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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
HONORABLE ANDREW J. GUILFORD, JUDGE PRESIDING  
HSINGCHING HSU, )  
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Plaintiff, )  
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 )  
Vs. ) No. SACV15-0865-AG  
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 )  
PUMA BIOTECHNOLOGY, ET AL, )  
 )  
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Defendants. )  
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REPORTER'S TRANSCRIPT OF PROCEEDINGS  
*JURY TRIAL, DAY 2*  
SANTA ANA, CALIFORNIA  
WEDNESDAY, JANUARY 16, 2019

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

2 ---

3 THE CLERK: All rise.

4 (Open court - jury present)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19          I will list them for you:

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

1       them controls.

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 jurors.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 The plaintiff will call their first witness.

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

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

24 THE COURT: Yes, you may. Thank you.

25 **Kerin Adelson, Plaintiffs' witness, sworn**

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

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

5                           **DIRECT EXAMINATION**

6 BY MR. FORGE:

7 Q. Good morning, Dr. Adelson.

8 A. Good morning.

9 Q. Dr. Adelson, where do you live?

10 A. I live in New Haven, Connecticut.

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

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

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

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

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



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

4 Q. Do you still treat real patients?

5 A. Absolutely. Yeah.

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

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

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

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

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

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

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

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

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

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

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

19 Q. Do you also occasionally work on clinical trials?

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

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

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

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

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

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

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

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

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

1 longer without their cancer growing.

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

5 A. Yes.

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

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

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

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

1 Q. How about the safety side of the equation?

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

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

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

16 Q. Why is it important to test both the efficacy and safety  
17 of --

18 A. Because, you know, everything in medicine is a weight  
19 between risk and benefit. Certainly for very, very large  
20 benefits, patients might be willing to tolerate more side  
21 effects or more toxicity with the goal of a very substantial  
22 increase in their chance of living for a longer time or being  
23 cured of their disease.

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

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

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

6 A. Yes.

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

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

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

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

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

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

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

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

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

22 Q. How long have you been at Yale?

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

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

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

3 A. University of California at Santa Cruz.

4 Q. What was your major there?

5 A. American literature.

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

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

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

17 Q. Where did you go after Columbia?

18 A. Then I went to Yale for medical school.

19 Q. How long was that?

20 A. Four years.

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

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



1 actually chose a specialty.

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

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

7 Q. What after Mt. Sinai?

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

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

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

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

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

1 A. So then I went back to Mt. Sinai School of Medicine as  
2 an academic breast cancer oncologist.

3 Q. How long did you practice there?

4 A. About seven and a half years.

5 Q. Could you give us a sense of how many patients you  
6 saw --

7 A. Yeah.

8 Q. -- on an everyday basis?

9 A. So I was very busy. I saw probably 23 breast cancer  
10 patients a day, three and a half days a week. And then the  
11 remainder of my time was spent sometimes just following up on  
12 issues that patients were having but also doing  
13 administrative work with quality and the electronic health  
14 record.

15 Q. You mentioned earlier that these are ongoing  
16 relationships. Could you describe to us a little bit more  
17 the nature of the relationship in terms of is it purely  
18 clinical and scientific?

19 A. It's both. It's all of the above. And, you know, it's  
20 really a privilege to take care of women with breast cancer.  
21 They're incredibly motivated to do everything they can to  
22 make sure that their disease doesn't come back.

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

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

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

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

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

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

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

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

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

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

7               THE COURT: Yes.

8               MR. FORGE: Can everyone see that?

9               THE WITNESS: Am I supposed to get up?

10       BY MR. FORGE:

11       Q.     If you can reach without standing up --

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

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

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

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

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

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

6 A. Yes.

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

9 A. Uh-huh.

10 Q. What is HER-2 positive breast cancer?

11 A. So HER-2 is a growth factor that is expressed on about  
12 20 percent of breast cancer cells. Back before I did my  
13 training, patients with HER-2 positive breast cancers had a  
14 much worse prognosis. The cancer cells grew rapidly. They  
15 metastasized early, and it was a very bad kind of breast  
16 cancer to have.

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

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

1           So when I think about drugs, that's a home run.

2       Right? It's a drug that dramatically improves benefit

3       without improving -- without worsening suffering.

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

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

10      Q.    Do you testify strictly for plaintiffs?

11      A.    No.

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

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

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

17      A.    Probably about 20.

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

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

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

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

1 Q. Do you -- are you paid on an hourly basis?

2 A. Yes.

3 Q. And how much is the hourly rate?

4 A. So when I first started working on this case, my hourly  
5 rate was \$600. Now it's \$700.

6 Q. How about for testifying in court such as today?

7 A. When I first started on this case, it was 6,000, and I  
8 have -- it has gone up to 8,000.

9 Q. Now, is your compensation tied in any way, shape, or  
10 form to the outcome of this case?

11 A. No.

12 Q. Is it tied in any way to specific opinions you must  
13 give?

14 A. No.

15 Q. Is it influenced in any way by the -- is your -- are  
16 your opinions influenced in any way by your compensation?

17 A. No.

18 Q. Now, Dr. Adelson, you've told us what HER-2 positive  
19 breast cancer is. Could you please explain, keeping that  
20 time frame in mind, what the standard of care for HER-2  
21 positive breast cancer was in that 2014-2015 time frame?

22 A. Yeah. So the standard of care was for patients to  
23 receive chemotherapy along with Herceptin for a few months,  
24 followed by Herceptin alone until a year. When that  
25 chemotherapy was given, it could either be before surgery to

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

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

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

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

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

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

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



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

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

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

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

18 A. So when a patient is going through any chemotherapy, so,  
19 say, neoadjuvant chemotherapy, all of the regimens for HER-2  
20 positive breast cancer will make them lose their hair.

21 Nausea and vomiting is very common, although we have good  
22 drugs to try to prevent that that are often successful.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 Q. How long does the hormone modification treatment last?

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

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

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

1       care.

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

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

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

16              So patients will actually be responsible for over  
17      \$2,000 a month, which is, as you know, more than many people  
18      earn.

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

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

25              There's become increasing awareness that patients

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

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

13 Q. Are you familiar with the phrase financial toxicity?

14 A. Yes.

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

16 A. Yes.

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

19 A. Yes.

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

23 A. Yes.

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

1 HER-2 positive?

2 A. About 20 percent.

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

5 A. Yes.

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

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

15 THE COURT: Excuse me.

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

18 MR. FORGE: Okay, Your Honor.

19 THE WITNESS: Okay. I hear you.

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

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

7 BY MR. FORGE:

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

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

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



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

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

7 So if we say that a treatment reduces the risk of  
8 recurrence by 50 percent, that sounds great. But that  
9 50 percent has to be applied to the patient's risk to begin  
10 with. So if the patient has a 90 percent risk of recurrence  
11 based on how aggressive their disease is and the number of  
12 lymph nodes involved, and I reduce that 90 percent by half,  
13 the patient gets a 45 percent benefit, right? It's half of  
14 90. That's a huge benefit.

15 But if the patient is likely to do well anyway,  
16 either because their disease is lower risk or because they're  
17 going to receive excellent treatments -- say a patient has a  
18 five percent risk of recurrence, I can still reduce that by  
19 50 percent. But the absolute benefit for that patient is  
20 only two and a half percent.

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

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

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

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

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

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

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

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

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

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

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

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

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

17    Q.     Are there medicines, antidiarrheal medications?

18    A.     Yes.

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

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

1 Q. In terms of quality of life, have your patients  
2 expressed concerns about both diarrhea and constipation?

3 A. Yes.

4 Q. And in terms of impact on their lives, is there a big  
5 disparity between the two?

6 A. No. I think actually sometimes constipation can be even  
7 more distressing. Patients will get admitted to the  
8 hospital. They can get admitted with either, but with  
9 constipation they actually can have almost a blockage in the  
10 bowel where, you know, they can't eat and they're vomiting,  
11 you know, a lot of bloating, real abdominal pain and  
12 discomfort. That's the extreme. You know, otherwise it can  
13 just be comfortable.

14 Q. Is constipation one of the side effects of Imodium?

15 A. Yes.

16 Q. Is the scientific name for that loperamide?

17 A. Yes.

18 Q. Now let's talk about the ExteNET results. Are you  
19 familiar with the ExteNET results as presented at the ASCO  
20 conference in 2015?

21 A. Yes.

22 Q. Let's take a look at the abstracts first.

23 MR. FORGE: Your Honor, I would move into evidence  
24 -- I don't believe there's any objection to Exhibit 503.

25 THE COURT: Just a moment.

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

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

5 THE WITNESS: I have 798.

6 MR. FORGE. Okay.

7 THE COURT: All right. Hold on.

8 THE WITNESS: There's nothing under that.

9 THE COURT: Just a moment.

10 What exhibit are you moving in?

11 MR. FORGE: 798, Your Honor.

12 THE COURT: Any objection?

13 THE WITNESS: Is that the abstract?

14 MR. FORGE: Yes.

15 THE WITNESS: Okay.

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

19 THE COURT: All right. You object?

20 MS. JOHNSON: Yes, Your Honor.

21 THE COURT: Response?

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

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

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

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

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

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

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

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

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

17 THE COURT: Do you move Exhibit 503?

18 MR. FORGE: Yes, Your Honor.

19 THE COURT: Any objection?

20 MS. JOHNSON: No, Your Honor.

21 THE COURT: Okay. 503 is admitted.

22 **(Exhibit 503 received.)**

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

1 BY MR. FORGE:

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

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

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

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

15 A. 2.3 percent.

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

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

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

23 A. 67 percent.

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

1 A. The only population in this abstract, yes.

2 Q. Yes. If you look up above that table, we can focus in  
3 really the first line of that second page.

4 A. I don't --

5 Q. Okay. We're going to focus in on the first line of the  
6 second page. And what did that abstract reveal in terms of  
7 the grade-three diarrhea rate?

8 A. 40 percent of patients had grade-three diarrhea.

9 Q. Okay. Now, if you could, please, turn to Exhibit 176 in  
10 your binder.

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

12 THE COURT: Any objection to 176?

13 MS. JOHNSON: No objection.

14 THE COURT: 176 is admitted.

15 Proceed.

16 **(Exhibit 176 received.)**

17 BY MR. FORGE:

18 Q. Dr. Adelson, when -- after an abstract for a conference  
19 such as ASCO, is there a presentation of the results?

20 A. Yes. So the -- you know, some presentations get  
21 actually oral presentations where the -- the doctor or the  
22 investigator who led the study gets up in front of a large  
23 audience and goes through slides. Some studies just get  
24 posters.

25 Q. Now, if you could, please, turn to page 17 of



1 Exhibit 176.

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

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

5 A. Okay.

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

9 A. It was nearly 17 percent, 16.8.

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

13 A. Yes.

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

16 A. Yes.

17 Q. With the constipation side effect?

18 A. Yes.

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

21 A. Yes.

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

25 THE COURT: Any objection?

1 MS. JOHNSON: No, Your Honor.

2 THE COURT: 639 and 741 are admitted.

3 **(Exhibits 639 and 741 received.)**

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

8 (Audiotape recording played)

9 BY MR. FORGE:

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

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

19 Q. Now, this particular question that Dr. Vogl asks was how  
20 many people are still taking -- how many people actually  
21 finished a year of the stuff. Dr. Chan responded,  
22 61 percent.

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

25 A. 39 percent.

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

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

5 THE COURT: Any objection?

6 MS. JOHNSON: No, Your Honor.

7 THE COURT: 124 is admitted.

8 **(Exhibit 124 received.)**

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

11 BY MR. FORGE:

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

13 A. Okay. Yes.

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

18 A. 27.6.

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

21 THE COURT: Yes.

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

24 BY MR. FORGE:

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

1 to try to straighten out that exhibit.

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

4 A. Yes.

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

7 A. No.

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

10 BY MR. FORGE:

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

13 A. No.

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

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

18 BY MR. FORGE:

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

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

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

4 A. Drug A, of course.

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

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

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

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

19 Q. And the fourth row, for the dropouts due to adverse  
20 events, for drug A, five to ten percent; for drug B,  
21 27.6 percent overall, 16.8 percent due to diarrhea alone,  
22 which drug would be the drug of choice?

23 A. Drug A.

24 Q. Are any of these close calls?

25 A. No.

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

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

8 Q. Now --

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

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

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

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

1 Q. 3.4 percent?

2 A. 3.3. Yeah, 3.3 percent.

3 MR. FORGE: Thank you, Dr. Adelson. I have nothing  
4 further.

5 THE WITNESS: Thank you.

6 THE COURT: Cross-examination.

7 MS. JOHNSON: Take a moment to get the cross  
8 binders up to the witness.

9 THE COURT: So we have two binders for this  
10 witness?

11 MR. CLUBOK: No, Your Honor.

12 MS. JOHNSON: We have one. They had one.

13 THE COURT: That means we have two binders for this  
14 witness?

15 MS. JOHNSON: Yes, Your Honor.

16 THE COURT: All right, folks.

17 MS. JOHNSON: May I approach, Your Honor?

18 THE COURT: Yes.

19 May I ask, in the plaintiffs' binder, how many of  
20 the exhibits did we actually use out of how many? What  
21 percentage since we're under percentages?

22 MR. FORGE: Your Honor, I can count those up.

23 THE COURT: I'm just saying, we are getting a lot  
24 of binders. I'm concerned about the efficiency of how  
25 multiple binders and multiple exhibits can lead to confusion.

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

5 Proceed.

6 MR. FORGE: Thank you, Your Honor.

7 MS. JOHNSON: Thank you, Your Honor.

8 **CROSS-EXAMINATION**

9 BY MS. JOHNSON:

10 Q. Good morning, Dr. Adelson.

11 A. Good morning.

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

13 A. Correct.

14 Q. You're not a statistician?

15 A. No.

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

18 A. No.

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

21 A. No.

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

23 A. No.

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



1 A. No.

2 Q. You're not an expert on securities disclosures?

3 A. No.

4 Q. And you're certainly not an expert on securities  
5 disclosures made on conference calls to investors?

6 A. No.

7 Q. And looking at the chart, which I would be happy to put  
8 back up if you still have the demonstrative.

9 MS. JOHNSON: Can I use your own demonstrative?

10 MR. FORGE: Sure.

11 BY MS. JOHNSON:

12 Q. I'll put it back up.

13 A. Okay.

14 Q. Looking at your chart there, is it correct to say you  
15 haven't engaged in any methodology to determine whether in  
16 this case the CEO of Puma said anything during the conference  
17 call that -- whether it meets the standard for disclosures to  
18 investors, right?

19 A. I don't -- no. I don't even know the criteria for that.  
20 But I have read his transcript and have read the claims that  
21 they made about efficacy of the drug.

22 Q. Right. But you haven't engaged in any methodology to  
23 compare those to what he was obligated to disclose under the  
24 securities laws, right?

25 A. I don't know the securities laws.

1 Q. You testified that you're being paid here for your  
2 testimony. You were contacted by the plaintiffs' lawyers a  
3 couple of years ago to start work on this case?

4 A. Yes.

5 Q. And you are -- you were being paid an hourly rate for  
6 your work to review materials, right?

7 A. Yes.

8 Q. \$700 an hour, I think you said?

9 A. It was 600 for the majority of the time I worked on it.

10 Q. And then it increased to 700?

11 A. Yes.

12 Q. And you're being paid here today a daily rate for your  
13 testimony that is now \$8,000 a day?

14 A. Yes.

15 Q. Do you get paid for that work separately from your work  
16 as a practicing breast cancer oncologist?

17 A. Yes.

18 Q. And as a doctor, with that hat on, it's not your  
19 practice to read press releases from pharmaceutical  
20 companies, right?

21 A. Actually, the -- you can't avoid the press releases.  
22 They come through Medscape and everything into my e-mail. So  
23 I do hear press releases about new drugs.

24 Q. But in this case it's certainly the case that you did  
25 not read Puma's press release at the time it came out in July

1 of 2014, right?

2 A. I don't recall reading it.

3 Q. Instead, you read the press release in this case with  
4 your testifying expert hat on, correct?

5 A. Correct.

6 Q. And you didn't dial in to the conference call on  
7 July 22nd --

8 A. No.

9 Q. -- as part of your regular work?

10 A. No.

11 Q. You read the transcript and listened to the audio as  
12 part of your testifying work?

13 A. I didn't -- I read the transcript. I did not listen to  
14 the audio.

15 Q. Okay. You read the transcript. Where did you first  
16 learn about neratinib as a practicing oncologist?

17 MR. FORGE: Your Honor, I'm going to object.  
18 Motion in limine number four.

19 MS. JOHNSON: Where she learned about the drug is  
20 not --

21 THE COURT: You know, the problem with all the  
22 motions in limine, as I stated, sometimes they become  
23 relevant in another context.

24 I'm going to overrule the objection and simply tell  
25 the witness to briefly answer that question, as briefly as

1 possible.

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

5 BY MS. JOHNSON:

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

9 A. Correct.

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

13 A. Correct.

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

16 A. Yes.

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

20 A. Right.

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

24 A. Right. Yes.

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

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

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

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

10 A. I believe that's right.

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

14 A. I always have my doctor hat on.

15 Q. Do you recall being deposed in this case?

16 A. Yes.

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

19 A. Yes.

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

22 A. Yes.

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

25 A. Yes.

1 Q. Would you turn to page 63 and focus on lines 23 to 25,  
2 going on to the next page, page 64, line 1. Do you see that?

3 A. Sorry. So I'm looking at page 61 -- where am I looking  
4 again?

5 Q. There are four pages on a page.

6 A. Yep.

7 Q. And 63 is the upper right-hand box.

8 A. Okay. Yep.

9 Q. Line 23?

10 A. Uh-huh.

11 Q. Down to page 64, which is right under it, line 1. Do  
12 you see that?

13 A. Yes.

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

15 THE COURT: Any objection?

16 MR. FORGE: No, Your Honor.

17 THE COURT: You may.

18 MS. JOHNSON: Thank you.

19 Clip 14.

20 (Portion of videotape recording played)

21 BY MS. JOHNSON:

22 Q. Were you asked that question and you gave that answer?

23 A. I suppose I did.

24 Q. Thank you. Would you agree that there's been tremendous  
25 success in treating breast cancer to date?

1 A. Yes.

2 Q. And over 80 percent of patients are cured based on the  
3 standard of care that existed before neratinib came on the  
4 scene, right?

5 A. Yes.

6 Q. Wouldn't you agree that because there's been such  
7 success, there's a relatively small amount of patients left  
8 to treat that aren't already treated by the existing standard  
9 of care before neratinib?

10 A. I think what you mean is that there is a relatively  
11 smaller number of patients left to help because most patients  
12 are going to do well without additional treatment. Yes,  
13 that's true.

14 Q. Right.

15 But in a perfect world in the field of breast  
16 cancer oncology, the goal should be to reduce cancer  
17 recurrence to as close to zero as possible; wouldn't you  
18 agree?

19 A. Again, it's a risk-balance ratio, so of course we want  
20 to cure as many people as we can. But we also need to  
21 minimize the toxicities people have. And the issue of  
22 overtreatment is acutely profound in the field right now and  
23 being talked about all the time.

24 Q. Yeah. And you testified earlier that patients should be  
25 educated about the different treatments and side effects so

1       that they can make an educated decision?

2       A.     Absolutely.

3       Q.     But if there's a company working to develop a treatment  
4       that will give patients the option of what to talk about,  
5       that would be a good thing; wouldn't you agree?

6       A.     Yes.

7       Q.     So neratinib was being studied in order to treat that  
8       relatively small group of patients that don't respond well to  
9       the existing standard of care, right?

10      A.     Yes.

11      Q.     All right. Let's talk about the ExteNET trial. You in  
12      your report -- what you testified earlier is that you want to  
13      be precise with patients about what the absolute benefit is  
14      so that they can make an informed decision, right?

15      A.     Correct.

16      Q.     In your report -- and you can turn to it if you like.  
17      It's the tab called report, expert report -- at page 20 --

18      A.     Yes.

19      Q.     -- there in the middle you give an illustration, and you  
20      say: Assume a hundred of my patients take neratinib.  
21      Slightly more than two them might benefit in terms of living  
22      longer before the cancer recurs than without treatment.

23                     Do you see that?

24      A.     Yes.

25      Q.     But slightly more than two of them might benefit is not



1 correct, right?

2 A. Slightly more than two will benefit. We corrected that.

3 Q. When you were deposed --

4 A. Yes.

5 Q. -- you talked about correcting that?

6 A. Yes.

7 Q. So it's precise -- it's -- the right way to say it is  
8 that every patient who takes neratinib has a potential to  
9 benefit?

10 A. Not exactly, because the ExteNET trial was  
11 disproportionately weighted to higher-risk patients than the  
12 general HER-2 positive population because they changed the  
13 eligibility criteria for the trial and only included  
14 node-positive patients.

15 Q. Later in the study, right?

16 A. Yes.

17 Q. But statistically speaking -- I'm talking about the  
18 actual ExteNET trial. Statistically speaking for those  
19 patients who were in the trial, every patient who took  
20 neratinib in the trial had the potential to benefit, correct?

21 A. If -- no, because when you actually look at the subgroup  
22 analyses, the patients who were ER negative did not benefit,  
23 and the patients who were node negative looked like they  
24 didn't benefit.

25 But on average in the ExteNET population, which was

1 enriched for higher-risk patients, the absolute benefit was  
2 2.3 percent.

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

5 A. Correct.

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

8 A. Correct.

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

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

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

15 BY MS. JOHNSON:

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

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

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

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

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

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

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

15           THE COURT: Any objection?

16           MR. FORGE: No, Your Honor.

17           THE COURT: You may.

18           MS. JOHNSON: Clip 58.

19           (Videotape recording played)

20    BY MS. JOHNSON:

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

23    A.    Yes.

24           MS. JOHNSON: We can take a break.

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

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

2 Thank you. Remember, don't discuss the case.  
3 Don't research the case. Keep an open mind. See you in  
4 15 minutes.

5 THE CLERK: All rise.

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

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

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

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

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

17 Go ahead.

18 THE CLERK: All rise.

19 (Open court - jury present)

20 THE COURT: Continue.

21 BY MS. JOHNSON:

22 Q. Dr. Adelson --

23 A. Yes.

24 Q. -- would you turn now to Exhibit 102 in your binder.

25 Exhibit 102 is a copy of the July 22nd, 2014, press release.

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

3 MR. FORGE: No objection.

4 THE COURT: 102 is admitted.

5 **(Exhibit 102 received)**

6 BY MS. JOHNSON:

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

10 A. Yes.

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

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

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

17 A. Got it.

18 Q. -- topline results --

19 A. Yes.

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

25 A. Correct.

1 Q. And that's the name for Herceptin?

2 A. Yes.

3 Q. And then in the third paragraph, the press release  
4 announces the results. It says the primary end point of the  
5 trial was disease-free survival, DFS. The results of the  
6 trial demonstrated that treatment with neratinib resulted in  
7 a 33 percent improvement in disease-free survival versus  
8 placebo.

9 A. Yes.

10 Q. Do you see that?

11 A. Yes.

12 Q. The hazard ratio .67, and statistically significant  
13 p-value of .0046, right?

14 A. Yes.

15 Q. It's not your testimony here today that anything in this  
16 press release was untrue, correct?

17 A. Correct.

18 Q. You talked a lot earlier about the standard of care in  
19 breast cancer treatment, right?

20 A. Yes.

21 Q. You recall that testimony? And you said that a standard  
22 of care is a universally accepted treatment that a patient  
23 should expect to receive irrespective of where they are?

24 A. Assuming that they are healthy enough to tolerate it.

25 Q. And you also testified that a positive clinical trial

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

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

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

12 A. No.

13 Q. You participate on tumor boards --

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

16 (Record read)

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

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

23 MS. JOHNSON: I appreciate that.

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

1       appeal.   Go ahead.

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

3       BY MS. JOHNSON:

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

6       A.     Yes.

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

10      A.     Correct.

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

15      A.     Yes.

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

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

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

23             MR. FORGE:   Understand, Your Honor.

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



1 (Pause in proceedings)

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

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

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

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

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

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

22 MS. JOHNSON: It is.

23 THE COURT: Okay.

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

1 THE COURT: Briefly.

2 MS. JOHNSON: The witness testified --

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

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

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

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

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

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

17 All right. Thank you, Your Honor.

18 BY MS. JOHNSON:

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

20 A. Yes.

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

22 A. Yes.

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

24 A. Yes.

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

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

4 A. Correct.

5 MR. FORGE: Objection, Your Honor. Foundation.

6 THE COURT: Sustained as to foundation.

7 BY MS. JOHNSON:

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

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

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

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

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

18 THE COURT: Sustained as to foundation.

19 Well, I'll just say sustained.

20 BY MS. JOHNSON:

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

23 A. Yes.

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

1 the frequency with which you see patients?

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

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

7 THE WITNESS: So --

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

10 THE WITNESS: Yes.

11 THE COURT: Next question.

12 BY MS. JOHNSON:

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

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

17 THE COURT: This is an expert witness.

18 Overruled.

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

24 BY MS. JOHNSON:

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

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

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

7 THE COURT: Overruled.

8 THE WITNESS: Yes.

9 BY MS. JOHNSON:

10 Q. Thank you.

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

15 A. Yes.

16 Q. But 2.3 percent and the DFS difference of 91.6 versus  
17 93.9 were not the only statistics disclosed in the ASCO  
18 abstract that we looked at and the ASCO conference, right?

19 A. Right.

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

23 A. Right.

24 Q. Yes?

25 A. Yes.

1 Q. And, in fact, in your demonstrative earlier you pointed  
2 out one of those subgroups. You called it ER positive?

3 A. Yes.

4 Q. And that is the subgroup that means estrogen-receptor  
5 positive patients?

6 A. Yes.

7 Q. And that's the same thing. Sometimes it's referred to  
8 as hormone-receptor positive patients?

9 A. They're not exactly the same, but -- so you could be  
10 estrogen negative and progesterone positive and still be  
11 called hormone positive.

12 Q. In the ExteNET study there was a subgroup called  
13 hormone-receptor positive, right?

14 A. Right.

15 Q. And the data for that subgroup which you said was  
16 66 percent of all HER-2 positive patients was higher than  
17 2.3 percent, correct?

18 A. Yes.

19 Q. And you believe there was about a 4.4 percent absolute  
20 DFS benefit for the subgroup that you called out on your  
21 demonstrative, correct?

22 A. Correct -- enriched again for node-positive patients,  
23 who are inherently higher risk.

24 Q. The node-negative or positive subgroups were tested in  
25 the ExteNET trial as well, right?

1 A. Right.

2 Q. And would you say that a four percent absolute DFS  
3 benefit is more than a marginal benefit?

4 A. Yes.

5 Q. There's another cut of the data in the ExteNET trial for  
6 what's called centrally confirmed HER-2 positive patients,  
7 right?

8 A. Right.

9 Q. And doctors can confirm whether a patient actually has  
10 the HER-2 gene mutation by testing either in the doctor's  
11 office or in a central lab?

12 A. No. You only have access to central testing when you're  
13 participating in a clinical trial, not in everyday practice.

14 Q. Great clarification. So in the clinical trial patients  
15 can be confirmed either by their doctor or, because it's a  
16 clinical trial, by this centralized lab, right?

17 A. It depends on the trial. Some trials require central  
18 confirmation and some do not.

19 Q. And the ExteNET trial did not, correct?

20 A. You know, honestly I don't remember. I know they had a  
21 centrally confirmed, but I don't remember if it was a  
22 requirement.

23 Q. You do recall that the results of the centrally  
24 confirmed patient population were presented in the ASCO  
25 presentation?

1 A. Yes.

2 Q. Let's look at that. Again, it's Exhibit 176. Let's  
3 look first at slide 14. Again, this is the ExteNET data  
4 actually presented at the ASCO conference on June 1, 2015,  
5 and this is the subgroup that we just talked about by  
6 hormone-receptor positive on the left and hormone-receptor  
7 negative on the right, correct?

8 A. Correct.

9 Q. And the difference there on -- by hormone-receptor  
10 positive, the numbers are 91.2 and 95.4. Do you agree with  
11 me?

12 A. Yes.

13 Q. For a difference of 4.2 percent, right?

14 A. Correct.

15 Q. And then in the centrally confirmed population which is  
16 on the next slide, on slide 15, on the right is the graph for  
17 centrally confirmed, and the difference is 90.6 to 94.7. Do  
18 you see that?

19 A. Yes.

20 Q. For a 4.1 percent difference?

21 A. Yes.

22 Q. And you would agree again that a 4.1 percent difference  
23 is more than a marginal benefit?

24 A. Yes.

25 Q. And by the way, centrally confirmed testing, is that



1 sometimes called the fish test?

2 A. No.

3 Q. Is it -- depends by lab?

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

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

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

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

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

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

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

15 MR. FORGE: Objection, Your Honor. Foundation.

16 THE WITNESS: So in the ExteNET study --

17 THE COURT: Hold on. There was an objection.

18 THE WITNESS: Sorry.

19 THE COURT: Response?

20 MS. JOHNSON: I could ask the foundation question.

21 THE COURT: Please do. Ask some foundational  
22 questions.

23 BY MS. JOHNSON:

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

1 A. Yes.

2 Q. And you've studied the subpopulations including the  
3 centrally confirmed subpopulation, right?

4 A. Right. But the overall data they reported was not the  
5 overall benefit that they reported. The primary end point  
6 was not in the centrally confirmed HER-2 population. It was  
7 in the overall locally confirmed HER-2 population. That's  
8 the important difference I'm trying to get at.

9 BY MS. JOHNSON:

10 Q. The 2.3 percent meaning?

11 A. Yes.

12 Q. And then within that there was a centrally confirmed  
13 population which is the 4.2 percent -- 4.1 percent that we're  
14 looking at, correct?

15 A. Correct.

16 Q. Did you also have an opportunity to look at the  
17 centrally confirmed hormone-receptor positive population,  
18 putting these two together?

19 A. You know, I cannot remember, but I would be happy to  
20 look if you show it to me.

21 Q. Okay. Great. Would you turn to Exhibit 886.

22 MS. JOHNSON: I would move 886 into evidence.

23 THE COURT: Any objection?

24 MR. FORGE: No, Your Honor.

25 THE COURT: 886 is admitted.

1                   **(Exhibit 886 received.)**

2       BY MS. JOHNSON:

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

7       A.     Correct.

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

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

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

20                   Do you see that?

21      A.     Yes.

22      Q.     So what that means is the placebo arm ended up at  
23      88.4 percent for this particular subpopulation, right?

24      A.     Yes.

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

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

3 A. Yes.

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

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

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

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

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

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

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

23 Q. Highest HER-2?

24 A. Yes.

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

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

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

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

9 A. The p-value is less than --

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

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

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

19 A. Less than 300?

20 Q. Per arm?

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

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

24 A. Correct.

25 Q. You've characterized the absolute benefit of Herceptin

1 as a dramatic benefit; is that fair?

2 A. Yes.

3 Q. And that benefit was eight to ten percent overall?

4 A. Yes.

5 Q. And by the way, I wanted to ask you about the patient  
6 population of HER-2 positive. In your testimony here today,  
7 you said only 20 percent of breast cancer patients are HER-2  
8 positive, right?

9 A. 20 to 25 percent, yeah.

10 Q. 20 to 25. There is literature that says 25 to  
11 30 percent; isn't that correct?

12 A. I think there's literature that is all over the board,  
13 and it has to do with how you define HER-2 positivity, which  
14 has evolved over time as well.

15 Q. And in your testimony by deposition, you indicated it  
16 was 25 to 30 percent as well; didn't you?

17 A. Maybe so.

18 Q. Okay. It can be a range?

19 A. It's a range.

20 Q. It's a range from 20 percent to 30 percent depending on  
21 how you define HER-2 positive?

22 A. All right.

23 Q. Then let's talk about the Kaplan-Meier curve. This is  
24 one, I guess. We can just look at what's up here. But let's  
25 look at the primary end point, which is 176 again, because

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

3 I wanted to look at that Kaplan-Meier curve for the  
4 primary end point, which is slide 10. And notice that at  
5 12 months, the difference is 2.2 percent. Would you agree  
6 with me, 95.6?

7 A. You're showing it here.

8 Q. To 97.8?

9 A. Yes.

10 Q. That's 2.2 percent difference. And at three years it's  
11 91.6 and 93.9 of course, which is a difference of  
12 2.3 percent, right?

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

16 Q. Certainly the curves are not narrowing, correct?

17 A. Correct.

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

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

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



1 Q. But we can all agree that the curves are not narrowing,  
2 correct?

3 A. Correct.

4 Q. So are you aware of the data that Puma had available to  
5 it in July of 2014?

6 A. I don't know how far out they had followed patients at  
7 that point off the top of my head, no.

8 Q. Are you aware that the trial was started in 2009?

9 A. Yes.

10 Q. And that by 2013-14, there had been many patients on the  
11 trial for more than two years at that point?

12 MR. FORGE: Objection, Your Honor. Vague as to  
13 many.

14 THE COURT: Overruled.

15 THE WITNESS: Again, I don't know how many, you  
16 know, had gone beyond the two years at that point. Again,  
17 the analysis was limited to two years as the end point, so I  
18 don't even know if they had really done the analysis beyond  
19 that. It's not in anything I've read.

20 BY MS. JOHNSON:

21 Q. So you don't know what analysis Puma had done internally  
22 to look at that data that was available beyond the two-year  
23 point, correct?

24 A. Correct.

25 Q. And you have not seen in this case any analysis of that

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

3 A. Right.

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

7 A. I did.

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

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

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

17 A. Right.

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

20 A. Right.

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

23 A. Correct.

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

1 A. Right.

2 Q. Yet you testified earlier that you got into breast  
3 cancer work because of the opportunity to follow patients for  
4 many, many years, correct?

5 A. Correct.

6 Q. So it's important in the real world with your doctor  
7 hat, if I can use that phrase again, to follow patients for  
8 many, many years, correct?

9 A. Correct.

10 Q. And so only for purposes of this analysis do you stop  
11 looking at the data and cut it off and look at the curves at  
12 just two years, right?

13 A. Right.

14 Q. You've heard -- you've -- let's talk about safety, which  
15 is your next line there on your chart. You have certainly  
16 reviewed the Herceptin label, correct?

17 A. Correct.

18 Q. And it's fair to say that a label is what provides the  
19 prescribing information to the physician about how a  
20 prescription medication is supposed to be used?

21 A. Correct.

22 Q. And it's also fair to say that a label includes  
23 information on side effects?

24 A. Yes.

25 Q. And who makes Herceptin?

1 A. Genentech.

2 Q. And you're a consultant for Genentech, right?

3 A. Yes. Not -- not exactly a consultant. I've done  
4 advisory boards where I have spoken for them.

5 Q. And you've received grants?

6 A. Yes, research funding.

7 Q. You've received research funding from Genentech?

8 A. Yes, but totally unrelated to any drugs.

9 Q. And you didn't -- I checked your expert report. You  
10 didn't happen to disclose that you were an advisor for  
11 Genentech or that you received grant funding for clinical  
12 research from Genentech?

13 A. I may not have had any grant funding when I first  
14 started working on this.

15 Q. Let's look at the date of your expert report.

16 A. Uh-huh.

17 Q. The first one is there in your binder. It's the end of  
18 2018; is that correct?

19 A. Yep. Can I ask you a question? Was I required to  
20 disclose in my expert report? This is not the same thing as  
21 publishing a manuscript, just to --

22 THE COURT: Actually you need to ask the next  
23 question.

24 MS. JOHNSON: Right.

25

1 BY MS. JOHNSON:

2 Q. So requirement or not, it does not appear in your expert  
3 report that you are an advisor or consultant for Genentech,  
4 right?

5 A. Again, I haven't been an advisor for Genentech. I've  
6 received research funding, and I have spoken at their  
7 conferences on shared decision making, not anything to do  
8 with their drugs or drug approval.

9 Q. Okay. Would you turn to tab B in your binder.

10 A. (Witness complies.)

11 Q. Did you speak on a panel called differentiating among  
12 the CDK4/6 inhibitors in the management of metastatic breast  
13 cancer?

14 A. Yes. This was a CME, and they don't even tell you when  
15 you do these CMEs. It's separate from the pharma company, so  
16 I actually didn't even know who provided the funding. CMEs  
17 are considered objective educational conferences.

18 Q. And you were a panelist at that conference?

19 A. Yes.

20 Q. If you would just turn to the second page.

21 A. Uh-huh.

22 Q. Did you not disclose the following relevant financial  
23 relationships, colon, served as an advisor or consultant for  
24 Genentech?

25 A. Yes. So they give you -- you have to select a box, and

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

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

9 A. Yeah.

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

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

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

15 A. Yes.

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

18 A. Yes.

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

21 A. Black box warning for cardiac toxicity?

22 Q. Correct. Yes. Good.

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

24 Q. Good memory.

25 A. Okay.

1 Q. Are you aware that a black box warning typically appears  
2 on a prescription drug label when it is designed to call  
3 attention to serious or life-threatening risks?

4 A. Yes.

5 Q. Let's turn to the Herceptin warning label. It's at tab  
6 984. In the course of your work, you have reviewed the  
7 Herceptin warning labels?

8 A. Not in recent years. You know, I've been using the drug  
9 for so long. But when it first came out, yes.

10 Q. Is this Exhibit 984 a copy of one of those Herceptin FDA  
11 labels?

12 A. Yes.

13 MS. JOHNSON: I would move Exhibit 984 into  
14 evidence.

15 MR. FORGE: No objection, Your Honor.

16 THE COURT: 984 is admitted.

17 **(Exhibit 984 received.)**

18 MS. JOHNSON: Let's put up the first page.

19 BY MS. JOHNSON:

20 Q. So that warning label that I talked about with this  
21 black box that indicates life-threatening risk for Herceptin  
22 says, Warning: Cardiomyopathy, infusion reaction,  
23 embryofetal toxicity, and pulmonary toxicity; right?

24 A. Yes.

25 THE COURT: I'm sorry. Excuse me. This concerns

1 984?

2 MS. JOHNSON: Yes, Your Honor.

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

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

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

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

16 984 is admitted. Please look into the situation  
17 that my exhibit list is incomplete.

18 Go ahead.

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

20 BY MS. JOHNSON:

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

24 A. Yes.

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



1 heart failure?

2 A. Yes.

3 Q. Infusion reaction, that refers to the fact that  
4 Herceptin is an IV administered drug, right?

5 A. Yes. It's -- well, they're describing an allergic  
6 reaction.

7 Q. Right. So there can be allergic reactions to  
8 intravenous infusion, meaning the IV, right?

9 A. There can be allergic reactions to any drug.

10 Q. But particularly ones that are administered by IV, there  
11 can be an infusion reaction, correct?

12 A. I don't know if that's any more common than reactions to  
13 oral drugs. But, yes, absolutely. Anything that is infused  
14 into a patient can potentially cause an allergic reaction.

15 Q. And pulmonary toxicity means damage to the lungs  
16 basically, right?

17 A. Yes.

18 Q. And neratinib does not cause any of these adverse events  
19 like cardiomyopathy, congestive heart failure, infusion  
20 reactions, et cetera, that are listed on this label?

21 A. So I actually would have to look at the early phase I  
22 studies in neratinib to see if it had no cardiac toxicity,  
23 but I don't remember off the top of my head any cardio  
24 toxicity reported disproportionately in the neratinib  
25 population of ExteNET.

1 Q. In fact, after reviewing all of the ExteNET data, you  
2 concluded that there was no indication that neratinib causes  
3 any long-term adverse side effects, correct?

4 A. No. Neratinib hasn't been around long enough to know if  
5 it has long-term toxicity. It's too new a drug. So I would  
6 not say that.

7 THE COURT: You had a negative followed by correct,  
8 and actually I don't know what her no means.

9 MS. JOHNSON: Okay.

10 BY MS. JOHNSON:

11 Q. Was there any indication -- was there any indication in  
12 the ExteNET data that you reviewed that there were long-term  
13 adverse side effects?

14 A. It's totally inappropriate to discuss long-term side  
15 effects from a study that stopped reporting at two years.  
16 Long-term side effects can happen much later.

17 Q. But the good news is that if you were talking to a  
18 patient about neratinib, you would not have to warn her of  
19 long-term negative side effects associated with the use of  
20 neratinib, correct?

21 A. I would say that we don't know yet what the long-term  
22 potential toxicities are because it's a very new drug.

23 Q. But you would not say when you're doing your list of  
24 pros and cons about the drug, you wouldn't add any long-term  
25 side effects, correct?

1 A. Correct.

2 Q. Let's talk briefly about diarrhea.

3 A. Okay.

4 Q. Not -- neratinib is a tyrosine kinase inhibitor, right?

5 A. Tyrosine, right.

6 Q. Known as TKI?

7 A. Yes.

8 Q. Especially to people like me.

9 And before you had heard of neratinib, you knew  
10 that diarrhea was a side effect of TKIs, right?

11 A. Yes.

12 Q. And there are a huge number of TKIs that are FDA  
13 approved, right?

14 A. Yes.

15 Q. And for those drugs that got FDA approval, it's known  
16 that the incidences of grade-three diarrhea ranges up to  
17 about 50 percent, correct?

18 A. It depends on which TKIs. Some have much more what we  
19 call GI, gastrointestinal, toxicity than others.

20 Q. And the range runs up to about 50 percent; isn't that  
21 true?

22 A. Yes. I would -- I would say overall diarrhea is usually  
23 about 50 percent. Grade-three off the top of my head I don't  
24 know because I'm so focused on breast cancer at this point.

25 A lot of TKIs are used in other malignancies. There's only

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

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

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

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

9 A. What number?

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

12 A. Yeah.

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

14 THE COURT: Any objection?

15 MR. FORGE: No, Your Honor.

16 THE COURT: Yes, you may.

17 MS. JOHNSON: Clip 26.

18 (Videotape recording played)

19 BY MS. JOHNSON:

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

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

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

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

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

8 A. Correct.

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

11 A. Correct.

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

14 A. Yes.

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

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

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

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

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

8 Q. But --

9 A. It was in the protocol.

10 Q. Thank you.

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

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

16 THE COURT: Another negative followed by the word  
17 correct.

18 MS. JOHNSON: Got to work on that.

19 BY MS. JOHNSON:

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

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

3 A. So patients can drop out of a study for a multitude of  
4 reasons, and the dropout rate in the neratinib arm was  
5 39 percent. It was, I think, about 17 percent in the placebo  
6 arm. Of those 39 percent who dropped out in the neratinib  
7 arm, 27 percent had dropped out due to side effects.

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

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

15 A. Sure.

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

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

20 Q. The exhibit binder --

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

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

24 A. Correct.

25 Q. That means discontinuation of treatment on drug?

1 A. Yes.

2 Q. That does not mean one way or the other whether they  
3 dropped out of the study, right?

4 A. Right.

5 Q. Okay. Finally, you talked about the cost --

6 THE COURT: Just one moment. Do you know there's a  
7 clear-all button? You see where it says clear all? Hit it  
8 right there. Boom.

9 THE WITNESS: Thank you.

10 THE COURT: Good. Go ahead.

11 BY MS. JOHNSON:

12 Q. You talked about the cost of drugs being an important  
13 factor in whether patients will accept a treatment, right?

14 A. Yes.

15 Q. Isn't it the case -- and then you talked about a crisis  
16 in healthcare and that insurance ends up paying less and  
17 less, right?

18 A. Yes.

19 Q. Isn't it true that neratinib is likely to be covered by  
20 insurance?

21 MR. FORGE: Objection, Your Honor. Beyond the  
22 scope of the opinion offered. It's also in-limine number  
23 four.

24 THE COURT: Also what?

25 MR. FORGE: In-limine number four.



1 THE COURT: Overruled.

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

7 BY MS. JOHNSON:

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

11 A. I think they have a --

12 MR. FORGE: Your Honor --

13 THE COURT: Yes.

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

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

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

19 THE COURT: The objection is overruled. Thank you.

20 THE WITNESS: So we're talking about today or in  
21 2015?

22 BY MS. JOHNSON:

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

1 opportunity to take that drug based on inability to pay?

2 A. So I am not aware of the details of that policy. I will  
3 say that in my experience with compassionate-use programs  
4 from pharmaceutical companies, the patients have to qualify  
5 by having an income level that is low enough to allow, I  
6 think, the pharmaceutical company to make up the difference.  
7 I would imagine this, like all other co-pay assistance  
8 programs, likely does have a financial limit.

9 Q. But again, you're not aware of Puma's policy with regard  
10 to covering that kind of cost, correct?

11 A. Correct.

12 MS. JOHNSON: Thank you. No further questions.

13 THE COURT: Thank you.

14 Redirect.

15 **REDIRECT EXAMINATION**

16 BY MR. FORGE:

17 Q. Doctor, Ms. Johnson asked you a number of questions  
18 about subpopulations, but she didn't ask you about the  
19 subpopulation for distant disease-free survival. Are you  
20 familiar with that term, distant disease-free survival?

21 A. Yes.

22 Q. What does distant disease-free survival represent?

23 A. That is the percentage of patients who do not develop a  
24 distant metastasis. It's distant metastasis that lead people  
25 to die from their cancers, so that is the most relevant end

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

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

6 A. No, it did not.

7 MR. FORGE: Nothing further.

8 THE COURT: Recross.

9 **RECROSS-EXAMINATION**

10 BY MS. JOHNSON:

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

16 A. No.

17 MS. JOHNSON: Thank you.

18 MR. FORGE: No further questions, Your Honor.

19 May the witness be excused?

20 THE COURT: Yes. I will excuse the witness.

21 Thank, you, Doctor.

22 Plaintiff will call its next witness.

23 MR. FORGE: Thank you, Your Honor.

24 Your Honor, may I approach just to --

25 THE COURT: Yes, you may.

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

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

5 THE COURT: Good for you.

6 **Nicholas Jewell, Plaintiff's witness, sworn**

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

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

11 THE CLERK: Thank you.

12 **DIRECT EXAMINATION**

13 BY MR. COUGHLIN:

14 Q. Good morning, Doctor.

15 A. Good morning.

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

17 A. Yes.

18 Q. Can you tell us what a biostatistician is?

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

22 Q. And how do you become a biostatistician?

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

1 Q. And do you have both those?

2 A. Yes.

3 Q. And can you give us a little of your educational  
4 background?

5 A. Yes. My undergraduate degree was in applied mathematics  
6 from the University of Edinburgh, followed by a Ph.D. in  
7 mathematics also from the University of Edinburgh. Then  
8 post-doctoral experience in biostatistics at the University  
9 of California Berkeley, Stanford University, and the  
10 University of Edinburgh before taking a faculty position.

11 Q. A faculty position at Berkeley?

12 A. No. My first faculty position was at Princeton  
13 University on the east coast. And then I moved to the  
14 University of California Berkeley.

15 Q. And when was that?

16 A. I returned to Berkeley in 1981. So I -- I have been  
17 there for close to 40 years.

18 Q. And what are some of the positions you've held at  
19 Berkeley?

20 A. Well, primarily I've served as a professor of  
21 biostatistics through that entire period, but for a term I  
22 worked in the office of the chancellor as the vice provost  
23 for the Berkeley campus. Then I worked as vice provost for  
24 the whole University of California system, which has now ten  
25 campuses.

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

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

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

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

14 A. Yes.

15 Q. And about how many matters?

16 A. I probably provided testimony in somewhere between 40 or  
17 50 litigation cases.

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

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

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

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

1 challenged in, yes.

2 Q. Right. Has anybody ever excluded your testimony?

3 A. In those 40 or 50 cases, maybe on about three, maybe two  
4 or three part of my testimony was excluded by a judge. In  
5 one case it was excluded entirely. Ironically that was a  
6 case where one judge accepted the testimony and in one court  
7 and another judge excluded it in another court for the same  
8 testimony.

9 Q. Is that analysis that you did, is that the same analysis  
10 that you undertook in this case?

11 A. No. Those cases involved much more complex  
12 biostatistical work where I was analyzing or reanalyzing  
13 clinical trial data, which I did not do in this case.

14 Q. You accepted data and analyzed the data as presented; is  
15 that correct?

16 A. In this case, yes.

17 Q. Okay. And you're here to explain some of the terms that  
18 are at issue in this case; is that right?

19 A. Yes, if you ask me.

20 Q. Okay. I'll try to get there as soon as I can.

21 So about how long have you been working on this  
22 case?

23 A. I would say it's probably about two years.

24 Q. And your rate is?

25 A. \$700 per hour for consulting.

1 Q. So I think it's a little over \$100,000 that you've been  
2 paid in this case?

3 A. Well, I've never actually added it up, but it sounds  
4 about right.

5 Q. I added it up. It's expensive, right?

6 A. Yeah. I tried to do a good job.

7 Q. Okay.

8 At any time during this engagement, did we ask you  
9 to reach any certain conclusion?

10 A. No.

11 Q. Okay. Would you do -- have you ever done that? Would  
12 you do that?

13 A. No. That would be unethical.

14 Q. Okay. So let's turn to what you did do in this case and  
15 why you did it.

16 If we could take a look at demonstrative number  
17 three.

18 Dr. Jewell, could you explain -- and this is just  
19 to help the jury to look as you explain what you intend to  
20 talk about here in this case as we move forward. If we could  
21 first start with -- let's start and talk about some of the  
22 things here like the p-value, the hazard rates, the  
23 Kaplan-Meier curves. And what do you intend to offer there?

24 A. Well, I'm absolutely happy to try and explain briefly in  
25 layman terms what these terms mean because they're complex



1 and technical.

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

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

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

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

13 MR. CLUBOK: Objection, Your Honor. Leading.

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

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

18 Will you be offering this witness as an expert?

19 MR. COUGHLIN: Yes.

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

23 BY MR. COUGHLIN:

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

1 A. Yes.

2 Q. Okay. Let's talk about hazard rates. Could you tell us  
3 what those are?

4 A. Hazard rates measure the rate at which events happen.  
5 In this case, we're talking about reoccurrences of cancer or  
6 death. It measures the rate at which this happens during the  
7 time of follow-up, how quickly people in the population  
8 suffer these events.

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

13 BY MR. COUGHLIN:

14 Q. Was that done in this case?

15 A. Yes.

16 Q. Okay. Let's talk about the next value. Can you talk  
17 about Kaplan-Meier curves and tell us what those are?

18 A. Well, as others have said, Kaplan-Meier curves -- and  
19 we've been looking at a few of them in this case -- they  
20 measure over time the fraction of patients in a treatment  
21 group who suffer the event -- in this case a cancer  
22 reoccurrence or death.

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

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

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

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

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

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

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

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

22 Q. So here we have an absolute value or delta of  
23 2.3 percent at the end of the study. How would you figure  
24 out the number needed to treat?

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

1 divided by 2.3 percent. So it's around 43 or 44.

2 Q. Okay. And now the next term there, we see a number  
3 needed to harm. Do you see that?

4 A. I do.

5 Q. And what does that mean?

6 A. The number needed to harm is the same kind of concept  
7 but now referring to adverse effects or safety events. It  
8 measures on average the number of patients who need to be  
9 treated with the new drug in order for one more adverse event  
10 to occur than would have under the standard of care or  
11 control arm.

12 Q. And how is this number arrived at? What figures go into  
13 this number, number needed to harm?

14 A. Well, it's the same really as the number needed to  
15 treat. It's just one over the difference in the fraction of  
16 people who have the adverse event in the treatment group  
17 minus the fraction of people who have the adverse event in  
18 the placebo or control group.

19 Q. Okay. Next, did you analyze the data in the ExteNET  
20 trial?

21 A. I did not analyze the data, but I looked at the results  
22 of the trial. I did not actually do any reanalysis. I've  
23 never actually had access to the original ExteNET data, but I  
24 did analyze the reporting of the results.

25 Q. Okay. And let's take a look at a few more terms.

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

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

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

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

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

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

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

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

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

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

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

12 THE COURT: Without objection, 129 is admitted.

13 **(Exhibit 129 received.)**

14 MS. SMITH: No objection.

15 BY MR. COUGHLIN:

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

17 A. I did.

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

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

24 Q. Why is this document prepared before the trial?

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

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

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

12 Q. You reviewed this SAP; is that correct?

13 A. I did review the statistical analysis plan.

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

16 MS. SMITH: Objection. Leading, Your Honor.

17 BY MR. COUGHLIN:

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

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

21 Q. Okay. Let's take a look into the plan. If we turn to  
22 13 of 61 at 3.1.1, can you tell us what the -- 3.1.1  
23 describes the primary objective. Can you tell us what that  
24 is?

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

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

8 Q. Had you reviewed other statistical analysis plans  
9 before?

10 A. Yes, many.

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

13 A. Yes.

14 Q. How many?

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

17 Q. Hundreds?

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

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

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



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

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

6       A.     Yes.

7       Q.     Did you analyze that data?

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

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

12      A.     Correct.

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

15      A.     Yes, I see that.

16      Q.     Can you tell us what that refers to?

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

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

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

5 Q. And what are the two first numbers there, the .079 and  
6 .049 per person per year? What do those refer to?

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

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

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

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

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

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

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

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

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

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

17 Q. Okay. And they achieved what?

18 A. Well, as we've heard, they actually achieved  
19 2.3 percent.

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

23 A. I do.

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

1 end point?

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

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

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

17 A. No.

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

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

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

25 A. Yes, almost always.

1 Q. Does that relate to your NNH, number needed to harm?

2 A. Yes. The safety data would allow you to compute numbers  
3 needed to harm for any particular adverse event.

4 Q. And in this case you did both an analysis of a number  
5 needed to harm and a number needed to treat; is that correct?

6 A. I did.

7 Q. Okay. Had you done that before?

8 A. Yes.

9 Q. How many times?

10 A. Well, that's such a simple calculation, I've certainly  
11 taught it and done it hundreds of times.

12 Q. Okay. Let's flip over to what we'll call demonstrative  
13 number four. I believe this is a Kaplan-Meier curve that you  
14 prepared. Could you explain what this is?

15 A. Yes. This was in my report an illustration of trying to  
16 educate the reader as to what a Kaplan-Meier curve is and  
17 what it represents. This was actually taken from a real  
18 clinical trial, and it's comparing two treatment groups.  
19 I've just color-coded them here, one red and one blue.

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

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

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

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

9           In this case this was a three-year trial,  
10 36 months. And what you want to look at when you look at  
11 those curves is ultimately the first thing is, is there one  
12 systematically below the other, because that reflects that a  
13 larger fraction are -- let's put it the other way around. A  
14 smaller fraction are staying disease free.

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

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

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

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

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

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

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

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

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

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

8 So in this case the absolutely risk difference  
9 would be 25 percent, the difference between 50 percent and  
10 25 percent.

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

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

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

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

25 A. That is correct.



1 Q. And then you compared it to how that was reported to the  
2 public; is that correct?

3 A. Well, I don't know -- it was in that investor call in  
4 July of 2014, and I believe that was publicly available.  
5 Yes, that was the comparison I did.

6 Q. Okay. Let's take a look at Exhibit 123.

7 MR. COUGHLIN: I'd move for Exhibit 123 to be  
8 admitted. I don't believe there's any objection, Your Honor.

9 THE COURT: Without objection 123 is admitted.

10 **(Exhibit 123 received.)**

11 MS. SMITH: No objection, Your Honor.

12 BY MR. COUGHLIN:

13 Q. So have you seen this document before?

14 A. I have.

15 Q. Okay. Can you tell us what it is?

16 A. This is an e-mail communicating the results of the  
17 ExteNET trial from the statisticians at Puma to the -- to  
18 their bosses, I guess, to the people who are going to -- who  
19 wanted to know the results.

20 Q. And you accepted the date of July 17, 2014; is that  
21 correct?

22 A. Yes. The date of the e-mail is in July 2014, July 7th.

23 Q. And did you accept the attached or the validated results  
24 of the 304 primary and secondary end points?

25 A. Yes. The 3004 [sic] is just referring to the trial name

1 by a code.

2 Q. Okay. It's referring to the ExteNET trial by a code, a  
3 number code; is that right?

4 A. Correct.

5 Q. Okay. Let's go into this document, and if we could look  
6 at page 8 of 35. I believe page 8 of 35 reports the summary  
7 of the topline efficacy; is that correct?

8 A. Correct. So that was in these results provided to  
9 Mr. Auerbach and his colleagues at that time.

10 Q. Okay. Let's take a look at the top line of that. And  
11 I'd like you to go across that line and explain what those  
12 numbers mean for the hazard ratio, the p-value, as well as  
13 the absolute difference.

14 A. So these are the results of the ExteNET trial. This is  
15 the primary end point, DFS, as we discussed. And in the  
16 first two numbers they're giving that end of the  
17 Kaplan-Meier, that fraction who are disease free and  
18 surviving at the end of the two years.

19 So you can see for the neratinib group, the drug  
20 group, 93.9 percent had not had an event in those first two  
21 years. In the control or placebo group, the comparison group  
22 who did not get neratinib, the equivalent end of the  
23 Kaplan-Meier curve or percentage is 91.6. So slightly more  
24 in the control group had had the event.

25 Q. Actually, what is the absolute difference there?

1 A. The absolute difference that we've been talking about is  
2 just 93.9 percent minus 91.6 percent. And that is  
3 2.3 percent. That's the absolute risk difference. That's  
4 the gap between the Kaplan-Meier curves at two years.

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

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

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

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

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

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

1           The quantitative comparison of that pace was  
2 two-thirds. So that says if -- whatever the rate was in the  
3 placebo group, it was one-third less. That's just one minus  
4 .67, .33, one-third less in the neratinib group than the  
5 placebo group.

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

8 A. I do.

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

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

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

20 Q. Okay. And what about that second year?

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

25 Q. So were the curves widening?

1 A. Well, statistically, no. As Dr. Adelson commented,  
2 there's no difference statistically because that difference  
3 of .1 percent is in the range of what you would expect just  
4 from random variation. I wouldn't get excited if it had been  
5 2.1 or 2.3. It tells me very little in any sense of a trend.  
6 So to me they're the same.

7 Q. All right.

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

12 Q. In the second year?

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

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

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

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

25 A. I do.

1 Q. Can you tell us what that is?

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

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

16 Q. You're showing 20 percent of the whole curve; is that  
17 correct?

18 A. That's right. You're only showing from .8 to 1.

19 Q. So it accentuates or accents the curves?

20 A. It just allows your eye to see the difference.

21 MS. SMITH: Objection. Leading.

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

24 BY MR. COUGHLIN:

25 Q. Can you tell us what the end of those curves would

1 represent?

2 A. The end of the curves at two years, just before  
3 25 months on the X axis, that's the percent who have not had  
4 the event in the two groups. The neratinib group here is the  
5 upper one. It's not labeled here, but that's the neratinib  
6 group. The lower one is the placebo group.

7 That number on the Y axis at the end for the  
8 neratinib group would have been the -- I think it was  
9 93.9 percent that we just looked at. And the equivalent for  
10 the end of the curve for the lower one, the placebo group, is  
11 91.6. And you can see that on the Y axis. That's where  
12 those numbers came from in the tables.

13 Q. And you prepared a demonstrative, is that right,  
14 demonstrative PDEM05; is that correct? This is the curve?

15 A. I did, yes. So, yes. So I made it a little clearer on  
16 this curve because that particular curve in the analysis  
17 results wasn't coded, so I just coded it in color because I  
18 find I'm getting older and my eyes respond to color better.

19 Q. So it's still the same 20 percent that was in the  
20 earlier?

21 A. It's still the same. I just copied the curve and  
22 colored it red and blue. The blue here is the placebo group  
23 or standard of care group. The red is the neratinib group.  
24 There's the -- I've marked on there the end points  
25 specifically so you can see where they're coming from, the

1 93.9 percent and the 91.6 percent. And there's the  
2 difference between the neratinib group and the placebo group.

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

10 In the bottom of the --

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

12 A. Okay.

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

15 A. Well, they're somewhat related. It's not far off here.  
16 If you look at what, you know, what's the difference between  
17 70 events and 109? That's roughly a reduction of a third.  
18 If you take 109 and reduce it by a third, you get pretty  
19 close to 70.

20 So there's no magic here. That's not exactly how  
21 the hazard curve is computed because we statisticians know  
22 that that can be inaccurate to do that calculation. Why?  
23 Because you'll see on the bottom of the curve the number at  
24 risk. You can see at the beginning there was essentially  
25 1,410 in each group -- not quite, give or take a few that



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

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

11 That happened at a slightly higher rate in the  
12 neratinib arm than the placebo arm, so the Kaplan-Meier  
13 adjusts for that rate of dropout. So the hazard ratio is  
14 .67, but you're not far off if you just compare 70 to 109.

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

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

24 (Pause in proceedings)

25 THE COURT: All right, sir. Please continue.

1 BY MR. COUGHLIN:

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

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

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

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

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

21 A. No, not at all.

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

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

1 absolute risk difference. At this point in case, two years.  
2 You don't actually need to know the hazard rate, which is  
3 .67, hazard ratio, .67. So there you can see in the blue  
4 part at the bottom, there's the two pieces of information you  
5 need from the Kaplan-Meier curve.

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

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

15 Q. And how do you do that?

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

18 Q. The next demonstrative, number eight?

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

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

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

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

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

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

13               MS. SMITH: No objection.

14               THE COURT: Wait a minute. 124?

15               MR. COUGHLIN: 124.

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

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

20      BY MR. COUGHLIN:

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

23      A.     I did.

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

1 A. Yes. So that's the date just beyond the e-mail we  
2 looked at before at stretch break. This is July 18th.

3 Q. One day later?

4 A. I can't remember. Is it one day? It's very close,  
5 yeah.

6 Q. Tell us what this document is.

7 A. So this is now a separate communication from the  
8 statistician, one of the statisticians or epidemiologists  
9 studying the data. The previous one transmitted the efficacy  
10 results. This is now transmitting the safety results for the  
11 ExteNET study.

12 Q. Okay. Let's turn in to this document -- and it says  
13 they are now validated. Did you accept that?

14 A. I did.

15 Q. If we turn in to this document and we will go to page 8  
16 of 272, what are AEs?

17 A. Adverse events. So these are the toxic -- results  
18 arising from the toxicity of the drug in the neratinib arm or  
19 just in general any event that happens during the study. The  
20 adverse events, this is obvious here in the placebo group  
21 also.

22 Q. Okay. Let's take a look at the grade-three diarrhea.  
23 Can you see what that is?

24 A. I don't see grade-three diarrhea on this slide. Oh,  
25 there it is. Thank you. I was looking just at the row --

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

7 That tells you -- that second column tells you that  
8 39.9 percent of the neratinib patients suffered grade-three  
9 diarrhea at some point during the two years, 562 actual  
10 women. On the right-hand side, you're seeing the equivalent  
11 numbers for the placebo group, and you can see in the placebo  
12 group only 23 of the placebo patients suffered severe  
13 diarrhea, or 1.6 percent.

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

18 A. Okay.

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

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

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

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

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

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

15      A.     The median.

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

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

22      Q.     1.6 --

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

1 reflects that this has been caused by the drug.

2 Q. Let's flip over to the next page, page 10 of 272. It  
3 talks about treatment discontinued, and it has diarrhea at  
4 the top. Can you tell us what those numbers mean?

5 A. Well, these are characteristics of people who had  
6 diarrhea in the -- or were caused by diarrhea. Sometimes  
7 people would try and reduce the dose. You can see that's the  
8 last row. Did you have a dose reduction?

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

14 But in the third one, the treatment  
15 discontinuation, that means that the patient suffered from  
16 diarrhea sufficiently that that was the reason they asked to  
17 stop taking their treatment. And you can see in the -- that  
18 was over 200 patients, women, in the neratinib arm, about  
19 17 percent of the entire group, stopped taking the drug  
20 because of the diarrhea side effects they were suffering.

21 Q. Okay. Then finally we'll go to the last page of that --  
22 not the last page. It's page 266 of 272.

23 A. Yes. I have it.

24 Q. Can you tell us what that refers to?

25 A. This is a similar talking about adverse events, as you



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

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

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

13 A. I have it.

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

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

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

1 39.9 percent of the neratinib patients suffered grade three  
2 or higher or severe diarrhea. I also need the same number to  
3 compare in the placebo group, and there it is. It's  
4 1.6 percent, represents those 23 patients, 23 women.

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

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

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

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

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

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

25 THE COURT: Without objection 103 is admitted.

1                   **(Exhibit 103 received.)**

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

5                   THE COURT: Without objection 748 admitted.

6                   **(Exhibit 748 received)**

7 BY MR. COUGHLIN:

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

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

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

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

21 A. Yes.

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

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

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

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

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

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

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

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

1 different definitions of outcome that were not the primary  
2 one.

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

5 A. That is correct.

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

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

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

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

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

17 (Portion of audiotape recording played)

18 MR. COUGHLIN: Stop that right there.

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

20 (Portion of audiotape recording played)

21 BY MR. COUGHLIN:

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

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

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

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

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

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

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

21           And so Dr. Werber would move away from that  
22 assuming that the absolute risk, the disease-free survival,  
23 86 percent of the placebo group did not have the event in the  
24 two years. And you asked me to compare that to what the  
25 actual data was that's in the top there.

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

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

6       A.    Yes.

7       Q.    How?

8       A.    So we've just established Dr. Werber asked the question  
9       about the placebo disease-free survival rate. The answer  
10      came back comfort with the number 86 percent. The truth was  
11      91.6 percent. We already -- they already knew from the press  
12      release and the earlier statement --

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

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

17      Q.    The data.

18      A.    Yeah. The data was 91.6 percent.

19            Then to calculate, well, what must have been the  
20      disease-free survival proportion in the neratinib group? You  
21      take the 86 percent, and that means 14 percent actually had  
22      the event. If 86 percent didn't have the event, that means  
23      14 percent did. And you said, wait a minute. I've been told  
24      that that's reduced by one-third, by the drug in the  
25      neratinib arm. So 14 percent gets reduced by one-third.

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

7           And they can see that's exactly what Dr. Werber,  
8 he's obviously doing that calculation in his head quickly.  
9 It's not hard. He comes back immediately saying, well, if  
10 you said 86 percent in the placebo arm, and we know the  
11 hazard ratio is two-thirds, that tells me it's 90 or  
12 91 percent. Just doing exactly what I did.

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

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

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

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

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

24           THE CLERK: All rise.

25           (Open court - jury not present)



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

2 (Open court - jury present)

3 THE COURT: Welcome back, everyone.

4 You may continue.

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

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

11 MR. COUGHLIN: I agree, Your Honor.

12 THE COURT: Okay. Go ahead.

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

15 BY MR. COUGHLIN:

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

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

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

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

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

9 Q. And let's hear --

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

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

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

16 (Audiotape recording played)

17 BY MR. COUGHLIN:

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

21 A. That is my understanding, yes.

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

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

3 THE WITNESS: Yes. I'm fine.

4 BY MR. COUGHLIN:

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

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

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

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

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

18 A. I have it.

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

21 A. So this just summarizes our conversation. The top part  
22 of the demonstrative reflects the trial results with regard  
23 to the success of the trial in terms of efficacy, how well  
24 the drug was preventing reoccurrence.

25 It shows that the trial results reflected an

1 absolute difference of benefit, how much -- what fraction the  
2 patients benefited because of neratinib, the 2.3 percent as  
3 we discussed this morning. The investor call, however, left  
4 the impression that that rate, that absolute difference was  
5 four to five percent, as we also discussed this morning --

6 Q. Okay.

7 A. -- the number needed treat. Therefore the data showed  
8 43. On average you need to treat 43 women with neratinib to  
9 see one less have a recurrence than under placebo. But the  
10 investor call left the impression that that number needed to  
11 treat was somewhere between 20 and 25.

12 Q. Why is that number important?

13 A. Well, that shows that the number needed to treat -- the  
14 people listening to the information got it wrong by a factor  
15 of two. And the number needed to treat is just a measure of  
16 the impact of the drug, how many patients will need to be  
17 treated to get a difference. And that will influence  
18 physicians' assessment of the impact of the drug.

19 Q. Okay. And let's take the number needed to harm.

20 A. So that was the numbers we were just discussing about  
21 severe diarrhea -- well, not -- we were discussing this  
22 morning the 40 percent or 39.9 percent got severe diarrhea  
23 under neratinib as compared to 1.6 percent with placebo.

24 That reflected a number needed to harm of 2.6. So  
25 three women treated with neratinib on average will produce

1 one more case of severe diarrhea. The 29 to 30 percent that  
2 was the answer to that question or an answer given regarding  
3 diarrhea gets the number needed to harm higher at 3.5, 3.6,  
4 not quite double in this case but about 30 or 40 percent  
5 higher.

6 And then the final row is just the discontinuation  
7 of treatment. Those were the numbers we were just  
8 discussing. The 16.8 percent discontinued because of  
9 diarrhea; 27.6 percent of neratinib women discontinued  
10 because of any adverse effect, whereas the investor call gave  
11 the impression that number would be anticipated to be five to  
12 ten percent. So that was off by a factor of more than two if  
13 you look at all adverse effects.

14 MR. COUGHLIN: Thank you, Doctor. No further  
15 questions.

16 THE COURT: All right.

17 Cross-examination.

18 MS. SMITH: Your Honor, may I approach the witness  
19 with an examination binder?

20 THE COURT: You may.

21 **CROSS-EXAMINATION**

22 BY MS. SMITH:

23 Q. Good afternoon, Dr. Jewell.

24 A. Good afternoon.

25 Q. I'm Colleen Smith. You may remember me as the person

1 who took your deposition?

2 A. Yes.

3 Q. All right. Now, Dr. Jewell, earlier today you testified  
4 that your area of expertise is biostatistics, correct?

5 A. Yes.

6 Q. You aren't an expert in what should be disclosed to  
7 investors; are you?

8 A. No.

9 Q. You have no particular expertise with communications  
10 with investors?

11 A. No.

12 Q. You also have no expertise in what is customarily  
13 disclosed in public company press releases?

14 A. No.

15 Q. And you have no expertise with respect to what is  
16 customarily disclosed in an analyst call?

17 A. No.

18 Q. You have no expertise as an analyst?

19 A. No.

20 Q. In fact, you have never even participated in an analyst  
21 call; have you?

22 A. No. I'm a statistician at a university.

23 Q. So what would be meaningful to an individual investor is  
24 beyond the realm of a biostatistical expert such as yourself,  
25 right?

1 A. I have no opinion in what's meaningful to investors on  
2 an investor call.

3 Q. Now, you were asked to comment on some exchanges with  
4 analysts in the analyst call, Exhibit 103, that we have just  
5 reviewed, and you just testified that some of the statements  
6 on that call left a certain impression. Do you remember that  
7 testimony?

8 A. Yes.

9 Q. But you don't have any expertise that would qualify you  
10 to offer opinions about what an analyst might be thinking in  
11 connection with a question on an analyst call; do you?

12 A. No. I have no opinion what they may have been thinking  
13 when they asked the questions. I can only go by the  
14 questions asked.

15 Q. And you've not undertaken any investigation or review to  
16 determine what analyst investors actually took away from  
17 those exchanges on the analyst call?

18 A. Well, I hadn't seen any of that information at the time  
19 of my deposition. I subsequently have seen documents about  
20 how some of the information was transmitted from analysts on  
21 that call.

22 Q. But before forming your opinions in this case, you did  
23 not review any of those documents?

24 A. No. It has no bearing on my opinion.

25 Q. And you didn't review -- before forming your opinions in

1 this case, you didn't review any of those analyst reports?

2 A. No. It has no bearing on my opinions.

3 Q. Now, you're not offering an opinion about when  
4 information needs to be disclosed to investors, correct?

5 A. No. I've already answered that I'm not an expert on  
6 investor calls.

7 Q. All right. Let's talk about your opinions with respect  
8 to the number needed to treat. The number needed to treat is  
9 something you calculated, right?

10 A. Yes. It's simply one over the 2.3 percent. So it's a  
11 very simple calculation in that case.

12 Q. Sure, but that's your calculation which you walked  
13 through here earlier today with the jury, correct?

14 A. Correct.

15 Q. There was no discussion of the term number needed to  
16 treat on the July 2014 analyst call; was there?

17 A. No.

18 Q. And none of the analysts asked any questions about the  
19 term number needed to treat; did they?

20 A. No. They only asked about the difference in the risk  
21 essentially.

22 Q. That phrase doesn't appear anywhere in the analyst call  
23 transcript?

24 A. No. The number needed to treat is simply a way of  
25 making that information about difference in benefit more



1 understandable to a lay person or a physician. So I find it  
2 helpful. But if you don't, that's fine.

3 Q. It's not in the analyst call?

4 A. No.

5 Q. And you aren't offering the opinion that the number  
6 needed to treat was a prespecified end point of the ExteNET  
7 trial; are you?

8 A. Well, as I testified at the deposition, the Kaplan-Meier  
9 was prespecified in the difference in benefit. The  
10 2.3 percent comes directly from that. And the number needed  
11 to treat is a five-second calculation beyond that.

12 So if the information in the statistical analysis  
13 plan is -- was divided, which it ultimately was, the number  
14 needed to treat is there also. It's not a new number that  
15 needs any new information about the data.

16 Q. So you were deposed in this case, as we've already  
17 established. And when you were deposed, you took an oath to  
18 answer the questions truthfully; is that correct?

19 A. Correct.

20 Q. I'd like to direct your attention to your deposition  
21 transcript, which should be in the white binder in front of  
22 you.

23 A. Uh-huh.

24 Q. If you would turn to page 102, lines 17 to 20.

25 MS. SMITH: Your Honor, may I play a video clip?

1 THE COURT: Any objection?

2 MR. COUGHLIN: Your Honor, I think she's first got  
3 to ask him if he remembers what the context is. If she wants  
4 to impeach him with it, she can do that. But it's probably  
5 quicker just to play it. So, no objection.

6 THE COURT: Counsel, I think you are correct, and I  
7 appreciate your work towards efficiently moving forward.

8 Play it.

9 MS. SMITH: Thank you, Your Honor.

10 Clip number 23, please.

11 (Videotape recording played)

12 BY MS. SMITH:

13 Q. Did I ask you that question and did you give that  
14 answer?

15 A. Yes, but you didn't play the next part of the --

16 Q. The answer to my question was yes?

17 A. I'm answering the question.

18 THE COURT: Let's have the next question. Your  
19 attorney may ask further questions if he wishes.

20 THE WITNESS: Okay.

21 THE COURT: Actually, no. Let me restate.  
22 Plaintiffs' counsel may ask further questions if they wish.

23 MR. COUGHLIN: Thank you, Your Honor.

24 THE COURT: That's an important point.

25 Go ahead.

1 BY MS. SMITH:

2 Q. Dr. Jewell, you aren't offering any opinions about  
3 whether -- well, let me back up. You calculated the NNT for  
4 the ExteNET trial as 43, correct?

5 A. Correct.

6 Q. And you aren't offering any opinions about whether 43 is  
7 a tolerable number needed to treat; are you?

8 A. No. That's for physicians to decide, not me.

9 Q. And you're not a physician?

10 A. No. I already said that.

11 Q. Let's talk about your opinions with respect to the  
12 safety profile. In one of your slides -- I think it was  
13 demonstrative number three -- you stated that you had  
14 analyzed whether the statement accurately describes the  
15 benefit risk profile of neratinib; is that right?

16 A. Could you repeat the question?

17 Q. Sure. If you want to take a look at it, you can. It's  
18 slide number three of your demonstrative slides. You stated  
19 that you analyzed whether the statement accurately describes  
20 the benefit risk profile of neratinib in the ExteNET study?

21 A. I'm not sure what you're pointing --

22 Q. Sure. Could you look at slide number three of your  
23 demonstrative in the black binder.

24 A. Sorry. I got it now.

25 Q. Okay. And if you look at the bullet points there toward

1 the bottom of the page, one of your statements says that you  
2 analyzed whether the diarrhea rates as reported on the  
3 July 22, 2014, call accurately described the benefit risk  
4 profile of neratinib. Do you see that?

5 A. I do.

6 Q. But isn't it true that you actually have no opinion  
7 about the risk benefit profile of neratinib?

8 A. Well, I'm just -- you're saying that's the basis of a  
9 risk profile. I'm not saying I'm going to opine about the  
10 actual decisions that a physician or a patient might make,  
11 but just the information about safety is part of the benefit  
12 risk profile. That's all I meant by that.

13 Q. So you have no opinion about the risk benefit profile?

14 A. As I indicated, that's for physicians and patients to  
15 discuss.

16 Q. So you aren't offering any opinion about what a  
17 meaningful clinical benefit would be?

18 A. No. That's again for physicians and patients to  
19 discuss.

20 Q. All right. So then with respect to the number needed to  
21 harm, again that was something that you calculated,  
22 Dr. Jewell, correct?

23 A. Correct.

24 Q. And that's not a number or that's not a statistic that  
25 was discussed on the July 2014 analyst call; is it?

1 A. No.

2 Q. That term was not used by any of the analysts on that  
3 call?

4 A. No.

5 Q. No questions were asked about the number needed to harm?

6 A. No. The questions were asked about diarrhea rates or  
7 discontinuation from adverse events.

8 Q. Nowhere in the transcript does the phrase number needed  
9 to harm appear, right?

10 A. No.

11 Q. Now, with respect to your number needed to harm, you  
12 calculated that based on the diarrhea rate in the ExteNET  
13 study, right?

14 A. Correct.

15 Q. You didn't calculate a number needed to harm based on  
16 any other studies in which Imodium prophylaxis was used; did  
17 you?

18 A. Well, Imodium prophylaxis was used in the ExteNET study,  
19 but I didn't do the number needed to harm for any other  
20 study.

21 Q. I thought your testimony, Dr. Jewell, was that Imodium  
22 prophylaxis was not used but that Imodium may have been  
23 prescribed in another fashion.

24 A. I'm not sure if I understand the difference between  
25 prescribed and used in another fashion.

1 Q. Let me ask the question differently. Isn't it true that  
2 Imodium prophylaxis was not part of the clinical trial  
3 protocol for the ExteNET study?

4 A. I wouldn't -- I don't agree with that statement, no.  
5 That is not my understanding. I didn't opine on it in my  
6 report, but that's not my understanding.

7 Q. Okay. So you think that Imodium prophylaxis was part of  
8 the clinical trial protocol for the ExteNET study?

9 A. Well, I can't speak to the Puma version of the protocol.  
10 The Wyeth version of the protocol specifically mentions  
11 diarrhea medications being made available to patients from  
12 day one.

13 But what's really important is what actually  
14 happened in the trial, and certainly Imodium was used by  
15 patients in the ExteNET trial. So I'm confused as to why you  
16 would say it wasn't.

17 Q. All right. You didn't review that aspect of the  
18 clinical trial protocol?

19 A. I just told you what I know of my memory from the  
20 documents. I would have to go back to the Puma -- the last  
21 amendment. There was, as you know, many amendments to the  
22 protocol over the years. I can remember the first one, which  
23 was the Wyeth protocol, but I can't remember today if they  
24 maintained that part of the protocol in the last amendment.

25 Q. You haven't done any analysis to -- in terms of

1 understanding what investors knew about the diarrhea rates  
2 associated with neratinib; have you?

3 A. No. You would have to ask investors to know what they  
4 knew, not me.

5 Q. Earlier today you also mentioned validation. You  
6 haven't done any work to determine whether or not Puma's  
7 safety data had in fact been validated by July 22nd, 2014;  
8 have you?

9 A. No. I can only report on what I read from Puma  
10 documents regarding the validation. I personally have not  
11 been able of course to confirm or deny those.

12 Q. And you haven't reviewed all of the documents in this  
13 case that are relevant to that issue?

14 THE COURT: Hold on. Repeat it and slow down a  
15 bit.

16 BY MS. SMITH:

17 Q. You haven't reviewed the documents in this case that  
18 would allow you to form an opinion as to whether the  
19 validation procedures had been completed or not by July 2014?

20 A. No. I have no additional information beyond what Puma  
21 reported.

22 Q. Now, you spent some time talking about the  
23 discontinuation rates due to diarrhea and adverse events.  
24 The discontinuation rates -- a discontinuation rate means  
25 that a patient stopped taking the treatment, and in this case

1 that was neratinib, right?

2 A. That is correct.

3 Q. Okay. And those are discontinuation rates, not dropout  
4 rates, right?

5 A. Well, there's a little bit of a confusion in the  
6 investor call. People use those word differently, so you  
7 have to be specific about what you mean by a dropout rate.

8 There was a discussion this morning with the first  
9 witness. If you're using dropout rate to say complete  
10 withdrawal so no further information was available on that  
11 patient, that's different from treatment discontinuation  
12 where you may stay on the trial, still information about  
13 cancer recurrence maybe being measured, but you're not taking  
14 the treatment any longer. That's important to make that  
15 distinction.

16 Q. Right. Okay. So a discontinuation rate can be  
17 different from a dropout rate where a patient has completely  
18 withdrawn from the study and you have no information about  
19 that patient?

20 A. That is correct. Both, of course, occurred in the  
21 trial, and the numbers are known for both of those  
22 characteristics.

23 Q. Okay. Well, let's actually take a look at Exhibit 124.  
24 That should be in your black binder. If you would go to page  
25 10 of -- page 10. If you look at the fourth one down on this



1 table, it says withdrawal from study, correct?

2 A. Correct.

3 Q. Okay. So this would be the number of patients who  
4 withdrew from the neratinib trial due to diarrhea, right?

5 A. I assume that is people who were completely lost to  
6 follow-up and indicated that they were leaving because of  
7 diarrhea, correct.

8 Q. So people who dropped out of the study due to diarrhea?

9 A. Meaning that they ceased all -- yeah, all measurements  
10 were ceased from these patients, as compared to the treatment  
11 discontinuation, which is the line above, which means they  
12 wished to stop the treatment but they were willing to stay in  
13 the trial with regards to follow-up.

14 Q. Okay. And the number here for the number of patients  
15 who withdrew from the study or dropped out due to diarrhea is  
16 1.6 percent?

17 A. Correct.

18 Q. That's a very different number from 27.6 percent?

19 A. Well, they're completely different events. As I say,  
20 you may have a toxic reaction to a drug and wish to stop  
21 treatment, but you may be perfectly willing for your  
22 follow-up visits to record whether you have a cancer  
23 recurrence. Those are completely obviously quite different  
24 decisions.

25 Q. Right. And 1.6 percent is not the same as 16.8 percent?

1 A. Is that a question?

2 Q. It is.

3 A. Yes. They're different numbers.

4 Q. All right.

5 MS. SMITH: You can take that down. Thank you.

6 BY MS. SMITH:

7 Q. Let's talk a little bit about the Kaplan-Meier curves.  
8 You started off your testimony here today, I think, by  
9 offering a tutorial of sorts on the Kaplan-Meier curves.

10 THE COURT: Slow down a bit.

11 MS. SMITH: Thank you, Your Honor.

12 BY MS. SMITH:

13 Q. The Kaplan-Meier curve -- and then you looked at  
14 Kaplan-Meier curves for the ExteNET trial; is that right?

15 A. For the primary outcome I did, yes.

16 Q. And those were Kaplan-Meier curves for two years?

17 A. They were. That is correct.

18 Q. And you are not offering any opinions about the  
19 information beyond two years; is that right?

20 A. Well, you can ask me a question about it. I know the  
21 information that was available at the time beyond two years,  
22 but I didn't -- I was not asked a question about that this  
23 morning.

24 Q. So it wasn't part of your charge to look at the  
25 information past two years, right?

1 A. No, not specifically, but I have seen the documents  
2 regarding the information available beyond two years, within  
3 the third year, for example. But I haven't been asked a  
4 question. So until I'm asked a question, I won't say  
5 anything.

6 Q. Well, you say you've seen the documents, but didn't I  
7 hear you testify earlier that you haven't actually seen the  
8 ExteNET clinical trial database?

9 A. Yes. So there's a difference between database, which is  
10 huge for this trial, information on 2,800 patients, and  
11 documents that Puma provided regarding that data. I've seen  
12 the latter but not the former.

13 Q. So you haven't done any analysis in the ExteNET trial  
14 database to evaluate what's happening with the Kaplan-Meier  
15 curves after two years?

16 A. Let me say again, I've not been -- I've not had access  
17 to the original data, so I can't reconstruct and show they're  
18 correct or not. I have taken them at face value. But I've  
19 also seen Puma documents that go beyond two years describing,  
20 for example, the number of additional cancer reoccurrences in  
21 the third year.

22 If you wish to ask a question, I certainly will,  
23 but I don't want to offer an opinion unless you ask a  
24 question.

25 Q. What's happening with the Kaplan-Meier curves past two

1 years is not part of your opinion?

2 A. I know the information, but I did not write about it in  
3 my report. If you wish to ask me a question, I'm more than  
4 happy to respond.

5 Q. I just want to understand what your opinions are in this  
6 case.

7 So, Dr. Jewell, you testified a bit earlier today  
8 about the compensation you receive for testifying. You were  
9 hired by the plaintiffs' law firm in this case. That's  
10 Robbins Geller, right?

11 A. That is correct.

12 Q. And you have been hired as an expert by Robbins Geller  
13 in the past; haven't you?

14 A. A couple of times, yes.

15 Q. Two times at least?

16 A. Two or three, I would say, at the most.

17 Q. And those cases also involved pharmaceutical drugs?

18 A. Yeah, I believe so, yes.

19 Q. One was Xylox?

20 A. Correct.

21 Q. One was Pharmacia?

22 A. Well, that's not a drug. That was the name of the case.

23 Q. I see. Was there a drug involved in that case?

24 A. Yes.

25 Q. Okay. In fact, you've been -- as you testified, you've

1       been retained as an expert many times before?

2       A.     Correct, about 40 to 50 times.

3       Q.     All right. And you also said that in some of those  
4       cases, your expert testimony has been excluded by a Court?

5       A.     Yes. It's been entirely excluded in one case, as I  
6       mentioned this morning. As I said, ironically, it's a little  
7       hard to talk about because it was accepted by one Court in  
8       its entirety and rejected by another Court in its entirety.

9       Q.     Okay. And by excluded, you mean the judges in those  
10      cases refused to allow your opinions to be considered, right?

11      A.     Well, I'm not a lawyer. My understanding is the  
12      opposing counsel challenged my testimony, and the judge had  
13      determined not to allow it to be entered into the -- as  
14      evidence.

15      Q.     All right. In fact, one of those cases related to the  
16      drug Lipitor; is that right?

17      A.     That was one of the cases in which only part of my  
18      testimony was excluded. That was one of the two or three  
19      where I said that only part was excluded, and that was a case  
20      in Lipitor.

21      Q.     And for that part of your opinion that was excluded,  
22      didn't the Court say that you had engaged or improperly  
23      engaged in --

24               MR. COUGHLIN: Your Honor, I have to object. We've  
25      gone beyond. They didn't challenge this witness in this

1 case, and now we're talking about opinions in other cases and  
2 they're asking details.

3 THE COURT: Overruled.

4 MS. SMITH: Thank you, Your Honor.

5 BY MS. SMITH:

6 Q. So in one of those cases -- again, this is the Lipitor  
7 case. Isn't it true that in that case the Court concluded  
8 that in order to reach your conclusion, you had improperly  
9 engaged in a results-driven methodology?

10 A. Yes, that was the opinion of the Court. Of course, with  
11 all due respect, I don't rule or make opinions about law, and  
12 sometimes Courts and judges make mistakes about statistics.  
13 That was an egregious mistake.

14 But I did say this morning that part of the  
15 complexity of that case was it involved a very substantial  
16 amount of data analysis of a clinical trial -- actually  
17 several clinical trials, much more complicated than the  
18 issues here, and the judge just didn't understand the  
19 statistics unfortunately. But that's the way it goes.

20 Q. That wasn't the only time that a Court has excluded your  
21 opinions?

22 A. As I indicated this morning, that was the only time the  
23 entire testimony was excluded, having previously been  
24 accepted by another -- another challenge by a different  
25 Court.

1 Q. Well, let's talk about another one of these decisions.  
2 You recall that your opinion or a portion of your opinions  
3 was excluded in a case involving Zolof?

4 A. Correct.

5 Q. And in that case isn't it true that the Court expressed  
6 concern that you had selectively relied on a statistical  
7 principle in a results-driven manner?

8 A. As again I indicated, those cases are actually slightly  
9 related. Again, that case involved me re-analyzing clinical  
10 trial data. The judge in this case misunderstood what the  
11 statistics I was doing did, with all due respect.

12 Q. And that Court also concluded that your opinion  
13 testimony was likely to confuse or mislead the jury?

14 A. I disagree with that. Of course, I would be happy to  
15 discuss it in detail if you would like, but it's hard for  
16 other people to understand without getting into the details.  
17 That is a flatly wrong statement in my opinion.

18 Q. You disagree with it, but that is in fact what the Court  
19 said; isn't it?

20 A. Yes.

21 MS. SMITH: I have no further questions.

22 THE COURT: All right. Thank you.

23 Any redirect?

24 MR. COUGHLIN: Yes, Your Honor. I'd like to put up  
25 the next part of that depo clip that we looked at.

1 THE COURT: Yes, please.

2 (Portion of videotape recording played).

3 **REDIRECT EXAMINATION**

4 BY MR. COUGHLIN:

5 Q. Isn't that what you just answered prior to that?

6 A. That's what I was trying to interject and say, because  
7 it was cut off in the first when I said it wasn't part of the  
8 investor call. It wasn't a prespecified end point, that that  
9 was my full answer just as I gave today. It's immediately  
10 calculable from what was prespecified and what was discussed  
11 on the investor call.

12 Q. There was a lot of questions of you about diarrhea and  
13 diarrhea rates. I'd like you to look a look at  
14 Exhibit 1043 -- which has had no objection to, Your Honor.

15 THE COURT: 1043, you're moving its admission?

16 MR. COUGHLIN: Yes.

17 THE COURT: 1043 is admitted without objection.

18 **(Exhibit 1043 received.)**

19 BY MR. COUGHLIN:

20 Q. If you take a look at 1043 -- it's a little hard to  
21 read, but if we can focus on the top couple of lines.

22 A. Yes. I'm looking.

23 MR. COUGHLIN: And blow that up.

24 BY MR. COUGHLIN:

25 Q. I think those numbers, if you take a look at those



1 numbers, they talk about how many patients -- how many  
2 patients are on antidiarrheal medication. And this is the  
3 ExteNET study; is that correct?

4 A. Yes. This is the ExteNET study, and this refers to what  
5 I was discussing about my confusion on the question because  
6 it clearly indicates here in the ExteNET study that  
7 87.4 percent of neratinib patients took some antidiarrheal  
8 medication.

9 Q. And you refer to the Wyeth SAP, and the Wyeth SAP said  
10 what about providing antidiarrheal medication?

11 A. The Wyeth protocol for this ExteNET study indicated that  
12 antidiarrheal medication should be made available to all  
13 patients, and they recommended being available from day one.

14 If you drop the box there and you go down that  
15 table, you can see of those 1,230 patients in the neratinib  
16 arm, almost all of them took some antidiarrheal medication  
17 for reasons that should now be obvious because that's a lot  
18 of diarrhea.

19 You can see further down there that 70 percent of  
20 those people who got antidiarrheal in the neratinib arm took  
21 it within the first week of being exposed to the drug. So  
22 they started on this very early on. Now, whether they  
23 started on before they'd even taken a single pill is not  
24 indicated by this table, but they took it within the first  
25 week, almost all of them.

1 Q. Okay. Let's go all the way down to where it talks about  
2 taking antidiarrheal medication in a prophylactic manner --  
3 loperamide down at the bottom of the page?

4 A. Yes. I see it, I think.

5 Q. Do you see what that says? It talks about how many  
6 patients were taking that in that manner, and it has a number  
7 there.

8 A. Yes. These are neratinib patients. It's a little bit  
9 cut off, the 336.

10 Q. Okay.

11 A. And they were taking Imodium, loperamide, specifically.  
12 Before we were talking about any antidiarrheal medication.  
13 They were taking that in a prophylactic way during the trial.

14 Q. We talked -- we talked first about people taking it in  
15 the first week, and that was the majority up above, and that  
16 was 70 percent Imodium and another percent other  
17 antidiarrheal.

18 But here we're talking about in a prophylactic way,  
19 and we've got a certain number. Is it taking it before you  
20 start the drug, or is it taking it after a hold and then  
21 restarting?

22 A. Well, I would have to -- if you mean -- the box is  
23 covering a little bit of that information.

24 Q. If we can make it a little bigger?

25 A. Just a little bigger up above. Thank you. That's fine.

1 So there you can see it's the number of neratinib patients  
2 taking Imodium following what's called a dose hold. What  
3 that meant is they probably had -- it says a dose reduction  
4 for diarrhea.

5 So what -- let's just say it in plain words. These  
6 patients started the drug. They had diarrhea sufficiently  
7 badly that in conjunction with the physicians in charge, they  
8 decided either to reduce the dose to try and mitigate the  
9 diarrhea, or hold off, stop taking the drug for a bit.

10 After that had happened, the diarrhea went away.  
11 Then they were -- these particular patients, 158, were then  
12 said, hey, take the Imodium now even though you're not  
13 suffering from diarrhea now to try and prevent it coming back  
14 again.

15 MR. COUGHLIN: I have no further questions, Your  
16 Honor.

17 THE COURT: Anything else?

18 MS. SMITH: No further questions, Your Honor.

19 THE COURT: Thank you, sir. You may step down.  
20 The plaintiff will call its next witness.

21 MR. COUGHLIN: Your Honor, could I take one minute  
22 and I'll be right back?

23 THE COURT: Yes, you may.

24 MR. COUGHLIN: Thank you.

25 THE COURT: Everyone else, feel free to stretch,

1 stand, or whatever they like. Well, not whatever. Within  
2 reason.

3 And here's some good news for some of you. We will  
4 be meeting at 9:00 tomorrow, not 8:00. Okay?

5 (Pause in proceedings)

6 MR. COUGHLIN: My next witness is Mr. Auerbach.

7 THE COURT: Please take the stand, Mr. Auerbach.

8 **Alan Auerbach, Plaintiff's witness, sworn**

9 THE CLERK: If you will please state and spell your  
10 first and last name for the record.

11 THE WITNESS: Alan Auerbach. Last name is spelled  
12 A-u-e-r-b-a-c-h.

13 **DIRECT EXAMINATION**

14 BY MR. COUGHLIN:

15 Q. Good afternoon, Mr. Auerbach.

16 A. Good afternoon.

17 Q. I'd like to take you through -- you're the founder of  
18 Puma; is that correct?

19 A. That is correct.

20 Q. And you're the CEO?

21 A. That is correct.

22 Q. Okay. And I'd like to take you through some of the  
23 initial founding documents. I'd like you to open up the  
24 black binder next to you, and the first exhibit we have is  
25 Exhibit 1034, which is a 10Q that is signed by you dated

1 November 14th, 2011.

2 MR. COUGHLIN: I'd like to move for the admission  
3 of that document.

4 THE COURT: Document number?

5 MR. COUGHLIN: Document number 1034.

6 MS. JOHNSON: No objection.

7 THE COURT: Document 1034 is admitted.

8 **(Exhibit 1034 received.)**

9 BY MR. COUGHLIN:

10 Q. Mr. Auerbach, do you recognize this document?

11 A. Yes, I do.

12 Q. Okay. I'd like you to take a look into the document and  
13 actually page 13 of the actual document. It's 16 of 27.  
14 Actually I'm going to move you back one page to page 12 at  
15 the top, the first paragraph.

16 Is it correct that Puma was incorporated September  
17 15th, 2010?

18 A. That is correct.

19 Q. Okay. And you were the largest shareholder; is that  
20 right?

21 A. That is correct.

22 Q. Okay. Let's flip over to page 13. Under stock equity,  
23 it says common stock, that Puma issued four million shares of  
24 common stock to its founder and CEO in September 2010; do you  
25 see that -- for \$400?

1 A. Yes.

2 Q. At a P -- at a .0001 per share?

3 A. That is correct.

4 Q. And that you contributed capital totaling 61,000 and  
5 68,000; is that right?

6 A. Correct.

7 Q. About a 150,000?

8 A. Correct.

9 Q. Okay. So your initial investment was \$400?

10 A. The initial capital put into Puma prior to neratinib  
11 being licensed was actually in the hundreds of thousands of  
12 dollars. When the company was founded, the goal was to find  
13 cancer drugs to license. The only dollars spent for  
14 neratinib was the \$150,000.

15 So I didn't feel right having the shareholders  
16 charged with that, if you will, for the other drugs I looked  
17 at. I just took the funds that were used for the acquisition  
18 of neratinib.

19 Q. Okay. So you had -- so apparently, in the next  
20 paragraph, it's authorized for 25 million, but there weren't  
21 25 million shares outstanding. Actually right below the \$400  
22 number, it's 25 million were authorized; is that right?

23 A. Can you guide me to where --

24 Q. Yeah. Page 13.

25 A. Yes.

1 Q. Okay. If I move over to page 14, I think it talks about  
2 your \$150,000 investment. Do you see that, on September 2nd,  
3 2011, you advanced Puma 150,000, and that's what you were  
4 talking about?

5 A. That's correct.

6 Q. You converted that into 40,000 shares; is that right?

7 A. Correct.

8 Q. Okay. And that was on October 6th, 2011?

9 A. Correct.

10 Q. And is that when you did some initial funding at 375 a  
11 share? That's about, you know, what it comes out to when  
12 other investors came in?

13 A. Yes. That's correct.

14 Q. Okay. There were about 25 to 27 other investors  
15 invested with you at the time?

16 A. I seem to remember the number being a little bit larger.  
17 We had some institutions and we had some retail as well. But  
18 I seem to recall the number was slightly larger than that but  
19 in the ballpark, yes.

20 Q. Okay. And if you flip over to the next page, page 15,  
21 it talks about warrants issued to the CEO. It talks about a  
22 number of warrants that are being issued to you to keep your  
23 ownership share at about 20 percent. Do you see that?

24 A. Yes. Correct.

25 Q. And during this time frame, from this time frame on,

1 your ownership did fluctuate somewhere between 17 and 21 of  
2 the company; is that about right?

3 A. With the company was founded, the initial investor who  
4 put in the largest amount of money, which is typically  
5 referred as to the lead investor, the offer they had made to  
6 me was that on the first financing the company did, I got  
7 what's referred to as antidilution protection, meaning that I  
8 was allowed to maintain my 20 percent ownership in the  
9 company.

10 Going forward I did not maintain that 20 percent  
11 antidilution protection, just on the first financing that  
12 occurred after the one in 2011.

13 Q. And that -- and actually that was in October 24, 2012,  
14 is when you got that antidilution of 2.1 million shares for  
15 \$16 a share? Does that sound about right?

16 A. I believe that sounds about right.

17 Q. Because you had done an offering about that time, so  
18 they gave it to you at the offering price, I believe?

19 A. I believe that's correct.

20 Q. And that kept you at your 20 percent at that time?

21 A. That's correct.

22 Q. In the 2014-2015 time frame, how far down below -- the  
23 number I saw was maybe 17 percent. How far down below 20 did  
24 you go?

25 A. I don't keep track of that on a regular basis. I --



1 Q. Am I in the ballpark?

2 A. I believe it's somewhere in the, you know, ballpark, 15  
3 to 18 percent range.

4 Q. Okay. Let's take a look at exhibit -- let's take a look  
5 at Exhibit 129, if you would. Take a look at that, and then  
6 flip over to the first page. I think it might help you  
7 recognize exactly what that is.

8 A. (Witness reviewing document)

9 Q. Do you recognize what this document is?

10 A. Yes. This would be the statistical analysis plan for  
11 the ExteNET trial.

12 Q. And this is a plan that Puma drew up; is that correct?

13 A. Yes.

14 Q. And this is a plan that followed the ownership of Wyeth  
15 and then Pfizer, and then this was the third statistical  
16 analysis plan; is that correct?

17 A. I seem to remember there were more statistical analysis  
18 plans than just these three, but this was the first major one  
19 that Puma did.

20 Q. Right. Correct me if I'm wrong or off by some -- I  
21 don't think it's an important factor right yet, but I seem to  
22 remember there were, like, 13 amendments, but there were  
23 really three primary global amendments to this plan; is that  
24 correct?

25 A. I believe that's correct.

1 Q. Okay. So that's dated July 3rd, 2014. What -- I'd like  
2 to move into that document and talk to you about those  
3 amendments if that's all right.

4 A. Sure.

5 Q. If we take a look at page 9 of 55. At the bottom it's  
6 Exhibit 129, page 11 of 61. I'm looking at the actual  
7 numbers of the document.

8 A. Correct.

9 Q. So this is the global -- first of all, it starts the  
10 original protocol by Wyeth. Do you see that?

11 A. Yes.

12 Q. So Wyeth developed -- discovered, developed, or started  
13 the development of this drug; is that correct?

14 A. That is correct.

15 Q. Okay. And then when Pfizer bought Wyeth, they took over  
16 the development of this drug; is that correct?

17 A. Correct.

18 Q. Okay. Now, this first protocol, this did not involve  
19 you; is that correct?

20 A. That is correct.

21 Q. Okay. And that was in February 2010 with Pfizer; is  
22 that right?

23 A. That is correct.

24 Q. Okay. And if I flip over to the next page -- well,  
25 let's start with what happens here. It appears, because I

1 want to understand how the population changed, it appears  
2 that some studies came out indicating that the risk of tumor  
3 reoccurrence was lower than expected when the study was  
4 originally designed, and they modified the study as a result;  
5 is that right?

6 A. That is correct.

7 Q. Okay. And the modification changed from allowing HER-2  
8 positive -- I want to be on the same page with that so we  
9 know what we're talking about. It's been talked about  
10 here -- HER-2 positive to instead of node-negative and  
11 node-positive just to node-positive; is that correct?

12 A. Just to clarify, node-negative and node-positive means  
13 at the time of the diagnosis of the disease, is the disease  
14 just in the breast or had it spread outside the breast to the  
15 lymph nodes. So that's node-negative and node-positive.

16 Q. We had a doctor this morning explain some of those  
17 terms. Thank you. So this, in quote, enriched the  
18 population of people that were more at risk; is that right?

19 A. That is correct.

20 Q. Okay. Now, correct me if I'm wrong. My understanding  
21 is the HER-2 positive population is approximately somewhere  
22 between 20 and 30 percent of the overall breast cancer  
23 population; is that right?

24 A. No. My understanding is it's between 15 to 20 percent  
25 of the overall breast cancer population.

1 Q. You think it's lower than that?

2 A. That's my understanding.

3 Q. Okay. Let's just go with 20 percent, catches both our  
4 numbers. So the HER-2 positive population is about  
5 20 percent of the overall population, and the node-positive  
6 versus negative, node-negative is about 80 percent of the  
7 overall breast population; is that about right?

8 A. That is not correct. There was a publication -- I'm  
9 forgetting the date -- that looked at the percent of  
10 node-negative and node-positive cancer, breast cancer,  
11 worldwide. I thought the node -- it was roughly 50/50,  
12 50 percent node-negative and 50 percent node-positive in the  
13 United States.

14 Q. In the United States?

15 A. In the United States. So just to clarify worldwide, in  
16 certain other countries they don't have as good of a medical  
17 standard of care. So oftentimes women aren't going to the  
18 doctor to get checked, et cetera.

19 In the United States we have a very good standard  
20 of care, so women are indeed going so they can get diagnosed  
21 earlier.

22 Q. If the American Cancer Society had it at about  
23 77 percent node-negative, would you dispute that figure?

24 A. I would say that -- I don't know what the date of that  
25 publication is, but I would say -- we looked at the

1 publications more recently, and it was 50/50.

2 Q. This was a recent look at the publication that you  
3 looked at? Is that what you're saying?

4 A. That's the publication I remember.

5 Q. So if their publication was 2017, 2018 --

6 THE COURT: Yes. Boy, take a deep breath. Take a  
7 deep breath. Slow down.

8 MR. COUGHLIN: I will, Your Honor.

9 MS. JOHNSON: Your Honor, I would interpose an  
10 objection based on the mill number four by plaintiff to the  
11 use of later -- to the reference to later studies.

12 MR. COUGHLIN: I was just clarifying what he said.  
13 He said he looked at --

14 THE COURT: Hold on. Excuse me. Did an answer  
15 come in? I was spending time on slowing down.

16 Just one second.

17 All right. The last question was: There was a  
18 recent look at the publication that you looked at. Is that  
19 what you're saying? That's the publication I remember.

20 Do you object to any of that?

21 MS. JOHNSON: Not that one, Your Honor.

22 THE COURT: Okay. Then we'll be ready if there's  
23 another one. Go ahead.

24 BY MR. COUGHLIN:

25 Q. So let's move down -- so that was a -- so if we talk --

1 if we take a look at approximately how many subjects, were  
2 3,300 enrolled at that time, or was that the target to be  
3 enrolled?

4 A. That was the target to be enrolled.

5 Q. Okay. But 3,300 had not been enrolled at that time; is  
6 that correct?

7 A. That is correct.

8 Q. Okay. And so that's -- then the new criteria is that  
9 node-positive disease, randomization with one year of  
10 completion of a prior -- that's Herceptin, right?

11 A. That's correct.

12 Q. Okay -- therapy. So they had changed the population; is  
13 that right?

14 A. Yes. There had been data presented at the San Antonio  
15 breast cancer meeting 2009 or 2010 which showed that patients  
16 had a higher risk of their breast cancer coming back if they  
17 either had node-positive disease or they were within one year  
18 of finishing Herceptin, also known as trastuzumab on the  
19 screen.

20 THE COURT: Hold on. Also known as?

21 THE WITNESS: Trastuzumab. That's the second to  
22 last word there.

23 THE COURT: It is on the screen. Go ahead.

24 BY MR. COUGHLIN:

25 Q. Trastuzumab is Herceptin?

1 A. Herceptin, correct. So the protocol was modified to  
2 enrich for a higher risk population which, based on that  
3 study, that would be what this is referring to.

4 Q. Okay. Now let's talk about the next -- so the study was  
5 modified that way. Now let's talk about the next -- the  
6 global protocol amendment number nine. Take a look at that.

7 A. Correct.

8 Q. It says Pfizer stopped enrollment of new subjects with  
9 global amendment nine and limited it to two years. Do you  
10 see that?

11 A. Correct.

12 Q. It says the consequences of this amendment impact the  
13 original study objectives of evaluating the long-term  
14 efficacy of neratinib in the extended adjuvant setting. Do  
15 you see that?

16 A. That's correct.

17 Q. Did you agree with that?

18 A. It was done before we bought the drugs, so there wasn't  
19 much we could do about it.

20 Q. Were you involved in that decision?

21 A. They had notified us early on. This was clearly a dual  
22 protocol amendment. It was going to take six to nine months  
23 to get things done.

24 So when we were talking to them about licensing  
25 neratinib, which was in October 2011, they had told us that

1 that was something they were planning on doing for budgetary  
2 reasons, because obviously stopping enrolling in the trial  
3 and only following patients for five years instead of for two  
4 is much cheaper.

5 So what they were looking to do was reduce the  
6 budget for this trial, and that was their solution to doing  
7 that.

8 Q. Okay. Let's take a look at Exhibit 745, which is the  
9 next exhibit in line in your folder.

10 A. (Witness complies.)

11 Q. I want you to take a look at the letter dated  
12 December 20th, 2011, which is from Phil Goss, who was the  
13 head of the academic steering committee then. And you're  
14 cc'd on that letter. Apparently involved in a phone call  
15 that's talked about there?

16 A. Correct.

17 Q. Do you recognize this letter?

18 A. Yes, I do.

19 Q. Okay. And you were involved in a phone call with the  
20 academic steering committee at the time?

21 A. Correct.

22 Q. Okay. And if you flip over to the second page of that  
23 letter, it says --

24 MR. COUGHLIN: I'd move for the admission of this  
25 letter. There's no objection.



1 THE COURT: Exhibit number?

2 MR. COUGHLIN: Exhibit number 745.

3 THE COURT: Without objection 745 is admitted.

4 **(Exhibit 745 received.)**

5 BY MR. COUGHLIN:

6 Q. Dr. Goss is comparing --

7 MR. COUGHLIN: If we flip over to the second page  
8 of that, page 4 of 5, and blow that paragraph up.

9 BY MR. COUGHLIN:

10 Q. It says: To summarize, this is not a trial to prove --

11 THE COURT: Please slow down.

12 MR. COUGHLIN: Sorry. In fact, I won't read it.  
13 If you could read it, Doctor, and give everybody else a  
14 chance -- I mean, Mr. Auerbach.

15 THE WITNESS: Uh-huh.

16 BY MR. COUGHLIN:

17 Q. At the time were you on the phone with Pfizer and  
18 indicated that the future goal of ExteNET is limited to  
19 collecting safety data?

20 A. I was not on that phone call, no.

21 Q. So this is wrong or somebody else from your shop was on  
22 the phone?

23 A. No. I was not on the phone when they had the  
24 conversation with Dr. Goss.

25 Q. Okay. So when it says there Pfizer -- would anybody

1 else at your company have been on the phone when it says  
2 Pfizer and Puma indicated that the future goal of ExteNET is  
3 limited to collecting safety data?

4 A. I was not on the call where that was discussed.

5 Q. So Dr. Goss just had misinformed them about that?

6 A. We had a call when I acquired the drug with Dr. Goss,  
7 and at the time that this academic steering committee was in  
8 place, they were being very heavily compensated from Wyeth  
9 and Pfizer, specifically I believe each of them was making --  
10 they were receiving compensation that I would ballpark was  
11 somewhere in the range of 200,000 to 400,000 dollars per  
12 year.

13 And since this trial was going to be going  
14 somewhere between five and ten years, that was obviously a  
15 very large sum of money. I was on a call with Dr. Goss when  
16 I was introduced to him, and the first question he asked was  
17 whether Puma was going to be continuing to compensate the  
18 academic steering committee in the same manner.

19 I said that was unlikely because we were a small  
20 company and didn't have that type of money, and that was when  
21 he got quite upset, and that was kind of the last  
22 conversation I remember with him.

23 Q. And he had designed the study; is that right?

24 A. He had -- he was the original one with the concept for  
25 the study. The entire academic steering committee designed

1 the study.

2 Q. And he resigned; is that right?

3 A. That is correct.

4 Q. Okay. And you're saying it was -- that Pfizer had a  
5 problem with the funding; is that right?

6 A. Originally the study, the truncation of the study,  
7 reducing the number of patients involved, and the duration of  
8 the follow-up was done by Pfizer as part of a budget  
9 situation they had.

10 They had a new -- Pfizer had a new chief executive  
11 officer, a gentleman named Ian Read, who is a very, very nice  
12 guy. And Ian came into Pfizer late 2009, if I remember this  
13 correctly. In 2010 he announced a very large research and  
14 development budget cut. It was approximately \$1.5 billion,  
15 if I remember correctly.

16 Specifically their cancer group -- because Pfizer  
17 is a very large company that has lots of drugs. They have  
18 drugs for cardiovascular disease, for neurology, et cetera.  
19 The budget for the oncology group, the cancer group, I  
20 believe was cut somewhere in the range of 60 to 70 percent.

21 Q. Okay. Let me ask you some more questions, sir. So  
22 you're saying it was Pfizer who made this decision to cut the  
23 study?

24 A. They had contacted me telling me they were making this  
25 decision, yes.

1 Q. If I could have you take a look at --

2 THE COURT: Let me say, since we're talking about  
3 statistics, if the normal rate of transcription is a hundred  
4 pages, you folks are at about 130. You're just coming in  
5 fast.

6 Now, I'm married to a woman that talks very fast.  
7 This court reporter takes down words quicker than any I have  
8 known. But, you know, sometimes, especially when technical  
9 information is coming in, it's good just to pause a little  
10 and make sure it's soaking in.

11 And here's the scary thing. She can record  
12 thoughts quicker than my mind can process them. Now, the  
13 jury might be better than I am, but I'm saying when the  
14 thoughts come in too fast, it's very hard to process them  
15 all. Okay?

16 MR. COUGHLIN: Well said, Your Honor.

17 THE COURT: Go ahead.

18 BY MR. COUGHLIN:

19 Q. If you could take a look at Exhibit 883. It should be  
20 the next in line.

21 MR. COUGHLIN: This exhibit, no objection to this  
22 exhibit, Your Honor, except for a limiting instruction for  
23 all of the analyst reports and type things. I think this is  
24 a little different. This is actually Mr. Auerbach talking.

25 THE COURT: Number what?

1 MR. COUGHLIN: Exhibit 883.

2 THE COURT: Without objection 883 is admitted.

3 MR. COUGHLIN: Thank you, Your Honor.

4 **(Exhibit 883 received)**

5 BY MR. COUGHLIN:

6 Q. I'd ask you to turn over to page 3 of this exhibit.  
7 This exhibit is dated October 16, 2014. If you look at  
8 page 3, I'm going down to the bottom where the questioner,  
9 Matt Allen, is asking you questions about some of the changes  
10 that we're talking about right now. Okay?

11 A. Sure.

12 Q. And he first goes over the first change that we talked  
13 about from the node-negative to the node-positive with you.  
14 Do you see that?

15 A. Yes.

16 Q. Okay. And then we get into: All in all the study had  
17 both node-negative and node-positive, but clearly the  
18 majority, 80 percent, are node-positive. Do you see that?

19 A. Yes.

20 Q. Did that -- was that correct about -- when they shut the  
21 study down, if I understand it, the population was set at  
22 about 2,800?

23 A. Correct.

24 Q. Okay. So 80 percent of that population was  
25 node-positive?

1 A. Yeah, roughly. Yes.

2 Q. And if we go on, it says, it talks about shutting it  
3 down: At the time we stopped the enrollment because Puma was  
4 a small company and we didn't have the financial resources to  
5 continue running it. So we stopped the enrollment at 2,800  
6 patients, which had a minor effect on statistical assumptions  
7 and continued running -- so I'm on page 4 of 15?

8 A. Yes. Correct.

9 Q. Okay. There it says that Puma is the one who cut it  
10 down for financial reasons. Do you see that?

11 A. No. Where are you? Can you please point?

12 Q. Right at the top of that -- I'm on page 4 of the UBS  
13 report, which is page 4 of 15, at the top of the page in the  
14 middle of that paragraph. You first talk about node-negative  
15 and node-positive amendment?

16 A. Yes.

17 Q. It says: At the time we stopped enrollment because Puma  
18 was a small company and we didn't have the financial  
19 resources to continue running it. So we stopped enrollment  
20 at 2,800 patients, which had minor effect on statistical  
21 assumptions. Do you see that?

22 A. Yes. There's a little more context to that.

23 Q. Okay. Your counsel can ask you about it. I'm just  
24 saying that's what you said at the time, right?

25 A. Yeah. We didn't have the resources to continue

1 enrolling and continue -- if there was a decision to be made  
2 of stick with Pfizer's design, which was to stop enrollment  
3 and truncate it to two years, or say, no, we're going to, you  
4 know, go back to the original design.

5 At that time we did not have the resources to go  
6 back to the original design.

7 Q. Well, it doesn't say that. It just says that: At the  
8 time we stopped enrollment because Puma was a small company  
9 and we didn't have the financial resources to continue  
10 running it. Okay? So it says that not Pfizer stopped it but  
11 you stopped it.

12 A. Well, no. I think you saw the amendment was actually  
13 Pfizer, not Puma.

14 Q. Well, that's your statistical amendment. Pfizer still  
15 owned the drug, so they're the ones who had to amend it. But  
16 they amended it because you were going to license it from  
17 them, right, and they stopped --

18 A. No. It was done beforehand.

19 Q. The enrollment stopped before you licensed it, right?

20 A. What I'm saying is that the decision to amend the trial  
21 had -- was done before obviously that plan was written, et  
22 cetera.

23 Q. Right. But you were on the phone call with the academic  
24 steering committee when they complained about stopping the  
25 study because it would impact the results, right?

1 THE COURT: I'm sorry. You're not going to get  
2 clear record. That was really fast. I must say, you know,  
3 right now in my brain I'm trying to pick out everything you  
4 said, and I'm not processing and I don't think the reporting  
5 is coming out.

6 MR. COUGHLIN: Okay, Your Honor. I'll just move  
7 on. I'll let the document speak for itself, Your Honor.  
8 It's already admitted.

9 BY MR. COUGHLIN:

10 Q. Let's go back to the amendments if we could because  
11 there's a third one I want to talk to you about.

12 A. Sure.

13 Q. It's in the analysis plan.

14 You amended the -- I'll refer to it as a SAP if  
15 that's all right.

16 A. Sure.

17 Q. You amended the SAP in January of 2014, is that right,  
18 before you unblinded the study? Correct?

19 A. Yes. The decision to modify the study, though, was in  
20 2013.

21 Q. Right. This was actually implementing that amendment?

22 A. Yes. Correct. It was begun -- the work on this was  
23 begun, I would believe, somewhere around August through  
24 September of 2013.

25 Q. Okay. And when you decided to reinstate follow-up of



1 those patients beyond two years, right, that had been -- two  
2 years had gone by where you had not been collecting that  
3 data; is that correct?

4 A. I'm sorry. Can you repeat the question, please?

5 Q. When it was amended and shut down --

6 A. The trial was never shut down. It continued to be  
7 followed.

8 Q. When the study was truncated, if I might use that word,  
9 okay, down to a two-year study with a certain set number of  
10 patients, 2,800, okay, you quit testing those people, central  
11 testing those people; is that correct?

12 A. No, I don't believe that's correct. We continued -- the  
13 patients who completed enrollment in October of 2011  
14 continued to be treated with the drug or a placebo for a year  
15 and then continued to be followed for another year.

16 Q. Okay. Let's take a look -- I'm going to skip ahead just  
17 for a moment so we don't use terms that are out of whack. If  
18 we could go to Exhibit 124 in your book. And maybe you just  
19 want to look at it on the screen.

20 If we go to Exhibit 124, page 15 at 272, this  
21 document 124 is your safety deck from 7/18/2014, and it --  
22 this is under the issues to be addressed. It says central  
23 HER-2 testing and bio markers not done for all patients.  
24 Testing discontinued as of amendment nine.

25 We were just looking at amendment nine, right?

1 A. Uh-huh.

2 Q. So the testing was discontinued?

3 A. The central HER-2 testing I recall was done for all the  
4 patients or the very large majority. The bio markers, that  
5 is accurate. The bio marker work was not done.

6 Q. But this doesn't say or. It says central HER-2 testing  
7 and bio markers not done for all patients. Testing  
8 discontinued as of amendment nine.

9 A. Again, my recollection is we did do central HER-2  
10 testing on not 100 percent but a very large majority of the  
11 patients, whoever we got a sample for. The bio markers,  
12 that's correct. We did not. Again, I didn't write this, so  
13 I can't really discuss the accuracy of it.

14 Q. Well, you received it in July of 2014?

15 A. Correct.

16 Q. You didn't raise an issue with it then to your  
17 knowledge?

18 A. To my knowledge I did not.

19 Q. Okay. Let's talk about that, because we heard a little  
20 bit about subgroups, and we heard about central testing  
21 earlier today. There appear to be some documents from you  
22 saying we're lacking this data of 40 percent of this central  
23 testing that are later on. Do you remember that?

24 A. No. I would need to refresh my memory on that.

25 Q. Okay. We'll go over that a little later. I didn't want

1 to skip so far ahead.

2 So let's go back to Exhibit 129.

3 MR. COUGHLIN: Your Honor, this might be a good  
4 time to take a break.

5 THE COURT: If we take a break now, it means the  
6 court reporter will have 90 minutes of fast talking. We'll  
7 take a break now. Just slow down.

8 MR. COUGHLIN: I'll slow down, Your Honor.

9 THE COURT: We'll be back in 15 minutes.

10 Thank you.

11 (Recess taken from 2:46 p.m. until 3:01 p.m.)

12 (Open court - jury present)

13 THE COURT: Welcome back.

14 Please continue.

15 MR. COUGHLIN: Thank you.

16 BY MR. COUGHLIN:

17 Q. Mr. Auerbach, we were on the -- we were in the  
18 statistical analysis plan. I'd like you to turn to page 25  
19 -- 22 of 55 in that plan, page 24 of 61 for the control out  
20 of Exhibit 129. Page 22 of 55.

21 I believe we read earlier that the primary end  
22 point of this, the primary objective of this study is to  
23 compare disease-free survival with women in early-stage  
24 HER-2/neu overexpressed amplified breast cancer.

25 Exhibit 129, page 24 of 61.

1 I'm going to direct you to those. Do you have  
2 those charts?

3 A. Yes.

4 Q. It says the efficacy end points and analysis methods.  
5 Now, were you involved -- did Wyeth have the same three types  
6 of analysis to be done on the disease-free survival?

7 A. Can you clarify that questions?

8 Q. Did they have the same method to analyze the  
9 disease-free survival rates?

10 A. I believe. I don't --

11 Q. I think it never changed, Mr. Auerbach.

12 A. I don't remember if the Wyeth plan and our plan used the  
13 same. I don't remember that.

14 Q. I'm pretty sure it never changed, just for a little  
15 background. And you understand what these three methods are,  
16 right, and how they're calculated?

17 A. That's correct.

18 Q. Okay. So the first one there was the Kaplan-Meier plot.  
19 Do you see that?

20 A. Yes.

21 Q. And that gives you the absolute difference; is that  
22 correct?

23 A. That's correct.

24 Q. Okay. And then the stratified log-rank test, one-sided  
25 with 2.5 percent significant level. Is that the p-value?

1 A. Yes. That's one of them, yeah.

2 Q. Okay. And then there's the Cox proportional hazards  
3 model stratified to estimate the treatment hazard ratio.

4 Do you see that?

5 A. Yes.

6 Q. Okay. And so when you got the results of the ExteNET  
7 studies that were unblinded in July of 2014, did you apply  
8 those three tests to analyze the data?

9 A. I remember that we did the Kaplan-Meier plot. I  
10 remember that we did the stratified log-rank test. I don't  
11 remember if the Cox analysis was done.

12 Q. Okay. Let's take a look at Exhibit 123. Actually,  
13 before we go to 123, which are the results, let's look at the  
14 exhibit before that in your book, 877.

15 Do you recognize what 877 is?

16 A. Yes, I do.

17 Q. And 877 is an 8K. I believe there's been no objection  
18 to it, and it contains both the Pfizer updates to the  
19 licensing agreement --

20 THE COURT: Do you move its admission?

21 MR. COUGHLIN: I do.

22 THE COURT: Any objection?

23 MS. JOHNSON: No objection.

24 THE COURT: 877 admitted.

25 **(Exhibit 877 received.)**

1 THE COURT: Please don't put it on the screen until  
2 it's admitted.

3 Go ahead.

4 BY MR. COUGHLIN:

5 Q. So I'd like you to flip -- and the first press release  
6 there is attached, an amendment that you did with Pfizer, is  
7 that right, to your licensing agreement?

8 A. Yes.

9 Q. Okay. And Puma took on more of the cost, and Pfizer was  
10 going to get less of the back-end revenues; is that correct?

11 A. Correct.

12 Q. Okay. And then you also released the ExteNET results on  
13 July 22nd, 2014; is that right?

14 A. Correct.

15 Q. And you released those about an hour, hour and a half,  
16 hour and 20 minutes before you had the press -- the analyst  
17 call; is that right?

18 A. I believe it was somewhere in that time frame, yes.

19 Q. Okay. And in that press release you have the 33 --  
20 about the third paragraph down, you talk about the hazard  
21 ratio, and that hazard ratio of .67 gave you a 33 percent  
22 improvement. Do you see that?

23 A. Yes, I do.

24 Q. And that was information from the topline of your  
25 results; is that right?

1 A. That's correct.

2 Q. And that hazard ratio was connected to your topline; is  
3 that right?

4 A. That's correct.

5 Q. Okay. Let's switch over to Exhibit 123.

6 MR. COUGHLIN: I think this has been admitted. I'm  
7 sure it has.

8 THE COURT: What's the number again?

9 MR. COUGHLIN: 123.

10 THE COURT: It's admitted.

11 BY MR. COUGHLIN:

12 Q. So take a look at that and make sure you recognize what  
13 it is, Mr. Auerbach.

14 A. Yes.

15 Q. So this is dated July 17, 2014, to you, and it says:  
16 Attached are the validated results. And it's the efficacy  
17 results; is that correct?

18 A. Correct.

19 Q. Okay. And do you remember receiving these in 2014?

20 A. Yes, I do.

21 Q. Okay. Let's flip in to see what the topline results  
22 were. If we take -- if we flip to page 8 of 35, or page 6 of  
23 the document, it has a summary of the topline efficacy; is  
24 that right?

25 A. That is correct.

1 Q. And these are the two-year, 28-day results; is that  
2 right?

3 A. That is correct.

4 Q. Okay. So let's take a look at the DFS at the very top.  
5 Do you see that top line?

6 A. Yes, I do.

7 Q. Okay. And those 93.9 and 91.6, right, do you see that  
8 -- see those rates there?

9 A. Yes.

10 Q. Where do they come from?

11 A. Those are the Kaplan-Meier estimates of the disease-free  
12 survival for the neratinib and the placebo arms as of the  
13 time point of two years plus 28 days.

14 Q. And the absolute difference was 2.3; is that right?

15 A. That is correct.

16 Q. Okay. And that's associated with that hazard ratio .67,  
17 right?

18 A. That is correct.

19 Q. There's no other -- and you can look down to the amended  
20 intent to treat. And there's no other hazard ratio  
21 associated with .67; is that right?

22 A. To clarify your question, please, when you say there's  
23 no --

24 Q. I'm just asking, that's the only .67 hazard ratio in  
25 that table; is that correct?



1 A. Yes. That's correct.

2 Q. Okay. The different -- let's go down and go ahead and  
3 let's go through each one. So the next line contains the  
4 ductal, right?

5 A. Yes, correct. The next line is the definition of  
6 disease-free survival that includes precancerous tumors which  
7 are premalignant, if you will. In breast cancer you can have  
8 tumors that are actually cancer. Then you can have ones that  
9 are precancerous lesions. These are ones that have a very  
10 high probability of becoming cancerous. We call those either  
11 premalignant lesions, or the technical term is called ductal  
12 carcinoma in situ, or DCIS. So this would be the definition  
13 that includes those premalignant lesions.

14 Q. And that's the second line down, right?

15 A. That is correct.

16 Q. And then we have the distance. The next line is the  
17 DDFS?

18 A. That is correct.

19 Q. Okay. And then we have the time one, TTDR?

20 A. Just to clarify, the distant recurrences are the tumors  
21 that, when they come back, are far away from the breast. So  
22 this could be in the lungs or in the liver and things like  
23 that. And when the cancer has spread that far, it is  
24 unfortunately usually indicative of the patient, you know,  
25 progressing very rapidly and unfortunately moving toward

1 death.

2 So we tend to look at distant disease-free  
3 survival, so the tumors that came back and were located far  
4 away, because showing a benefit there can be a good indicator  
5 of the overall survival of the patient.

6 Q. Okay. Then the next -- the next box after that is we  
7 have the amended intent to treat population; is that right?

8 A. That is correct.

9 Q. And that amended intent to treat population, that was  
10 the population for the study stopping at two years with no  
11 follow-up; is that correct?

12 A. My recollection of this is that the amended intent to  
13 treat population was defined earlier than the time point  
14 you're suggesting. I'm remembering it was the third  
15 amendment, I thought. But it is meant to -- the intent to  
16 treat population includes all of the patients in the study,  
17 both the node-negative and the node-positive. So those were  
18 the cancers within the breast and those where it's gone  
19 outside.

20 Q. You're right, Mr. Auerbach. It is the third amendment.

21 A. Thank you. I thought they were still enrolling at that  
22 time.

23 Q. And then they stopped with the ninth amendment?

24 A. So the amended intent to treat population as I recall is  
25 meant to be the higher-risk patients, so the ones where the

1 disease was found outside. They were node-positive. That's  
2 my recollection of that.

3 Q. Okay. But your primary end point now, because you had  
4 amended this, changed this back to the intent to treat  
5 population; is that correct?

6 A. Correct.

7 Q. Okay. So down below that is table 3.02. That seems to  
8 break the DFS intent to treat population into one-year and  
9 two-year stratification. Do you see that?

10 A. Yes, that is correct.

11 Q. Okay. So let's talk about the one year at the topline  
12 results, the DFS intent to treat population. Is that -- am I  
13 correct that that's taking the topline from above and  
14 breaking it out into two years, first year and then second  
15 year?

16 A. Yes. That is correct.

17 Q. Okay. So the first year, if you follow that along,  
18 follow that line over, you have an absolute difference, a  
19 risk difference of 2.2; is that correct?

20 A. That is correct.

21 Q. And then it goes to 2.3; is that right?

22 A. Yes. That is correct.

23 Q. Okay. So those are the results that were received about  
24 four or five days before that press release on July 22nd; is  
25 that right?

1 A. That -- I seem to recall it was somewhere in that four  
2 to five days, yes.

3 Q. Okay. And then to the right over here to the -- well,  
4 we'll skip that page. We'll come back to that.

5 If we switch -- if we flip over to page 12 of 35,  
6 that's actually the Kaplan-Meier curve that is associated  
7 with that intent to treat population; is that correct?

8 A. Yes, correct -- truncated, yes.

9 Q. When you say truncated, what do you mean by truncated?

10 A. This does not represent all of the data we had. It is  
11 just the data on the patients starting at time zero and going  
12 to the time point of 24 -- two years plus 28 days.

13 Q. So that's what you mean by truncated, because you had  
14 other events and other patients after that, right?

15 A. Correct.

16 Q. Because it started in 2009, and this was cutting off all  
17 patients under your censoring rule, if I might use that word,  
18 at two years, 28 days; is that right?

19 A. Correct, but we had data longer than that.

20 Q. You had data on more patients that you'd been following  
21 longer?

22 A. Correct.

23 Q. Okay. Now, do you recall how many events in those  
24 patients that you had that you followed longer?

25 A. I don't recall the number.

1 Q. Would eight sound like the topline of that number?

2 A. I don't remember what the number was.

3 Q. It was very small, right?

4 A. I believe the events in the entire study were smaller  
5 than we expected. I seem to remember we originally thought  
6 we would -- in the study as a whole, I seem to remember we  
7 got less events total than we expected.

8 So if we got less events past two years, that  
9 would, you know, be in line with what we saw in the study as  
10 a whole.

11 Q. Right, into the third year I think you had seven events  
12 and one in the fourth. Does that sound right?

13 A. It may be. I don't remember. That might be correct.

14 Q. Did you think you could do a statistical analysis going  
15 out with those few events?

16 A. I think you can do a statistical analysis on data  
17 irrespective of how many events you have. It's important to  
18 look at all of your data, not just looking at the data when  
19 the events number hit a certain level.

20 Q. And were you worried about the patients that you had  
21 stopped at two years, 28 days, or you were still following  
22 those patients?

23 A. I'm sorry?

24 Q. Were you still following those patients that had  
25 initiated the study and gone two years and 28 days? Is it

1 your testimony that you were still following -- they were  
2 still in the study years three, four, and five?

3 A. We had followed up -- we had amended the study in -- we  
4 were starting to do it in 2013, officially in 2014, where we  
5 went back and were recollecting the data on all of the  
6 patients.

7 Q. You reconsented?

8 A. Yes.

9 Q. You went back and got reconsent from those patients to  
10 continue the follow-up in years three, four, and five?

11 A. Correct.

12 Q. At the time of this, you had done no analysis, though,  
13 of that data. You had done no Kaplan-Meier curves or  
14 anything like that; is that correct?

15 A. At the time of this analysis, we did an analysis on all  
16 of the patients irrespective of how long they've been in the  
17 study, so including those who had been in for longer than two  
18 years.

19 In terms of analyzing the data on, you know, all of  
20 the patients we had to go back and reconsent, we were still  
21 in the process of getting that data. So we didn't analyze it  
22 because the data was still coming in because we were going to  
23 follow them for five years.

24 Because the data was still coming in, we didn't --  
25 we cut the database as of what we had in July of 2014.

1 Anything we got beyond that we didn't do any additional  
2 analyses on.

3 Q. The report here talks about the two years, 28 days and  
4 those patients that were in that two-year, 28-day cut; is  
5 that right?

6 A. That's correct.

7 Q. Okay. And when you refer in that conference call that  
8 you had later to curves widening, you're not referring to  
9 these curves; are you?

10 A. The question on the conference call, as I recall, was  
11 asking about the curves beyond two years. And I believe the  
12 statement we had made was that we had a small number of  
13 patients going out beyond that, which was accurate. And I  
14 recall seeing that data back in July of 2014.

15 And as I recall, the benefit was 2.3 percent at two  
16 years and approximately 3.5 percent at three years. That was  
17 what I recalled.

18 Q. But you've never been able to produce, reproduce to us,  
19 any of that contemporaneous data from that time, right? You  
20 don't remember who showed it to you, on what computer it was  
21 on, how you were given it, who brought it into your office.  
22 You don't remember any of those things; do you?

23 A. I remember that it --

24 MS. JOHNSON: Objection. Compound.

25 THE COURT: Sustained. Any answer will be

1 stricken.

2 BY MR. COUGHLIN:

3 Q. Do you remember somebody came in and showed you those  
4 curves widening out into the future?

5 A. I do remember someone coming to me and showing me the  
6 curves. I remember that it -- the benefit at that time.  
7 Again, it was a small number, and that's subject to change as  
8 we got more data. I remember the benefit was 2.3 percent at  
9 two years and 3.5 percent at three years.

10 Q. And you don't have -- you know you have not produced any  
11 contemporaneous data to us from that time period, right, that  
12 shows that, contemporaneous from that time period, those  
13 curves that you just talked about?

14 A. My understanding is that we recreated those curves using  
15 the data that was available in July of 2014, and that the  
16 data did indeed show that the DFS rate at two years was  
17 2.3 percent and at three years was 3.5 percent.

18 Q. Let's talk about that for a second. We asked for that  
19 in discovery. We didn't get that. You couldn't find it.  
20 Okay. Then you went back in and recreated it.

21 There's currently a dispute about whether that data  
22 shows that, okay? But that's what you're saying. Something  
23 that was created in 2018 is what you've showing -- what  
24 you're talking about right now?

25 MS. JOHNSON: Objection. Compound. Move to



1 strike.

2 THE COURT: Move to strike. Did you hear an  
3 answer?

4 MS. JOHNSON: No, Your Honor. Just the line.

5 THE COURT: Please rephrase.

6 BY MR. COUGHLIN:

7 Q. The graph that you're talking about was actually  
8 produced in 2018 by Mr. Bin Yao; is that correct?

9 A. That's correct.

10 Q. And that's the graph you're talking about here in court  
11 today?

12 A. That is correct.

13 Q. You don't have any contemporaneous evidence of that  
14 graph from back then; is that correct?

15 A. We do not have the exact graph that was shown to me in  
16 July of 2014. My understanding is there are other team  
17 members who remember showing that to me and other team  
18 members who remember seeing that. But we have not produced  
19 the exact document that was July of 2014, but we have  
20 recreated that using the data that was available in July of  
21 2014.

22 Q. Well, you haven't produced any document from 2014 that  
23 shows that data, right?

24 A. We have not produced the document from -- that was  
25 created in July of 2014. We have produced the data created

1 using the data from July 2014.

2 Q. Who created that document in 2014?

3 A. That was done by Puma.

4 Q. No. Who? Who at Puma created that document? We know  
5 we talked to Claire Sherman, and she did not create that  
6 document. Mr. Bin Yao did not have access to the data until  
7 after you had had this press conference. Who at Puma created  
8 that document at that time frame?

9 MS. JOHNSON: Objection. Compound.

10 BY MR. COUGHLIN:

11 Q. Who at Puma created that document you were just talking  
12 about?

13 A. My understanding is that Claire Sherman has testified  
14 that she may have run that analysis, and I don't know who was  
15 the one who physically created it, because, you know, when  
16 documents get shown to me, I often don't ask who created  
17 this? Who did the analysis? Who typed this, et cetera. It  
18 just gets shown to me.

19 Q. Well, you know, she first said she didn't. Then she  
20 came back and said maybe she did after you said that maybe  
21 you saw it; is that right?

22 MS. JOHNSON: Objection. Improper impeachment.

23 BY MR. COUGHLIN:

24 Q. Let's move on, Mr. Auerbach.

25 Let's take a look at Exhibit 124. Let me ask a

1 question back on that one. So when you were talking on the  
2 separation, you were not talking about these curves, right,  
3 separating, on the phone call, in the conference call?

4 A. As I remember the conference call, the call came -- the  
5 question came from Dr. Howard Liang. I believe his last name  
6 is L-i-a-n-g. And the question was specifically referring to  
7 the data beyond two years.

8 So that is correct. I was only referring to the  
9 data beyond two years.

10 Q. Okay. And events beyond two years?

11 A. Correct.

12 Q. And the three and four year?

13 A. The third was the one we had data on. I don't think we  
14 had any data on the fourth.

15 Q. Actually one event.

16 Let's take a look at Exhibit 124. So this is dated  
17 a day --

18 MR. COUGHLIN: This has been admitted.

19 BY MR. COUGHLIN:

20 Q. This is the safety results, July 18th, 2014. Do you see  
21 that?

22 A. Yes.

23 Q. Okay. And these were sent to you on the 18th of July.  
24 Any reason to doubt that?

25 A. No, I do not have any reason to doubt that.

1 Q. Okay. And it says they are now validated?

2 A. You're correct. The e-mail says they are now validated.  
3 I believe this meant that they had been validated by our  
4 external statistical consultant Rho but not validated by  
5 Puma.

6 Q. That's your understanding?

7 A. That is my understanding.

8 Q. Okay. Let's take a look into the document.

9 So when you got this document, you reviewed it,  
10 right? Is that correct?

11 A. To my recollection, yes, that is correct.

12 Q. Okay. And if we flip in to the document to page 8 of  
13 272, most frequent AE?

14 A. Yes, correct.

15 Q. Okay. So you got this document and the reported AEs  
16 that for diarrhea, you got -- the numbers was, for grade  
17 three or better, was 39.9 percent; is that correct?

18 A. Correct.

19 Q. For neratinib, okay. And you said you were concerned  
20 about this 35.4 percent; is that correct?

21 A. Actually we were concerned about the diarrhea rates in  
22 the trial as a whole. But, yes, we were concerned about the  
23 35.4 percent in the placebo arm.

24 Q. Okay. Now, you see the diarrhea rate for the placebo at  
25 grade three or better is 1.6 percent?

1 A. That's correct.

2 Q. Okay. So the numbers you had before the conference call  
3 was that you had grade-three diarrhea at about 40 percent and  
4 placebo about 1.6; is that right?

5 A. That is correct.

6 Q. Okay. And if you flip over to page 10 of 272, diarrhea  
7 treatment discontinuation. Do you see that?

8 A. Yes, I do.

9 Q. Okay. And that treatment discontinuation rate for  
10 diarrhea alone was 16.8; is that correct?

11 A. That is correct.

12 Q. Okay. And if now we flip to page -- all the way in the  
13 back, and I believe it's 260 something, 266. It says adverse  
14 events leading to discontinuation, about the fifth line down,  
15 that's at 27.6 percent. Do you see that?

16 A. Yes.

17 Q. That's also a number you had before that conference  
18 call; is that right?

19 A. That is correct.

20 Q. Okay. Now, let's take a look at the conference -- the  
21 actual transcript of the conference call, and talk about some  
22 of the statements there.

23 You have seen this transcript before, Exhibit 103;  
24 is that correct? Did you find it?

25 A. Yes. Yes, I've seen this before.

1 Q. Okay. So in that transcript you first gave a, let's  
2 say, background to the results before you took questions; is  
3 that -- would that be a correct statement?

4 A. Yes, that is correct.

5 Q. Okay. And you'd gotten the results and they had been  
6 unblinded, and you were going to announce it to the public,  
7 and you issued the press release; is that right?

8 A. That is correct.

9 Q. Okay. And if you take a look -- and we'll go to the --  
10 if we flip over to the first page, about the fourth paragraph  
11 down, and that is page 4 of 15, that's where you repeat the  
12 statement of the 33 percent improvement of disease-free  
13 survival. Do you see that?

14 A. Yes.

15 Q. Okay. And that was associated with a 2.3 absolute  
16 difference; is that right?

17 A. Yes. That is correct.

18 Q. And if we flip over to the next page, the second  
19 paragraph from the bottom, it says -- no. This is page 3 of  
20 15.

21 A. Oh, the page before. Yes.

22 Q. Down at the bottom I'm talking about from a safety  
23 perspective?

24 A. Uh-huh.

25 Q. And you said: From a safety perspective, the company

1 has not yet seen the safety results from the ExteNET trial  
2 for neratinib as the data is still being validated; is that  
3 correct?

4 A. That is correct.

5 Q. Okay. Let's take a look over into the question and  
6 answer if we could.

7 Mr. Auerbach, did you think it was necessary to  
8 tell the investors on that call that you had actually gotten  
9 validated data, at least from Rho, and that you were  
10 concerned about the high diarrhea rate?

11 A. The data had not been validated internally. And we have  
12 seen in the past that oftentimes when our external  
13 contractors validate something and then we validate it, that  
14 the data can change quite dramatically.

15 So we weren't very comfortable, you know, putting  
16 that data out until we had fully validated it.

17 Q. Okay. That number never changed, right, that  
18 39.9 percent?

19 A. No, it did not.

20 Q. Okay. And nor did the 16.8 percent discontinuation rate  
21 due to diarrhea. That number never changed, right?

22 A. Correct.

23 Q. Nor did the 27.6 percent ever change, right, with the AE  
24 discontinuation?

25 A. That did not change, correct.

1 Q. So none of those numbers changed at all?

2 A. That's correct.

3 Q. You didn't think it was important at all to, say, give a  
4 qualification? Hey, we've got some numbers we're concerned  
5 about?

6 A. We didn't know if they were going to change, so we  
7 waited for the validation to be completed.

8 Q. Did you think it was okay to just give numbers anyway  
9 from other tests or other things like that when you had that  
10 data sitting in front of you?

11 A. I'm sorry. Can you repeat the question?

12 Q. Did you think it was okay during the conference call to  
13 give numbers out like five and ten percent discontinuation  
14 rate and things like that when you had that data from Rho  
15 that had been at least validated by Rho in front of you?

16 A. So I believe we're confusing two different topics. The  
17 data on the five to ten percent was not referring to the  
18 discontinuation rate. It was referring to the dropout rate.  
19 Those are two distinct things.

20 Q. You're talking about the dropout rate altogether out of  
21 the study?

22 A. So just if I can please define -- may I please define  
23 the difference?

24 Q. Yes, you can.

25 A. So discontinuation rate is that the patient stops taking



1 neratinib but they continue to be followed. So they go to  
2 their doctor every three months. The doctor does a physical  
3 exam where they physically touch them and, you know, they can  
4 feel around for any evidence of tumors coming back.

5 They still get CT scans, which are like X-rays. So  
6 they're still being followed looking for -- to see if their  
7 cancer has come back. Dropout means they have stopped  
8 completely out of the study, and they sign a document saying:  
9 I'm completely dropping out of this study. You do not get  
10 any more data from me.

11 So discontinuation is you continue to get  
12 measurements on those patients. Dropout, in dropout you  
13 actually -- the minute they drop out of the study, that's the  
14 last measurement you get. Dropouts are particularly  
15 concerning because, you know, as you can imagine, if you've  
16 got, say, 1,000 patients who you followed for two years, and  
17 you say that after two years 90 percent of them or, you know,  
18 900 of them are still alive and haven't had their cancer come  
19 back.

20 But if you have a hundred of them who dropped out,  
21 those hundred may have had their cancer come back or those  
22 hundred may have died. So it -- you know, it decreases the  
23 accuracy of that estimate. So the dropout, which is what was  
24 being referred to on the conference call, was people who  
25 dropped out of the study, so we stopped getting data on them.

1           I believe there was actually a comment made about  
2     the missing of the data and that reference. That was the  
3     number we were referring to.

4     Q.    That's what you were referring to?

5     A.    That's what the analysts were asking as well.

6     Q.    They had asked for the --

7     A.    No.

8     Q.    -- discontinuation rate on the AEs, and he did qualify.  
9     He had said before dropouts, and then he said  
10    discontinuation. But you didn't think it was important to  
11    qualify that and say, hey, we've got a discontinuation rate  
12    of 16.8 percent to diarrhea alone?

13    A.    I'm sorry. Can you please show me in the --

14    Q.    Well, we had looked at the 16.8 percent and -- we're  
15    going to go over the transcript.

16    A.    Okay. The question, as I recall, was specifically  
17    asking about dropouts.

18    Q.    Okay. We're going to get to that question. Let's start  
19    with efficacy.

20           MR. COUGHLIN: Could we play clip number four.

21           And if you turn to page 5 of 15.

22           (Audiotape recording played)

23           MR. COUGHLIN: Let's stop that for a second.

24    BY MR. COUGHLIN:

25    Q.    So you make that statement that you think it's going to

1 be in line with 29 to 30 percent that you've seen in prior  
2 studies with neratinib as a monotherapy, and yet you had  
3 validated data from Rho that said it was 39.9, the diarrhea  
4 rate, correct?

5 A. Yeah. I believe the comments are being taken a little  
6 out of context. May we go back, please, to the introductory  
7 comments?

8 Q. Sure.

9 A. Thank you. If we could please go to page 3 of 15,  
10 please. There we go, that second paragraph that starts from  
11 the bottom that starts with from a safety perspective.

12 May we please highlight that paragraph?

13 Q. Sure.

14 A. Thank you. Wonderful.

15 So I will read the paragraph. Is that okay if I  
16 read that?

17 Q. Yes.

18 A. From a safety perspective, the company has not yet seen  
19 the safety results from the ExteNET trial for neratinib as  
20 the data is still being validated. Historically the main  
21 adverse event that has been seen with neratinib has been a  
22 gastrointestinal adverse event, and more specifically  
23 diarrhea. In previous studies performed prior to Puma  
24 licensing neratinib, grade-three or higher diarrhea was seen  
25 in approximately 30 percent or more of the patients treated

1 with neratinib. In these previous historical studies,  
2 diarrhea was typically a first-cycle effect. So one of the  
3 interesting aspects of neratinib as a drug --

4 Q. All right. All right. Let me ask the question. You  
5 wanted to read that. That's fine. I'll let your counsel  
6 follow up with you on that. What I want to ask is if we go  
7 back there and we talk about what the study is. Sitting in  
8 front of you -- when you make the statement of 29 to  
9 30 percent, sitting in front of you is a 39.9 percent number  
10 from Rho.

11 It might not have been validated by you, although  
12 there's no evidence of that. It might not have been  
13 validated by you, but what you gave to the market was that  
14 you saw 29 to 30 percent when the number you had sitting in  
15 front of you which you admit you had was 39.9; is that  
16 correct?

17 MS. JOHNSON: Objection. Compound. Misstates the  
18 record.

19 THE COURT: Overruled. He can correct the record,  
20 and it's cross-examination.

21 You may answer.

22 THE WITNESS: What we were referring to was that  
23 first cycle effect that I referred to. So the diarrhea with  
24 neratinib always occurs -- grade three, which is the severe,  
25 always occurs in the first month. And then the incidence of

1 it, the frequency of it, tapers off after that. And that  
2 first month is always the highest, and that was what we were  
3 referring to in the opening comments.

4 And if I remember correctly, the first-cycle  
5 diarrhea with neratinib the first month was -- the  
6 grade-three percentage was somewhere around 28-ish percent.  
7 So that was what we were referring to, the 29 to 30.

8 BY MR. COUGHLIN:

9 Q. That's what you say you're referring to. You think the  
10 market understood that?

11 A. I seem to remember having conversations with investors,  
12 and they understood that point.

13 Q. Now, you go on to say right there in that paragraph:  
14 Now, again, they didn't use any prophylaxis.

15 Do you see that?

16 A. Yes.

17 Q. Okay. Now, we've just seen that there was prophylaxis  
18 being used of hold and dose and that most people, according  
19 to the Wyeth SAP, were started from day one on an  
20 antidiarrheal or Imodium. You know that, right?

21 A. No. That is actually incorrect. Let me just, if I can,  
22 do you mind if I --

23 Q. You can do that with your counsel. Okay? You can ask  
24 and you can correct the record.

25 We just looked at a document, and you were here

1 looking at it, document number 1043, which says that  
2 87.4 percent of the people in neratinib were on antidiarrheal  
3 medication, right?

4 A. After the diarrhea occurred, correct.

5 Q. Okay. And that then they had a prophylaxis number of  
6 about 25 percent after a dose hold; is that correct?

7 A. That's correct, and that's referred to as secondary  
8 prophylaxis. This is, you've already had diarrhea and you're  
9 trying to prevent a second occurrence of it. What we're  
10 referring to here is what's called primary prophylaxis.  
11 You're trying to prevent the first bad, severe diarrhea from  
12 occurring.

13 Q. So before anybody even takes the drug, you give them an  
14 antidiarrheal medication, right?

15 A. That is correct.

16 THE COURT: Let's slow down a little bit.

17 BY MR. COUGHLIN:

18 Q. Before they ever take the drug, you give them an  
19 antidiarrheal medication; is that right?

20 A. That is correct.

21 Q. And do you think the market understood that 87 percent  
22 of these people were on some type of diarrhea medication?

23 A. After the diarrhea occurred, yes. The number you're  
24 quoting, the 87 percent, is people who took Imodium after the  
25 diarrhea already occurred. What we're trying to do for the

1 patients is prevent it from occurring.

2 Q. And you say giving that did prevent it from occurring;  
3 is that right?

4 A. Yes. The studies that Puma did with the drug using  
5 primary prophylaxis, so, trying to prevent severe diarrhea  
6 from occurring, not occur again after it already occurred, we  
7 were successful in doing that. Our studies showed that  
8 whereas typically the grade-three diarrhea rate was anywhere  
9 between 30 and 50 percent, we were able to prevent it and  
10 reduce it down to anywhere between 0 and 17 percent.

11 Q. In fact, those are the three studies that you were  
12 quoted in the ASCO trial; is that correct?

13 A. I believe that is correct.

14 Q. And those three studies had, I think, a total -- one  
15 study had eight patients. One study had 41 patients. And I  
16 think another study had, like, 28 patients. Those are the  
17 three studies you're referring to?

18 A. I seem to remember there were four studies. But the  
19 number, it was not thousands of patients. That's correct.

20 Q. There was another one, and it had eight patients.

21 A. Okay. There was probably hundreds of patients, yes.

22 Q. What do you mean, hundreds?

23 THE COURT: Hold on. You're talking over each  
24 other.

1 BY MR. COUGHLIN:

2 Q. The studies that you referred to in the ASCO  
3 presentation that you had Dr. Chan put in, okay, have a  
4 limited number of patients in them that add up to less than a  
5 hundred, the three studies that you added.

6 A. I don't remember the numbers specifically, but it was  
7 certainly small numbers, yes.

8 Q. Okay. And those are the studies -- and compared to this  
9 2,800 women study, those are the studies you were relying on  
10 when you gave your answer?

11 A. Yes. That's correct.

12 Q. Okay.

13 MR. COUGHLIN: Let's go on to finish off the  
14 efficacy of that clip, clip number four.

15 And we're on page 5 of 15, Mr. Auerbach.

16 (Audiotape recording played)

17 BY MR. COUGHLIN:

18 Q. Let's talk about those numbers. So when Dr. Werber, he  
19 says, you're thinking that if I'm correct, DFS is probably  
20 around mid to high 80s, around 86 percent or so in the  
21 control arm.

22 Your answer: I would be comfortable with that  
23 number.

24 That would be 86 percent; right?

25 A. No, that is incorrect. We were actually endorsing the



1 mid to high 80s range.

2 Q. And that's your testimony, that you were endorsing a  
3 range there, not a number?

4 A. Yes. Correct.

5 Q. And you looked at all the analyst reports because your  
6 in-house person sent them to you in the next couple of days,  
7 and you saw everybody else wrote that it was between 86 and  
8 91? Do you remember getting those analyst reports?

9 A. I remember getting the analyst reports. I don't  
10 specifically remember everyone writing it was between 86 and  
11 91. I seem to remember there was a range that people  
12 discussed, and I remember those ranges being anywhere between  
13 two and six percent.

14 Q. We'll take a look at those.

15 Did you call any of the analysts? Did you write  
16 the analysts? Did you e-mail the analysts that had it wrong  
17 and said 86 to 91 and say, hey, you must have misunderstood  
18 me?

19 THE COURT: Hold on. Start the question again,  
20 please.

21 MR. COUGHLIN: Okay.

22 BY MR. COUGHLIN:

23 Q. Did you -- when you looked at those analyst reports that  
24 you said you saw that had the 86, because you saw some --

25 THE COURT: You're going just as fast.

1 BY MR. COUGHLIN:

2 Q. You looked at some analyst reports that had 86 to 91  
3 percent, correct?

4 A. Yes. I remember that.

5 Q. Okay. And did you e-mail those analysts or call those  
6 analysts and say: You've got the numbers wrong. That might  
7 mislead the market that we had an absolute difference, double  
8 what we already got? Did you do that?

9 A. That's -- you're taking those comments somewhat out of  
10 context. May we go back to the transcript?

11 Q. No. Just answer my question. Did you call the analysts  
12 and correct those analysts that they had gotten that wrong  
13 and that they had doubled your market that you had indicated?

14 A. The market we were referring to was comparing to the  
15 Herceptin adjuvant studies. That would be that -- again, to  
16 try to compare the ExteNET data to the Herceptin adjuvant  
17 studies, which you can see in my comments, we said the  
18 placebo arm is in line with the Herceptin adjuvant --

19 Q. Mr. Auerbach, that's not what I'm asking you. I'm  
20 asking you, when those analyst reports came out the next two  
21 days and had 86 to 91 as the absolute difference for the  
22 ExteNET study, did you call them and say, hey, or e-mail them  
23 because you were in constant e-mail contact, did you call  
24 them or e-mail them to tell them they had gotten it wrong by  
25 double?

1 A. They had not gotten it wrong, because if you looked at  
2 the centrally confirmed population, which is what is measured  
3 in their Herceptin adjuvant studies, and if --

4 THE COURT: Slow down.

5 THE WITNESS: Sorry. I don't believe they had  
6 gotten it wrong because if you looked at the centrally  
7 confirmed population, the centrally confirmed HER-2  
8 population and ExteNET, which is the correct group to compare  
9 to the Herceptin adjuvant studies, it showed a benefit of  
10 4.1 percent.

11 BY MR. COUGHLIN:

12 Q. Mr. Auerbach, you look at the centrally confirmed -- you  
13 had the KL curve [sic] done for the centrally confirmed group  
14 for the first time by Bin Yao, or at least he says it was the  
15 first time when you asked him for it. That was March 4th,  
16 2015.

17 So are you saying that you were talking about the  
18 centrally confirmed group right here?

19 A. Yes. We had those curves back in July.

20 Q. You didn't produce any contemporaneous centrally  
21 confirmed curves from that time.

22 A. I believe we have produced the data from July with that  
23 data.

24 Q. Oh, no. You're talking about -- are you talking about  
25 the 2018 curve that was thrown up by Bin Yao? I'm talking

1 about contemporaneous curves around this time frame for the  
2 centrally confirmed group. There are none that we know of.  
3 Are you saying they exist?

4 A. They may or they may not exist. I don't remember if we  
5 looked for them, so I don't know the answer to that.

6 Q. Okay. We're going to look at an e-mail in March of 2015  
7 when you asked those to be run.

8 A. Okay.

9 Q. And then we're going to find that you say how much of  
10 this data do we have. Would it surprise you to know you had  
11 less than 60 percent of the data for the centrally confirmed?

12 MS. JOHNSON: Objection. These are not questions.  
13 It's improper argument.

14 THE COURT: It's cross. Overruled.

15 BY MR. COUGHLIN:

16 Q. Would you be surprised to learn that you wrote, oh, we  
17 only have 60 percent? Would you be surprised?

18 A. We were still getting the centrally confirmed data in,  
19 as I remember it. As I remember this correctly, a lot of the  
20 centrally confirmed tests had not yet been run. They were  
21 still being run.

22 Q. So you knew at this time frame that you only had  
23 60 percent of the centrally confirmed; is that right?

24 A. Yeah. If we only had 60 percent, then I would have been  
25 comfortable with that number.

1 Q. And you knew that -- did you know it or not?

2 A. Yes. I remember knowing that, yes.

3 Q. Okay. And did you think you knew it back here in July?

4 A. Yes, I knew that.

5 Q. And you're saying that you thought somebody ran you --  
6 ran some KM curves in July 2014 with centrally confirmed for  
7 you?

8 A. My recollection is that when we saw this data, we had  
9 asked the question of a lot of these patients. So just to  
10 clarify, we invite -- may I clarify what centrally confirmed  
11 means?

12 Q. I'll ask you about it a little later. Centrally  
13 confirmed, you send it to a central lab to get confirmation,  
14 correct?

15 A. Yeah. The important part here is that the false  
16 positive rates with HER-2 testing is anywhere from 15 to  
17 20 percent, meaning that if you go to your doctor's office,  
18 he does a test saying you have HER-2 disease, there's a 15 to  
19 20 percent false positive rate.

20 Q. It's a better testing than the local testing; is that  
21 right?

22 A. That is correct.

23 THE COURT: Folks, I need to say the transcript of  
24 these proceedings is subject to doubt. That's the record  
25 you're making. That's the record we're going to have to live

1 with. Please work more carefully on creating a proper  
2 record. I don't know what more I can do except to say that  
3 you're making the transcript largely worthless.

4 If anyone wants to make a point on appeal, I have  
5 some questions about whether the transcript accurately  
6 reflects what's being said.

7 Continue.

8 MR. COUGHLIN: Understand, Your Honor.

9 THE COURT: I keep hearing that, but I hear you  
10 gearing up and getting fast in very short order. There's  
11 nothing more I can do except to say the transcript is now  
12 questionable.

13 Okay. Go ahead.

14 MR. COUGHLIN: Okay.

15 BY MR. COUGHLIN:

16 Q. When you gave these numbers that we talked about, you  
17 gave an actual -- basically a hazard rate by talking about  
18 the 33 percent improvement, right?

19 A. Correct. That was the primary end point of the trial,  
20 yes.

21 Q. That hazard rate only applied to the 2.3 percent  
22 absolute difference; is that correct?

23 A. That's correct.

24 Q. So when you gave that hazard rate to Dr. Werber and you  
25 said you thought you could get the numbers that he came up

1 with, 90, 91, with a 33 percent improvement, you were  
2 referring to the topline results, the absolute difference at  
3 2.3 percent, correct?

4 A. No. That is incorrect. We were referring to the  
5 centrally confirmed.

6 Q. You were referring to the centrally confirmed group?

7 A. Both the ITT and centrally confirmed would still fall  
8 within the range we were giving. We were guiding to a range  
9 that was anywhere between one and six percent.

10 Q. But that centrally confirmed group that you run -- and  
11 we'll take a look at those curves that you run later -- has a  
12 different hazard ratio than this group; isn't that correct?

13 A. Yes. It's a lower hazard ratio, so better improvement.

14 Q. So when you refer to 33 percent, it was only -- that  
15 hazard ratio only refers to one group, 2.3 percent?

16 A. Correct.

17 Q. Let's go to page 7 of 15. I think it's clip eight. If  
18 you could take a look at the paragraphs where we talked about  
19 this a little bit. Howard was asking the question, Howard  
20 Liang.

21 (Audiotape recording played)

22 BY MR. COUGHLIN:

23 Q. Let's take a look at that. Now, you weren't saying that  
24 your curves were at six percent, seven percent, and  
25 eight percent, et cetera; were you?

1 A. No. What I believe I was referring to is that the  
2 magnitude of the benefit going out past two years is one  
3 percent, as you can see, going from year two to three. That  
4 was where we were guiding to.

5 Q. That's what you were trying to guide to when you made  
6 that statement of going out in the future years; is that  
7 right?

8 A. That is correct.

9 Q. And that's -- that's the curves that you say you were  
10 looking at when you made that statement; is that right?

11 A. Again, the curves I was looking at showed the benefit to  
12 be 2.3 percent at year two and 3.5 percent at year three.

13 Q. So it was not the curves from the study itself. It was  
14 some other curves that you say were created; is that right?

15 A. No. It was the curves from the study itself that showed  
16 the data for all patients all time points going out beyond  
17 two years.

18 Q. Going out beyond the two years -- at the end of this  
19 study going out to years three and four, all the patients  
20 that you still had; is that right?

21 A. I remember seeing data going out to year three. I don't  
22 remember seeing data that got to year four.

23 Q. And can you recall how many events were in that data?

24 A. I do not recall that.

25 Q. Eight sound right for year four and seven for year



1 three?

2 A. I don't remember.

3 Q. Do you know if what censoring rule that you applied to  
4 this curve that didn't exist at the time, I guess, that's  
5 been reproduced in 2018, do you know what censoring rule you  
6 applied? In other words, did you apply Puma's censoring rule  
7 or the FDA rule?

8 A. So the curve had been created in July of 2014, and it  
9 was created using the FDA's censoring rule because that was  
10 one that we knew that the FDA would accept.

11 Q. So you didn't apply the Puma censoring rule to those new  
12 curves -- but you didn't apply the Puma censoring rules to  
13 the ones you created in 2018, right?

14 A. For those curves we did not because there was a -- when  
15 we applied to the two-year data, when we used either the FDA  
16 censoring rule or the Puma, the results were identical. They  
17 didn't matter.

18 When we did it to the Puma censoring rule and the  
19 FDA one, I believe there were some issues with it because our  
20 censoring rule was a little too rigid. And we knew from the  
21 get-go that the FDA had already told us that our censoring  
22 rule was incorrect, and they told us this multiple times.

23 So the FDA censoring rule was the safer one to go  
24 with because, again, our goal here is to help cancer  
25 patients. And our goal here is to have a drug that we can

1 get FDA approved and therefore help cancer patients with. So  
2 using the FDA's censoring rule was the correct one to use.

3 Q. Now, you didn't start using the FDA's censoring rule  
4 until March of 2015; is that correct?

5 A. No, that is not correct.

6 Q. That's not the first submission in that time frame that  
7 you started submitting to the FDA?

8 A. No. We had been told early on when we were amending the  
9 protocol. Prior to unblinding the study, we had brought in a  
10 statistical consultant to help us out, and the statistical  
11 consultant had said to us from the get-go, your censoring  
12 rule is inaccurate and the FDA is going to have problems with  
13 it. You need to use the rule that they recommend in their  
14 FDA guidance documents.

15 Q. But when you applied for breakthrough, you know,  
16 breakthrough designation in 2014, you submitted the  
17 Kaplan-Meier curves with the Puma censoring rule; isn't that  
18 correct?

19 A. On the two-year data, if you used the FDA censoring rule  
20 or the Puma censoring rule, the data was the same.

21 Q. But you used the Puma censoring rule?

22 A. I don't remember which one we used. We may have used  
23 the Puma. I don't remember.

24 Q. Okay. Now, Mr. Auerbach, did you think there was some  
25 prohibition for you to present the absolute difference in the

1 press release?

2 A. To clarify, are you referring to the absolute DFS  
3 difference?

4 Q. Yes.

5 A. So when you get results from a clinical trial, very  
6 important validation of that data within the medical  
7 community and the breast cancer community is to present this  
8 at a medical meeting because this is where the doctors learn  
9 about it for the first time, and this is where they get  
10 comfortable with it and decide they can eventually prescribe  
11 this to their patients.

12 Every medical conference has a rule that you need  
13 to be very careful not to present too much data in the public  
14 and that all the data you present needs to be confidential;  
15 and that if you have presented data publicly, it excludes you  
16 from being able to present it at these medical conferences.

17 Q. Mr. Auerbach, I'm asking you if that's what you believe,  
18 that you couldn't present the actual DFS rates; is that  
19 right?

20 A. That's correct.

21 Q. Okay. And yet you did present DFS rates. You gave the  
22 guidance of the 86 to the 90, 91; isn't that correct?

23 A. We gave a guidance which was a range of mid to high 80s  
24 and 90 and 91, which would be a range of between one or two  
25 and six percent -- one and six percent, I should say. Giving

1 a range does not give the data. So we were -- that's why we  
2 were comfortable giving a range but not giving the actual  
3 data.

4 Q. Now, Dr. Chan presented this information at ASCO; is  
5 that right?

6 A. Yes, she did.

7 Q. Okay. And when asked if it was her opinion that if you  
8 disclosed additional details in the July 22nd press release,  
9 could that have jeopardized the ability to present the  
10 ExteNET clinical data at a major medical conference? She  
11 responded, I don't believe so. Did you know that?

12 A. I was not aware of that. But again, Dr. Chan is not the  
13 one who makes the decision of what gets accepted to a  
14 conference and what doesn't.

15 Q. Let's take a look at Exhibit 744, please.

16 A. (Witness complies.)

17 Q. Do you remember receiving this exhibit?

18 MR. COUGHLIN: I'd like to move this in. There's  
19 no objection.

20 THE COURT: Number what?

21 MR. COUGHLIN: Number 744.

22 THE COURT: 744 is admitted.

23 **(Exhibit 744 received.)**

24 BY MR. COUGHLIN:

25 Q. Do you remember after getting off your conference call

1 that Puma's shares were skyrocketing that day and went up  
2 262 percent?

3 A. Yes, I do remember that.

4 Q. So you were aware of that?

5 A. Yes, I was.

6 Q. Let's turn to Exhibit 479.

7 MR. COUGHLIN: There's no objection to that, Your  
8 Honor.

9 THE COURT: 709?

10 MR. COUGHLIN: No, 479.

11 THE COURT: 479 is admitted without objection.

12 **(Exhibit 479 received)**

13 BY MR. COUGHLIN:

14 Q. So these are some analyst reports created after or a  
15 little later in the market after your conference call  
16 July 22nd, 2014. We saw these names Matt and Yaron that were  
17 asking questions on that conference call. And can you tell  
18 us who Mariann Ohanesian is?

19 A. Yes. Mariann is the head of investor relations at Puma.

20 Q. Okay. And she would pass on to you the analyst reports  
21 from the day; is that correct?

22 A. That is correct.

23 Q. And then you would get the analyst reports and read the  
24 analyst reports; is that right?

25 A. Usually that's correct, yes.

1 Q. Okay. So let's take a look at the first analyst report,  
2 the City analyst report that came out that night after that  
3 conference call. Actually it came out July 23rd. It says  
4 July 23rd on it at the top, but it was, I guess, late after  
5 the market.

6 If we take a look at the first page and take a look  
7 down at the best case scenario, read that paragraph to  
8 yourself for a second.

9 A. (Witness reading)

10 Q. So you got this analyst report from Dr. Werber; is that  
11 correct?

12 A. Correct.

13 Q. And you had quite a bit of e-mail and discussions with  
14 Dr. Werber on the phone; is that correct?

15 A. That's correct.

16 Q. Okay. And so you saw that he was saying: We estimate  
17 that neratinib achieved a two-year DFS rate of around 90 to  
18 91 percent versus 86 percent for a placebo. Do you see that?

19 A. Yes, correct.

20 Q. And the hazard ratio that is associated with that  
21 is .67; is that correct?

22 A. That is correct.

23 Q. And that's with the intent to treat population, right?

24 A. My assumption was he was referring to the centrally  
25 confirmed HER-2 because we had said -- made the analogy of

1 the Herceptin adjuvant trials.

2 Q. You never mentioned the word centrally confirmed on this  
3 conference call?

4 A. It was actually mentioned in the Q&A.

5 Q. In the Q&A about centrally confirmed?

6 A. I believe there was a question from Howard Liang where  
7 he referred to the HER negative patients, which would be --  
8 and those would be the false positives, the centrally  
9 confirmed who did not get -- you know, did not have a  
10 positive --

11 Q. So you think -- but this hazard ratio is not the hazard  
12 ratio associated with that centrally confirmed group. We  
13 just talked about that, and that hazard ratio was, like, .52,  
14 right?

15 A. It was a lower hazard ratio, so a better benefit. So we  
16 were comfortable with investors assuming it was, you know,  
17 the benefit of .67 in that group.

18 Q. But here they're assuming that it's your intent to treat  
19 population of the absolute results that you announced, okay,  
20 and that was the .67. And that hazard ratio is only  
21 associated with half the benefit that's indicated here.

22 A. So the guidance that we had given on the call or that we  
23 were attempting to give on the call was that the benefit seen  
24 in the trial ranged anywhere from one to six percent. So  
25 that would encompass both the intent to treat population

1 where it was 2.3 percent and also encompass the centrally  
2 confirmed HER-2 population which was 4.1 percent.

3 Q. Let's take a look at the next analyst report from UBS  
4 that was also attached to the same e-mail, so it's the same  
5 exhibit number, 479, page 15 of 24.

6 I'm going down to the key points and support  
7 numbers. It talks about commentary is improved as the FDA  
8 could accept adjuvant as a confirmatory study. Commentary on  
9 the call adds to our --

10 THE COURT: Hold on. Please say it slowly enough  
11 and clearly enough that we can understand.

12 MR. COUGHLIN: Commentary on the call adds to our  
13 confidence that the DFS curves apparently widen over time,  
14 and neratinib appears active in all subgroups examined,  
15 suggesting broad utilization.

16 BY MR. COUGHLIN:

17 Q. Do you see that?

18 A. Yes, I do.

19 Q. Okay.

20 A. Just to clarify if I may.

21 Q. Sure.

22 A. May a clarify something that you said, please?

23 Q. Sure.

24 A. Okay. Point number two, you'll notice it says, the  
25 result also increases the chances of success of neratinib in



1 other segments and indications which are significant  
2 opportunities but now look small compared to adjuvant. In  
3 particular, we think the neoadjuvant outlook is improved as  
4 the FDA could accept adjuvant as a confirmatory study.

5 I just want to be clear he was referring to a  
6 different study and a different population of patients there.

7 Q. I understand. But when he talks about the curve  
8 widening, he was referring to your comment, right?

9 A. Correct.

10 Q. That's really all I was talking about. Let's take a  
11 look at the next day, the analyst report from the next day,  
12 Exhibit 301, July 23rd, 2014. This is Howard Liang's  
13 statement, his analyst report.

14 MR. COUGHLIN: I'd like to move this into evidence,  
15 Exhibit 301, with no objection, Your Honor.

16 THE COURT: Without objection 301 is admitted.

17 **(Exhibit 301 received.)**

18 BY MR. COUGHLIN:

19 Q. If we go down to the best case scenario, in our view --

20 MS. JOHNSON: I'm sorry to break in, Your Honor.  
21 We have discussed a limiting instruction stipulation for all  
22 of the various analyst reports.

23 Counsel mentioned it. It hasn't been worked out  
24 yet, but I just wanted to note for the record that there may  
25 be an agreed-upon limiting instruction that would apply to

1 the analyst reports.

2 MR. COUGHLIN: We agree with that, Your Honor.  
3 There's not going to be a dispute about the instruction to be  
4 given about these analyst reports.

5 THE COURT: All right. To urge your negotiations  
6 along, it seems to me there should be such a limiting  
7 instruction, and I would inclined to provide it even if it  
8 wasn't stipulated.

9 Go ahead.

10 MR. FORGE: Your Honor, with so many people talking  
11 past each other in some of these discussions, we have agreed  
12 on the language on the limiting instruction.

13 MS. JOHNSON: Right.

14 MR. COUGHLIN: Yes, we have. So we can give it at  
15 any time, I think. It's not necessary to give it -- well, we  
16 should give it sooner probably rather than later, maybe  
17 tomorrow morning or later tonight.

18 THE COURT: I'll leave it up to you to supply what  
19 you think needs to be supplied when you think it needs to be  
20 supplied.

21 MR. COUGHLIN: Okay.

22 BY MR. COUGHLIN:

23 Q. So let's take a look at the best case scenario in the  
24 middle: DFS for the control arm was in line with historical  
25 Herceptin adjuvant studies likely in the range of 86 to

1 87 percent, which suggests a 91 percent DFS in the drug arm  
2 or absolute difference of four percent.

3 Do you see that?

4 A. Yes, I do.

5 Q. Okay. Did you call up Howard and say, hey, you got it  
6 wrong, Howard?

7 A. No, I did not. His report, first of all, states the  
8 best case scenario, which means he had probably a medium case  
9 scenario or base case scenario or other scenarios as well,  
10 which, my understanding from talking to investors who had  
11 spoken with him, he did have a scenario modeling, which  
12 suggested a wide range, in line with the range we gave.

13 Again, you know, the four percent number is the  
14 correct number for the centrally confirmed.

15 Q. Okay. I was just asking you if you had called him. You  
16 hadn't.

17 If we go to page 15 of Exhibit 301, that's the  
18 Cowen report. If we go to the ExteNET, looks like a home  
19 run. It says treatment with neratinib resulted in a  
20 33 percent improvement in DFS versus placebo with the hazard  
21 ratio of .67. Do you see that there?

22 A. Yes, I do.

23 Q. It goes on: We estimate a three-year DFS rate of 85 to  
24 87 for the control arm, so it's likely the three-year DFS on  
25 neratinib approached the low 90s. Do you see that?

1 A. Yes, correct.

2 Q. Did you call Mr. Schmidt at Cowen and say, hey, you've  
3 got that wrong? You've associated a hazard ratio that's  
4 something else; it doesn't go with the centrally confirmed?  
5 Did you call him and tell him that?

6 A. Well, his range as I look at it is anywhere from three  
7 to six percent. I'm assuming low 90s is 90 to 91. If I  
8 assume 85 to 87 is 85 to 87, that would be a range of  
9 anywhere between three and six percent.

10 So I -- could we please go down to the next  
11 paragraph on the report?

12 Q. Actually we're going to move on. If your counsel wants  
13 to go down to the next paragraph, they can do that. Okay?

14 A. Okay. Yeah.

15 Q. If we could take a look at Exhibit 576. And don't put  
16 576 up. Take a look at it first. This is on e-mail from  
17 Robert Glassman to you. It's dated August 19, 2014. You  
18 received it and made comments about it in Exhibit 499.

19 MR. COUGHLIN: And, Your Honor, they've objected to  
20 this. I don't know what the objection, what the basis of the  
21 objection. This is the sales document for Puma that the  
22 bankers were preparing and showing to potential purchasers.

23 He received this in the ordinary course of  
24 business. He made --

25 THE COURT: Hold on. I need him to say that, not

1       you.

2               Let's first ask if there's an objection. Okay.

3       I'm looking at Exhibit 576. It is a few pages long.

4               Do you move its admission?

5       MR. COUGHLIN: I do, Your Honor.

6       THE COURT: And the defense says?

7       MS. JOHNSON: What -- with the -- with the same  
8       limiting instruction we'd be fine with it, Your Honor.

9       MR. COUGHLIN: That's fine, Your Honor.

10       THE COURT: Okay. Great. Then 576 is admitted.

11       Thank you, Ms. Johnson. I appreciate it.

12               **(Exhibit 576 received)**

13       THE COURT: It's up -- don't expect me to follow up  
14       and give limiting instructions unless they're provided to me.

15       MR. COUGHLIN: Absolutely, Your Honor.

16       THE COURT: Okay. Go ahead.

17       BY MR. COUGHLIN:

18       Q. So if you flip -- so I want you to look at that, 576.

19       And actually let's look right at what we're going to look at.

20       The first page says Robert Glassman. And who is Robert  
21       Glassman?

22       A. Robert Glassman is an investment banker for Bank of  
23       America, Merrill Lynch. He's also a medical doctor, and he's  
24       also a cancer doctor.

25       Q. He says: Alan, this is the profile we shared with Merck

1 and Celgene. Any comments, issues welcome. Rob.

2 Do you see that?

3 A. That is correct.

4 Q. And let's take a look into this document. The jury can  
5 look at it, and we might come back to it and talk about it.  
6 But I want you to go all the way to the back: We believe  
7 most concerns can be mitigated. Down at the bottom it says  
8 market risk. It says the three-year DFS benefit in adjuvant  
9 breast cancer roughly translates into an absolute five  
10 percent of breast cancer patients.

11 Do you see that?

12 A. Yes.

13 Q. Okay. And I want to talk about that in a second. But I  
14 want to flip over to 499, which is your response to his  
15 request for comments.

16 A. Okay.

17 MR. COUGHLIN: I'd move 499 in. It's not objected  
18 to.

19 THE COURT: Without objection 499 is admitted.

20 **(Exhibit 499 received)**

21 BY MR. COUGHLIN:

22 Q. I believe this is you responding to Rob's questions to  
23 you; is that correct?

24 A. I need to review this. One second.

25 Q. Okay.

1 A. (Witness reading) Yes, this was me responding to him.

2 Q. Okay. And what you're correcting there is he had  
3 mentioned in that paragraph we looked at, that blurb, that he  
4 was referring to a three-year DFS benefit, and you said it  
5 was really a two-year; is that correct?

6 A. Yeah. I seem to remember this. The analysis in the  
7 trial is a two-year analysis. But as investors were, you  
8 know, trying to do comparisons between the Herceptin adjuvant  
9 trials and the ExteNET trial, they kept trying to compare the  
10 time points from the Herceptin adjuvant trials with the time  
11 points in ExteNET.

12 So many of them had started to reference the  
13 two-year analysis in ExteNET as a three-year analysis because  
14 that would -- you know, the standard of care as patients get  
15 adjuvant Herceptin for a year and then two years, that would  
16 be the way to do the cross-trial comparison.

17 Q. I understand. It took me a while, but I understand.

18 Down below in the middle of the paragraph, you say:  
19 You may want also to mention that the curves are continuing  
20 to separate, so by the five-year analysis the absolute DFS  
21 rate should be larger than it is at two-year time point.

22 Do you see that?

23 A. That's correct.

24 Q. Huh?

25 A. Yes.

1 Q. Do you see that?

2 A. Yes.

3 Q. Do you still agree that was a correct and honest  
4 statement at the time?

5 A. Well, at the time what we had seen was the data in  
6 July 2014 that showed that our benefit went from 2.3 percent  
7 at two years to 3.5 percent at three years. So our  
8 assumption was that it would continue.

9 Q. Again, you've not produced any document contemporaneous  
10 with that time frame showing that benefit?

11 A. We have produced a document that shows that the data  
12 from July 2014 that we had in our possession as of July 2014  
13 showed a DFS benefit of 2.3 percent at two years and  
14 3.5 percent at three years.

15 Q. We're still talking about the Bin Yao document created  
16 in 2018?

17 A. I don't know what time frame it was created, but it was  
18 from the same data set.

19 Q. Just recently.

20 A. But am I correct it was from the same data set?

21 Q. We don't believe so. There's a dispute about it, but I  
22 wanted you to testify about it. If that was your belief --

23 A. I don't know --

24 THE COURT: Hold on. A little fast. You talked  
25 over him before he finished.



1 THE WITNESS: My apologies.

2 THE COURT: Now you may answer.

3 THE WITNESS: I don't know the time frame as to  
4 when that was created, but I know it was the same data set.

5 BY MR. COUGHLIN:

6 Q. Okay. Let's talk about that. They're talking about --  
7 then you go on to talk about priced at 4K per month, and it  
8 would be a \$4.3 billion in worldwide sales. Do you see that?

9 A. Yes.

10 Q. So what you're trying to do here is sell the company  
11 right now; is that right?

12 A. That is incorrect.

13 Q. Well, you've got a banker putting together a  
14 presentation with a DFS rate of five percent going out to  
15 investors. And isn't that to sell the company?

16 A. That is incorrect information.

17 Q. Okay. Now, this banker, this wasn't the first note you  
18 got from these bankers that they had met with companies. Did  
19 you get a similar one the month before in August?

20 THE COURT: Hold on.

21 BY MR. COUGHLIN:

22 Q. This wasn't the first note you had gotten like this from  
23 the bankers. Hadn't you already gotten one back in August  
24 that they had presented to some other companies?

25 A. We get communications from bankers on a regular basis.

1 And, you know, just to clarify, a lot of large investment  
2 banking firms -- Bank of America is one of them -- have a lot  
3 of relationships with large pharmaceutical companies.

4 Sometimes those companies are interested in  
5 research and development collaborations. Sometimes they're  
6 interested in partnerships, which, those partnerships could  
7 be we do a joint partnership where we sell and market the  
8 drug together. Or they can also be interested in, you know,  
9 acquiring the entire technology as a whole.

10 Obviously we don't have those relationships. They  
11 do. So they will very often ask bankers to, you know, do a  
12 presentation on a certain technology, a certain drug, a  
13 certain company.

14 I have a fiduciary responsibility to the investors  
15 in this company. If someone e-mails me or contacts me saying  
16 we just met with pharmaceutical company ABC and they wanted  
17 us to do a presentation on Puma, whether I want to do that  
18 research collaboration or I want to do that sales and  
19 marketing partnership or I want to sell the company, is  
20 irrelevant.

21 I have a fiduciary responsibility to investors.  
22 When I get those type of communications, as a fiduciary  
23 responsibility to the investors I have to respond to them and  
24 be helpful.

25 Q. Did you ever sign a confidentiality agreement with any,

1     like, Celgene or Merck so that they could look at your data?

2     A.    We -- I seem to remember we did have CDAs with various  
3     companies in place over various years. I don't remember  
4     specifically for these two entities if they were in place  
5     exactly in, this appears to be, September 20th, 2014.

6                 I don't remember if we had CDAs in place at that  
7     time. I know we've had CDAs in place with pharmaceutical  
8     companies.

9     Q.    At different times?

10    A.    At different -- well, it may have been signed before but  
11    were still active.

12    Q.    Right. We have -- we don't have a signed CDA with  
13    either Merck or Celgene around this time frame. That doesn't  
14    surprise you, though, right? It wouldn't necessarily  
15    surprise you, right?

16    A.    In September 2014, that would sound accurate, yes.

17    Q.    Okay. Let's take a look at Exhibit 497.

18                 MR. COUGHLIN: I'd like to move this document in,  
19    Your Honor. It's not -- I don't think it's been objected to.

20                 MS. JOHNSON: It has been objected to.

21                 MR. COUGHLIN: Oh. Well, Your Honor, I'd like --

22                 THE COURT: Hold on.

23                 The objection is?

24                 MS. JOHNSON: It's -- I would propose a limiting  
25    instruction that the document -- it's hearsay, but we can

1 waive that objection subject to a limiting instruction that  
2 the information in here is not necessarily true, but it is a  
3 business record.

4 THE COURT: Is that acceptable to you?

5 MR. COUGHLIN: It is, Your Honor.

6 THE COURT: Okay.

7 So, folks, there's something called hearsay. I'm  
8 sure you've all heard of it. It means when you -- oh, stated  
9 simply, you offer something that someone else says and you  
10 offer it for the truth of what was said.

11 Well, they've agreed that this document can come in  
12 but not for the truth of anything, any facts that it includes  
13 within it. So document number 497 is admitted, but if it  
14 says in there it was a rainy day on Wednesday, it's not  
15 admitted to prove that. It's admitted for other reasons, not  
16 to prove the facts that might be in it.

17 I hope that's clear enough.

18 Go ahead. It's admitted, 497.

19 **(Exhibit 497 received.)**

20 BY MR. COUGHLIN:

21 Q. Could you take a look at this, Mr. Auerbach.

22 A. Yes.

23 Q. Do you remember receiving this nondisclosure agreement  
24 from -- or this proposal from Celgene?

25 A. Yes, I do.

1 Q. And it had a confidentiality agreement attached to it.  
2 Did you see that also?

3 A. That is correct.

4 Q. And you didn't sign that; is that correct?

5 A. We did not sign it during this time period.

6 Q. Right. You didn't sign it during the time period from  
7 2014 to 2015; is that correct?

8 A. Yes. As I remember this, Celgene had flown out to have  
9 dinner with me and had stated that they had an interest in  
10 potentially acquiring the company. Again, I have a fiduciary  
11 responsibility to the investors. Whether I want to do that  
12 or I don't want to do that, I have to accept those type of  
13 invitations.

14 I had said to them when we had dinner that the next  
15 step in due diligence would be to schedule a time for either  
16 them to fly to Los Angeles -- they're located in New  
17 Jersey -- for them to fly to Los Angeles to do an entire  
18 meeting to do due diligence, or for me to fly to New Jersey,  
19 either. And then at that point we could move forward.

20 Q. And they make a proposal to acquire a hundred percent of  
21 the outstanding shares of the company for \$10 billion; is  
22 that correct?

23 A. Correct.

24 Q. Okay. And that was just a couple months after your  
25 July 22nd conference call; is that correct?

1 A. Yes, that is correct.

2 Q. And you did not sign this confidentiality agreement; is  
3 that correct?

4 A. I had contacted them to schedule the follow-up meeting,  
5 and they did not ever get back to me. So we never moved the  
6 CDA forward because the purpose of the CDA would have been  
7 that meeting.

8 MR. COUGHLIN: Your Honor, I think this might be a  
9 good time.

10 THE COURT: Excellent. We will break now and we'll  
11 meet tomorrow at 9:00, not at 8:00.

12 We are moving along nicely here, and it has been  
13 rainy outside.

14 So we'll meet you at 9:00 tomorrow. Remember,  
15 don't discuss this case. Keep an open mind, and don't do any  
16 research on the case.

17 Thank you.

18 THE CLERK: All rise.

19 (Open court - jury not present)

20 THE COURT: All right, sir. You may step down.

21 See you all at 9:00.

22 MR. GRONBORG: Your Honor, there are a few  
23 discovery -- excuse me, evidentiary issues that we would like  
24 to raise if possible that we can deal with -- there's three  
25 of them -- that would make tomorrow much more efficient in at

1 least putting together deposition designations, as well as  
2 one that we'd probably have to worry about ringing the bell.

3 THE COURT: All right. So we've identified three  
4 discovery issues or evidentiary issues, correct?

5 MR. GRONBORG: Yes.

6 THE COURT: Is there anything else that anyone  
7 wishes to handle right now?

8 MS. JOHNSON: The only thing I would raise is I  
9 asked to do a proffer for Dr. Adelson, sustaining of the  
10 objection based on ML four. It would be short.

11 THE COURT: You want to make a proffer?

12 MS. JOHNSON: Correct, just for the record.

13 THE COURT: Go ahead.

14 MS. JOHNSON: Thank you.

15 THE COURT: I thought you were going to do that at  
16 the first break. But, you know, I must say when people offer  
17 to make proffers or offer stipulations, I usually leave it up  
18 to them to bring up. So go ahead.

19 MS. JOHNSON: Thank you, Your Honor.

20 Just for the record, the testimony I would have  
21 elicited had that objection not been sustained would have  
22 been that the Yale tumor board recommended consideration of  
23 neratinib to patients as part of an appropriate standard of  
24 care, that Dr. Adelson was part of that panel who agreed as a  
25 group that neratinib was an appropriate standard of care for

1 actual patients, and that Dr. Adelson had spoken with  
2 colleagues and agreed that some patients are appropriate for  
3 neratinib and would have prescribed it if the patient had  
4 wanted it, thereby agreeing that neratinib is part of an  
5 appropriate standard of care.

6 I can cite to the deposition sections if that's  
7 helpful.

8 THE COURT: If you'll appeal, you'll be able to  
9 cite then. I will accept your proffer as it is made. But  
10 I'm telling you, that certainly seems to come right within  
11 the motion in limine. It's after the class period and --  
12 you've made your proffer.

13 MS. JOHNSON: Yes. And the argument is that they  
14 opened the door by --

15 THE COURT: I don't think they had opened the door  
16 by that time. But in all fairness, I don't think you said  
17 they opened the door. There was times during the afternoon  
18 examination when I was thinking about whether they had opened  
19 the door.

20 You've made your record.

21 MS. JOHNSON: Thank you, Your Honor.

22 THE COURT: Good. Now, what do we need to do here?

23 MR. GRONBORG: Your Honor, the issue number one is  
24 with respect to three documents. If I can approach, I can  
25 hand them to you.



1           THE COURT: I thought -- well, okay. I thought  
2           there were three things we need to describe. Now there's one  
3           with three things.

4           MR. GRONBORG: There's one with three things.

5           THE COURT: The only reason I say that is I think  
6           it's fair to let the staff and everybody know what's going on  
7           here.

8           Okay. We have these three documents. What do you  
9           want me to do with them?

10          MR. GRONBORG: Your Honor, these are three  
11          communications from Alan Auerbach. They involve the company  
12          Pfizer.

13          The defendants have taken the position that these  
14          are documents that would be excluded by their motion in  
15          limine number two which, as you will recall, excluded  
16          evidence of a dispute with Pfizer.

17          None of these documents will be used to have any  
18          discussion or raise any dispute. We are willing to redact  
19          the letters DR in there. They go directly to the testimony  
20          we just heard.

21          Specifically, if you don't mind, if I could have  
22          you turn to Exhibit 482, page 3 of 4 of Exhibit 482, the  
23          first full paragraph.

24          THE COURT: Why are you reading this?

25          MR. GRONBORG: To establish the relevancy and how

1 it has nothing to do with a dispute with Pfizer. It has to  
2 do directly with the testimony we just heard.

3 THE COURT: Okay. Let's start with this. The  
4 plaintiff moves Exhibit 475, 482, and 795. Is there any  
5 objection?

6 MS. JOHNSON: Yes, Your Honor.

7 THE COURT: To all of them?

8 MS. JOHNSON: Yes.

9 THE COURT: What's the objection?

10 MS. JOHNSON: Based on the Court's order on  
11 defendant's motion in limine number two to exclude evidence  
12 of Puma's dispute with third-party Pfizer. These go directly  
13 to that dispute. It does not change anything if you redact  
14 the actual words that refer to the dispute. The evidence  
15 goes to that dispute, and we would not have a -- all the  
16 arguments in the motion in limine, we would have to have an  
17 opportunity to put on evidence of that trial-within-a-trial  
18 sideshow.

19 THE COURT: Okay. Perhaps it might be helpful if  
20 you identified the types of statements in these exhibits that  
21 cause you concern.

22 MS. JOHNSON: For example, Exhibit 482 is one of a  
23 number of correspondences between Puma and Pfizer in the  
24 exact dispute that was the subject of the motion in limine.

25 THE COURT: You -- no offense, but you've just said

1 the whole document. I was hoping it identified specific  
2 language in there that you think raises the issue. You know,  
3 you have much more familiarity with these documents than I  
4 do. I mean, what specific language are we talking about?

5 MS. JOHNSON: Having just gotten these, they -- the  
6 letters are -- you know, I cannot at this minute direct you  
7 to specific language, but the letters --

8 THE COURT: But, you see, I have to do that. So  
9 that means I have to read it all and figure out where the  
10 issue lies. I can't be abstract here. If you can tell me  
11 where you think it improperly raises facts covered by the  
12 motion in limine, that helps. Or I can read the motion in  
13 limine. I can read the exhibits cover to cover.

14 I'm just trying to look for a shorter way of doing  
15 this. Maybe there's a shorter way. Can you tell me?

16 MS. JOHNSON: Yeah. I'll give you a better  
17 example. Exhibit 795 on the first page in the --

18 THE COURT: Now, hold on. 795, first page.  
19 Uh-huh.

20 MS. JOHNSON: In the context of this back and forth  
21 between Pfizer and Puma, the first bullet point, someone from  
22 Pfizer is saying in response to a question by Yaron Werber  
23 regarding DFS rates, Alan implied that he knew the DFS rates  
24 of the active and control arms.

25 In response to a question by Howard Liang regarding

1 longer-term follow-up, Alan implied knowledge of DFS rates  
2 beyond two years, et cetera. This dispute was over whether  
3 Pfizer was entitled to information that was within Puma's  
4 control, among many other aspects of that dispute which we  
5 would have to litigate.

6 Plaintiffs I presume would use it to show that  
7 information was not provided to Pfizer. Plaintiffs will want  
8 to say that shows he doesn't have it. Our defense would be  
9 they're not entitled to it, and we would be going down a  
10 rabbit hole of that separate dispute.

11 THE COURT: I think this information can be  
12 presented without any reference, knowledge, or anything  
13 concerning the dispute. I mean, the jury doesn't need to  
14 know about the Pfizer dispute in looking at this information,  
15 and I believe my motion in limine was directed at the Pfizer  
16 dispute.

17 I don't see, for example, how those bullet points  
18 informs the jury that there's a Pfizer dispute.

19 MS. JOHNSON: Plaintiffs' use of it will.  
20 Plaintiff will use it to say if he didn't give it to Pfizer,  
21 he must not have had it. And we would have --

22 THE COURT: Is that what you intend to do?

23 MR. GRONBORG: I think their concern is we're going  
24 to --

25 THE COURT: You're not answering my question, but

1 go ahead.

2 MR. GRONBORG: Actually we're going to use his own  
3 statements where he tells Pfizer, for example, to switch to  
4 the other exhibit when they're asking for subgroup, for  
5 example, the centrally confirmed subgroup that he says he  
6 has, that he is telling another entity in September of 2014  
7 that it's going to take three to four weeks to get that  
8 information.

9 THE COURT: Okay. You didn't answer my question,  
10 which makes me inclined to agree with Ms. Johnson. She posed  
11 a question, and you didn't answer it.

12 MR. GRONBORG: Perhaps I didn't understand the  
13 question, then.

14 THE COURT: Well, maybe you just listen to it.  
15 Would you state your situation again.

16 MS. JOHNSON: We understand that plaintiff will use  
17 this information to suggest Pfizer's asking for it. Puma is  
18 saying we don't have it. We need to find it. It would take  
19 some time.

20 Plaintiff will use this back and forth to suggest  
21 that Mr. Auerbach did not have the information at this time.  
22 That's not true because it was in the context of a business  
23 dispute. We would be entitled to put on evidence -- we would  
24 have to put on evidence of what the nature of the dispute  
25 was, what Pfizer was entitled to under the license agreement,

1 why Mr. Auerbach was making these statements to a separate  
2 third party. That is exactly what motion in limine two goes  
3 to.

4 And I believe that Mr. Gronborg is saying that is  
5 what they would use the evidence to suggest.

6 THE COURT: Okay. That's a different question  
7 you're posing now than the one I asked plaintiffs' counsel  
8 about.

9 Yes. Go ahead.

10 MR. GRONBORG: I was going to try and answer the  
11 question with an example from the document which is 495 and  
12 say it is actually showing what a fairly contemporaneous  
13 record of what Mr. Auerbach is saying he does have.

14 For example, where he says it appears based on a  
15 preliminary analysis that the absolute difference in DF  
16 curves is separating by approximately 0.5 percent per year.  
17 So he is providing information about what he does have. It's  
18 not being used to --

19 THE COURT: Okay. You know, when I -- correct me  
20 if I'm wrong. There were quite a few motions in limine, but  
21 it seems to me my granting the motion in limine was I didn't  
22 want to get into a discussion of the other bit of litigation.

23 I don't know that this requires even reference to  
24 the fact that there was other litigation. Why would it  
25 require reference to the fact that there was other

1 litigation?

2 MS. JOHNSON: Your Honor, because they're going to  
3 characterize his statements to Pfizer. We can't defend that  
4 without explaining the --

5 THE COURT: What would you explain? Would you  
6 explain, well, there was litigation, so I couldn't turn over  
7 all the information? I'm trying to get in how the litigation  
8 comes into play, and that's what I'm not understanding.

9 MS. JOHNSON: The back and forth between the two  
10 involves Pfizer mischaracterizing the data; Alan responding.  
11 These are not the only three pieces of correspondence. You'd  
12 have to track them all to say, okay, first, Pfizer said this.  
13 Then Alan said this. And Pfizer characterized the data like  
14 this.

15 So if you take one of them out of context without  
16 explaining the dispute, the jury will be misled. That was  
17 the argument in our motion.

18 THE COURT: Do you intend to reference the  
19 litigation?

20 MR. GRONBORG: Not at all.

21 THE COURT: That was a clear answer. Do you think  
22 you can present this as information without reference to the  
23 litigation?

24 MR. GRONBORG: Yes.

25 THE COURT: I think he can, too.

1 MS. JOHNSON: I think he can, too, but we can't.  
2 We would have to reference it in order to explain the context  
3 for the --

4 THE COURT: How is that? I mentioned you would  
5 have to say, well, there was litigation, so we weren't  
6 forthcoming. How do you have to reference the litigation?

7 MS. JOHNSON: Because it explains the relationship  
8 between the parties.

9 THE COURT: How is the relationship relevant?

10 MS. JOHNSON: So just to, you know, back up,  
11 plaintiff is saying this information was relevant to what was  
12 said publicly. We know what those rules are. We know what's  
13 required under the securities laws. We have a basis for  
14 understanding whether he should or should have not said what  
15 he said. This is a private dispute that the jury doesn't  
16 understand the rules for.

17 THE COURT: What rules for the private dispute? I  
18 mean, information was either provided or not provided. Why  
19 do we need to reference anything about the litigation?

20 MS. JOHNSON: Because it was governed by a complex  
21 licensing agreement that governed the parties' rights and  
22 relationships. We would have to explain --

23 THE COURT: Why can't you say it was governed by a  
24 complex licensing agreement? That doesn't reference the  
25 litigation.



1 MS. JOHNSON: The facts of the agreement and the  
2 fact of the litigation explains the context for the  
3 statements if the plaintiff is going to suggest data did or  
4 did not exist at a certain time, that Mr. Auerbach lied or  
5 didn't lie to Pfizer. We need to understand the context.

6 THE COURT: I keep trying to probe why that's  
7 necessary, and I'm not getting sufficient answers.

8 So what else about this would anyone like to say?

9 MS. JOHNSON: My request would be that because we  
10 didn't know that these particular three documents were going  
11 to be the subject of this argument, that you give us a bit of  
12 time tomorrow morning to articulate it.

13 THE COURT: You can reargue it tomorrow morning.  
14 For now the tentative is to allow it with firm instructions  
15 to counsel not to mention the litigation, not to mention  
16 things that require a reference to the litigation. But so  
17 far I haven't seen that.

18 And it sounds a little bit like you don't want  
19 these in and you're trying to tie it into the litigation.  
20 But I think they can come in without reference to the  
21 litigation. And by the way, you'll note on all these motions  
22 in limine, you may or may not recall me saying the problem  
23 with motions in limine is you cabin all these things but have  
24 relevance beyond the cabining.

25 We have an example this morning where it was

1 relevant beyond the little cabin, and then in the trial we  
2 spent a lot of time defining the cabin and its limitations  
3 instead of just looking at the facts itself.

4 So you're welcome tomorrow morning to present  
5 further argument. The key thing I want to know is how will  
6 you be required to reference the litigation. You can  
7 reference lots of things about licensing, et cetera. I don't  
8 know that you're going to reference we were in litigation so  
9 he couldn't be forthcoming. I'm not sure that's a good  
10 argument. I'm not sure you want to make that to the jury.  
11 But, I mean, that kind of thing I would listen to.

12 For reasons the jury doesn't need to be familiar  
13 with, there was a privilege involved and he felt he needed to  
14 stand by the privilege -- something like that. I'm not sure  
15 there is a privilege involved here in relation to the  
16 litigation.

17 I just need to see it tied more to the litigation.  
18 So convince me of that tomorrow, and we'll go forward with  
19 that.

20 When will you be using this?

21 MR. GRONBORG: I anticipate tomorrow.

22 THE COURT: With Mr. Auerbach?

23 MR. GRONBORG: Yes.

24 THE COURT: Okay.

25 What other issues do we have besides these three

1 documents?

2 MR. GRONBORG: My colleague, Ms. Conn, she'll  
3 handle the next. And to deflect a little from here, it is  
4 one that is more than one within it.

5 THE COURT: I didn't understand that, but go ahead.

6 MS. SMITH: Thank you, Your Honor.

7 THE COURT: Just a moment. Did you need something?

8 MS. SMITH: I just want to know how long, because  
9 I'm --

10 THE COURT: Exactly. I'm trying to get how long.

11 Now, I understand there's three issues, and we just  
12 took care of one?

13 MS. CONN: Correct, Your Honor.

14 THE COURT: Now let's take care of two.

15 How much time do you need?

16 MS. CONN: I can be done in ten minutes, I think.

17 THE COURT: Well, begin by telling me what it is  
18 you want the Court to do.

19 MS. CONN: Okay, Your Honor. Tomorrow as part of  
20 our witness plan, time permitting and depending on how long  
21 we take with Mr. Auerbach, we were intending to show some  
22 depositions.

23 I'm happy to report we've resolved many, many of  
24 our objections, but there are two witnesses to whom  
25 defendants still object to plaintiffs' designations.

1           THE COURT: Okay. You know, it's just so helpful  
2 to me if you say, Your Honor, we'll need you to review  
3 transcripts and rule on some objections. But you've now  
4 talked for a minute, and you haven't told me what you want me  
5 to do. It's just helpful, the way my brain operates, to ask  
6 me what you want and then we'll go into all the background.

7           What do you want me to do?

8           MS. CONN: I would like you to review, and I have a  
9 correction. It's only one witness at this point. We're  
10 still negotiating on the second witness. As to one witness I  
11 would like you to review our designations and defendant's  
12 objections and make rulings on those objections.

13          THE COURT: Do you have a transcript? Do you  
14 remember yesterday I asked for it? Maybe you don't remember,  
15 yesterday I asked for it so I could be ahead of the curve.  
16 You have a transcript and you want me to review it?

17          MS. CONN: Yes, Your Honor.

18          THE COURT: If you give it to me, I can do that.

19          (Document handed to the Court)

20          THE COURT: All right. So I have in front of me a  
21 transcript for Eric Schmidt. I can read this tonight. I  
22 mean, did you have any other idea? I mean, do you want me to  
23 -- I'll read it tonight. So tell me what the color coding  
24 is.

25          MS. CONN: Okay. So the -- orange highlighting is

1 plaintiffs' designations.

2 THE COURT: Okay.

3 MS. CONN: Yellow highlighting is defendant's  
4 designations.

5 THE COURT: Uh-huh.

6 MS. CONN: Anything with a red box around it  
7 indicates there is an objection to that testimony.

8 THE COURT: Okay.

9 MS. CONN: And in the margin of the document is the  
10 basis of the objection.

11 THE COURT: Very good. Well stated.

12 All right. Now, I hope some thought went into  
13 these. I do find more often than not it's actually someone  
14 not directly related to the litigation who likes to say  
15 foundation to everything.

16 MS. CONN: If I may, Your Honor --

17 THE COURT: This is good. I'm looking at page 138  
18 and there's a box and it says hearsay. So do I -- I only  
19 have to see where there are red boxes, right?

20 MS. CONN: That's correct, Your Honor.

21 THE COURT: But there aren't that many red boxes.  
22 I mean, I can do that easily. Okay. I'll go through and  
23 make those rulings.

24 MS. CONN: Thank you. To be clear, all objections  
25 are defendant's at this point. I think they may have

1 inadvertently objected to some of their own designations, but  
2 they're all defendant's objections.

3 THE COURT: Okay. We'll see. That's number two?

4 MS. CONN: Yes. And number three --

5 THE COURT: Before we get to number three --

6 MS. CONN: We're going to take number three off the  
7 table.

8 THE COURT: So we're done?

9 MS. CONN: We're done.

10 THE COURT: So here's the issue that always comes  
11 up on these. You have this on videotape? How good is your  
12 videographer?

13 MS. CONN: Pretty good.

14 THE COURT: If I give it to you at nine, can the  
15 videographer do what he needs to do?

16 MR. COUGHLIN: Yes, Your Honor.

17 THE COURT: Okay. All right.

18 Could we all be here at 8:45?

19 MS. CONN: Yes, Your Honor.

20 THE COURT: I will give you my rulings and give you  
21 a brief chance to argue. We'll have a brief chance to argue  
22 on yours -- and this is actually going to come after  
23 Mr. Auerbach; correct?

24 MS. CONN: That is correct.

25 THE COURT: Okay. So that's what we'll do. So

1 we'll see you all at 8:45 tomorrow. Good.

2 Thank you.

3 (Proceedings adjourned at 4:49 p.m.)

4 CERTIFICATE

5 I HEREBY CERTIFY THAT THE FOREGOING IS A TRUE AND CORRECT  
6 TRANSCRIPT OF THE STENOGRAPHICALLY RECORDED PROCEEDINGS IN  
7 THE ABOVE MATTER.

8 FEES CHARGED FOR THIS TRANSCRIPT, LESS ANY CIRCUIT FEE  
9 REDUCTION AND/OR DEPOSIT, ARE IN CONFORMANCE WITH THE  
10 REGULATIONS OF THE JUDICIAL CONFERENCE OF THE UNITED STATES.

11  
12 /s/ Miriam V. Baird

01/17/2019

13 MIRIAM V. BAIRD  
14 OFFICIAL REPORTER

DATE

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