way you're going to report or analyze the data. So that's usually set in stone before the data is analyzed.

Q. You reviewed this SAP; is that correct?

A. I did review the statistical analysis plan.

Q. And it seemed to be a good plan to analyze the data in this case?

MS. SMITH: Objection. Leading, Your Honor.

BY MR. COUGHLIN:

Q. Was it -- describe this plan in your own words.

A. The plan was to me relatively standard and straightforward.

Q. Okay. Let's take a look into the plan. If we turn to 13 of 61 at 3.1.1, can you tell us what the -- 3.1.1 describes the primary objective. Can you tell us what that is?

A. Yes. So in randomized clinical trials, there's usually

multiple objectives because you're spending a lot of money collecting data and recruiting patients and following them. But it's important that there is usually identified a primary objective because otherwise there's a tendency to search through all sorts of comparisons to find one you like and present that as the result. So that is standard not to do that by declaring a primary objective.

Q. Had you reviewed other statistical analysis plans before?

A. Yes, many.

Q. Had you participated or reviewed or analyzed other clinical trials before?

A. Yes.

Q. How many?

A. Well, I've analyzed many, countless numbers over my entire career.

Q. Hundreds?

A. I would say somewhere between 50 to 100. I probably analyzed actual raw data from a clinical trial.

Q. Okay. And if you take -- if we -- let's turn to part -- the next page over, which is page 14 of 61, part A. Can you tell us what part A refers to and why it's important?

A. This is describing the primary end point of the trial. First of all, it's giving you instructions for the follow-up period, two years, give or take 28 days.

It's capturing the fact that in addition to death, which is what OS stands for, overall survival, it's describing that all recurrent disease events will be the primary measure of outcome to compare the two groups.

Q. Okay. And was that done in this trial?

A. Yes.

Q. Did you analyze that data?

A. Again, I did not analyze the data. I just analyzed the way the data was reported by the company.

Q. You analyzed the way they reported the data; is that right?

A. Correct.

Q. Okay. If we flip over to page 16 of 61, there's a paragraph that starts: From global amendment three.

A. Yes, I see that.

Q. Can you tell us what that refers to?

A. This is actually a technical description of how the study was designed. So this is the sort of wish list before, what we think might happen, because companies and individuals designing trials need to think ahead as to what might happen because they need to determine how many patients to recruit in order for there to be a reasonable chance to detect the kind of treatment effect they would like to show.

If you only recruited ten patients to a randomized clinical trial, it doesn't matter how good the outcome is,

you're not going to be able to tell the difference between the treatment group and control group because there's just too much variation, not enough information statistically to be sure you've seen a real difference.

Q. And what are the two first numbers there, the .079 and .049 per person per year? What do those refer to?

A. So that's referring to the hazard, the incidence rate, how frequently the events were expected to happen, how frequently they expected to see occurrences, reoccurrences of the cancer in the first year, in the second year of the study in the placebo arm.

So that would be as a background what they thought. We're going to see this many events per hundred patients essentially.

Q. And they have a hazard ratio that they appear to be shooting for, and that's .667; is that correct?

A. Yes. So they were now declaring we want to recruit enough patients that if the rate of events was about 7.9, so that's seven to eight patients per hundred were likely to be a recurring in the standard of care arm in the first year; and then 4.9, about five in the second, so about 12 per hundred in the placebo arm.

How many patients will we need to recruit if in fact the difference is a reduction of risk of one-third. That was the target. This was before any data was collected.

This was the calculations needed to determine how many patients we're going to have to recruit, how big a trial do we need.

Q. Now, that target that is there, can you figure out what absolute delta that they were trying to achieve from those two numbers?

A. Well, you can't from the .667, because as others have said already, that's a relative comparison. But you can from the .079 and .049. You can calculate the absolute difference that you would get if the hazard rate were in fact .667.

Q. And what does this paragraph tell you about what the target might have been?

A. Right. So for that particular hazard ratio, with that anticipated event rate in the placebos, they were expecting to see or planning a trial big enough to detect an absolute risk difference of a little bit higher than four percent.

Q. Okay. And they achieved what?

A. Well, as we've heard, they actually achieved 2.3 percent.

Q. Okay. Let's take a look at page 24 of 61. Could you take a look at table 9.1, efficacy end points and analysis methods. Do you see that?

A. I do.

Q. Okay. Can you tell us how they were attempting what the difference methods to analyze the end point here, the primary

end point?

A. Well, as I indicated, this was part of the statistical analysis plan, so this is the recipe for the statisticians. Once the data is collected, once it is locked, once everything has been measured, how are they supposed to analyze the data and present it.

They're committing to this in advance so there's no monkey business once they've seen the data. And the three particular outputs that were in the recipe were the Kaplan-Meier plots, a test which produced the p-value, how you're going to compare the Kaplan-Meier curves, and a way of measuring that hazard rate ratio that we've talked about before and a way of providing some measure of how precisely that's estimated.

Q. Can you get the absolute difference from the hazard ratio?

A. No.

Q. Can you get the hazard ratio from the Kaplan-Meier plot?

A. Well, you can with many complex calculations. You can get the hazard ratio from the Kaplan-Meier plots but not the reverse.

Q. Okay. Let's take a look at page 35 of 55. Under 10 there it says safety evaluation. Is it common to have a safety evaluation in a clinical trial?

A. Yes, almost always.

Q. Does that relate to your NNH, number needed to harm?
A. Yes. The safety data would allow you to compute numbers needed to harm for any particular adverse event.
Q. And in this case you did both an analysis of a number needed to harm and a number needed to treat; is that correct?
A. I did.
Q. Okay. Had you done that before?
A. Yes.
Q. How many times?
A. Well, that's such a simple calculation, I've certainly taught it and done it hundreds of times.
Q. Okay. Let's flip over to what we'll call demonstrative number four. I believe this is a Kaplan-Meier curve that you prepared. Could you explain what this is?
A. Yes. This was in my report an illustration of trying to educate the reader as to what a Kaplan-Meier curve is and what it represents. This was actually taken from a real clinical trial, and it's comparing two treatment groups. I've just color-coded them here, one red and one blue.

On the left-hand axis, the Y axis, you'll see it's capturing that fraction or percent. So at the beginning, on the X axis when time is zero, 100 percent of the patients are disease free, have not had the event obviously because they haven't been followed.

As time goes on, you can see at six months in this

-- in these two Kaplan-Meier curves some people in the population, some fraction have started to have the event, and the Y axis measures the fraction who have not had the negative event, who are disease free and surviving.

You can see in the blue group at six months it's somewhere around 95 percent. In the red group it's somewhere around 90 percent at six months. And then it does that for each time point until the end of the trial.

In this case this was a three-year trial, 36 months. And what you want to look at when you look at those curves is ultimately the first thing is, is there one systematically below the other, because that reflects that a larger fraction are -- let's put it the other way around. A smaller fraction are staying disease free.

So in this case the red group is below the blue. That means a smaller percent are disease free or not having the event. So that's bad. You'd rather be in the blue group here than in the red group. Then, of course, the statistical challenge is to see are these differences in these plots, could these be explained just by random variation, or is this a systematic effect, in other words, a benefit for the red group systematically.

One thing I do want to point out, this is a case where you can see by the three years a very significant majority of the patients particularly in the red group had

suffered the event. So you're seeing the whole Kaplan-Meier curve here from zero to a hundred percent.

Q. You call it a curve, but it seems to be a jagged line. What is happening there?

A. It's jagged because the Kaplan-Meier curve has that little step. Every time an event happens, a single event even but sometimes there's multiple events in a given day if it's measuring events by the day, and that makes that little jag went down because now suddenly events have happened.

So the way I like to think of a Kaplan-Meier curve is to imagine a hurdle race, and you're measuring at the beginning. So there's a whole stack of hurdles, 36 hurdles maybe, out in front of a group of people racing.

At the beginning no one has fallen. They're all at the starting line. We've all seen this on TV in the Olympics. Then as the runners race, at the first hurdle a fraction of the runners might fall, and that will be maybe one percent of them fall. That means 99 percent are still running. That's what the Kaplan-Meier curve represents at the first hurdle, the first month, what percent have not fallen.

And then, of course, you go on to the next hurdle and then some more fall. So those little jags, if you will, at each hurdle some fraction are falling, meaning in this case specifically they have a reoccurrence of cancer or die.

Q. Okay. And at the end you get an absolute difference here; is that right?

A. In this case the absolute difference would be -- you get it, of course, all the way along. But at 36 months it would be the difference between the percent still free of an event at 36 months, which is about 25 percent in the red group and about 50 percent in the blue group.

So in this case the absolutely risk difference would be 25 percent, the difference between 50 percent and 25 percent.

Q. Once you have that absolute difference, you can figure out the number needed to treat and the number needed to harm?

A. Yes. It would be just one over that difference. In this case 1 over 25 percent is at four. So what that would mean in this case, in this example, would be you only need to treat four people with the red drug in order to see one of them doing better than if they had been blue.

So in other words, on average, for every four people you treat, one of them will do better than if they had not received the treatment.

Q. Okay. Now, you analyzed what the company -- in this case you analyzed what the company received as far as their efficacy report and their safety report in July of 2014; is that correct?

A. That is correct.

Q. And then you compared it to how that was reported to the public; is that correct?
A. Well, I don't know -- it was in that investor call in July of 2014, and I believe that was publicly available. Yes, that was the comparison I did.
Q. Okay. Let's take a look at Exhibit 123.
MR. COUGHLIN: I'd move for Exhibit 123 to be admitted. I don't believe there's any objection, Your Honor.
THE COURT: Without objection 123 is admitted.
(Exhibit 123 received.)
MS. SMITH: No objection, Your Honor.
BY MR. COUGHLIN:
Q. So have you seen this document before?
A. I have.
Q. Okay. Can you tell us what it is?
A. This is an e-mail communicating the results of the ExteNET trial from the statisticians at Puma to the -- to their bosses, I guess, to the people who are going to -- who wanted to know the results.
Q. And you accepted the date of July 17, 2014; is that correct?
A. Yes. The date of the e-mail is in July 2014, July 7th.
Q. And did you accept the attached or the validated results of the 304 primary and secondary end points?
A. Yes. The 3004 [sic] is just referring to the trial name

by a code.
Q. Okay. It's referring to the ExteNET trial by a code, a number code; is that right?
A. Correct.
Q. Okay. Let's go into this document, and if we could look at page 8 of 35. I believe page 8 of 35 reports the summary of the topline efficacy; is that correct?
A. Correct. So that was in these results provided to Mr. Auerbach and his colleagues at that time.
Q. Okay. Let's take a look at the top line of that. And I'd like you to go across that line and explain what those numbers mean for the hazard ratio, the p-value, as well as the absolute difference.
A. So these are the results of the ExteNET trial. This is the primary end point, DFS, as we discussed. And in the first two numbers they're giving that end of the Kaplan-Meier, that fraction who are disease free and surviving at the end of the two years.

So you can see for the neratinib group, the drug group, 93.9 percent had not had an event in those first two years. In the control or placebo group, the comparison group who did not get neratinib, the equivalent end of the Kaplan-Meier curve or percentage is 91.6. So slightly more in the control group had had the event.
Q. Actually, what is the absolute difference there?

A. The absolute difference that we've been talking about is just 93.9 percent minus 91.6 percent. And that is 2.3 percent. That's the absolute risk difference. That's the gap between the Kaplan-Meier curves at two years.

Q. Okay. Then we have the .67. Can you tell us what that is?

A. Again, that's a comparison of the rate at which these events -- we can see the events are happening. Some were between six to eight percent of the patients in the two groups. And those events are happening. They may be happening rapidly at the beginning and then slowing down, or slow at the beginning and rapid -- it doesn't really matter.

They're measuring that rate at which those people are having -- these women are having the events, and comparing the speed at which those events are happening in the neratinib group to the placebo.

The neratinib group pace at which the events was happening was two-thirds of the placebo group.

Q. So there was a 33 percent improvement if I -- how would you say that?

A. Well, so it's two-thirds in the neratinib group. So that's just reflecting exactly coming from the 93.9 and 91.6, not just from those numbers but from the whole curve. It's reflecting that slightly fewer of the neratinib patients were suffering reoccurrences or death than in the placebo group.

The quantitative comparison of that pace was two-thirds. So that says if -- whatever the rate was in the placebo group, it was one-third less. That's just one minus .67, .33, one-third less in the neratinib group than the placebo group.

Q. Let's take a look at table 3.02. It says DFS and DFS-DCIS rate summary. Do you see that?

A. I do.

Q. Can you explain what is happening there, what analysis is being done there?

A. Well, focusing just here on the top numbers, which again is the primary end point, that's disease-free survival, it's actually just breaking down those numbers we just looked at by what was the issue at the end of the first year.

And then you can see the 93.9 and the 91.6. That's what we just looked at. That's the two-year. But it also provides how wide the gap was at the end of the first year. You can see the gap there was -- I think it was previously shown this morning -- 2.2 percent at one year.

Q. Okay. And what about that second year?

A. At the end of the second year is the one we just talked -- that's at the end of the trial at this point. It was 2.3 percent was the difference between the Kaplan-Meier curves at two years.

Q. So were the curves widening?

A. Well, statistically, no. As Dr. Adelson commented, there's no difference statistically because that difference of .1 percent is in the range of what you would expect just from random variation. I wouldn't get excited if it had been 2.1 or 2.3. It tells me very little in any sense of a trend. So to me they're the same.

Q. All right.

A. So all of the benefit -- what this table tells you is all of the benefit of the drug in comparison to the standard of care group came in the first year, not in the second. There was no difference.

Q. In the second year?

A. Once you survive to one year, it made no difference whether you took neratinib -- of course, you weren't taking it at that point anymore. But at that point there was no difference between the neratinib group and the placebo group after the second year.

Q. The curves don't seem to be narrowing, though; is that correct?

A. As I said, it wouldn't -- if it had been the other direction by .1 percent, I would have had the same reaction. They're the same.

Q. Okay. Let's take a look at page 12 of 35. Do you have that?

A. I do.

Q. Can you tell us what that is?
A. So here now are the actual Kaplan-Meier curves. We've seen them before for the ExteNET trial, and there you can see it's starting at a hundred percent or one. They've actually labeled it here as one down to zero rather than percent, but that's like a hundred percent, one. Then it goes down to .98 is the next little tick on the wax. That's 98 percent, and so on.

Notice here you're not actually seeing the whole Kaplan-Meier curve down to zero because there's -- these are -- most of these patients are not having an event. We don't get that far down. So that's been truncated down there. People do that to try and highlight the difference, because otherwise it's hard on the eyes. These curves would look much closer together if you did the whole curve.

Q. You're showing 20 percent of the whole curve; is that correct?
A. That's right. You're only showing from .8 to 1.
Q. So it accentuates or accents the curves?
A. It just allows your eye to see the difference.

MS. SMITH: Objection. Leading.

THE COURT: Hold on just a moment. There was an objection. Sustained.

BY MR. COUGHLIN:
Q. Can you tell us what the end of those curves would

represent?
A. The end of the curves at two years, just before 25 months on the X axis, that's the percent who have not had the event in the two groups. The neratinib group here is the upper one. It's not labeled here, but that's the neratinib group. The lower one is the placebo group.
That number on the Y axis at the end for the neratinib group would have been the -- I think it was 93.9 percent that we just looked at. And the equivalent for the end of the curve for the lower one, the placebo group, is 91.6. And you can see that on the Y axis. That's where those numbers came from in the tables.
Q. And you prepared a demonstrative, is that right, demonstrative PDEM05; is that correct? This is the curve?
A. I did, yes. So, yes. So I made it a little clearer on this curve because that particular curve in the analysis results wasn't coded, so I just coded it in color because I find I'm getting older and my eyes respond to color better.
Q. So it's still the same 20 percent that was in the earlier?
A. It's still the same. I just copied the curve and colored it red and blue. The blue here is the placebo group or standard of care group. The red is the neratinib group. There's the -- I've marked on there the end points specifically so you can see where they're coming from, the

93.9 percent and the 91.6 percent. And there's the difference between the neratinib group and the placebo group.

And on the right there, that's just so this doesn't become mystical in any way. There's no magic in this here even though it keeps me in a job. The numbers of people suffering the events were 70 in the neratinib group. You can see that on the right. And 109 in the standard of care or placebo group. That's the numbers and when they happened that allow you to calculate these curves.

In the bottom of the --

Q. Let's talk about those two numbers for a second.

A. Okay.

Q. Those two numbers look very similar to the hazard ratio of 67. Are they? Are they related?

A. Well, they're somewhat related. It's not far off here. If you look at what, you know, what's the difference between 70 events and 109? That's roughly a reduction of a third. If you take 109 and reduce it by a third, you get pretty close to 70.

So there's no magic here. That's not exactly how the hazard curve is computed because we statisticians know that that can be inaccurate to do that calculation. Why? Because you'll see on the bottom of the curve the number at risk. You can see at the beginning there was essentially 1,410 in each group -- not quite, give or take a few that

were not allowed to participate for one reason or another. But it's about 1,409 in the neratinib group and 1,412 in the placebo group. You can see by 20 months there's only a thousand or so in each group.

That's -- some people have dropped out because they've had a reoccurrence, but most of those have dropped out for other reasons that we've heard about earlier this morning. They withdrew from the study. They were no longer being followed. We didn't know what would be happening to those.

That happened at a slightly higher rate in the neratinib arm than the placebo arm, so the Kaplan-Meier adjusts for that rate of dropout. So the hazard ratio is .67, but you're not far off if you just compare 70 to 109.

Q. Let's take a look at your next -- you then did the number needed to treat --

THE COURT: Before we do that, we are going to go until noon right now. But we're going to take just a brief break and let the jury stand and stretch. We're going a little bit longer without a break, so we are going to go to noon before we take a formal break. But if the jury just wants to stand around and stretch for a couple of minutes, you may.

(Pause in proceedings)

THE COURT: All right, sir. Please continue.

BY MR. COUGHLIN:

Q. Doctor, I'm going to move over to your next demonstrative, PDEM06. We've talked a little bit about this number needed to treat. Can you explain what it is?

A. Yes. So this is just again a way of understanding what that absolute risk difference means and how you can translate it into a way of thinking. This is the definition I gave earlier.

So it's on average, in this case, the number of women who need to be treated with neratinib in order to see one of them do better than if they just had the standard of care. So if this were a very small number, that would mean the drug was particularly efficacious.

You immediately start treating a handful of women, you see at least one of them doing better. If it's a very large number, it doesn't mean it's bad. It just means it's not the difference between the active -- the drug and the placebo group is not that great.

Q. You're not offering an opinion whether it's bad or good; are you?

A. No, not at all.

Q. Let's take a look at your next demonstrative, 07. Can you explain how you arrive at the number needed to treat?

A. So this is just going again through the calculation. So to calculate the number needed to treat, you need to know the

absolute risk difference. At this point in case, two years. You don't actually need to know the hazard rate, which is .67, hazard ratio, .67. So there you can see in the blue part at the bottom, there's the two pieces of information you need from the Kaplan-Meier curve.

And I should in defense of my own job, I should say calculating Kaplan-Meier curves does require a fair amount of technical skill and statistical software. It's not trivial. There's the numbers you need from the Kaplan-Meier curves that we already saw, the 93.9 percent in the neratinib group and the 91.6 in the placebo group. That difference we've heard before is 2.3 percent.

Once I have the 2.3 percent, then calculating the number needed to treat is straightforward.

Q. And how do you do that?

A. Well, I think it's on the next demonstrative. I did it --

Q. The next demonstrative, number eight?

A. Yeah. So you just take that 2.3 percent and divide it into one. So one over 2.3 percent, 2.3 percent is 0.023. You just get your calculator. One divided by .023 is exactly or approximately 43. So the -- the number is what it is, but the interpretation that one understands the number is important, that says that you need to treat on average 43 women, eligible women, with neratinib in order to see one of

them doing better than if they had only had the standard of care.

Q. Now, you're not arguing against the hazard ratio that they had here of .67; are you?

A. No. It's a different comparison number. This is just another number. The literature shows that physicians understand the number needed to treat more effectively than they do the hazard ratio.

Q. Okay. Let's go to the next exhibit, Exhibit Number 128. No. I'm sorry. Exhibit 124.

MR. COUGHLIN: I'd move for the admission of 124, and I believe there's no objection, Your Honor.

MS. SMITH: No objection.

THE COURT: Wait a minute. 124?

MR. COUGHLIN: 124.

THE COURT: It was already admitted, I think. In any event, it's admitted.

MR. COUGHLIN: Oh, it came in earlier. Sorry, Your Honor. Thank you.

BY MR. COUGHLIN:

Q. If we take a look at Exhibit 124, did you examine this document?

A. I did.

Q. And this is dated July 18, 2014. Did you accept that date?

A. Yes. So that's the date just beyond the e-mail we looked at before at stretch break. This is July 18th.
Q. One day later?
A. I can't remember. Is it one day? It's very close, yeah.
Q. Tell us what this document is.
A. So this is now a separate communication from the statistician, one of the statisticians or epidemiologists studying the data. The previous one transmitted the efficacy results. This is now transmitting the safety results for the ExteNET study.
Q. Okay. Let's turn in to this document -- and it says they are now validated. Did you accept that?
A. I did.
Q. If we turn in to this document and we will go to page 8 of 272, what are AEs?
A. Adverse events. So these are the toxic -- results arising from the toxicity of the drug in the neratinib arm or just in general any event that happens during the study. The adverse events, this is obvious here in the placebo group also.
Q. Okay. Let's take a look at the grade-three diarrhea. Can you see what that is?
A. I don't see grade-three diarrhea on this slide. Oh, there it is. Thank you. I was looking just at the row --

the top row is diarrhea. You can see the list of adverse events, some of which we've heard about before. But the top row is diarrhea, and the two columns -- the first column is just any diarrhea, and the second column is the more severe diarrhea, so-called grade-three diarrhea or higher, grade three or grade four.

That tells you -- that second column tells you that 39.9 percent of the neratinib patients suffered grade-three diarrhea at some point during the two years, 562 actual women. On the right-hand side, you're seeing the equivalent numbers for the placebo group, and you can see in the placebo group only 23 of the placebo patients suffered severe diarrhea, or 1.6 percent.

Q. Let's go to the next page, page 9 of 272. I think the grade-three diarrhea is just a repeat from the page before, but I'd like to direct your attention down to grade three and what those numbers are at the bottom.

A. Okay.

Q. The 2.0, tell us what those numbers indicate.

A. Well, this is actually trying to record or report the median duration of diarrhea events in days. So when you have an episode of diarrhea, how long did it last? We actually heard different numbers this morning of five days, but this particular slide deck shows two days. It sets the median. That just says half the patients had longer episodes of

diarrhea than two days and half had less than two days.

I do want to emphasize here, because I was getting confused this morning, this is an episode of diarrhea, meaning not -- that's defined specifically. You start having diarrhea and it ends. You recover. You stop having diarrhea for a bit. It doesn't mean you don't have another episode.

And, of course, in this trial many of these patients, these 500 or so patients that were suffering episodes of diarrhea, had more than one. It's not that you only had diarrhea for two or three or five days during the entire two years. It's just one episode lasted that long. Then two weeks later you could have it again.

Q. So let me ask you, I'm trying to figure out. It looks like the median -- is that what you said?

A. The median.

Q. That the median between the placebo arm and the neratinib arm are the same. Are they the same?

A. Well, that's just saying when a patient has grade-three diarrhea, the median is about the same in the placebo group. But if you look at the numbers above, very few patients in the placebo group had grade-three diarrhea.

Q. 1.6 --

A. Yeah, 23 out of over a thousand. So that was very unusual in the placebo group and very common, 40 percent, in the neratinib group. That -- by the way, that difference

reflects that this has been caused by the drug.
Q. Let's flip over to the next page, page 10 of 272. It talks about treatment discontinued, and it has diarrhea at the top. Can you tell us what those numbers mean?
A. Well, these are characteristics of people who had diarrhea in the -- or were caused by diarrhea. Sometimes people would try and reduce the dose. You can see that's the last row. Did you have a dose reduction?

You notice ironically in the placebo arm, eight women had a dose reduction because of diarrhea even though in fact they were just getting a lactose pill. They were having -- diarrhea was being caused presumably by something else.

But in the third one, the treatment discontinuation, that means that the patient suffered from diarrhea sufficiently that that was the reason they asked to stop taking their treatment. And you can see in the -- that was over 200 patients, women, in the neratinib arm, about 17 percent of the entire group, stopped taking the drug because of the diarrhea side effects they were suffering.
Q. Okay. Then finally we'll go to the last page of that -- not the last page. It's page 266 of 272.
A. Yes. I have it.
Q. Can you tell us what that refers to?
A. This is a similar talking about adverse events, as you

can see from the title. The one that's highlighted there is now looking at the same concept. How many women stopped taking the treatment now, not just because of diarrhea but for any of the adverse effects? There were others in there that we didn't focus on -- nausea, vomiting, and so on.

In that case almost 400 of the original 1,400 patients stopped taking the treatment during the year, the first year of the study, because of the toxic effects they were suffering. And then there's the similar comparison number in the placebo arm.

Q. Okay. Let's take a look at your next demographic, number ten.

A. I have it.

Q. Can you explain what's going on here?

A. Well, this is the numbers you need to now compute the number needed to harm. Remember, the number needed to harm is on average the number of women that need to be treated with neratinib to see one extra adverse event than had they been treated with a placebo. It's a measure of how common you get the adverse events more than on the neratinib than you do on the placebo.

So just as before, to calculate the number needed to harm, I need to know the fraction of women who suffered the adverse event. And what's being boxed in red there is the specific severe diarrhea, grade three or higher. That's

39.9 percent of the neratinib patients suffered grade three or higher or severe diarrhea. I also need the same number to compare in the placebo group, and there it is. It's 1.6 percent, represents those 23 patients, 23 women.

The difference between those is the difference in risk of severe diarrhea comparing neratinib to placebo. That difference is 39.9 minus 1.6. That's about 38 percent. That's in the little writing at the bottom, 40 minus two percent essentially.

To do the number needed to harm, I just need to take one and divide by 38 percent. You can see that in the text following that, so I'm just walking through the calculation here on the demonstrative. And that's 2.6.

So that means on average, if you treat less than three women with neratinib, you would expect to see one of them having a case of severe diarrhea than you would have seen had they not had neratinib.

So, in other words, it was very common. It's just reflecting that very common, that 40 percent, and much more common than in the placebo group.

Q. Let's take a look at -- let's move to the next, Exhibit 103.

MR. COUGHLIN: I'd move for the admission of 103. It might have already been moved in. No?

THE COURT: Without objection 103 is admitted.

(Exhibit 103 received.)

MR. COUGHLIN: And with it goes an audiotape, Exhibit 748. And there's no objection to that either, Your Honor.

THE COURT: Without objection 748 admitted.

(Exhibit 748 received)

BY MR. COUGHLIN:

Q. Now, part of your task in this case was to take a look at the studies we just reviewed and then also compare them to the numbers that Mr. Auerbach gave on July 22nd, 2014; is that correct?

A. Yes. So now this really reflected the chronological order of my work, so I had looked at the results from the ExteNET trial. I now had a pretty good idea of the efficacy, the risk difference, the absolute risk difference, the relative hazard. I knew all that.

Now I turned to the investor call where that information was being released to some extent.

Q. Okay. Let's take a look at -- you prepared some demographics for that, right? Is that correct, some slides?

A. Yes.

Q. So let's take a look at your demographic number 11. What's on this graph?

A. Well, on the top from my memory -- because I'm getting up there and I don't remember numbers the way I used to --

that's just a refresher of what we've just seen of the results of the trial. These were the results that Mr. Auerbach had received in the July dates that we just looked at, not long before this call, so they were fresh in his memory.

There's the topline. There's the DFS, the primary outcome. We've seen that already, 93.9, 91.6. There's the hazard ratio and the p-value. Then at the bottom we now are turning to what actually was said during that call.

Q. You're not taking any issue with this 33 percent improvement; is that correct?

A. Correct. And that was released in the press release before -- just before the call. And that was accurately reflecting that .67. There you can see it. It came from those output. There's the .67 in the first row of primary outcome for the trial for DFS. So there we see that that's where that .67 number comes from, and it's accurately reflected in the press release and in the call.

Q. Now, the only place that this -- where is the only place this number, this hazard ratio of .67, correlates to the Kaplan-Meier curve or the absolute difference?

A. That hazard ratio you can see is coming from the DFS, the primary outcome. We're talking about the primary outcome for the entire trial. That's what the .67 refers to. You get different results as you tweak different subgroups and

different definitions of outcome that were not the primary one.

Q. But that's the only one that the .67 applies to; is that right?

A. That is correct.

Q. And that's the absolute difference, the 2.3?

A. That's the one that goes along with the absolute difference of 2.3 percent, yes.

Q. Let's flip to your next demographic, number 12. Tell us what this reflects.

A. So this demonstrative, again it's got the information from the results at the top. It's a refresher. There's the DFS in the first line. Then this is now -- at the bottom parts of the investor call which went beyond discussing the hazard ratio into questions about the absolute risk.

Q. Let's listen to that clip, clip number four.

(Portion of audiotape recording played)

MR. COUGHLIN: Stop that right there.

You can play it. It's only a sentence.

(Portion of audiotape recording played)

BY MR. COUGHLIN:

Q. Let's stop and go over exactly what was asked. So the first question that was asked, one is, give us a little bit of a sense of what was the DFS on the control arm first. And then they asked about safety.

Let's talk about the efficacy first. What was Mr. Auerbach's -- what was Mr. Yaron Werber's more specific question as to that?

A. So this was the very first question I believe in the investor call. They immediately wanted to know what's the absolute risk in the placebo arm, because the relative hazard rate of point -- the hazard ratio of .67 does not convey that information, as we discussed.

To understand the impact of any drug, you need to know the absolute risk, not just the relative comparison.

Q. So he says: And around 86 percent. And Mr. Auerbach says: I would be comfortable with that number. What does that 86 percent compare to if you look up into the placebo?

A. So Dr. Werber says he's guessing because he's told it's been in line of previous trials. So as we saw yesterday in the opening statements, he was guessing around 86 percent.

Then Mr. Auerbach confirms, yes, I'm comfortable with that number, not referring to the range in my opinion, the mid to high 80s, but the 86 percent. That number to me is the 86 percent.

And so Dr. Werber would move away from that assuming that the absolute risk, the disease-free survival, 86 percent of the placebo group did not have the event in the two years. And you asked me to compare that to what the actual data was that's in the top there.

The truth was it was 91.6 percent, or 92 percent. So he was off.

Q. I can take the 86 percent -- how do you figure out, if you're given the 86 percent and you're given the hazard ratio of .67, can you figure out what the absolute difference is?

A. Yes.

Q. How?

A. So we've just established Dr. Werber asked the question about the placebo disease-free survival rate. The answer came back comfort with the number 86 percent. The truth was 91.6 percent. We already -- they already knew from the press release and the earlier statement --

Q. Let me stop you from right there. You're not opining about the truth or anything like that? You're just talking about --

A. The data. When I say the truth, I mean the data.

Q. The data.

A. Yeah. The data was 91.6 percent.

Then to calculate, well, what must have been the disease-free survival proportion in the neratinib group? You take the 86 percent, and that means 14 percent actually had the event. If 86 percent didn't have the event, that means 14 percent did. And you said, wait a minute. I've been told that that's reduced by one-third, by the drug in the neratinib arm. So 14 percent gets reduced by one-third.

Now, a third of 14 is four and two-thirds. So that means when you take that off of 14, the number who got the event in the neratinib arm had to be between nine and ten percent. That means if you take that from a hundred, that means 90 to 91 percent had to be disease-free in the neratinib arm.

And they can see that's exactly what Dr. Werber, he's obviously doing that calculation in his head quickly. It's not hard. He comes back immediately saying, well, if you said 86 percent in the placebo arm, and we know the hazard ratio is two-thirds, that tells me it's 90 or 91 percent. Just doing exactly what I did.

And then Mr. Auerbach said, yes, he did that calculation correctly. Given the numbers we gave, that's the reasonable number.

THE COURT: Let me ask, how much longer with this witness?

MR. COUGHLIN: I think, Your Honor, we should take a break now, and I'll come back with another 15, 20 minutes.

THE COURT: I agree. So we'll take our 90-minute break and be back at 1:30. Thank you.

Remember, don't discuss the case. Keep an open mind. Don't research the case.

THE CLERK: All rise.

(Open court - jury not present)

(Recess taken from 12:04 p.m. until 1:30 p.m.)

(Open court - jury present)

THE COURT: Welcome back, everyone.

You may continue.

MR. COUGHLIN: Thank you, Your Honor. With the break I was able to cut it down a little, so hopefully I'll be a little quicker.

THE COURT: Well, you know, actually with complicated subjects, quicker because you have less to say but not quicker because you say it faster.

MR. COUGHLIN: I agree, Your Honor.

THE COURT: Okay. Go ahead.

THE WITNESS: If I could, I left my binder there. Could someone bring it up to me? Thank you. Thanks a lot.

BY MR. COUGHLIN:

Q. Doctor, I think what we were doing now is that after reviewing the biostats that were in the reports from Puma, we were comparing those to the statements of Mr. Auerbach on July 22nd.

So I'd like to go back to that, and I'd like to go to the graphic number 15. I'd like you to tell us what that graphic represents.

A. Yes. So before the break we were discussing the percentage of neratinib patients who chose to discontinue treatment because of diarrhea, grade-three diarrhea. And

this particular demonstrative shows the percentage of neratinib patients who discontinued treatment with neratinib because of any adverse effect, not just including diarrhea.

And you can see on the fifth row of this table that the data showed, the safety data showed that was received just before this call, that that number was 27.6 percent. So by -- just under 400 neratinib patients ceased to take their treatment because they couldn't tolerate side effects.

Q. And let's hear --

THE COURT: May I just say, the demonstrative we're speaking about is projecting onto the screen, Exhibit 124 and Exhibit 103.

MR. COUGHLIN: Thank you, Your Honor. I think both of those have been admitted.

If we could listen to Mr. Auerbach for a second.

(Audiotape recording played)

BY MR. COUGHLIN:

Q. The graph up above that you were referring to, Exhibit 24, which has the 27.6 percent, that was in the report he received on the 18th on the safety data?

A. That is my understanding, yes.

Q. And if we go to the next slide, it is page 10 of 272. You don't have it in there. You have it in the bigger part. But page 10 of 272, 127 [sic]. You don't have to -- 124, sorry.

THE COURT: Page 10 of Exhibit 124. You can see it on the screen, I think.

THE WITNESS: Yes. I'm fine.

BY MR. COUGHLIN:

Q. So we just talked about overall discontinuance as to AE. And can you tell us what the treatment discontinuation as to diarrhea was?

A. Yes. So this was just due to diarrhea of any form, and it was about 230 or so neratinib patients stopped treatment because of diarrhea. That's reflecting 16.8 percent of the original 1,200 or so patients.

Q. So is even that number higher than what Mr. Auerbach said the total was?

A. 16.8 percent is definitely higher than five to ten percent.

Q. And then you have a summary slide, and it's graphic number 16.

A. I have it.

Q. Okay. Can you explain what you were trying to communicate here?

A. So this just summarizes our conversation. The top part of the demonstrative reflects the trial results with regard to the success of the trial in terms of efficacy, how well the drug was preventing reoccurrence.

It shows that the trial results reflected an

absolute difference of benefit, how much -- what fraction the patients benefited because of neratinib, the 2.3 percent as we discussed this morning. The investor call, however, left the impression that that rate, that absolute difference was four to five percent, as we also discussed this morning --

Q. Okay.

A. -- the number needed treat. Therefore the data showed 43. On average you need to treat 43 women with neratinib to see one less have a recurrence than under placebo. But the investor call left the impression that that number needed to treat was somewhere between 20 and 25.

Q. Why is that number important?

A. Well, that shows that the number needed to treat -- the people listening to the information got it wrong by a factor of two. And the number needed to treat is just a measure of the impact of the drug, how many patients will need to be treated to get a difference. And that will influence physicians' assessment of the impact of the drug.

Q. Okay. And let's take the number needed to harm.

A. So that was the numbers we were just discussing about severe diarrhea -- well, not -- we were discussing this morning the 40 percent or 39.9 percent got severe diarrhea under neratinib as compared to 1.6 percent with placebo.

That reflected a number needed to harm of 2.6. So three women treated with neratinib on average will produce

one more case of severe diarrhea. The 29 to 30 percent that was the answer to that question or an answer given regarding diarrhea gets the number needed to harm higher at 3.5, 3.6, not quite double in this case but about 30 or 40 percent higher.

And then the final row is just the discontinuation of treatment. Those were the numbers we were just discussing. The 16.8 percent discontinued because of diarrhea; 27.6 percent of neratinib women discontinued because of any adverse effect, whereas the investor call gave the impression that number would be anticipated to be five to ten percent. So that was off by a factor of more than two if you look at all adverse effects.

MR. COUGHLIN: Thank you, Doctor. No further questions.

THE COURT: All right.

Cross-examination.

MS. SMITH: Your Honor, may I approach the witness with an examination binder?

THE COURT: You may.

CROSS-EXAMINATION

BY MS. SMITH:

Q. Good afternoon, Dr. Jewell.

A. Good afternoon.

Q. I'm Colleen Smith. You may remember me as the person

who took your deposition?
A. Yes.
Q. All right. Now, Dr. Jewell, earlier today you testified that your area of expertise is biostatistics, correct?
A. Yes.
Q. You aren't an expert in what should be disclosed to investors; are you?
A. No.
Q. You have no particular expertise with communications with investors?
A. No.
Q. You also have no expertise in what is customarily disclosed in public company press releases?
A. No.
Q. And you have no expertise with respect to what is customarily disclosed in an analyst call?
A. No.
Q. You have no expertise as an analyst?
A. No.
Q. In fact, you have never even participated in an analyst call; have you?
A. No. I'm a statistician at a university.
Q. So what would be meaningful to an individual investor is beyond the realm of a biostatistical expert such as yourself, right?

A. I have no opinion in what's meaningful to investors on an investor call.
Q. Now, you were asked to comment on some exchanges with analysts in the analyst call, Exhibit 103, that we have just reviewed, and you just testified that some of the statements on that call left a certain impression. Do you remember that testimony?
A. Yes.
Q. But you don't have any expertise that would qualify you to offer opinions about what an analyst might be thinking in connection with a question on an analyst call; do you?
A. No. I have no opinion what they may have been thinking when they asked the questions. I can only go by the questions asked.
Q. And you've not undertaken any investigation or review to determine what analyst investors actually took away from those exchanges on the analyst call?
A. Well, I hadn't seen any of that information at the time of my deposition. I subsequently have seen documents about how some of the information was transmitted from analysts on that call.
Q. But before forming your opinions in this case, you did not review any of those documents?
A. No. It has no bearing on my opinion.
Q. And you didn't review -- before forming your opinions in

this case, you didn't review any of those analyst reports?
A. No. It has no bearing on my opinions.
Q. Now, you're not offering an opinion about when information needs to be disclosed to investors, correct?
A. No. I've already answered that I'm not an expert on investor calls.
Q. All right. Let's talk about your opinions with respect to the number needed to treat. The number needed to treat is something you calculated, right?
A. Yes. It's simply one over the 2.3 percent. So it's a very simple calculation in that case.
Q. Sure, but that's your calculation which you walked through here earlier today with the jury, correct?
A. Correct.
Q. There was no discussion of the term number needed to treat on the July 2014 analyst call; was there?
A. No.
Q. And none of the analysts asked any questions about the term number needed to treat; did they?
A. No. They only asked about the difference in the risk essentially.
Q. That phrase doesn't appear anywhere in the analyst call transcript?
A. No. The number needed to treat is simply a way of making that information about difference in benefit more

understandable to a lay person or a physician. So I find it helpful. But if you don't, that's fine.

Q. It's not in the analyst call?

A. No.

Q. And you aren't offering the opinion that the number needed to treat was a prespecified end point of the ExteNET trial; are you?

A. Well, as I testified at the deposition, the Kaplan-Meier was prespecified in the difference in benefit. The 2.3 percent comes directly from that. And the number needed to treat is a five-second calculation beyond that.

So if the information in the statistical analysis plan is -- was divided, which it ultimately was, the number needed to treat is there also. It's not a new number that needs any new information about the data.

Q. So you were deposed in this case, as we've already established. And when you were deposed, you took an oath to answer the questions truthfully; is that correct?

A. Correct.

Q. I'd like to direct your attention to your deposition transcript, which should be in the white binder in front of you.

A. Uh-huh.

Q. If you would turn to page 102, lines 17 to 20.

MS. SMITH: Your Honor, may I play a video clip?

THE COURT: Any objection?

MR. COUGHLIN: Your Honor, I think she's first got to ask him if he remembers what the context is. If she wants to impeach him with it, she can do that. But it's probably quicker just to play it. So, no objection.

THE COURT: Counsel, I think you are correct, and I appreciate your work towards efficiently moving forward.

Play it.

MS. SMITH: Thank you, Your Honor.

Clip number 23, please.

(Videotape recording played)

BY MS. SMITH:

Q. Did I ask you that question and did you give that answer?

A. Yes, but you didn't play the next part of the --

Q. The answer to my question was yes?

A. I'm answering the question.

THE COURT: Let's have the next question. Your attorney may ask further questions if he wishes.

THE WITNESS: Okay.

THE COURT: Actually, no. Let me restate. Plaintiffs' counsel may ask further questions if they wish.

MR. COUGHLIN: Thank you, Your Honor.

THE COURT: That's an important point.

Go ahead.

BY MS. SMITH:
Q. Dr. Jewell, you aren't offering any opinions about whether -- well, let me back up. You calculated the NNT for the ExteNET trial as 43, correct?
A. Correct.
Q. And you aren't offering any opinions about whether 43 is a tolerable number needed to treat; are you?
A. No. That's for physicians to decide, not me.
Q. And you're not a physician?
A. No. I already said that.
Q. Let's talk about your opinions with respect to the safety profile. In one of your slides -- I think it was demonstrative number three -- you stated that you had analyzed whether the statement accurately describes the benefit risk profile of neratinib; is that right?
A. Could you repeat the question?
Q. Sure. If you want to take a look at it, you can. It's slide number three of your demonstrative slides. You stated that you analyzed whether the statement accurately describes the benefit risk profile of neratinib in the ExteNET study?
A. I'm not sure what you're pointing --
Q. Sure. Could you look at slide number three of your demonstrative in the black binder.
A. Sorry. I got it now.
Q. Okay. And if you look at the bullet points there toward

the bottom of the page, one of your statements says that you analyzed whether the diarrhea rates as reported on the July 22, 2014, call accurately described the benefit risk profile of neratinib. Do you see that?

A. I do.

Q. But isn't it true that you actually have no opinion about the risk benefit profile of neratinib?

A. Well, I'm just -- you're saying that's the basis of a risk profile. I'm not saying I'm going to opine about the actual decisions that a physician or a patient might make, but just the information about safety is part of the benefit risk profile. That's all I meant by that.

Q. So you have no opinion about the risk benefit profile?

A. As I indicated, that's for physicians and patients to discuss.

Q. So you aren't offering any opinion about what a meaningful clinical benefit would be?

A. No. That's again for physicians and patients to discuss.

Q. All right. So then with respect to the number needed to harm, again that was something that you calculated, Dr. Jewell, correct?

A. Correct.

Q. And that's not a number or that's not a statistic that was discussed on the July 2014 analyst call; is it?

A. No.
Q. That term was not used by any of the analysts on that call?
A. No.
Q. No questions were asked about the number needed to harm?
A. No. The questions were asked about diarrhea rates or discontinuation from adverse events.
Q. Nowhere in the transcript does the phrase number needed to harm appear, right?
A. No.
Q. Now, with respect to your number needed to harm, you calculated that based on the diarrhea rate in the ExteNET study, right?
A. Correct.
Q. You didn't calculate a number needed to harm based on any other studies in which Imodium prophylaxis was used; did you?
A. Well, Imodium prophylaxis was used in the ExteNET study, but I didn't do the number needed to harm for any other study.
Q. I thought your testimony, Dr. Jewell, was that Imodium prophylaxis was not used but that Imodium may have been prescribed in another fashion.
A. I'm not sure if I understand the difference between prescribed and used in another fashion.

Q. Let me ask the question differently. Isn't it true that Imodium prophylaxis was not part of the clinical trial protocol for the ExteNET study?
A. I wouldn't -- I don't agree with that statement, no. That is not my understanding. I didn't opine on it in my report, but that's not my understanding.
Q. Okay. So you think that Imodium prophylaxis was part of the clinical trial protocol for the ExteNET study?
A. Well, I can't speak to the Puma version of the protocol. The Wyeth version of the protocol specifically mentions diarrhea medications being made available to patients from day one.

But what's really important is what actually happened in the trial, and certainly Imodium was used by patients in the ExteNET trial. So I'm confused as to why you would say it wasn't.
Q. All right. You didn't review that aspect of the clinical trial protocol?
A. I just told you what I know of my memory from the documents. I would have to go back to the Puma -- the last amendment. There was, as you know, many amendments to the protocol over the years. I can remember the first one, which was the Wyeth protocol, but I can't remember today if they maintained that part of the protocol in the last amendment.
Q. You haven't done any analysis to -- in terms of

understanding what investors knew about the diarrhea rates associated with neratinib; have you?

A. No. You would have to ask investors to know what they knew, not me.

Q. Earlier today you also mentioned validation. You haven't done any work to determine whether or not Puma's safety data had in fact been validated by July 22nd, 2014; have you?

A. No. I can only report on what I read from Puma documents regarding the validation. I personally have not been able of course to confirm or deny those.

Q. And you haven't reviewed all of the documents in this case that are relevant to that issue?

THE COURT: Hold on. Repeat it and slow down a bit.

BY MS. SMITH:

Q. You haven't reviewed the documents in this case that would allow you to form an opinion as to whether the validation procedures had been completed or not by July 2014?

A. No. I have no additional information beyond what Puma reported.

Q. Now, you spent some time talking about the discontinuation rates due to diarrhea and adverse events. The discontinuation rates -- a discontinuation rate means that a patient stopped taking the treatment, and in this case

that was neratinib, right?
A. That is correct.
Q. Okay. And those are discontinuation rates, not dropout rates, right?
A. Well, there's a little bit of a confusion in the investor call. People use those word differently, so you have to be specific about what you mean by a dropout rate.
There was a discussion this morning with the first witness. If you're using dropout rate to say complete withdrawal so no further information was available on that patient, that's different from treatment discontinuation where you may stay on the trial, still information about cancer recurrence maybe being measured, but you're not taking the treatment any longer. That's important to make that distinction.
Q. Right. Okay. So a discontinuation rate can be different from a dropout rate where a patient has completely withdrawn from the study and you have no information about that patient?
A. That is correct. Both, of course, occurred in the trial, and the numbers are known for both of those characteristics.
Q. Okay. Well, let's actually take a look at Exhibit 124. That should be in your black binder. If you would go to page 10 of -- page 10. If you look at the fourth one down on this

table, it says withdrawal from study, correct?
A. Correct.
Q. Okay. So this would be the number of patients who withdrew from the neratinib trial due to diarrhea, right?
A. I assume that is people who were completely lost to follow-up and indicated that they were leaving because of diarrhea, correct.
Q. So people who dropped out of the study due to diarrhea?
A. Meaning that they ceased all -- yeah, all measurements were ceased from these patients, as compared to the treatment discontinuation, which is the line above, which means they wished to stop the treatment but they were willing to stay in the trial with regards to follow-up.
Q. Okay. And the number here for the number of patients who withdrew from the study or dropped out due to diarrhea is 1.6 percent?
A. Correct.
Q. That's a very different number from 27.6 percent?
A. Well, they're completely different events. As I say, you may have a toxic reaction to a drug and wish to stop treatment, but you may be perfectly willing for your follow-up visits to record whether you have a cancer recurrence. Those are completely obviously quite different decisions.
Q. Right. And 1.6 percent is not the same as 16.8 percent?

A. Is that a question?
Q. It is.
A. Yes. They're different numbers.
Q. All right.
MS. SMITH: You can take that down. Thank you.
BY MS. SMITH:
Q. Let's talk a little bit about the Kaplan-Meier curves. You started off your testimony here today, I think, by offering a tutorial of sorts on the Kaplan-Meier curves.
THE COURT: Slow down a bit.
MS. SMITH: Thank you, Your Honor.
BY MS. SMITH:
Q. The Kaplan-Meier curve -- and then you looked at Kaplan-Meier curves for the ExteNET trial; is that right?
A. For the primary outcome I did, yes.
Q. And those were Kaplan-Meier curves for two years?
A. They were. That is correct.
Q. And you are not offering any opinions about the information beyond two years; is that right?
A. Well, you can ask me a question about it. I know the information that was available at the time beyond two years, but I didn't -- I was not asked a question about that this morning.
Q. So it wasn't part of your charge to look at the information past two years, right?

A. No, not specifically, but I have seen the documents regarding the information available beyond two years, within the third year, for example. But I haven't been asked a question. So until I'm asked a question, I won't say anything.

Q. Well, you say you've seen the documents, but didn't I hear you testify earlier that you haven't actually seen the ExteNET clinical trial database?

A. Yes. So there's a difference between database, which is huge for this trial, information on 2,800 patients, and documents that Puma provided regarding that data. I've seen the latter but not the former.

Q. So you haven't done any analysis in the ExteNET trial database to evaluate what's happening with the Kaplan-Meier curves after two years?

A. Let me say again, I've not been -- I've not had access to the original data, so I can't reconstruct and show they're correct or not. I have taken them at face value. But I've also seen Puma documents that go beyond two years describing, for example, the number of additional cancer reoccurrences in the third year.

If you wish to ask a question, I certainly will, but I don't want to offer an opinion unless you ask a question.

Q. What's happening with the Kaplan-Meier curves past two

years is not part of your opinion?
A. I know the information, but I did not write about it in my report. If you wish to ask me a question, I'm more than happy to respond.
Q. I just want to understand what your opinions are in this case.
So, Dr. Jewell, you testified a bit earlier today about the compensation you receive for testifying. You were hired by the plaintiffs' law firm in this case. That's Robbins Geller, right?
A. That is correct.
Q. And you have been hired as an expert by Robbins Geller in the past; haven't you?
A. A couple of times, yes.
Q. Two times at least?
A. Two or three, I would say, at the most.
Q. And those cases also involved pharmaceutical drugs?
A. Yeah, I believe so, yes.
Q. One was Xylox?
A. Correct.
Q. One was Pharmacia?
A. Well, that's not a drug. That was the name of the case.
Q. I see. Was there a drug involved in that case?
A. Yes.
Q. Okay. In fact, you've been -- as you testified, you've

been retained as an expert many times before?
A. Correct, about 40 to 50 times.
Q. All right. And you also said that in some of those cases, your expert testimony has been excluded by a Court?
A. Yes. It's been entirely excluded in one case, as I mentioned this morning. As I said, ironically, it's a little hard to talk about because it was accepted by one Court in its entirety and rejected by another Court in its entirety.
Q. Okay. And by excluded, you mean the judges in those cases refused to allow your opinions to be considered, right?
A. Well, I'm not a lawyer. My understanding is the opposing counsel challenged my testimony, and the judge had determined not to allow it to be entered into the -- as evidence.
Q. All right. In fact, one of those cases related to the drug Lipitor; is that right?
A. That was one of the cases in which only part of my testimony was excluded. That was one of the two or three where I said that only part was excluded, and that was a case in Lipitor.
Q. And for that part of your opinion that was excluded, didn't the Court say that you had engaged or improperly engaged in --
MR. COUGHLIN: Your Honor, I have to object. We've gone beyond. They didn't challenge this witness in this

case, and now we're talking about opinions in other cases and they're asking details.

THE COURT: Overruled.

MS. SMITH: Thank you, Your Honor.

BY MS. SMITH:

Q. So in one of those cases -- again, this is the Lipitor case. Isn't it true that in that case the Court concluded that in order to reach your conclusion, you had improperly engaged in a results-driven methodology?

A. Yes, that was the opinion of the Court. Of course, with all due respect, I don't rule or make opinions about law, and sometimes Courts and judges make mistakes about statistics. That was an egregious mistake.

But I did say this morning that part of the complexity of that case was it involved a very substantial amount of data analysis of a clinical trial -- actually several clinical trials, much more complicated than the issues here, and the judge just didn't understand the statistics unfortunately. But that's the way it goes.

Q. That wasn't the only time that a Court has excluded your opinions?

A. As I indicated this morning, that was the only time the entire testimony was excluded, having previously been accepted by another -- another challenge by a different Court.

Q. Well, let's talk about another one of these decisions. You recall that your opinion or a portion of your opinions was excluded in a case involving Zoloft?

A. Correct.

Q. And in that case isn't it true that the Court expressed concern that you had selectively relied on a statistical principle in a results-driven manner?

A. As again I indicated, those cases are actually slightly related. Again, that case involved me re-analyzing clinical trial data. The judge in this case misunderstood what the statistics I was doing did, with all due respect.

Q. And that Court also concluded that your opinion testimony was likely to confuse or mislead the jury?

A. I disagree with that. Of course, I would be happy to discuss it in detail if you would like, but it's hard for other people to understand without getting into the details. That is a flatly wrong statement in my opinion.

Q. You disagree with it, but that is in fact what the Court said; isn't it?

A. Yes.

MS. SMITH: I have no further questions.

THE COURT: All right. Thank you.

Any redirect?

MR. COUGHLIN: Yes, Your Honor. I'd like to put up the next part of that depo clip that we looked at.

THE COURT: Yes, please.

(Portion of videotape recording played).

REDIRECT EXAMINATION

BY MR. COUGHLIN:

Q. Isn't that what you just answered prior to that?

A. That's what I was trying to interject and say, because it was cut off in the first when I said it wasn't part of the investor call. It wasn't a prespecified end point, that that was my full answer just as I gave today. It's immediately calculable from what was prespecified and what was discussed on the investor call.

Q. There was a lot of questions of you about diarrhea and diarrhea rates. I'd like you to look a look at Exhibit 1043 -- which has had no objection to, Your Honor.

THE COURT: 1043, you're moving its admission?

MR. COUGHLIN: Yes.

THE COURT: 1043 is admitted without objection.

(Exhibit 1043 received.)

BY MR. COUGHLIN:

Q. If you take a look at 1043 -- it's a little hard to read, but if we can focus on the top couple of lines.

A. Yes. I'm looking.

MR. COUGHLIN: And blow that up.

BY MR. COUGHLIN:

Q. I think those numbers, if you take a look at those

numbers, they talk about how many patients -- how many patients are on antidiarrheal medication. And this is the ExteNET study; is that correct?

A. Yes. This is the ExteNET study, and this refers to what I was discussing about my confusion on the question because it clearly indicates here in the ExteNET study that 87.4 percent of neratinib patients took some antidiarrheal medication.

Q. And you refer to the Wyeth SAP, and the Wyeth SAP said what about providing antidiarrheal medication?

A. The Wyeth protocol for this ExteNET study indicated that antidiarrheal medication should be made available to all patients, and they recommended being available from day one.

If you drop the box there and you go down that table, you can see of those 1,230 patients in the neratinib arm, almost all of them took some antidiarrheal medication for reasons that should now be obvious because that's a lot of diarrhea.

You can see further down there that 70 percent of those people who got antidiarrheal in the neratinib arm took it within the first week of being exposed to the drug. So they started on this very early on. Now, whether they started on before they'd even taken a single pill is not indicated by this table, but they took it within the first week, almost all of them.

Q. Okay. Let's go all the way down to where it talks about taking antidiarrheal medication in a prophylactic manner -- loperamide down at the bottom of the page?
A. Yes. I see it, I think.
Q. Do you see what that says? It talks about how many patients were taking that in that manner, and it has a number there.
A. Yes. These are neratinib patients. It's a little bit cut off, the 336.
Q. Okay.
A. And they were taking Imodium, loperamide, specifically. Before we were talking about any antidiarrheal medication. They were taking that in a prophylactic way during the trial.
Q. We talked -- we talked first about people taking it in the first week, and that was the majority up above, and that was 70 percent Imodium and another percent other antidiarrheal.

But here we're talking about in a prophylactic way, and we've got a certain number. Is it taking it before you start the drug, or is it taking it after a hold and then restarting?
A. Well, I would have to -- if you mean -- the box is covering a little bit of that information.
Q. If we can make it a little bigger?
A. Just a little bigger up above. Thank you. That's fine.

So there you can see it's the number of neratinib patients taking Imodium following what's called a dose hold. What that meant is they probably had -- it says a dose reduction for diarrhea.

So what -- let's just say it in plain words. These patients started the drug. They had diarrhea sufficiently badly that in conjunction with the physicians in charge, they decided either to reduce the dose to try and mitigate the diarrhea, or hold off, stop taking the drug for a bit.

After that had happened, the diarrhea went away. Then they were -- these particular patients, 158, were then said, hey, take the Imodium now even though you're not suffering from diarrhea now to try and prevent it coming back again.

MR. COUGHLIN: I have no further questions, Your Honor.

THE COURT: Anything else?

MS. SMITH: No further questions, Your Honor.

THE COURT: Thank you, sir. You may step down.

The plaintiff will call its next witness.

MR. COUGHLIN: Your Honor, could I take one minute and I'll be right back?

THE COURT: Yes, you may.

MR. COUGHLIN: Thank you.

THE COURT: Everyone else, feel free to stretch,

stand, or whatever they like. Well, not whatever. Within reason.

And here's some good news for some of you. We will be meeting at 9:00 tomorrow, not 8:00. Okay?

(Pause in proceedings)

MR. COUGHLIN: My next witness is Mr. Auerbach.

THE COURT: Please take the stand, Mr. Auerbach.

Alan Auerbach, Plaintiff's witness, sworn

THE CLERK: If you will please state and spell your first and last name for the record.

THE WITNESS: Alan Auerbach. Last name is spelled A-u-e-r-b-a-c-h.

DIRECT EXAMINATION

BY MR. COUGHLIN:

Q. Good afternoon, Mr. Auerbach.

A. Good afternoon.

Q. I'd like to take you through -- you're the founder of Puma; is that correct?

A. That is correct.

Q. And you're the CEO?

A. That is correct.

Q. Okay. And I'd like to take you through some of the initial founding documents. I'd like you to open up the black binder next to you, and the first exhibit we have is Exhibit 1034, which is a 10Q that is signed by you dated

November 14th, 2011.

MR. COUGHLIN: I'd like to move for the admission of that document.

THE COURT: Document number?

MR. COUGHLIN: Document number 1034.

MS. JOHNSON: No objection.

THE COURT: Document 1034 is admitted.

(Exhibit 1034 received.)

BY MR. COUGHLIN:

Q. Mr. Auerbach, do you recognize this document?

A. Yes, I do.

Q. Okay. I'd like you to take a look into the document and actually page 13 of the actual document. It's 16 of 27. Actually I'm going to move you back one page to page 12 at the top, the first paragraph.

Is it correct that Puma was incorporated September 15th, 2010?

A. That is correct.

Q. Okay. And you were the largest shareholder; is that right?

A. That is correct.

Q. Okay. Let's flip over to page 13. Under stock equity, it says common stock, that Puma issued four million shares of common stock to its founder and CEO in September 2010; do you see that -- for $400?

A. Yes.
Q. At a P -- at a .0001 per share?
A. That is correct.
Q. And that you contributed capital totaling 61,000 and 68,000; is that right?
A. Correct.
Q. About a 150,000?
A. Correct.
Q. Okay. So your initial investment was $400?
A. The initial capital put into Puma prior to neratinib being licensed was actually in the hundreds of thousands of dollars. When the company was founded, the goal was to find cancer drugs to license. The only dollars spent for neratinib was the $150,000.

So I didn't feel right having the shareholders charged with that, if you will, for the other drugs I looked at. I just took the funds that were used for the acquisition of neratinib.

Q. Okay. So you had -- so apparently, in the next paragraph, it's authorized for 25 million, but there weren't 25 million shares outstanding. Actually right below the $400 number, it's 25 million were authorized; is that right?
A. Can you guide me to where --
Q. Yeah. Page 13.
A. Yes.

Q. Okay. If I move over to page 14, I think it talks about your $150,000 investment. Do you see that, on September 2nd, 2011, you advanced Puma 150,000, and that's what you were talking about?
A. That's correct.
Q. You converted that into 40,000 shares; is that right?
A. Correct.
Q. Okay. And that was on October 6th, 2011?
A. Correct.
Q. And is that when you did some initial funding at 375 a share? That's about, you know, what it comes out to when other investors came in?
A. Yes. That's correct.
Q. Okay. There were about 25 to 27 other investors invested with you at the time?
A. I seem to remember the number being a little bit larger. We had some institutions and we had some retail as well. But I seem to recall the number was slightly larger than that but in the ballpark, yes.
Q. Okay. And if you flip over to the next page, page 15, it talks about warrants issued to the CEO. It talks about a number of warrants that are being issued to you to keep your ownership share at about 20 percent. Do you see that?
A. Yes. Correct.
Q. And during this time frame, from this time frame on,

your ownership did fluctuate somewhere between 17 and 21 of the company; is that about right?

A. With the company was founded, the initial investor who put in the largest amount of money, which is typically referred as to the lead investor, the offer they had made to me was that on the first financing the company did, I got what's referred to as antidilution protection, meaning that I was allowed to maintain my 20 percent ownership in the company.

Going forward I did not maintain that 20 percent antidilution protection, just on the first financing that occurred after the one in 2011.

Q. And that -- and actually that was in October 24, 2012, is when you got that antidilution of 2.1 million shares for $16 a share? Does that sound about right?

A. I believe that sounds about right.

Q. Because you had done an offering about that time, so they gave it to you at the offering price, I believe?

A. I believe that's correct.

Q. And that kept you at your 20 percent at that time?

A. That's correct.

Q. In the 2014-2015 time frame, how far down below -- the number I saw was maybe 17 percent. How far down below 20 did you go?

A. I don't keep track of that on a regular basis. I --

Q. Am I in the ballpark?
A. I believe it's somewhere in the, you know, ballpark, 15 to 18 percent range.
Q. Okay. Let's take a look at exhibit -- let's take a look at Exhibit 129, if you would. Take a look at that, and then flip over to the first page. I think it might help you recognize exactly what that is.
A. (Witness reviewing document)
Q. Do you recognize what this document is?
A. Yes. This would be the statistical analysis plan for the ExteNET trial.
Q. And this is a plan that Puma drew up; is that correct?
A. Yes.
Q. And this is a plan that followed the ownership of Wyeth and then Pfizer, and then this was the third statistical analysis plan; is that correct?
A. I seem to remember there were more statistical analysis plans than just these three, but this was the first major one that Puma did.
Q. Right. Correct me if I'm wrong or off by some -- I don't think it's an important factor right yet, but I seem to remember there were, like, 13 amendments, but there were really three primary global amendments to this plan; is that correct?
A. I believe that's correct.

Q. Okay. So that's dated July 3rd, 2014. What -- I'd like to move into that document and talk to you about those amendments if that's all right.
A. Sure.
Q. If we take a look at page 9 of 55. At the bottom it's Exhibit 129, page 11 of 61. I'm looking at the actual numbers of the document.
A. Correct.
Q. So this is the global -- first of all, it starts the original protocol by Wyeth. Do you see that?
A. Yes.
Q. So Wyeth developed -- discovered, developed, or started the development of this drug; is that correct?
A. That is correct.
Q. Okay. And then when Pfizer bought Wyeth, they took over the development of this drug; is that correct?
A. Correct.
Q. Okay. Now, this first protocol, this did not involve you; is that correct?
A. That is correct.
Q. Okay. And that was in February 2010 with Pfizer; is that right?
A. That is correct.
Q. Okay. And if I flip over to the next page -- well, let's start with what happens here. It appears, because I

want to understand how the population changed, it appears that some studies came out indicating that the risk of tumor reoccurrence was lower than expected when the study was originally designed, and they modified the study as a result; is that right?

A. That is correct.

Q. Okay. And the modification changed from allowing HER-2 positive -- I want to be on the same page with that so we know what we're talking about. It's been talked about here -- HER-2 positive to instead of node-negative and node-positive just to node-positive; is that correct?

A. Just to clarify, node-negative and node-positive means at the time of the diagnosis of the disease, is the disease just in the breast or had it spread outside the breast to the lymph nodes. So that's node-negative and node-positive.

Q. We had a doctor this morning explain some of those terms. Thank you. So this, in quote, enriched the population of people that were more at risk; is that right?

A. That is correct.

Q. Okay. Now, correct me if I'm wrong. My understanding is the HER-2 positive population is approximately somewhere between 20 and 30 percent of the overall breast cancer population; is that right?

A. No. My understanding is it's between 15 to 20 percent of the overall breast cancer population.

Q. You think it's lower than that?
A. That's my understanding.
Q. Okay. Let's just go with 20 percent, catches both our numbers. So the HER-2 positive population is about 20 percent of the overall population, and the node-positive versus negative, node-negative is about 80 percent of the overall breast population; is that about right?
A. That is not correct. There was a publication -- I'm forgetting the date -- that looked at the percent of node-negative and node-positive cancer, breast cancer, worldwide. I thought the node -- it was roughly 50/50, 50 percent node-negative and 50 percent node-positive in the United States.
Q. In the United States?
A. In the United States. So just to clarify worldwide, in certain other countries they don't have as good of a medical standard of care. So oftentimes women aren't going to the doctor to get checked, et cetera.

In the United States we have a very good standard of care, so women are indeed going so they can get diagnosed earlier.

Q. If the American Cancer Society had it at about 77 percent node-negative, would you dispute that figure?
A. I would say that -- I don't know what the date of that publication is, but I would say -- we looked at the

publications more recently, and it was 50/50.
Q. This was a recent look at the publication that you looked at? Is that what you're saying?
A. That's the publication I remember.
Q. So if their publication was 2017, 2018 --
THE COURT: Yes. Boy, take a deep breath. Take a deep breath. Slow down.
MR. COUGHLIN: I will, Your Honor.
MS. JOHNSON: Your Honor, I would interpose an objection based on the mill number four by plaintiff to the use of later -- to the reference to later studies.
MR. COUGHLIN: I was just clarifying what he said. He said he looked at --
THE COURT: Hold on. Excuse me. Did an answer come in? I was spending time on slowing down.
Just one second.
All right. The last question was: There was a recent look at the publication that you looked at. Is that what you're saying? That's the publication I remember.
Do you object to any of that?
MS. JOHNSON: Not that one, Your Honor.
THE COURT: Okay. Then we'll be ready if there's another one. Go ahead.
BY MR. COUGHLIN:
Q. So let's move down -- so that was a -- so if we talk --

if we take a look at approximately how many subjects, were 3,300 enrolled at that time, or was that the target to be enrolled?

A. That was the target to be enrolled.

Q. Okay. But 3,300 had not been enrolled at that time; is that correct?

A. That is correct.

Q. Okay. And so that's -- then the new criteria is that node-positive disease, randomization with one year of completion of a prior -- that's Herceptin, right?

A. That's correct.

Q. Okay -- therapy. So they had changed the population; is that right?

A. Yes. There had been data presented at the San Antonio breast cancer meeting 2009 or 2010 which showed that patients had a higher risk of their breast cancer coming back if they either had node-positive disease or they were within one year of finishing Herceptin, also known as trastuzumab on the screen.

THE COURT: Hold on. Also known as?

THE WITNESS: Trastuzumab. That's the second to last word there.

THE COURT: It is on the screen. Go ahead.

BY MR. COUGHLIN:

Q. Trastuzumab is Herceptin?

A. Herceptin, correct. So the protocol was modified to enrich for a higher risk population which, based on that study, that would be what this is referring to.
Q. Okay. Now let's talk about the next -- so the study was modified that way. Now let's talk about the next -- the global protocol amendment number nine. Take a look at that.
A. Correct.
Q. It says Pfizer stopped enrollment of new subjects with global amendment nine and limited it to two years. Do you see that?
A. Correct.
Q. It says the consequences of this amendment impact the original study objectives of evaluating the long-term efficacy of neratinib in the extended adjuvant setting. Do you see that?
A. That's correct.
Q. Did you agree with that?
A. It was done before we bought the drugs, so there wasn't much we could do about it.
Q. Were you involved in that decision?
A. They had notified us early on. This was clearly a dual protocol amendment. It was going to take six to nine months to get things done.
So when we were talking to them about licensing neratinib, which was in October 2011, they had told us that

that was something they were planning on doing for budgetary reasons, because obviously stopping enrolling in the trial and only following patients for five years instead of for two is much cheaper.

So what they were looking to do was reduce the budget for this trial, and that was their solution to doing that.

Q. Okay. Let's take a look at Exhibit 745, which is the next exhibit in line in your folder.

A. (Witness complies.)

Q. I want you to take a look at the letter dated December 20th, 2011, which is from Phil Goss, who was the head of the academic steering committee then. And you're cc'd on that letter. Apparently involved in a phone call that's talked about there?

A. Correct.

Q. Do you recognize this letter?

A. Yes, I do.

Q. Okay. And you were involved in a phone call with the academic steering committee at the time?

A. Correct.

Q. Okay. And if you flip over to the second page of that letter, it says --

MR. COUGHLIN: I'd move for the admission of this letter. There's no objection.

THE COURT: Exhibit number?

MR. COUGHLIN: Exhibit number 745.

THE COURT: Without objection 745 is admitted.

(Exhibit 745 received.)

BY MR. COUGHLIN:

Q. Dr. Goss is comparing --

MR. COUGHLIN: If we flip over to the second page of that, page 4 of 5, and blow that paragraph up.

BY MR. COUGHLIN:

Q. It says: To summarize, this is not a trial to prove --

THE COURT: Please slow down.

MR. COUGHLIN: Sorry. In fact, I won't read it. If you could read it, Doctor, and give everybody else a chance -- I mean, Mr. Auerbach.

THE WITNESS: Uh-huh.

BY MR. COUGHLIN:

Q. At the time were you on the phone with Pfizer and indicated that the future goal of ExteNET is limited to collecting safety data?

A. I was not on that phone call, no.

Q. So this is wrong or somebody else from your shop was on the phone?

A. No. I was not on the phone when they had the conversation with Dr. Goss.

Q. Okay. So when it says there Pfizer -- would anybody

else at your company have been on the phone when it says Pfizer and Puma indicated that the future goal of ExteNET is limited to collecting safety data?

A. I was not on the call where that was discussed.

Q. So Dr. Goss just had misinformed them about that?

A. We had a call when I acquired the drug with Dr. Goss, and at the time that this academic steering committee was in place, they were being very heavily compensated from Wyeth and Pfizer, specifically I believe each of them was making -- they were receiving compensation that I would ballpark was somewhere in the range of 200,000 to 400,000 dollars per year.

And since this trial was going to be going somewhere between five and ten years, that was obviously a very large sum of money. I was on a call with Dr. Goss when I was introduced to him, and the first question he asked was whether Puma was going to be continuing to compensate the academic steering committee in the same manner.

I said that was unlikely because we were a small company and didn't have that type of money, and that was when he got quite upset, and that was kind of the last conversation I remember with him.

Q. And he had designed the study; is that right?

A. He had -- he was the original one with the concept for the study. The entire academic steering committee designed

the study.
Q. And he resigned; is that right?
A. That is correct.
Q. Okay. And you're saying it was -- that Pfizer had a problem with the funding; is that right?
A. Originally the study, the truncation of the study, reducing the number of patients involved, and the duration of the follow-up was done by Pfizer as part of a budget situation they had.

They had a new -- Pfizer had a new chief executive officer, a gentleman named Ian Read, who is a very, very nice guy. And Ian came into Pfizer late 2009, if I remember this correctly. In 2010 he announced a very large research and development budget cut. It was approximately $1.5 billion, if I remember correctly.

Specifically their cancer group -- because Pfizer is a very large company that has lots of drugs. They have drugs for cardiovascular disease, for neurology, et cetera. The budget for the oncology group, the cancer group, I believe was cut somewhere in the range of 60 to 70 percent.
Q. Okay. Let me ask you some more questions, sir. So you're saying it was Pfizer who made this decision to cut the study?
A. They had contacted me telling me they were making this decision, yes.

Q. If I could have you take a look at --

THE COURT: Let me say, since we're talking about statistics, if the normal rate of transcription is a hundred pages, you folks are at about 130. You're just coming in fast.

Now, I'm married to a woman that talks very fast. This court reporter takes down words quicker than any I have known. But, you know, sometimes, especially when technical information is coming in, it's good just to pause a little and make sure it's soaking in.

And here's the scary thing. She can record thoughts quicker than my mind can process them. Now, the jury might be better than I am, but I'm saying when the thoughts come in too fast, it's very hard to process them all. Okay?

MR. COUGHLIN: Well said, Your Honor.

THE COURT: Go ahead.

BY MR. COUGHLIN:

Q. If you could take a look at Exhibit 883. It should be the next in line.

MR. COUGHLIN: This exhibit, no objection to this exhibit, Your Honor, except for a limiting instruction for all of the analyst reports and type things. I think this is a little different. This is actually Mr. Auerbach talking.

THE COURT: Number what?

MR. COUGHLIN: Exhibit 883.

THE COURT: Without objection 883 is admitted.

MR. COUGHLIN: Thank you, Your Honor.

(Exhibit 883 received)

BY MR. COUGHLIN:

Q. I'd ask you to turn over to page 3 of this exhibit. This exhibit is dated October 16, 2014. If you look at page 3, I'm going down to the bottom where the questioner, Matt Allen, is asking you questions about some of the changes that we're talking about right now. Okay?

A. Sure.

Q. And he first goes over the first change that we talked about from the node-negative to the node-positive with you. Do you see that?

A. Yes.

Q. Okay. And then we get into: All in all the study had both node-negative and node-positive, but clearly the majority, 80 percent, are node-positive. Do you see that?

A. Yes.

Q. Did that -- was that correct about -- when they shut the study down, if I understand it, the population was set at about 2,800?

A. Correct.

Q. Okay. So 80 percent of that population was node-positive?

A. Yeah, roughly. Yes.
Q. And if we go on, it says, it talks about shutting it down: At the time we stopped the enrollment because Puma was a small company and we didn't have the financial resources to continue running it. So we stopped the enrollment at 2,800 patients, which had a minor effect on statistical assumptions and continued running -- so I'm on page 4 of 15?
A. Yes. Correct.
Q. Okay. There it says that Puma is the one who cut it down for financial reasons. Do you see that?
A. No. Where are you? Can you please point?
Q. Right at the top of that -- I'm on page 4 of the UBS report, which is page 4 of 15, at the top of the page in the middle of that paragraph. You first talk about node-negative and node-positive amendment?
A. Yes.
Q. It says: At the time we stopped enrollment because Puma was a small company and we didn't have the financial resources to continue running it. So we stopped enrollment at 2,800 patients, which had minor effect on statistical assumptions. Do you see that?
A. Yes. There's a little more context to that.
Q. Okay. Your counsel can ask you about it. I'm just saying that's what you said at the time, right?
A. Yeah. We didn't have the resources to continue

enrolling and continue -- if there was a decision to be made of stick with Pfizer's design, which was to stop enrollment and truncate it to two years, or say, no, we're going to, you know, go back to the original design.

At that time we did not have the resources to go back to the original design.

Q. Well, it doesn't say that. It just says that: At the time we stopped enrollment because Puma was a small company and we didn't have the financial resources to continue running it. Okay? So it says that not Pfizer stopped it but you stopped it.

A. Well, no. I think you saw the amendment was actually Pfizer, not Puma.

Q. Well, that's your statistical amendment. Pfizer still owned the drug, so they're the ones who had to amend it. But they amended it because you were going to license it from them, right, and they stopped --

A. No. It was done beforehand.

Q. The enrollment stopped before you licensed it, right?

A. What I'm saying is that the decision to amend the trial had -- was done before obviously that plan was written, et cetera.

Q. Right. But you were on the phone call with the academic steering committee when they complained about stopping the study because it would impact the results, right?

THE COURT: I'm sorry. You're not going to get clear record. That was really fast. I must say, you know, right now in my brain I'm trying to pick out everything you said, and I'm not processing and I don't think the reporting is coming out.

MR. COUGHLIN: Okay, Your Honor. I'll just move on. I'll let the document speak for itself, Your Honor. It's already admitted.

BY MR. COUGHLIN:

Q. Let's go back to the amendments if we could because there's a third one I want to talk to you about.

A. Sure.

Q. It's in the analysis plan.

You amended the -- I'll refer to it as a SAP if that's all right.

A. Sure.

Q. You amended the SAP in January of 2014, is that right, before you unblinded the study? Correct?

A. Yes. The decision to modify the study, though, was in 2013.

Q. Right. This was actually implementing that amendment?

A. Yes. Correct. It was begun -- the work on this was begun, I would believe, somewhere around August through September of 2013.

Q. Okay. And when you decided to reinstate follow-up of

those patients beyond two years, right, that had been -- two years had gone by where you had not been collecting that data; is that correct?

A. I'm sorry. Can you repeat the question, please?

Q. When it was amended and shut down --

A. The trial was never shut down. It continued to be followed.

Q. When the study was truncated, if I might use that word, okay, down to a two-year study with a certain set number of patients, 2,800, okay, you quit testing those people, central testing those people; is that correct?

A. No, I don't believe that's correct. We continued -- the patients who completed enrollment in October of 2011 continued to be treated with the drug or a placebo for a year and then continued to be followed for another year.

Q. Okay. Let's take a look -- I'm going to skip ahead just for a moment so we don't use terms that are out of whack. If we could go to Exhibit 124 in your book. And maybe you just want to look at it on the screen.

If we go to Exhibit 124, page 15 at 272, this document 124 is your safety deck from 7/18/2014, and it -- this is under the issues to be addressed. It says central HER-2 testing and bio markers not done for all patients. Testing discontinued as of amendment nine.

We were just looking at amendment nine, right?

A. Uh-huh.
Q. So the testing was discontinued?
A. The central HER-2 testing I recall was done for all the patients or the very large majority. The bio markers, that is accurate. The bio marker work was not done.
Q. But this doesn't say or. It says central HER-2 testing and bio markers not done for all patients. Testing discontinued as of amendment nine.
A. Again, my recollection is we did do central HER-2 testing on not 100 percent but a very large majority of the patients, whoever we got a sample for. The bio markers, that's correct. We did not. Again, I didn't write this, so I can't really discuss the accuracy of it.
Q. Well, you received it in July of 2014?
A. Correct.
Q. You didn't raise an issue with it then to your knowledge?
A. To my knowledge I did not.
Q. Okay. Let's talk about that, because we heard a little bit about subgroups, and we heard about central testing earlier today. There appear to be some documents from you saying we're lacking this data of 40 percent of this central testing that are later on. Do you remember that?
A. No. I would need to refresh my memory on that.
Q. Okay. We'll go over that a little later. I didn't want

to skip so far ahead.

So let's go back to Exhibit 129.

MR. COUGHLIN: Your Honor, this might be a good time to take a break.

THE COURT: If we take a break now, it means the court reporter will have 90 minutes of fast talking. We'll take a break now. Just slow down.

MR. COUGHLIN: I'll slow down, Your Honor.

THE COURT: We'll be back in 15 minutes.

Thank you.

(Recess taken from 2:46 p.m. until 3:01 p.m.)

(Open court - jury present)

THE COURT: Welcome back.

Please continue.

MR. COUGHLIN: Thank you.

BY MR. COUGHLIN:

Q. Mr. Auerbach, we were on the -- we were in the statistical analysis plan. I'd like you to turn to page 25 -- 22 of 55 in that plan, page 24 of 61 for the control out of Exhibit 129. Page 22 of 55.

I believe we read earlier that the primary end point of this, the primary objective of this study is to compare disease-free survival with women in early-stage HER-2/neu overexpressed amplified breast cancer.

Exhibit 129, page 24 of 61.

I'm going to direct you to those. Do you have those charts?
A. Yes.
Q. It says the efficacy end points and analysis methods. Now, were you involved -- did Wyeth have the same three types of analysis to be done on the disease-free survival?
A. Can you clarify that questions?
Q. Did they have the same method to analyze the disease-free survival rates?
A. I believe. I don't --
Q. I think it never changed, Mr. Auerbach.
A. I don't remember if the Wyeth plan and our plan used the same. I don't remember that.
Q. I'm pretty sure it never changed, just for a little background. And you understand what these three methods are, right, and how they're calculated?
A. That's correct.
Q. Okay. So the first one there was the Kaplan-Meier plot. Do you see that?
A. Yes.
Q. And that gives you the absolute difference; is that correct?
A. That's correct.
Q. Okay. And then the stratified log-rank test, one-sided with 2.5 percent significant level. Is that the p-value?

A. Yes. That's one of them, yeah.
Q. Okay. And then there's the Cox proportional hazards model stratified to estimate the treatment hazard ratio.
Do you see that?
A. Yes.
Q. Okay. And so when you got the results of the ExteNET studies that were unblinded in July of 2014, did you apply those three tests to analyze the data?
A. I remember that we did the Kaplan-Meier plot. I remember that we did the stratified log-rank test. I don't remember if the Cox analysis was done.
Q. Okay. Let's take a look at Exhibit 123. Actually, before we go to 123, which are the results, let's look at the exhibit before that in your book, 877.
Do you recognize what 877 is?
A. Yes, I do.
Q. And 877 is an 8K. I believe there's been no objection to it, and it contains both the Pfizer updates to the licensing agreement --
THE COURT: Do you move its admission?
MR. COUGHLIN: I do.
THE COURT: Any objection?
MS. JOHNSON: No objection.
THE COURT: 877 admitted.
(Exhibit 877 received.)

THE COURT: Please don't put it on the screen until it's admitted.

Go ahead.

BY MR. COUGHLIN:

Q. So I'd like you to flip -- and the first press release there is attached, an amendment that you did with Pfizer, is that right, to your licensing agreement?

A. Yes.

Q. Okay. And Puma took on more of the cost, and Pfizer was going to get less of the back-end revenues; is that correct?

A. Correct.

Q. Okay. And then you also released the ExteNET results on July 22nd, 2014; is that right?

A. Correct.

Q. And you released those about an hour, hour and a half, hour and 20 minutes before you had the press -- the analyst call; is that right?

A. I believe it was somewhere in that time frame, yes.

Q. Okay. And in that press release you have the 33 -- about the third paragraph down, you talk about the hazard ratio, and that hazard ratio of .67 gave you a 33 percent improvement. Do you see that?

A. Yes, I do.

Q. And that was information from the topline of your results; is that right?

A. That's correct.
Q. And that hazard ratio was connected to your topline; is that right?
A. That's correct.
Q. Okay. Let's switch over to Exhibit 123.
MR. COUGHLIN: I think this has been admitted. I'm sure it has.
THE COURT: What's the number again?
MR. COUGHLIN: 123.
THE COURT: It's admitted.
BY MR. COUGHLIN:
Q. So take a look at that and make sure you recognize what it is, Mr. Auerbach.
A. Yes.
Q. So this is dated July 17, 2014, to you, and it says: Attached are the validated results. And it's the efficacy results; is that correct?
A. Correct.
Q. Okay. And do you remember receiving these in 2014?
A. Yes, I do.
Q. Okay. Let's flip in to see what the topline results were. If we take -- if we flip to page 8 of 35, or page 6 of the document, it has a summary of the topline efficacy; is that right?
A. That is correct.

Q. And these are the two-year, 28-day results; is that right?
A. That is correct.
Q. Okay. So let's take a look at the DFS at the very top. Do you see that top line?
A. Yes, I do.
Q. Okay. And those 93.9 and 91.6, right, do you see that -- see those rates there?
A. Yes.
Q. Where do they come from?
A. Those are the Kaplan-Meier estimates of the disease-free survival for the neratinib and the placebo arms as of the time point of two years plus 28 days.
Q. And the absolute difference was 2.3; is that right?
A. That is correct.
Q. Okay. And that's associated with that hazard ratio .67, right?
A. That is correct.
Q. There's no other -- and you can look down to the amended intent to treat. And there's no other hazard ratio associated with .67; is that right?
A. To clarify your question, please, when you say there's no --
Q. I'm just asking, that's the only .67 hazard ratio in that table; is that correct?

A. Yes. That's correct.
Q. Okay. The different -- let's go down and go ahead and let's go through each one. So the next line contains the ductal, right?
A. Yes, correct. The next line is the definition of disease-free survival that includes precancerous tumors which are premalignant, if you will. In breast cancer you can have tumors that are actually cancer. Then you can have ones that are precancerous lesions. These are ones that have a very high probability of becoming cancerous. We call those either premalignant lesions, or the technical term is called ductal carcinoma in situ, or DCIS. So this would be the definition that includes those premalignant lesions.
Q. And that's the second line down, right?
A. That is correct.
Q. And then we have the distance. The next line is the DDFS?
A. That is correct.
Q. Okay. And then we have the time one, TTDR?
A. Just to clarify, the distant recurrences are the tumors that, when they come back, are far away from the breast. So this could be in the lungs or in the liver and things like that. And when the cancer has spread that far, it is unfortunately usually indicative of the patient, you know, progressing very rapidly and unfortunately moving toward

death.

So we tend to look at distant disease-free survival, so the tumors that came back and were located far away, because showing a benefit there can be a good indicator of the overall survival of the patient.

Q. Okay. Then the next -- the next box after that is we have the amended intent to treat population; is that right?

A. That is correct.

Q. And that amended intent to treat population, that was the population for the study stopping at two years with no follow-up; is that correct?

A. My recollection of this is that the amended intent to treat population was defined earlier than the time point you're suggesting. I'm remembering it was the third amendment, I thought. But it is meant to -- the intent to treat population includes all of the patients in the study, both the node-negative and the node-positive. So those were the cancers within the breast and those where it's gone outside.

Q. You're right, Mr. Auerbach. It is the third amendment.

A. Thank you. I thought they were still enrolling at that time.

Q. And then they stopped with the ninth amendment?

A. So the amended intent to treat population as I recall is meant to be the higher-risk patients, so the ones where the

disease was found outside. They were node-positive. That's my recollection of that.

Q. Okay. But your primary end point now, because you had amended this, changed this back to the intent to treat population; is that correct?

A. Correct.

Q. Okay. So down below that is table 3.02. That seems to break the DFS intent to treat population into one-year and two-year stratification. Do you see that?

A. Yes, that is correct.

Q. Okay. So let's talk about the one year at the topline results, the DFS intent to treat population. Is that -- am I correct that that's taking the topline from above and breaking it out into two years, first year and then second year?

A. Yes. That is correct.

Q. Okay. So the first year, if you follow that along, follow that line over, you have an absolute difference, a risk difference of 2.2; is that correct?

A. That is correct.

Q. And then it goes to 2.3; is that right?

A. Yes. That is correct.

Q. Okay. So those are the results that were received about four or five days before that press release on July 22nd; is that right?

A. That -- I seem to recall it was somewhere in that four to five days, yes.
Q. Okay. And then to the right over here to the -- well, we'll skip that page. We'll come back to that.
If we switch -- if we flip over to page 12 of 35, that's actually the Kaplan-Meier curve that is associated with that intent to treat population; is that correct?
A. Yes, correct -- truncated, yes.
Q. When you say truncated, what do you mean by truncated?
A. This does not represent all of the data we had. It is just the data on the patients starting at time zero and going to the time point of 24 -- two years plus 28 days.
Q. So that's what you mean by truncated, because you had other events and other patients after that, right?
A. Correct.
Q. Because it started in 2009, and this was cutting off all patients under your censoring rule, if I might use that word, at two years, 28 days; is that right?
A. Correct, but we had data longer than that.
Q. You had data on more patients that you'd been following longer?
A. Correct.
Q. Okay. Now, do you recall how many events in those patients that you had that you followed longer?
A. I don't recall the number.

Q. Would eight sound like the topline of that number?
A. I don't remember what the number was.
Q. It was very small, right?
A. I believe the events in the entire study were smaller than we expected. I seem to remember we originally thought we would -- in the study as a whole, I seem to remember we got less events total than we expected.

So if we got less events past two years, that would, you know, be in line with what we saw in the study as a whole.

Q. Right, into the third year I think you had seven events and one in the fourth. Does that sound right?
A. It may be. I don't remember. That might be correct.
Q. Did you think you could do a statistical analysis going out with those few events?
A. I think you can do a statistical analysis on data irrespective of how many events you have. It's important to look at all of your data, not just looking at the data when the events number hit a certain level.
Q. And were you worried about the patients that you had stopped at two years, 28 days, or you were still following those patients?
A. I'm sorry?
Q. Were you still following those patients that had initiated the study and gone two years and 28 days? Is it

your testimony that you were still following -- they were still in the study years three, four, and five?

A. We had followed up -- we had amended the study in -- we were starting to do it in 2013, officially in 2014, where we went back and were recollecting the data on all of the patients.

Q. You reconsented?

A. Yes.

Q. You went back and got reconsent from those patients to continue the follow-up in years three, four, and five?

A. Correct.

Q. At the time of this, you had done no analysis, though, of that data. You had done no Kaplan-Meier curves or anything like that; is that correct?

A. At the time of this analysis, we did an analysis on all of the patients irrespective of how long they've been in the study, so including those who had been in for longer than two years.

In terms of analyzing the data on, you know, all of the patients we had to go back and reconsent, we were still in the process of getting that data. So we didn't analyze it because the data was still coming in because we were going to follow them for five years.

Because the data was still coming in, we didn't -- we cut the database as of what we had in July of 2014.

Anything we got beyond that we didn't do any additional analyses on.

Q. The report here talks about the two years, 28 days and those patients that were in that two-year, 28-day cut; is that right?

A. That's correct.

Q. Okay. And when you refer in that conference call that you had later to curves widening, you're not referring to these curves; are you?

A. The question on the conference call, as I recall, was asking about the curves beyond two years. And I believe the statement we had made what that we had a small number of patients going out beyond that, which was accurate. And I recall seeing that data back in July of 2014.

And as I recall, the benefit was 2.3 percent at two years and approximately 3.5 percent at three years. That was what I recalled.

Q. But you've never been able to produce, reproduce to us, any of that contemporaneous data from that time, right? You don't remember who showed it to you, on what computer it was on, how you were given it, who brought it into your office. You don't remember any of those things; do you?

A. I remember that it --

MS. JOHNSON: Objection. Compound.

THE COURT: Sustained. Any answer will be

stricken.
BY MR. COUGHLIN:
Q. Do you remember somebody came in and showed you those curves widening out into the future?
A. I do remember someone coming to me and showing me the curves. I remember that it -- the benefit at that time. Again, it was a small number, and that's subject to change as we got more data. I remember the benefit was 2.3 percent at two years and 3.5 percent at three years.
Q. And you don't have -- you know you have not produced any contemporaneous data to us from that time period, right, that shows that, contemporaneous from that time period, those curves that you just talked about?
A. My understanding is that we recreated those curves using the data that was available in July of 2014, and that the data did indeed show that the DFS rate at two years was 2.3 percent and at three years was 3.5 percent.
Q. Let's talk about that for a second. We asked for that in discovery. We didn't get that. You couldn't find it. Okay. Then you went back in and recreated it.
There's currently a dispute about whether that data shows that, okay? But that's what you're saying. Something that was created in 2018 is what you've showing -- what you're talking about right now?
MS. JOHNSON: Objection. Compound. Move to

strike.

THE COURT: Move to strike. Did you hear an answer?

MS. JOHNSON: No, Your Honor. Just the line.

THE COURT: Please rephrase.

BY MR. COUGHLIN:

Q. The graph that you're talking about was actually produced in 2018 by Mr. Bin Yao; is that correct?

A. That's correct.

Q. And that's the graph you're talking about here in court today?

A. That is correct.

Q. You don't have any contemporaneous evidence of that graph from back then; is that correct?

A. We do not have the exact graph that was shown to me in July of 2014. My understanding is there are other team members who remember showing that to me and other team members who remember seeing that. But we have not produced the exact document that was July of 2014, but we have recreated that using the data that was available in July of 2014.

Q. Well, you haven't produced any document from 2014 that shows that data, right?

A. We have not produced the document from -- that was created in July of 2014. We have produced the data created

using the data from July 2014.
Q. Who created that document in 2014?
A. That was done by Puma.
Q. No. Who? Who at Puma created that document? We know we talked to Claire Sherman, and she did not create that document. Mr. Bin Yao did not have access to the data until after you had had this press conference. Who at Puma created that document at that time frame?
MS. JOHNSON: Objection. Compound.
BY MR. COUGHLIN:
Q. Who at Puma created that document you were just talking about?
A. My understanding is that Claire Sherman has testified that she may have run that analysis, and I don't know who was the one who physically created it, because, you know, when documents get shown to me, I often don't ask who created this? Who did the analysis? Who typed this, et cetera. It just gets shown to me.
Q. Well, you know, she first said she didn't. Then she came back and said maybe she did after you said that maybe you saw it; is that right?
MS. JOHNSON: Objection. Improper impeachment.
BY MR. COUGHLIN:
Q. Let's move on, Mr. Auerbach.
Let's take a look at Exhibit 124. Let me ask a

question back on that one. So when you were talking on the separation, you were not talking about these curves, right, separating, on the phone call, in the conference call?

A. As I remember the conference call, the call came -- the question came from Dr. Howard Liang. I believe his last name is L-i-a-n-g. And the question was specifically referring to the data beyond two years.

So that is correct. I was only referring to the data beyond two years.

Q. Okay. And events beyond two years?

A. Correct.

Q. And the three and four year?

A. The third was the one we had data on. I don't think we had any data on the fourth.

Q. Actually one event.

Let's take a look at Exhibit 124. So this is dated a day --

MR. COUGHLIN: This has been admitted.

BY MR. COUGHLIN:

Q. This is the safety results, July 18th, 2014. Do you see that?

A. Yes.

Q. Okay. And these were sent to you on the 18th of July. Any reason to doubt that?

A. No, I do not have any reason to doubt that.

Q. Okay. And it says they are now validated?
A. You're correct. The e-mail says they are now validated. I believe this meant that they had been validated by our external statistical consultant Rho but not validated by Puma.
Q. That's your understanding?
A. That is my understanding.
Q. Okay. Let's take a look into the document.
So when you got this document, you reviewed it, right? Is that correct?
A. To my recollection, yes, that is correct.
Q. Okay. And if we flip in to the document to page 8 of 272, most frequent AE?
A. Yes, correct.
Q. Okay. So you got this document and the reported AEs that for diarrhea, you got -- the numbers was, for grade three or better, was 39.9 percent; is that correct?
A. Correct.
Q. For neratinib, okay. And you said you were concerned about this 35.4 percent; is that correct?
A. Actually we were concerned about the diarrhea rates in the trial as a whole. But, yes, we were concerned about the 35.4 percent in the placebo arm.
Q. Okay. Now, you see the diarrhea rate for the placebo at grade three or better is 1.6 percent?

A. That's correct.
Q. Okay. So the numbers you had before the conference call was that you had grade-three diarrhea at about 40 percent and placebo about 1.6; is that right?
A. That is correct.
Q. Okay. And if you flip over to page 10 of 272, diarrhea treatment discontinuation. Do you see that?
A. Yes, I do.
Q. Okay. And that treatment discontinuation rate for diarrhea alone was 16.8; is that correct?
A. That is correct.
Q. Okay. And if now we flip to page -- all the way in the back, and I believe it's 260 something, 266. It says adverse events leading to discontinuation, about the fifth line down, that's at 27.6 percent. Do you see that?
A. Yes.
Q. That's also a number you had before that conference call; is that right?
A. That is correct.
Q. Okay. Now, let's take a look at the conference -- the actual transcript of the conference call, and talk about some of the statements there.

You have seen this transcript before, Exhibit 103; is that correct? Did you find it?
A. Yes. Yes, I've seen this before.

Q. Okay. So in that transcript you first gave a, let's say, background to the results before you took questions; is that -- would that be a correct statement?
A. Yes, that is correct.
Q. Okay. And you'd gotten the results and they had been unblinded, and you were going to announce it to the public, and you issued the press release; is that right?
A. That is correct.
Q. Okay. And if you take a look -- and we'll go to the -- if we flip over to the first page, about the fourth paragraph down, and that is page 4 of 15, that's where you repeat the statement of the 33 percent improvement of disease-free survival. Do you see that?
A. Yes.
Q. Okay. And that was associated with a 2.3 absolute difference; is that right?
A. Yes. That is correct.
Q. And if we flip over to the next page, the second paragraph from the bottom, it says -- no. This is page 3 of 15.
A. Oh, the page before. Yes.
Q. Down at the bottom I'm talking about from a safety perspective?
A. Uh-huh.
Q. And you said: From a safety perspective, the company

has not yet seen the safety results from the ExteNET trial for neratinib as the data is still being validated; is that correct?

A. That is correct.

Q. Okay. Let's take a look over into the question and answer if we could.

Mr. Auerbach, did you think it was necessary to tell the investors on that call that you had actually gotten validated data, at least from Rho, and that you were concerned about the high diarrhea rate?

A. The data had not been validated internally. And we have seen in the past that oftentimes when our external contractors validate something and then we validate it, that the data can change quite dramatically.

So we weren't very comfortable, you know, putting that data out until we had fully validated it.

Q. Okay. That number never changed, right, that 39.9 percent?

A. No, it did not.

Q. Okay. And nor did the 16.8 percent discontinuation rate due to diarrhea. That number never changed, right?

A. Correct.

Q. Nor did the 27.6 percent ever change, right, with the AE discontinuation?

A. That did not change, correct.

Q. So none of those numbers changed at all?
A. That's correct.
Q. You didn't think it was important at all to, say, give a qualification? Hey, we've got some numbers we're concerned about?
A. We didn't know if they were going to change, so we waited for the validation to be completed.
Q. Did you think it was okay to just give numbers anyway from other tests or other things like that when you had that data sitting in front of you?
A. I'm sorry. Can you repeat the question?
Q. Did you think it was okay during the conference call to give numbers out like five and ten percent discontinuation rate and things like that when you had that data from Rho that had been at least validated by Rho in front of you?
A. So I believe we're confusing two different topics. The data on the five to ten percent was not referring to the discontinuation rate. It was referring to the dropout rate. Those are two distinct things.
Q. You're talking about the dropout rate altogether out of the study?
A. So just if I can please define -- may I please define the difference?
Q. Yes, you can.
A. So discontinuation rate is that the patient stops taking

neratinib but they continue to be followed. So they go to their doctor every three months. The doctor does a physical exam where they physically touch them and, you know, they can feel around for any evidence of tumors coming back.

They still get CT scans, which are like X-rays. So they're still being followed looking for -- to see if their cancer has come back. Dropout means they have stopped completely out of the study, and they sign a document saying: I'm completely dropping out of this study. You do not get any more data from me.

So discontinuation is you continue to get measurements on those patients. Dropout, in dropout you actually -- the minute they drop out of the study, that's the last measurement you get. Dropouts are particularly concerning because, you know, as you can imagine, if you've got, say, 1,000 patients who you followed for two years, and you say that after two years 90 percent of them or, you know, 900 of them are still alive and haven't had their cancer come back.

But if you have a hundred of them who dropped out, those hundred may have had their cancer come back or those hundred may have died. So it -- you know, it decreases the accuracy of that estimate. So the dropout, which is what was being referred to on the conference call, was people who dropped out of the study, so we stopped getting data on them.

I believe there was actually a comment made about the missing of the data and that reference. That was the number we were referring to.

Q. That's what you were referring to?

A. That's what the analysts were asking as well.

Q. They had asked for the --

A. No.

Q. -- discontinuation rate on the AEs, and he did qualify. He had said before dropouts, and then he said discontinuation. But you didn't think it was important to qualify that and say, hey, we've got a discontinuation rate of 16.8 percent to diarrhea alone?

A. I'm sorry. Can you please show me in the --

Q. Well, we had looked at the 16.8 percent and -- we're going to go over the transcript.

A. Okay. The question, as I recall, was specifically asking about dropouts.

Q. Okay. We're going to get to that question. Let's start with efficacy.

MR. COUGHLIN: Could we play clip number four.

And if you turn to page 5 of 15.

(Audiotape recording played)

MR. COUGHLIN: Let's stop that for a second.

BY MR. COUGHLIN:

Q. So you make that statement that you think it's going to

be in line with 29 to 30 percent that you've seen in prior studies with neratinib as a monotherapy, and yet you had validated data from Rho that said it was 39.9, the diarrhea rate, correct?

A. Yeah. I believe the comments are being taken a little out of context. May we go back, please, to the introductory comments?

Q. Sure.

A. Thank you. If we could please go to page 3 of 15, please. There we go, that second paragraph that starts from the bottom that starts with from a safety perspective.

May we please highlight that paragraph?

Q. Sure.

A. Thank you. Wonderful.

So I will read the paragraph. Is that okay if I read that?

Q. Yes.

A. From a safety perspective, the company has not yet seen the safety results from the ExteNET trial for neratinib as the data is still being validated. Historically the main adverse event that has been seen with neratinib has been a gastrointestinal adverse event, and more specifically diarrhea. In previous studies performed prior to Puma licensing neratinib, grade-three or higher diarrhea was seen in approximately 30 percent or more of the patients treated

with neratinib. In these previous historical studies, diarrhea was typically a first-cycle effect. So one of the interesting aspects of neratinib as a drug --

Q. All right. All right. Let me ask the question. You wanted to read that. That's fine. I'll let your counsel follow up with you on that. What I want to ask is if we go back there and we talk about what the study is. Sitting in front of you -- when you make the statement of 29 to 30 percent, sitting in front of you is a 39.9 percent number from Rho.

It might not have been validated by you, although there's no evidence of that. It might not have been validated by you, but what you gave to the market was that you saw 29 to 30 percent when the number you had sitting in front of you which you admit you had was 39.9; is that correct?

MS. JOHNSON: Objection. Compound. Misstates the record.

THE COURT: Overruled. He can correct the record, and it's cross-examination.

You may answer.

THE WITNESS: What we were referring to was that first cycle effect that I referred to. So the diarrhea with neratinib always occurs -- grade three, which is the severe, always occurs in the first month. And then the incidence of

it, the frequency of it, tapers off after that. And that first month is always the highest, and that was what we were referring to in the opening comments.

And if I remember correctly, the first-cycle diarrhea with neratinib the first month was -- the grade-three percentage was somewhere around 28-ish percent. So that was what we were referring to, the 29 to 30.

BY MR. COUGHLIN:

Q. That's what you say you're referring to. You think the market understood that?

A. I seem to remember having conversations with investors, and they understood that point.

Q. Now, you go on to say right there in that paragraph: Now, again, they didn't use any prophylaxis.

Do you see that?

A. Yes.

Q. Okay. Now, we've just seen that there was prophylaxis being used of hold and dose and that most people, according to the Wyeth SAP, were started from day one on an antidiarrheal or Imodium. You know that, right?

A. No. That is actually incorrect. Let me just, if I can, do you mind if I --

Q. You can do that with your counsel. Okay? You can ask and you can correct the record.

We just looked at a document, and you were here

looking at it, document number 1043, which says that 87.4 percent of the people in neratinib were on antidiarrheal medication, right?

A. After the diarrhea occurred, correct.

Q. Okay. And that then they had a prophylaxis number of about 25 percent after a dose hold; is that correct?

A. That's correct, and that's referred to as secondary prophylaxis. This is, you've already had diarrhea and you're trying to prevent a second occurrence of it. What we're referring to here is what's called primary prophylaxis. You're trying to prevent the first bad, severe diarrhea from occurring.

Q. So before anybody even takes the drug, you give them an antidiarrheal medication, right?

A. That is correct.

THE COURT: Let's slow down a little bit.

BY MR. COUGHLIN:

Q. Before they ever take the drug, you give them an antidiarrheal medication; is that right?

A. That is correct.

Q. And do you think the market understood that 87 percent of these people were on some type of diarrhea medication?

A. After the diarrhea occurred, yes. The number you're quoting, the 87 percent, is people who took Imodium after the diarrhea already occurred. What we're trying to do for the

patients is prevent it from occurring.
Q. And you say giving that did prevent it from occurring; is that right?
A. Yes. The studies that Puma did with the drug using primary prophylaxis, so, trying to prevent severe diarrhea from occurring, not occur again after it already occurred, we were successful in doing that. Our studies showed that whereas typically the grade-three diarrhea rate was anywhere between 30 and 50 percent, we were able to prevent it and reduce it down to anywhere between 0 and 17 percent.
Q. In fact, those are the three studies that you were quoted in the ASCO trial; is that correct?
A. I believe that is correct.
Q. And those three studies had, I think, a total -- one study had eight patients. One study had 41 patients. And I think another study had, like, 28 patients. Those are the three studies you're referring to?
A. I seem to remember there were four studies. But the number, it was not thousands of patients. That's correct.
Q. There was another one, and it had eight patients.
A. Okay. There was probably hundreds of patients, yes.
Q. What do you mean, hundreds?
THE COURT: Hold on. You're talking over each other.

BY MR. COUGHLIN:

Q. The studies that you referred to in the ASCO presentation that you had Dr. Chan put in, okay, have a limited number of patients in them that add up to less than a hundred, the three studies that you added.

A. I don't remember the numbers specifically, but it was certainly small numbers, yes.

Q. Okay. And those are the studies -- and compared to this 2,800 women study, those are the studies you were relying on when you gave your answer?

A. Yes. That's correct.

Q. Okay.

MR. COUGHLIN: Let's go on to finish off the efficacy of that clip, clip number four.

And we're on page 5 of 15, Mr. Auerbach.

(Audiotape recording played)

BY MR. COUGHLIN:

Q. Let's talk about those numbers. So when Dr. Werber, he says, you're thinking that if I'm correct, DFS is probably around mid to high 80s, around 86 percent or so in the control arm.

Your answer: I would be comfortable with that number.

That would be 86 percent; right?

A. No, that is incorrect. We were actually endorsing the

mid to high 80s range.
Q. And that's your testimony, that you were endorsing a range there, not a number?
A. Yes. Correct.
Q. And you looked at all the analyst reports because your in-house person sent them to you in the next couple of days, and you saw everybody else wrote that it was between 86 and 91? Do you remember getting those analyst reports?
A. I remember getting the analyst reports. I don't specifically remember everyone writing it was between 86 and 91. I seem to remember there was a range that people discussed, and I remember those ranges being anywhere between two and six percent.
Q. We'll take a look at those.

Did you call any of the analysts? Did you write the analysts? Did you e-mail the analysts that had it wrong and said 86 to 91 and say, hey, you must have misunderstood me?

THE COURT: Hold on. Start the question again, please.

MR. COUGHLIN: Okay.

BY MR. COUGHLIN:
Q. Did you -- when you looked at those analyst reports that you said you saw that had the 86, because you saw some --

THE COURT: You're going just as fast.

BY MR. COUGHLIN:
Q. You looked at some analyst reports that had 86 to 91 percent, correct?
A. Yes. I remember that.
Q. Okay. And did you e-mail those analysts or call those analysts and say: You've got the numbers wrong. That might mislead the market that we had an absolute difference, double what we already got? Did you do that?
A. That's -- you're taking those comments somewhat out of context. May we go back to the transcript?
Q. No. Just answer my question. Did you call the analysts and correct those analysts that they had gotten that wrong and that they had doubled your market that you had indicated?
A. The market we were referring to was comparing to the Herceptin adjuvant studies. That would be that -- again, to try to compare the ExteNET data to the Herceptin adjuvant studies, which you can see in my comments, we said the placebo arm is in line with the Herceptin adjuvant --
Q. Mr. Auerbach, that's not what I'm asking you. I'm asking you, when those analyst reports came out the next two days and had 86 to 91 as the absolute difference for the ExteNET study, did you call them and say, hey, or e-mail them because you were in constant e-mail contact, did you call them or e-mail them to tell them they had gotten it wrong by double?

A. They had not gotten it wrong, because if you looked at the centrally confirmed population, which is what is measured in their Herceptin adjuvant studies, and if --

THE COURT: Slow down.

THE WITNESS: Sorry. I don't believe they had gotten it wrong because if you looked at the centrally confirmed population, the centrally confirmed HER-2 population and ExteNET, which is the correct group to compare to the Herceptin adjuvant studies, it showed a benefit of 4.1 percent.

BY MR. COUGHLIN:

Q. Mr. Auerbach, you look at the centrally confirmed -- you had the KL curve [sic] done for the centrally confirmed group for the first time by Bin Yao, or at least he says it was the first time when you asked him for it. That was March 4th, 2015.

So are you saying that you were talking about the centrally confirmed group right here?

A. Yes. We had those curves back in July.

Q. You didn't produce any contemporaneous centrally confirmed curves from that time.

A. I believe we have produced the data from July with that data.

Q. Oh, no. You're talking about -- are you talking about the 2018 curve that was thrown up by Bin Yao? I'm talking

about contemporaneous curves around this time frame for the centrally confirmed group. There are none that we know of. Are you saying they exist?

A. They may or they may not exist. I don't remember if we looked for them, so I don't know the answer to that.

Q. Okay. We're going to look at an e-mail in March of 2015 when you asked those to be run.

A. Okay.

Q. And then we're going to find that you say how much of this data do we have. Would it surprise you to know you had less than 60 percent of the data for the centrally confirmed?

MS. JOHNSON: Objection. These are not questions. It's improper argument.

THE COURT: It's cross. Overruled.

BY MR. COUGHLIN:

Q. Would you be surprised to learn that you wrote, oh, we only have 60 percent? Would you be surprised?

A. We were still getting the centrally confirmed data in, as I remember it. As I remember this correctly, a lot of the centrally confirmed tests had not yet been run. They were still being run.

Q. So you knew at this time frame that you only had 60 percent of the centrally confirmed; is that right?

A. Yeah. If we only had 60 percent, then I would have been comfortable with that number.

Q. And you knew that -- did you know it or not?
A. Yes. I remember knowing that, yes.
Q. Okay. And did you think you knew it back here in July?
A. Yes, I knew that.
Q. And you're saying that you thought somebody ran you -- ran some KM curves in July 2014 with centrally confirmed for you?
A. My recollection is that when we saw this data, we had asked the question of a lot of these patients. So just to clarify, we invite -- may I clarify what centrally confirmed means?
Q. I'll ask you about it a little later. Centrally confirmed, you send it to a central lab to get confirmation, correct?
A. Yeah. The important part here is that the false positive rates with HER-2 testing is anywhere from 15 to 20 percent, meaning that if you go to your doctor's office, he does a test saying you have HER-2 disease, there's a 15 to 20 percent false positive rate.
Q. It's a better testing than the local testing; is that right?
A. That is correct.
THE COURT: Folks, I need to say the transcript of these proceedings is subject to doubt. That's the record you're making. That's the record we're going to have to live

with. Please work more carefully on creating a proper record. I don't know what more I can do except to say that you're making the transcript largely worthless.

If anyone wants to make a point on appeal, I have some questions about whether the transcript accurately reflects what's being said.

Continue.

MR. COUGHLIN: Understand, Your Honor.

THE COURT: I keep hearing that, but I hear you gearing up and getting fast in very short order. There's nothing more I can do except to say the transcript is now questionable.

Okay. Go ahead.

MR. COUGHLIN: Okay.

BY MR. COUGHLIN:

Q. When you gave these numbers that we talked about, you gave an actual -- basically a hazard rate by talking about the 33 percent improvement, right?

A. Correct. That was the primary end point of the trial, yes.

Q. That hazard rate only applied to the 2.3 percent absolute difference; is that correct?

A. That's correct.

Q. So when you gave that hazard rate to Dr. Werber and you said you thought you could get the numbers that he came up

with, 90, 91, with a 33 percent improvement, you were referring to the topline results, the absolute difference at 2.3 percent, correct?

A. No. That is incorrect. We were referring to the centrally confirmed.

Q. You were referring to the centrally confirmed group?

A. Both the ITT and centrally confirmed would still fall within the range we were giving. We were guiding to a range that was anywhere between one and six percent.

Q. But that centrally confirmed group that you run -- and we'll take a look at those curves that you run later -- has a different hazard ratio than this group; isn't that correct?

A. Yes. It's a lower hazard ratio, so better improvement.

Q. So when you refer to 33 percent, it was only -- that hazard ratio only refers to one group, 2.3 percent?

A. Correct.

Q. Let's go to page 7 of 15. I think it's clip eight. If you could take a look at the paragraphs where we talked about this a little bit. Howard was asking the question, Howard Liang.

(Audiotape recording played)

BY MR. COUGHLIN:

Q. Let's take a look at that. Now, you weren't saying that your curves were at six percent, seven percent, and eight percent, et cetera; were you?

A. No. What I believe I was referring to is that the magnitude of the benefit going out past two years is one percent, as you can see, going from year two to three. That was where we were guiding to.
Q. That's what you were trying to guide to when you made that statement of going out in the future years; is that right?
A. That is correct.
Q. And that's -- that's the curves that you say you were looking at when you made that statement; is that right?
A. Again, the curves I was looking at showed the benefit to be 2.3 percent at year two and 3.5 percent at year three.
Q. So it was not the curves from the study itself. It was some other curves that you say were created; is that right?
A. No. It was the curves from the study itself that showed the data for all patients all time points going out beyond two years.
Q. Going out beyond the two years -- at the end of this study going out to years three and four, all the patients that you still had; is that right?
A. I remember seeing data going out to year three. I don't remember seeing data that got to year four.
Q. And can you recall how many events were in that data?
A. I do not recall that.
Q. Eight sound right for year four and seven for year

three?
A. I don't remember.
Q. Do you know if what censoring rule that you applied to this curve that didn't exist at the time, I guess, that's been reproduced in 2018, do you know what censoring rule you applied? In other words, did you apply Puma's censoring rule or the FDA rule?
A. So the curve had been created in July of 2014, and it was created using the FDA's censoring rule because that was one that we knew that the FDA would accept.
Q. So you didn't apply the Puma censoring rule to those new curves -- but you didn't apply the Puma censoring rules to the ones you created in 2018, right?
A. For those curves we did not because there was a -- when we applied to the two-year data, when we used either the FDA censoring rule or the Puma, the results were identical. They didn't matter.

When we did it to the Puma censoring rule and the FDA one, I believe there were some issues with it because our censoring rule was a little too rigid. And we knew from the get-go that the FDA had already told us that our censoring rule was incorrect, and they told us this multiple times.

So the FDA censoring rule was the safer one to go with because, again, our goal here is to help cancer patients. And our goal here is to have a drug that we can

get FDA approved and therefore help cancer patients with. So using the FDA's censoring rule was the correct one to use.

Q. Now, you didn't start using the FDA's censoring rule until March of 2015; is that correct?

A. No, that is not correct.

Q. That's not the first submission in that time frame that you started submitting to the FDA?

A. No. We had been told early on when we were amending the protocol. Prior to unblinding the study, we had brought in a statistical consultant to help us out, and the statistical consultant had said to us from the get-go, your censoring rule is inaccurate and the FDA is going to have problems with it. You need to use the rule that they recommend in their FDA guidance documents.

Q. But when you applied for breakthrough, you know, breakthrough designation in 2014, you submitted the Kaplan-Meier curves with the Puma censoring rule; isn't that correct?

A. On the two-year data, if you used the FDA censoring rule or the Puma censoring rule, the data was the same.

Q. But you used the Puma censoring rule?

A. I don't remember which one we used. We may have used the Puma. I don't remember.

Q. Okay. Now, Mr. Auerbach, did you think there was some prohibition for you to present the absolute difference in the

press release?
A. To clarify, are you referring to the absolute DFS difference?
Q. Yes.
A. So when you get results from a clinical trial, very important validation of that data within the medical community and the breast cancer community is to present this at a medical meeting because this is where the doctors learn about it for the first time, and this is where they get comfortable with it and decide they can eventually prescribe this to their patients.

Every medical conference has a rule that you need to be very careful not to present too much data in the public and that all the data you present needs to be confidential; and that if you have presented data publicly, it excludes you from being able to present it at these medical conferences.
Q. Mr. Auerbach, I'm asking you if that's what you believe, that you couldn't present the actual DFS rates; is that right?
A. That's correct.
Q. Okay. And yet you did present DFS rates. You gave the guidance of the 86 to the 90, 91; isn't that correct?
A. We gave a guidance which was a range of mid to high 80s and 90 and 91, which would be a range of between one or two and six percent -- one and six percent, I should say. Giving

a range does not give the data. So we were -- that's why we were comfortable giving a range but not giving the actual data.

Q. Now, Dr. Chan presented this information at ASCO; is that right?

A. Yes, she did.

Q. Okay. And when asked if it was her opinion that if you disclosed additional details in the July 22nd press release, could that have jeopardized the ability to present the ExteNET clinical data at a major medical conference? She responded, I don't believe so. Did you know that?

A. I was not aware of that. But again, Dr. Chan is not the one who makes the decision of what gets accepted to a conference and what doesn't.

Q. Let's take a look at Exhibit 744, please.

A. (Witness complies.)

Q. Do you remember receiving this exhibit?

MR. COUGHLIN: I'd like to move this in. There's no objection.

THE COURT: Number what?

MR. COUGHLIN: Number 744.

THE COURT: 744 is admitted.

(Exhibit 744 received.)

BY MR. COUGHLIN:

Q. Do you remember after getting off your conference call

that Puma's shares were skyrocketing that day and went up 262 percent?

A. Yes, I do remember that.

Q. So you were aware of that?

A. Yes, I was.

Q. Let's turn to Exhibit 479.

MR. COUGHLIN: There's no objection to that, Your Honor.

THE COURT: 709?

MR. COUGHLIN: No, 479.

THE COURT: 479 is admitted without objection.

(Exhibit 479 received)

BY MR. COUGHLIN:

Q. So these are some analyst reports created after or a little later in the market after your conference call July 22nd, 2014. We saw these names Matt and Yaron that were asking questions on that conference call. And can you tell us who Mariann Ohanesian is?

A. Yes. Mariann is the head of investor relations at Puma.

Q. Okay. And she would pass on to you the analyst reports from the day; is that correct?

A. That is correct.

Q. And then you would get the analyst reports and read the analyst reports; is that right?

A. Usually that's correct, yes.

Q. Okay. So let's take a look at the first analyst report, the City analyst report that came out that night after that conference call. Actually it came out July 23rd. It says July 23rd on it at the top, but it was, I guess, late after the market.

If we take a look at the first page and take a look down at the best case scenario, read that paragraph to yourself for a second.

A. (Witness reading)

Q. So you got this analyst report from Dr. Werber; is that correct?

A. Correct.

Q. And you had quite a bit of e-mail and discussions with Dr. Werber on the phone; is that correct?

A. That's correct.

Q. Okay. And so you saw that he was saying: We estimate that neratinib achieved a two-year DFS rate of around 90 to 91 percent versus 86 percent for a placebo. Do you see that?

A. Yes, correct.

Q. And the hazard ratio that is associated with that is .67; is that correct?

A. That is correct.

Q. And that's with the intent to treat population, right?

A. My assumption was he was referring to the centrally confirmed HER-2 because we had said -- made the analogy of

the Herceptin adjuvant trials.
Q. You never mentioned the word centrally confirmed on this conference call?
A. It was actually mentioned in the Q&A.
Q. In the Q&A about centrally confirmed?
A. I believe there was a question from Howard Liang where he referred to the HER negative patients, which would be -- and those would be the false positives, the centrally confirmed who did not get -- you know, did not have a positive --
Q. So you think -- but this hazard ratio is not the hazard ratio associated with that centrally confirmed group. We just talked about that, and that hazard ratio was, like, .52, right?
A. It was a lower hazard ratio, so a better benefit. So we were comfortable with investors assuming it was, you know, the benefit of .67 in that group.
Q. But here they're assuming that it's your intent to treat population of the absolute results that you announced, okay, and that was the .67. And that hazard ratio is only associated with half the benefit that's indicated here.
A. So the guidance that we had given on the call or that we were attempting to give on the call was that the benefit seen in the trial ranged anywhere from one to six percent. So that would encompass both the intent to treat population

where it was 2.3 percent and also encompass the centrally confirmed HER-2 population which was 4.1 percent.

Q. Let's take a look at the next analyst report from UBS that was also attached to the same e-mail, so it's the same exhibit number, 479, page 15 of 24.

I'm going down to the key points and support numbers. It talks about commentary is improved as the FDA could accept adjuvant as a confirmatory study. Commentary on the call adds to our --

THE COURT: Hold on. Please say it slowly enough and clearly enough that we can understand.

MR. COUGHLIN: Commentary on the call adds to our confidence that the DFS curves apparently widen over time, and neratinib appears active in all subgroups examined, suggesting broad utilization.

BY MR. COUGHLIN:

Q. Do you see that?

A. Yes, I do.

Q. Okay.

A. Just to clarify if I may.

Q. Sure.

A. May a clarify something that you said, please?

Q. Sure.

A. Okay. Point number two, you'll notice it says, the result also increases the chances of success of neratinib in

other segments and indications which are significant opportunities but now look small compared to adjuvant. In particular, we think the neoadjuvant outlook is improved as the FDA could accept adjuvant as a confirmatory study.

I just want to be clear he was referring to a different study and a different population of patients there.

Q. I understand. But when he talks about the curve widening, he was referring to your comment, right?

A. Correct.

Q. That's really all I was talking about. Let's take a look at the next day, the analyst report from the next day, Exhibit 301, July 23rd, 2014. This is Howard Liang's statement, his analyst report.

MR. COUGHLIN: I'd like to move this into evidence, Exhibit 301, with no objection, Your Honor.

THE COURT: Without objection 301 is admitted.

(Exhibit 301 received.)

BY MR. COUGHLIN:

Q. If we go down to the best case scenario, in our view --

MS. JOHNSON: I'm sorry to break in, Your Honor. We have discussed a limiting instruction stipulation for all of the various analyst reports.

Counsel mentioned it. It hasn't been worked out yet, but I just wanted to note for the record that there may be an agreed-upon limiting instruction that would apply to

the analyst reports.

MR. COUGHLIN: We agree with that, Your Honor. There's not going to be a dispute about the instruction to be given about these analyst reports.

THE COURT: All right. To urge your negotiations along, it seems to me there should be such a limiting instruction, and I would inclined to provide it even if it wasn't stipulated.

Go ahead.

MR. FORGE: Your Honor, with so many people talking past each other in some of these discussions, we have agreed on the language on the limiting instruction.

MS. JOHNSON: Right.

MR. COUGHLIN: Yes, we have. So we can give it at any time, I think. It's not necessary to give it -- well, we should give it sooner probably rather than later, maybe tomorrow morning or later tonight.

THE COURT: I'll leave it up to you to supply what you think needs to be supplied when you think it needs to be supplied.

MR. COUGHLIN: Okay.

BY MR. COUGHLIN:

Q. So let's take a look at the best case scenario in the middle: DFS for the control arm was in line with historical Herceptin adjuvant studies likely in the range of 86 to

87 percent, which suggests a 91 percent DFS in the drug arm or absolute difference of four percent.

Do you see that?

A. Yes, I do.

Q. Okay. Did you call up Howard and say, hey, you got it wrong, Howard?

A. No, I did not. His report, first of all, states the best case scenario, which means he had probably a medium case scenario or base case scenario or other scenarios as well, which, my understanding from talking to investors who had spoken with him, he did have a scenario modeling, which suggested a wide range, in line with the range we gave.

Again, you know, the four percent number is the correct number for the centrally confirmed.

Q. Okay. I was just asking you if you had called him. You hadn't.

If we go to page 15 of Exhibit 301, that's the Cowen report. If we go to the ExteNET, looks like a home run. It says treatment with neratinib resulted in a 33 percent improvement in DFS versus placebo with the hazard ratio of .67. Do you see that there?

A. Yes, I do.

Q. It goes on: We estimate a three-year DFS rate of 85 to 87 for the control arm, so it's likely the three-year DFS on neratinib approached the low 90s. Do you see that?

A. Yes, correct.
Q. Did you call Mr. Schmidt at Cowen and say, hey, you've got that wrong? You've associated a hazard ratio that's something else; it doesn't go with the centrally confirmed? Did you call him and tell him that?
A. Well, his range as I look at it is anywhere from three to six percent. I'm assuming low 90s is 90 to 91. If I assume 85 to 87 is 85 to 87, that would be a range of anywhere between three and six percent.
So I -- could we please go down to the next paragraph on the report?
Q. Actually we're going to move on. If your counsel wants to go down to the next paragraph, they can do that. Okay?
A. Okay. Yeah.
Q. If we could take a look at Exhibit 576. And don't put 576 up. Take a look at it first. This is on e-mail from Robert Glassman to you. It's dated August 19, 2014. You received it and made comments about it in Exhibit 499.
MR. COUGHLIN: And, Your Honor, they've objected to this. I don't know what the objection, what the basis of the objection. This is the sales document for Puma that the bankers were preparing and showing to potential purchasers.
He received this in the ordinary course of business. He made --
THE COURT: Hold on. I need him to say that, not

you.

Let's first ask if there's an objection. Okay. I'm looking at Exhibit 576. It is a few pages long.

Do you move its admission?

MR. COUGHLIN: I do, Your Honor.

THE COURT: And the defense says?

MS. JOHNSON: What -- with the -- with the same limiting instruction we'd be fine with it, Your Honor.

MR. COUGHLIN: That's fine, Your Honor.

THE COURT: Okay. Great. Then 576 is admitted.

Thank you, Ms. Johnson. I appreciate it.

(Exhibit 576 received)

THE COURT: It's up -- don't expect me to follow up and give limiting instructions unless they're provided to me.

MR. COUGHLIN: Absolutely, Your Honor.

THE COURT: Okay. Go ahead.

BY MR. COUGHLIN:

Q. So if you flip -- so I want you to look at that, 576. And actually let's look right at what we're going to look at. The first page says Robert Glassman. And who is Robert Glassman?

A. Robert Glassman is an investment banker for Bank of America, Merrill Lynch. He's also a medical doctor, and he's also a cancer doctor.

Q. He says: Alan, this is the profile we shared with Merck

and Celgene. Any comments, issues welcome. Rob.

Do you see that?

A. That is correct.

Q. And let's take a look into this document. The jury can look at it, and we might come back to it and talk about it. But I want you to go all the way to the back: We believe most concerns can be mitigated. Down at the bottom it says market risk. It says the three-year DFS benefit in adjuvant breast cancer roughly translates into an absolute five percent of breast cancer patients.

Do you see that?

A. Yes.

Q. Okay. And I want to talk about that in a second. But I want to flip over to 499, which is your response to his request for comments.

A. Okay.

MR. COUGHLIN: I'd move 499 in. It's not objected to.

THE COURT: Without objection 499 is admitted.

(Exhibit 499 received)

BY MR. COUGHLIN:

Q. I believe this is you responding to Rob's questions to you; is that correct?

A. I need to review this. One second.

Q. Okay.

A. (Witness reading) Yes, this was me responding to him.
Q. Okay. And what you're correcting there is he had mentioned in that paragraph we looked at, that blurb, that he was referring to a three-year DFS benefit, and you said it was really a two-year; is that correct?
A. Yeah. I seem to remember this. The analysis in the trial is a two-year analysis. But as investors were, you know, trying to do comparisons between the Herceptin adjuvant trials and the ExteNET trial, they kept trying to compare the time points from the Herceptin adjuvant trials with the time points in ExteNET.

So many of them had started to reference the two-year analysis in ExteNET as a three-year analysis because that would -- you know, the standard of care as patients get adjuvant Herceptin for a year and then two years, that would be the way to do the cross-trial comparison.

Q. I understand. It took me a while, but I understand.

Down below in the middle of the paragraph, you say: You may want also to mention that the curves are continuing to separate, so by the five-year analysis the absolute DFS rate should be larger than it is at two-year time point.

Do you see that?

A. That's correct.
Q. Huh?
A. Yes.

Q. Do you see that?
A. Yes.
Q. Do you still agree that was a correct and honest statement at the time?
A. Well, at the time what we had seen was the data in July 2014 that showed that our benefit went from 2.3 percent at two years to 3.5 percent at three years. So our assumption was that it would continue.
Q. Again, you've not produced any document contemporaneous with that time frame showing that benefit?
A. We have produced a document that shows that the data from July 2014 that we had in our possession as of July 2014 showed a DFS benefit of 2.3 percent at two years and 3.5 percent at three years.
Q. We're still talking about the Bin Yao document created in 2018?
A. I don't know what time frame it was created, but it was from the same data set.
Q. Just recently.
A. But am I correct it was from the same data set?
Q. We don't believe so. There's a dispute about it, but I wanted you to testify about it. If that was your belief --
A. I don't know --
THE COURT: Hold on. A little fast. You talked over him before he finished.

THE WITNESS: My apologies.

THE COURT: Now you may answer.

THE WITNESS: I don't know the time frame as to when that was created, but I know it was the same data set.

BY MR. COUGHLIN:

Q. Okay. Let's talk about that. They're talking about -- then you go on to talk about priced at 4K per month, and it would be a $4.3 billion in worldwide sales. Do you see that?

A. Yes.

Q. So what you're trying to do here is sell the company right now; is that right?

A. That is incorrect.

Q. Well, you've got a banker putting together a presentation with a DFS rate of five percent going out to investors. And isn't that to sell the company?

A. That is incorrect information.

Q. Okay. Now, this banker, this wasn't the first note you got from these bankers that they had met with companies. Did you get a similar one the month before in August?

THE COURT: Hold on.

BY MR. COUGHLIN:

Q. This wasn't the first note you had gotten like this from the bankers. Hadn't you already gotten one back in August that they had presented to some other companies?

A. We get communications from bankers on a regular basis.

And, you know, just to clarify, a lot of large investment banking firms -- Bank of America is one of them -- have a lot of relationships with large pharmaceutical companies.

Sometimes those companies are interested in research and development collaborations. Sometimes they're interested in partnerships, which, those partnerships could be we do a joint partnership where we sell and market the drug together. Or they can also be interested in, you know, acquiring the entire technology as a whole.

Obviously we don't have those relationships. They do. So they will very often ask bankers to, you know, do a presentation on a certain technology, a certain drug, a certain company.

I have a fiduciary responsibility to the investors in this company. If someone e-mails me or contacts me saying we just met with pharmaceutical company ABC and they wanted us to do a presentation on Puma, whether I want to do that research collaboration or I want to do that sales and marketing partnership or I want to sell the company, is irrelevant.

I have a fiduciary responsibility to investors. When I get those type of communications, as a fiduciary responsibility to the investors I have to respond to them and be helpful.

Q. Did you ever sign a confidentiality agreement with any,

like, Celgene or Merck so that they could look at your data?
A. We -- I seem to remember we did have CDAs with various companies in place over various years. I don't remember specifically for these two entities if they were in place exactly in, this appears to be, September 20th, 2014.
I don't remember if we had CDAs in place at that time. I know we've had CDAs in place with pharmaceutical companies.
Q. At different times?
A. At different -- well, it may have been signed before but were still active.
Q. Right. We have -- we don't have a signed CDA with either Merck or Celgene around this time frame. That doesn't surprise you, though, right? It wouldn't necessarily surprise you, right?
A. In September 2014, that would sound accurate, yes.
Q. Okay. Let's take a look at Exhibit 497.
MR. COUGHLIN: I'd like to move this document in, Your Honor. It's not -- I don't think it's been objected to.
MS. JOHNSON: It has been objected to.
MR. COUGHLIN: Oh. Well, Your Honor, I'd like --
THE COURT: Hold on.
The objection is?
MS. JOHNSON: It's -- I would propose a limiting instruction that the document -- it's hearsay, but we can

waive that objection subject to a limiting instruction that the information in here is not necessarily true, but it is a business record.

THE COURT: Is that acceptable to you?

MR. COUGHLIN: It is, Your Honor.

THE COURT: Okay.

So, folks, there's something called hearsay. I'm sure you've all heard of it. It means when you -- oh, stated simply, you offer something that someone else says and you offer it for the truth of what was said.

Well, they've agreed that this document can come in but not for the truth of anything, any facts that it includes within it. So document number 497 is admitted, but if it says in there it was a rainy day on Wednesday, it's not admitted to prove that. It's admitted for other reasons, not to prove the facts that might be in it.

I hope that's clear enough.

Go ahead. It's admitted, 497.

(Exhibit 497 received.)

BY MR. COUGHLIN:

Q. Could you take a look at this, Mr. Auerbach.

A. Yes.

Q. Do you remember receiving this nondisclosure agreement from -- or this proposal from Celgene?

A. Yes, I do.

Q. And it had a confidentiality agreement attached to it. Did you see that also?
A. That is correct.
Q. And you didn't sign that; is that correct?
A. We did not sign it during this time period.
Q. Right. You didn't sign it during the time period from 2014 to 2015; is that correct?
A. Yes. As I remember this, Celgene had flown out to have dinner with me and had stated that they had an interest in potentially acquiring the company. Again, I have a fiduciary responsibility to the investors. Whether I want to do that or I don't want to do that, I have to accept those type of invitations.

I had said to them when we had dinner that the next step in due diligence would be to schedule a time for either them to fly to Los Angeles -- they're located in New Jersey -- for them to fly to Los Angeles to do an entire meeting to do due diligence, or for me to fly to New Jersey, either. And then at that point we could move forward.

Q. And they make a proposal to acquire a hundred percent of the outstanding shares of the company for $10 billion; is that correct?
A. Correct.
Q. Okay. And that was just a couple months after your July 22nd conference call; is that correct?

A. Yes, that is correct.
Q. And you did not sign this confidentiality agreement; is that correct?
A. I had contacted them to schedule the follow-up meeting, and they did not ever get back to me. So we never moved the CDA forward because the purpose of the CDA would have been that meeting.
MR. COUGHLIN: Your Honor, I think this might be a good time.
THE COURT: Excellent. We will break now and we'll meet tomorrow at 9:00, not at 8:00.
We are moving along nicely here, and it has been rainy outside.
So we'll meet you at 9:00 tomorrow. Remember, don't discuss this case. Keep an open mind, and don't do any research on the case.
Thank you.
THE CLERK: All rise.
(Open court - jury not present)
THE COURT: All right, sir. You may step down.
See you all at 9:00.
MR. GRONBORG: Your Honor, there are a few discovery -- excuse me, evidentiary issues that we would like to raise if possible that we can deal with -- there's three of them -- that would make tomorrow much more efficient in at

least putting together deposition designations, as well as one that we'd probably have to worry about ringing the bell.

THE COURT: All right. So we've identified three discovery issues or evidentiary issues, correct?

MR. GRONBORG: Yes.

THE COURT: Is there anything else that anyone wishes to handle right now?

MS. JOHNSON: The only thing I would raise is I asked to do a proffer for Dr. Adelson, sustaining of the objection based on ML four. It would be short.

THE COURT: You want to make a proffer?

MS. JOHNSON: Correct, just for the record.

THE COURT: Go ahead.

MS. JOHNSON: Thank you.

THE COURT: I thought you were going to do that at the first break. But, you know, I must say when people offer to make proffers or offer stipulations, I usually leave it up to them to bring up. So go ahead.

MS. JOHNSON: Thank you, Your Honor.

Just for the record, the testimony I would have elicited had that objection not been sustained would have been that the Yale tumor board recommended consideration of neratinib to patients as part of an appropriate standard of care, that Dr. Adelson was part of that panel who agreed as a group that neratinib was an appropriate standard of care for

actual patients, and that Dr. Adelson had spoken with colleagues and agreed that some patients are appropriate for neratinib and would have prescribed it if the patient had wanted it, thereby agreeing that neratinib is part of an appropriate standard of care.

I can cite to the deposition sections if that's helpful.

THE COURT: If you'll appeal, you'll be able to cite then. I will accept your proffer as it is made. But I'm telling you, that certainly seems to come right within the motion in limine. It's after the class period and -- you've made your proffer.

MS. JOHNSON: Yes. And the argument is that they opened the door by --

THE COURT: I don't think they had opened the door by that time. But in all fairness, I don't think you said they opened the door. There was times during the afternoon examination when I was thinking about whether they had opened the door.

You've made your record.

MS. JOHNSON: Thank you, Your Honor.

THE COURT: Good. Now, what do we need to do here?

MR. GRONBORG: Your Honor, the issue number one is with respect to three documents. If I can approach, I can hand them to you.

THE COURT: I thought -- well, okay. I thought there were three things we need to describe. Now there's one with three things.

MR. GRONBORG: There's one with three things.

THE COURT: The only reason I say that is I think it's fair to let the staff and everybody know what's going on here.

Okay. We have these three documents. What do you want me to do with them?

MR. GRONBORG: Your Honor, these are three communications from Alan Auerbach. They involve the company Pfizer.

The defendants have taken the position that these are documents that would be excluded by their motion in limine number two which, as you will recall, excluded evidence of a dispute with Pfizer.

None of these documents will be used to have any discussion or raise any dispute. We are willing to redact the letters DR in there. They go directly to the testimony we just heard.

Specifically, if you don't mind, if I could have you turn to Exhibit 482, page 3 of 4 of Exhibit 482, the first full paragraph.

THE COURT: Why are you reading this?

MR. GRONBORG: To establish the relevancy and how

it has nothing to do with a dispute with Pfizer. It has to do directly with the testimony we just heard.

THE COURT: Okay. Let's start with this. The plaintiff moves Exhibit 475, 482, and 795. Is there any objection?

MS. JOHNSON: Yes, Your Honor.

THE COURT: To all of them?

MS. JOHNSON: Yes.

THE COURT: What's the objection?

MS. JOHNSON: Based on the Court's order on defendant's motion in limine number two to exclude evidence of Puma's dispute with third-party Pfizer. These go directly to that dispute. It does not change anything if you redact the actual words that refer to the dispute. The evidence goes to that dispute, and we would not have a -- all the arguments in the motion in limine, we would have to have an opportunity to put on evidence of that trial-within-a-trial sideshow.

THE COURT: Okay. Perhaps it might be helpful if you identified the types of statements in these exhibits that cause you concern.

MS. JOHNSON: For example, Exhibit 482 is one of a number of correspondences between Puma and Pfizer in the exact dispute that was the subject of the motion in limine.

THE COURT: You -- no offense, but you've just said

the whole document. I was hoping it identified specific language in there that you think raises the issue. You know, you have much more familiarity with these documents than I do. I mean, what specific language are we talking about?

MS. JOHNSON: Having just gotten these, they -- the letters are -- you know, I cannot at this minute direct you to specific language, but the letters --

THE COURT: But, you see, I have to do that. So that means I have to read it all and figure out where the issue lies. I can't be abstract here. If you can tell me where you think it improperly raises facts covered by the motion in limine, that helps. Or I can read the motion in limine. I can read the exhibits cover to cover.

I'm just trying to look for a shorter way of doing this. Maybe there's a shorter way. Can you tell me?

MS. JOHNSON: Yeah. I'll give you a better example. Exhibit 795 on the first page in the --

THE COURT: Now, hold on. 795, first page. Uh-huh.

MS. JOHNSON: In the context of this back and forth between Pfizer and Puma, the first bullet point, someone from Pfizer is saying in response to a question by Yaron Werber regarding DFS rates, Alan implied that he knew the DFS rates of the active and control arms.

In response to a question by Howard Liang regarding

longer-term follow-up, Alan implied knowledge of DFS rates beyond two years, et cetera. This dispute was over whether Pfizer was entitled to information that was within Puma's control, among many other aspects of that dispute which we would have to litigate.

Plaintiffs I presume would use it to show that information was not provided to Pfizer. Plaintiffs will want to say that shows he doesn't have it. Our defense would be they're not entitled to it, and we would be going down a rabbit hole of that separate dispute.

THE COURT: I think this information can be presented without any reference, knowledge, or anything concerning the dispute. I mean, the jury doesn't need to know about the Pfizer dispute in looking at this information, and I believe my motion in limine was directed at the Pfizer dispute.

I don't see, for example, how those bullet points informs the jury that there's a Pfizer dispute.

MS. JOHNSON: Plaintiffs' use of it will. Plaintiff will use it to say if he didn't give it to Pfizer, he must not have had it. And we would have --

THE COURT: Is that what you intend to do?

MR. GRONBORG: I think their concern is we're going to --

THE COURT: You're not answering my question, but

go ahead.

MR. GRONBORG: Actually we're going to use his own statements where he tells Pfizer, for example, to switch to the other exhibit when they're asking for subgroup, for example, the centrally confirmed subgroup that he says he has, that he is telling another entity in September of 2014 that it's going to take three to four weeks to get that information.

THE COURT: Okay. You didn't answer my question, which makes me inclined to agree with Ms. Johnson. She posed a question, and you didn't answer it.

MR. GRONBORG: Perhaps I didn't understand the question, then.

THE COURT: Well, maybe you just listen to it.

Would you state your situation again.

MS. JOHNSON: We understand that plaintiff will use this information to suggest Pfizer's asking for it. Puma is saying we don't have it. We need to find it. It would take some time.

Plaintiff will use this back and forth to suggest that Mr. Auerbach did not have the information at this time. That's not true because it was in the context of a business dispute. We would be entitled to put on evidence -- we would have to put on evidence of what the nature of the dispute was, what Pfizer was entitled to under the license agreement,

why Mr. Auerbach was making these statements to a separate third party. That is exactly what motion in limine two goes to.

And I believe that Mr. Gronborg is saying that is what they would use the evidence to suggest.

THE COURT: Okay. That's a different question you're posing now than the one I asked plaintiffs' counsel about.

Yes. Go ahead.

MR. GRONBORG: I was going to try and answer the question with an example from the document which is 495 and say it is actually showing what a fairly contemporaneous record of what Mr. Auerbach is saying he does have.

For example, where he says it appears based on a preliminary analysis that the absolute difference in DF curves is separating by approximately 0.5 percent per year. So he is providing information about what he does have. It's not being used to --

THE COURT: Okay. You know, when I -- correct me if I'm wrong. There were quite a few motions in limine, but it seems to me my granting the motion in limine was I didn't want to get into a discussion of the other bit of litigation.

I don't know that this requires even reference to the fact that there was other litigation. Why would it require reference to the fact that there was other

litigation?

MS. JOHNSON: Your Honor, because they're going to characterize his statements to Pfizer. We can't defend that without explaining the --

THE COURT: What would you explain? Would you explain, well, there was litigation, so I couldn't turn over all the information? I'm trying to get in how the litigation comes into play, and that's what I'm not understanding.

MS. JOHNSON: The back and forth between the two involves Pfizer mischaracterizing the data; Alan responding. These are not the only three pieces of correspondence. You'd have to track them all to say, okay, first, Pfizer said this. Then Alan said this. And Pfizer characterized the data like this.

So if you take one of them out of context without explaining the dispute, the jury will be misled. That was the argument in our motion.

THE COURT: Do you intend to reference the litigation?

MR. GRONBORG: Not at all.

THE COURT: That was a clear answer. Do you think you can present this as information without reference to the litigation?

MR. GRONBORG: Yes.

THE COURT: I think he can, too.

MS. JOHNSON: I think he can, too, but we can't. We would have to reference it in order to explain the context for the --

THE COURT: How is that? I mentioned you would have to say, well, there was litigation, so we weren't forthcoming. How do you have to reference the litigation?

MS. JOHNSON: Because it explains the relationship between the parties.

THE COURT: How is the relationship relevant?

MS. JOHNSON: So just to, you know, back up, plaintiff is saying this information was relevant to what was said publicly. We know what those rules are. We know what's required under the securities laws. We have a basis for understanding whether he should or should have not said what he said. This is a private dispute that the jury doesn't understand the rules for.

THE COURT: What rules for the private dispute? I mean, information was either provided or not provided. Why do we need to reference anything about the litigation?

MS. JOHNSON: Because it was governed by a complex licensing agreement that governed the parties' rights and relationships. We would have to explain --

THE COURT: Why can't you say it was governed by a complex licensing agreement? That doesn't reference the litigation.

MS. JOHNSON: The facts of the agreement and the fact of the litigation explains the context for the statements if the plaintiff is going to suggest data did or did not exist at a certain time, that Mr. Auerbach lied or didn't lie to Pfizer. We need to understand the context.

THE COURT: I keep trying to probe why that's necessary, and I'm not getting sufficient answers.

So what else about this would anyone like to say?

MS. JOHNSON: My request would be that because we didn't know that these particular three documents were going to be the subject of this argument, that you give us a bit of time tomorrow morning to articulate it.

THE COURT: You can reargue it tomorrow morning. For now the tentative is to allow it with firm instructions to counsel not to mention the litigation, not to mention things that require a reference to the litigation. But so far I haven't seen that.

And it sounds a little bit like you don't want these in and you're trying to tie it into the litigation. But I think they can come in without reference to the litigation. And by the way, you'll note on all these motions in limine, you may or may not recall me saying the problem with motions in limine is you cabin all these things but have relevance beyond the cabining.

We have an example this morning where it was

relevant beyond the little cabin, and then in the trial we spent a lot of time defining the cabin and its limitations instead of just looking at the facts itself.

So you're welcome tomorrow morning to present further argument. The key thing I want to know is how will you be required to reference the litigation. You can reference lots of things about licensing, et cetera. I don't know that you're going to reference we were in litigation so he couldn't be forthcoming. I'm not sure that's a good argument. I'm not sure you want to make that to the jury. But, I mean, that kind of thing I would listen to.

For reasons the jury doesn't need to be familiar with, there was a privilege involved and he felt he needed to stand by the privilege -- something like that. I'm not sure there is a privilege involved here in relation to the litigation.

I just need to see it tied more to the litigation. So convince me of that tomorrow, and we'll go forward with that.

When will you be using this?

MR. GRONBORG: I anticipate tomorrow.

THE COURT: With Mr. Auerbach?

MR. GRONBORG: Yes.

THE COURT: Okay.

What other issues do we have besides these three

documents?

MR. GRONBORG: My colleague, Ms. Conn, she'll handle the next. And to deflect a little from here, it is one that is more than one within it.

THE COURT: I didn't understand that, but go ahead.

MS. SMITH: Thank you, Your Honor.

THE COURT: Just a moment. Did you need something?

MS. SMITH: I just want to know how long, because I'm --

THE COURT: Exactly. I'm trying to get how long.

Now, I understand there's three issues, and we just took care of one?

MS. CONN: Correct, Your Honor.

THE COURT: Now let's take care of two.

How much time do you need?

MS. CONN: I can be done in ten minutes, I think.

THE COURT: Well, begin by telling me what it is you want the Court to do.

MS. CONN: Okay, Your Honor. Tomorrow as part of our witness plan, time permitting and depending on how long we take with Mr. Auerbach, we were intending to show some depositions.

I'm happy to report we've resolved many, many of our objections, but there are two witnesses to whom defendants still object to plaintiffs' designations.

THE COURT: Okay. You know, it's just so helpful to me if you say, Your Honor, we'll need you to review transcripts and rule on some objections. But you've now talked for a minute, and you haven't told me what you want me to do. It's just helpful, the way my brain operates, to ask me what you want and then we'll go into all the background.

What do you want me to do?

MS. CONN: I would like you to review, and I have a correction. It's only one witness at this point. We're still negotiating on the second witness. As to one witness I would like you to review our designations and defendant's objections and make rulings on those objections.

THE COURT: Do you have a transcript? Do you remember yesterday I asked for it? Maybe you don't remember, yesterday I asked for it so I could be ahead of the curve. You have a transcript and you want me to review it?

MS. CONN: Yes, Your Honor.

THE COURT: If you give it to me, I can do that.

(Document handed to the Court)

THE COURT: All right. So I have in front of me a transcript for Eric Schmidt. I can read this tonight. I mean, did you have any other idea? I mean, do you want me to -- I'll read it tonight. So tell me what the color coding is.

MS. CONN: Okay. So the -- orange highlighting is

plaintiffs' designations.

THE COURT: Okay.

MS. CONN: Yellow highlighting is defendant's designations.

THE COURT: Uh-huh.

MS. CONN: Anything with a red box around it indicates there is an objection to that testimony.

THE COURT: Okay.

MS. CONN: And in the margin of the document is the basis of the objection.

THE COURT: Very good. Well stated.

All right. Now, I hope some thought went into these. I do find more often than not it's actually someone not directly related to the litigation who likes to say foundation to everything.

MS. CONN: If I may, Your Honor --

THE COURT: This is good. I'm looking at page 138 and there's a box and it says hearsay. So do I -- I only have to see where there are red boxes, right?

MS. CONN: That's correct, Your Honor.

THE COURT: But there aren't that many red boxes. I mean, I can do that easily. Okay. I'll go through and make those rulings.

MS. CONN: Thank you. To be clear, all objections are defendant's at this point. I think they may have

inadvertently objected to some of their own designations, but they're all defendant's objections.

THE COURT: Okay. We'll see. That's number two?

MS. CONN: Yes. And number three --

THE COURT: Before we get to number three --

MS. CONN: We're going to take number three off the table.

THE COURT: So we're done?

MS. CONN: We're done.

THE COURT: So here's the issue that always comes up on these. You have this on videotape? How good is your videographer?

MS. CONN: Pretty good.

THE COURT: If I give it to you at nine, can the videographer do what he needs to do?

MR. COUGHLIN: Yes, Your Honor.

THE COURT: Okay. All right.

Could we all be here at 8:45?

MS. CONN: Yes, Your Honor.

THE COURT: I will give you my rulings and give you a brief chance to argue. We'll have a brief chance to argue on yours -- and this is actually going to come after Mr. Auerbach; correct?

MS. CONN: That is correct.

THE COURT: Okay. So that's what we'll do. So

we'll see you all at 8:45 tomorrow. Good.

Thank you.

(Proceedings adjourned at 4:49 p.m.)

CERTIFICATE

I HEREBY CERTIFY THAT THE FOREGOING IS A TRUE AND CORRECT TRANSCRIPT OF THE STENOGRAPHICALLY RECORDED PROCEEDINGS IN THE ABOVE MATTER.

FEES CHARGED FOR THIS TRANSCRIPT, LESS ANY CIRCUIT FEE REDUCTION AND/OR DEPOSIT, ARE IN CONFORMANCE WITH THE REGULATIONS OF THE JUDICIAL CONFERENCE OF THE UNITED STATES.

/s/ Miriam V. Baird 01/17/2019

MIRIAM V. BAIRD
OFFICIAL REPORTER

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