FEDERAL TRADE COMMISSION

I N D E X

IN RE POM WONDERFUL LLC, ET AL.

TRIAL VOLUME 7

PUBLIC RECORD

JUNE 8, 2011

EXHIBITS	FOR ID	IN EVID	IN CAMERA	STRICKEN/REJECTED
CX				
(none)				
PX				
(none)				
RX				
(none)				
JX				
(none)				
DX				
(none)				

UNITED STATES OF AMERICA

BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL GLOBAL LLC,	)	
as successor in interest to	)	
Roll International Corporation,	)	
companies, and	)	Docket No. 9344
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually	)	
and as officers of the	)	
companies.	)	
	)	
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Wednesday, June 8, 2011

9:35 a.m.

TRIAL VOLUME 7

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Josett F. Whalen, RMR-CRR

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ON BEHALF OF THE FEDERAL TRADE COMMISSION:

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P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: Back on the record Docket 9344.

Are you ready to continue?

MS. VISWANATHAN: Yes.

JUDGE CHAPPELL: All right. Next question.

- - - - -

Whereupon --

MATTHEW TUPPER

a witness, called for examination, having been previously duly sworn, was examined and testified further as follows:

DIRECT EXAMINATION (resumed)

BY MS. VISWANATHAN:

Q. Good morning, Mr. Tupper.

A. Good morning.

Q. Yesterday when we left off, you were looking at CX 1029, a medical research portfolio, and I'd like you to look at page 3 of CX 1029, and we'll put it up on the screen as well.

Your Honor, I've just been informed that we might need to make an adjustment to that screen in order to be able -- for the witness to view it. Is it okay to approach?

JUDGE CHAPPELL: What do you mean?

BY MS. VISWANATHAN:

Q. Can you see it on the screen?

A. The screen looks fine, although, honestly, it's a little blurry, so I'll just look at the paper copy. That's fine. I've got it here.

JUDGE CHAPPELL: And I don't know why these monitors aren't working. You might want to have somebody look at that.

MS. BARNES: It might be off.

JUDGE CHAPPELL: That's almost as bad as not plugged in. Maybe that's even worse.

If the witness can't see it sufficiently, you'll need to give the witness a copy.

MS. VISWANATHAN: And he has paper copies up there.

BY MS. VISWANATHAN:

Q. So page 3 of this medical research summary is the page specifically summarizing POM's medical research on heart disease up to that point?

A. Yes.

Q. And at the top it says, "What Have We Learned"; correct?

A. Correct.

Q. And along the left there are two subcategories, arterial plaque and blood flow and pressure; correct?

A. Correct.

Q. I want to first focus on the human studies for arterial plaque, which is the second -- excuse me -- the third column.

Are you familiar with the term "carotid IMT"?

A. Yes, I am.

Q. And that's a measure that's correlated for arterial plaque; correct?

A. I don't know if it's correlated. It's a measure of -- it's actually an ultrasound image of the carotid artery which leads from the heart to the brain, and it essentially shows as a thickness of the wall of the artery, which includes the wall of the artery plus whatever plaque has accumulated inside the wall.

Q. And the first study listed under Carotid IMT Studies is the study that's listed as Aviram 2004 with 19 patients; correct?

A. That's correct.

Q. And the IMT result percent change relative to control group is a 40 percent reduction relative to control group?

A. I believe that's correct. Yes.

Q. I'd like to switch over and just quickly show you a couple of ads because my questions will then relate back to this chart.

If we could look at CX 0031.

This is an ad that's copyright 2004 and it says "Floss your arteries. Daily" at the top.

Is that an example of a headline that you were talking about yesterday?

A. Yes. I think we would typically refer to the red type there as the headline.

Q. And if we can look at the body copy -- and we can enlarge that for you -- one of the lines in the body copy towards the bottom says, "Just eight ounces a day can reduce plaque by up to 30 percent"; correct?

A. Correct.

Q. Okay. And then let's go to another ad. It's CX 0034.

And again, this is an ad, and the copyright date is 2005, and it says, the headline, "Amaze your cardiologist." And if we can look at the body copy in more detail, this one also says towards the end, "A glass a day can reduce plaque by up to 30 percent."

Do you see that?

A. Yes.

Q. If we could go back to the chart, page 3, that we were looking at.

Are these references to a 30 percent reduction in plaque based on the results of the Aviram study from

this chart?

A. I believe so. In fact I believe in both of those ads that you showed there was a reference at the bottom, and if I recall correctly from just a minute ago, I think it was the Aviram study.

Q. Like a footnote or a citation?

A. I believe so.

Q. Okay.

A. I believe so.

Q. And it says on the chart here that the Aviram study had 19 subjects; correct?

A. Yes, that's correct.

Q. Do you know if all of the 19 subjects drank pomegranate juice?

A. No, they didn't. There were two groups. One was drinking pomegranate juice. The other was on a placebo.

Q. Do you know whether the subjects in the Aviram study already had heart disease?

A. What I believe is that they had -- in fact, the title of the paper was something about stenosis, which is plaque buildup in the arteries, so I think they had been diagnosed as having built up plaque in their arteries. Yes.

Q. And do you know whether they were elderly

patients?

A. I can't remember the median or the average age, but I do recall that generally it was an older population.

Q. In their sixties and seventies?

A. I don't remember the age. I'm sorry.

Q. At the time of the previous two ads that I showed you, "Floss your arteries" and "Amaze your cardiologist," from 2004 and 2005, at that time would you have been consulted on the headlines of those ads in your capacity as president of POM Wonderful?

A. When you say "consulted" --

Q. Would you have reviewed those headlines before the ads were finalized?

A. Yes. I think I would have seen them in the process of the creative review and ideation, yes.

Q. And the same with the graphics and the body copy of the ads as well?

A. Typically, yes. Typically we'll look at an entire, what we call an execution of an ad, which is sort of blown up, placed on a board, put on a wall, and it would have the headline and it would have a graphic. Sometimes it would have body copy, sometimes not. Sometimes we would create body copy after creating the headlines.

Q. Who would make the determination as to whether to cite a particular study in a marketing campaign?

A. Well, I think it's -- I guess, can you rephrase the question.

Q. Yeah.

Well, how is the decision made, for example, to cite the Aviram results in a particular ad?

A. So if -- it's actually pretty straightforward. If we're going to be talking about the results of a particular study, then that's obviously the study that would be cited.

So in the example of the two ads that you showed, those were the results that we were discussing in the ads, so that was the study that was cited in the bottom of those ads.

Q. And in terms of the decision to, say, cite a particular study as opposed to more generally referring to health benefits, I mean, how is that decision made?

A. I'm sorry. I didn't follow you. Can you repeat that.

Q. Well, in the case -- in this case, a particular study was cited with a footnote at the bottom, and we've seen ads before where there was no particular study cited and there were no footnotes.

I guess my question is, you know, who makes the

decisions as to whether to put specific references to studies as opposed to more general ad copy in an ad?

A. Well, I think it depends on the nature of the ad. If we want to talk about a specific study, then obviously we would include the key pieces of information from that study in a citation. If it's going to be a more general discussion, for example, antioxidants and health or a number of different areas of health, then typically we -- I don't think in the past we've cited specific studies, but I could be -- I could be wrong about that.

Q. Well, again, I'm trying to figure out a clearer way to phrase the question.

I guess, were there times when POM decided to build an ad around a particular study?

A. Sure. There were instances where there were particular studies that we thought were important for the -- our consumers and for the public to be aware of, and that would form the basis for the body copy in the ad. Sure.

Q. So who decided to use the Aviram study in the "Amaze your cardiologist" ad, for example, that we just saw?

A. Well, that study which had been published in 2004 was one that we've cited and discussed for -- going

back to that time, and I don't recall the first time we made the decision to do that, to cite that study and discuss the results. That goes back pretty far. I don't recall.

Q. Is that the kind of decision that would have been made by, for example, you or Mrs. Resnick?

A. Very typically, yes.

Q. And who -- I guess, is there somebody in POM or POM marketing who has the final sign-off that allows ads to be sent out to the agency to be disseminated to the media?

A. If -- sure. If what you're referring to is the -- I mean, it's a multistage process from -- which can take quite a long time from, you know, ideation through to an ad appearing in, say, a magazine. But there is a final stage of both proofreading and then someone in the marketing team at POM reviewing the ad, basically proofing the proofreading, checking off that everything looks right, is spelled right, et cetera. And then typically it's the agency, Fire Station, who will forward that, the ad, typically in an electronic form along to the newspaper or the magazine, whatever media we're using in that case.

Q. And so then in the last stage at POM, would that be handled POM marketing or by somebody or, for example,

by you or Mrs. Resnick?

A. It would be -- the last stage would be handled by someone in POM marketing because either Lynda or I would have seen it beforehand and we would have agreed on the headlines and the copy, and so forth.

Q. So when you say you would have seen the headline, copy, and so forth, would you see the ads in essentially finished form before they were sent to the agency?

A. You mean me?

Q. Yes.

A. No. Not always. But in a different form, for example, the body copy I would have reviewed in text form, seen that, and then it would have gotten laid into the ad with all the graphics.

Q. Okay. Thanks.

Let's go back to -- well, we are there -- 1029 page 3. And I'm moving on to the next study, which is called Ornish 2005.

So this is a study that had 73 subjects, and it is for the same duration, 12 months, as the Aviram study.

Do you know whether this Ornish study had a placebo group?

A. My recollection is that it did, but I can't say

for sure. I believe it did.

Q. Do you -- I'm sorry. And according to the chart, POM's chart, the result of this study showed no change in IMT result as relative to control group; correct?

A. Actually my recollection is that the IMT result, although it didn't reach any statistically significant changes at the 12-month period, there were directional differences between the POM group, which showed signs of improvement, and the placebo group. But the study was not powered, didn't have as many subjects as we originally intended and as a result did not reach statistical significance. I think that's in the box here what the "no change" refers to.

Q. Was the study published?

A. No. I don't believe it was.

Q. You believe it was?

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

Q. Oh, sorry.

Okay. Let me show you one -- another ad, which is CX 0169. And this one is a -- the headline is "The power of POM, in one little pill." And there's a -- just to put a date on it, there's a coupon at the bottom that expires April 15, 2008, so it's approximately 2008.

And over to the right, next to the picture of the tree, this ad has a quote from Dr. Aviram saying, "Pomegranate juice pilot research suggests anti-atherosclerosis benefits."

Do you see that?

A. I do, yes.

Q. And "atherosclerosis" is another term for arterial plaque; right?

A. That's my understanding. Yes.

Q. Mine, too.

And so this ad contained a reference to the Aviram study even after POM had received the results of the Ornish 2005 study that found no statistically significant effect on arterial plaque; is that correct?

A. The timing of this is correct, although again, as I've explained, the Ornish study, to my recollection, showed a trend favoring the pomegranate juice group but was not powered to ultimately get to statistical significance.

Q. Because on the chart it does say no change in IMT results.

A. Correct, that's what the chart says.

Q. And actually there is a footnote in this ad as well. It's probably going to be hard to see in the paper. We can blow it up on the screen.

I'm not sure how visible that is.

But towards the bottom of that footnote, there's a reference to the Aviram study that says 19 patients drank POM Wonderful, a hundred percent POM Wonderful juice, pomegranate juice.

Do you see that?

A. I think you're talking about footnote number 5; is that right?

Q. Yes, I am.

And as you discussed, not all 19 patients in the Aviram study actually drank pomegranate juice; is that correct?

A. That is correct, yes.

Q. Because there was a control group, so there was a fewer number of people drank pomegranate juice; correct?

A. That's correct.

Q. Okay. And so was somebody responsible for checking the -- you know, the accuracy of these footnotes that were cited in the advertising?

A. Yes.

Q. And who would that be?

A. Ultimately it was me, so there appears to be a mistake here.

Q. Okay. Was there any discussion at POM regarding

whether to change the advertisements advertising heart health benefits after POM became aware of the Ornish IMT results?

A. Well, we're discussing the results of our science and how we communicate those results in advertising all the time based on what we learn, so that's a -- that's a constant, ongoing process.

Q. So the fact that Ornish ultimately did not result in a statistically significant change did not affect, you know, how POM was advertising heart health necessarily; correct?

A. My recollection is that we viewed those results as consistent with the body of research that had preceded it.

Q. Okay. Let's go back to 1029 page 3, the chart that we were looking at, and move on to the next study, which is Davidson 2007.

Okay. And according to the chart, this had -- the study had 290 subjects, and the ultimate study duration was 18 months; correct?

A. There were IMT measurements taken at 12 months, and then the final one, yes, was taken at 18 months.

Q. And after 18 months, it says no change in IMT results relative to control group; correct?

A. Correct.

Q. And we have -- yesterday we had seen a research agreement with Dr. Davidson's company Radiant Research. Do you remember that?

A. I do.

Q. And I believe that the contract was signed sometime in August 2003? Does that sound right?

A. I don't recall, but I'll take your word for it.

Q. Okay. And is it fair to say that POM was aware of the Davidson results from this IMT study as of April 2006?

A. Jeez, I don't remember exactly when we got the preliminary data, but 2006 does sound correct. Yes.

Q. Was the Davidson study listed on this chart, was it randomized and placebo-controlled?

A. I believe it was placebo-controlled. I believe it was randomized. I believe it was also double-blinded.

Q. Is this the largest heart disease study on POM juice that POM funded?

A. I believe it -- I believe it is the largest clinical on the cardiovascular system. I believe so.

Q. And was there a discussion at POM about changing advertising with respect to heart health benefit claims about atherosclerosis or arterial plaque after POM learned of the Davidson IMT results?

A. As I said before, the dialogue about our science and results and how we communicate those results to the public is a dynamic and ongoing one, and we are always discussing, especially when we learn new information, so that's the pattern.

Q. Did POM continue to run advertisements with references to the Aviram study even after it was aware that Dr. Davidson's data showed no effect on IMT in a large placebo-controlled, double-blind, randomized 18-month study?

A. It sounded like there were a couple questions there or a couple points there. But yes, we have continued to --

JUDGE CHAPPELL: Hold on a second. If you think there was more than one question or point there, she needs to rephrase so the record is clear. My point is, if you're answering a question, we need to know what question it was.

So rephrase, please.

MS. VISWANATHAN: Okay. Sure.

BY MS. VISWANATHAN:

Q. Did POM continue to run advertisements with references to the Aviram study even after it was aware of Dr. Davidson's data?

A. Yes. We've -- we have discussed Aviram's

results in advertising after that point. Yes.

Q. And as we said, Dr. Davidson's data showed no effect in a randomized, placebo-controlled, double-blind 18-month study; correct?

A. Well, Davidson's data showed many things. That was one thing that it showed, but there were many others as well, including, as it indicates on this chart, a statistically significant result at the 12-month point.

Q. Okay. So you're talking about on the chart at 12 months where the IMT result is a reduction of 1.3 percent change relative to control group?

A. Correct.

Q. And are you also referring to the patient group that says "hi-risk" where the IMT result is a reduction of between 2 and 5 percent?

A. Correct.

Q. Did the protocol for this study originally call for analyzing the subgroups?

A. I don't recall. I don't recall.

Q. Didn't Dr. Davidson's published paper say that these particular post hoc results should be interpreted with caution?

A. I believe it did. Yes.

Q. And didn't Dr. Davidson's paper, published

paper, also say because these subgroups were not based on preplanned analyses they would need to be confirmed in future investigations?

A. I believe it said that.

Q. Has POM cited any of the results of the Davidson study in its advertising and marketing materials regarding heart health?

A. I believe we have. Yes.

Q. And do you know what marketing materials those might have been?

A. The one for sure that comes to mind is our Web site. The study is featured I believe at the top of our section on cardiovascular, and I believe in our other marketing materials it's referenced as well.

Q. And are the subgroup analyses that we've just discussed, were they also described on the Web site?

A. I believe the entire paper, you know, in its full form is actually available for downloading and reading on the Web site.

Q. Well, eventually that Davidson study, as we've discussed, was published; correct?

A. Correct, it was.

Q. And it was not published until October 2009.

Does that sound right?

A. 2009 sounds correct. I don't know what part of

the year.

Q. By the way, when the Davidson study was published, was Dr. Harley Liker listed as a coauthor?

A. He may have been, but I don't recall for sure. I actually would be speculating.

Q. Okay. Well, maybe we can just bring that up quickly to refresh his recollection.

I'm sorry. It would be Exhibit 1199 in your book.

Okay. So on this it appears that Dr. Harley Liker was listed as an author; correct?

A. Correct. He's the second from the final author.

Q. Okay. And actually if you look at the acknowledgments or the -- I guess the list of affiliations down at the bottom left, it says where each investigator I guess is associated.

Do you see that?

A. I do.

Q. Okay. It says Dr. Liker is associated with UCLA; correct?

A. Let's see. He's listed as F, and F -- David Geffen School of Medicine, UCLA, correct.

Q. And his affiliation with POM overall is not listed here; correct?

A. No. It appears these are all academic affiliations that are listed.

Q. Do you know if UCLA as an institution had any formal involvement with the Davidson study in terms of being a study site, for example?

A. No, I don't believe it was a study site. I think that the study sites were all in Chicago and also in Dallas.

Q. And you had said that the Davidson results were posted on POM's Web site after they came out; correct?

A. Correct.

Q. I'd like to show you an ad, CX 0328.

This is a POMx advertisement with the headline "Your new healthcare plan." And the coupon on the bottom expires in April 2010, so it's approximately that time frame.

So this is an ad from either I assume late 2009 or early 2010 based on the expiration date; would that be fair to say?

A. Yeah. My recollection is that I kind of remember this headline. It came up as the whole healthcare reform debate was going on, hence the reference to "no town hall meeting required," which unfortunately I don't remember when that was, but I remember the context.

Q. Okay. Well, if you look at the right side of the ad, this ad which talks about the studies, the Davidson study is not referenced in this particular ad, is it?

A. That's correct.

Q. And this would have been after the Davidson results came out.

A. Possibly. Again, I don't remember the exact sequence of dates, but that's possible.

Q. Okay. Let's go back to CX 1029 and move on to the section on blood flow and pressure.

Okay. And at the top, the very top where it says "A) Blood Flow to Heart," there's reference to Ornish, n=45, increase 35 percent versus placebo.

Was this a reference to the study that was eventually published with Michael Sumner as the first author?

A. I don't recall who the first author was.

Q. Was this the -- was this the study about myocardial perfusion?

Is that -- does that ring a bell?

A. Yes. I believe that's what this study is.

Q. Was this a placebo-controlled study?

A. I believe it was. Yes.

Q. So the 45 -- I guess n=45 I assume means how

many patients were enrolled?

A. I believe that's correct, total number of patients, including both POM and placebo.

Q. So again the 45 patients were split into two groups; some drank POM juice and then some drank a placebo beverage?

A. Yes.

Q. Okay. If you recall, was this a study that the published results were for a duration of three months?

A. I believe that's correct. Yes.

Q. Did you review the protocol for the study?

A. I don't believe I did.

Q. So do you know whether the protocol for the study originally called for it to have a duration of 12 months?

A. Having sat here in the room yesterday, I recall the previous witness in discussion about that, so as of yesterday, yes.

Q. Actually let's -- if we could, just for a minute I want to go back to CX 328, which is the POMx ad we just saw.

Okay. Do you have it in front of you?

A. I do, yes.

Q. Okay. And again to the right, the right column, that's a discussion of the studies. Above the -- the

second to last paragraph, there's a quote from Dr. Dean Ornish: "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the American Journal of Cardiology, '05.

Do you see that?

A. I do.

Q. Is that a reference to this blood flow and the heart study on this chart?

A. I believe it is. I believe in fact that's a -- that may have been a quote from the publication itself.

Q. And if we can -- there's -- this one also has a footnote that says 1, 2 and 4. I don't know how easy it is for you to see the footnote, but we can bring it up on the screen.

Footnote 4 --

A. That doesn't help.

Q. No.

A. If you have a magnifying glass.

Q. I apologize.

A. I can kind of see it.

Q. Can you kind of see it?

Well, it starts 45 patients with coronary heart disease and myocardial ischemia drank eight ounces of pomegranate juice for three months.

Can you see that kind of?

A. Yes, I see that.

Q. Okay. And again because there was a placebo, isn't it true that actually not all 45 patients drank pomegranate juice?

A. I believe that to be correct. Yes.

Q. Okay. Let's go back to 1029 page 3 and move on to the blood pressure study.

Okay. And under Blood Pressure Studies, the first one listed is Aviram 2002 with ten subjects for two weeks; correct?

A. Correct.

Q. And the next is Aviram 2004 with 19 subjects for 52 weeks.

Is this the same Aviram study that we just discussed with respect to IMT?

A. I'm not sure. According to the years, it may be, but I don't recall.

Q. If we showed you the actual published study, would that help refresh your recollection?

A. Sure.

Q. Let's bring that up. It's 611. It's CX 611.

(Pause in the proceedings.)

Does that refresh your recollection as to whether the Aviram 2004 IMT study also looked at blood

pressure?

A. Yeah. It does appear that the 21 percent listed on that chart from the overview document coincides with the results reported in this Aviram study.

Q. Okay. According to the -- I guess the summary in the Aviram study?

A. Correct. I'm just reading the abstract at the beginning. I'm assuming that reflects the data reported in the study.

Q. That was actually my next question. If we turn to page 5 of the Aviram paper, and if you look at the top above the charts.

(Pause in the proceedings.)

So actually looking at that actual written body of the paper, it appears that the maximum blood pressure reduction after twelve months was only 12 percent; is that correct?

A. In this data set, that's correct. I don't know if that refers to what was on the abstract or not.

Q. Did POM's Web site state that the Aviram study showed a reduction of 21 percent in systolic blood pressure?

A. I don't recall whether we included that information on the Web site.

Q. And who was responsible for confirming the

accuracy of the actual scientific data that was posted on the Web site?

A. Well, ultimately that was my responsibility, and I would work with the head of our science program to make sure that we had the papers and the data from the researchers.

Q. So that would have been Mark Dreher at the time?

A. If this was during his tenure, it would have been Mark, yes.

Q. Okay. We can move back to 1029 and continue to look at the blood pressure studies.

And the next blood pressure study listed is Ornish 2004, 73 subjects for 52 weeks.

Is this the same 73-patient Ornish study referred to above in the arterial plaque section?

A. It looks like the number of patients are the same, but I don't -- on the surface it appears that way. I don't recall specifically that.

Q. But the systolic and diastolic blood pressure listed in the Ornish 2004 study showed no change relative to control.

That's what's reported here; correct?

A. Correct.

Q. And then moving on to the next column, it says

"Davidson 2007."

Again, I'm assuming this is the same Davidson 290-patient study that we had discussed above with respect to IMT?

A. It appears that way.

Q. And the blood pressure results for the Davidson study is also 0 percent reduction in both systolic and diastolic pressure versus control; correct?

A. Correct. That's what is listed here.

Q. Didn't POM run an ad with a POM juice bottle in a blood pressure cuff with the headline "Decompress"?

A. I believe we did. Yes.

Q. And that ad ran after POM was aware of the results of the Ornish and Davidson results on blood pressure?

A. I believe -- I can't remember the last time we've run that ad, but we've run it multiple times and I think as late as 2007, 2008, maybe even 2009.

Q. Let's move on to the same page of 1029, the second section of the chart, entitled Where Do We Go From Here?

And the first column says "End Game Scenarios," and maybe you can explain. Is this four possible choices or strategies about how the company could proceed with respect to heart disease?

A. These are meant to facilitate a discussion about options looking forward, and on the page were listed a few different options, and then those prompted a discussion during the meeting about a whole range of options.

Q. So looking at the first column or first row -- I'm sorry -- it says "Botanical Drug (Pills only), two different options: 'Prevent Heart Disease' (based on Death/Heart Attack data) and 'Lower Blood Pressure' (based on Systolic BP data)."

And the next column says "Required Action for Scenario."

What did you mean by "required action for scenario"?

A. I think this was to -- again, as a conversation starter to list out some of the things that would be involved in this case, for example, if we were pursuing a drug approval for POM.

Q. And so that would be if the company was seeking a drug approval for a "prevent heart disease" claim for POM products?

A. Regardless of the claim, these were our belief or our best guess as to what that road might entail.

Q. And in terms of what it might entail, just to be clear for the record, it says two studies for either

option, in total 1000++ patients, $20 million, ten-plus years; correct?

A. Correct.

Q. So did that mean that POM's view was that in order to make a claim that POM products prevent heart disease it would require two studies with a thousand-plus patients?

A. No. No. This was our belief as to actions, worst-case actions in certain senses, associated with getting a drug approval from the FDA.

Q. Well, was it the company's view that even without an FDA approval that they could advertise POM products that could prevent heart disease without these two studies and 1,000-plus patients?

A. Just to be clear, this section is all about drug approval and the many steps that go along with a drug approval process with the FDA.

Q. So was it POM's view that it could advertise these types -- it could not advertise these types of claims without FDA approval?

A. Yeah, I'm not quite sure what your question is there.

Q. Okay. Well, just if we look at the Botanical Drug column again, you said two different options, prevent heart disease or lower blood pressure,

and you say two studies required for each option, a thousand-plus patients, requires FDA approval.

My question was, was it POM's view that in order to actually make the claim that POM prevents heart disease, would it require FDA approval, 1,000-plus patients and two studies?

MS. DIAZ: Objection, Your Honor. I believe she's asking for a legal conclusion.

JUDGE CHAPPELL: Do you have a response?

MS. VISWANATHAN: I'm asking whether in his capacity as president of POM, along with the discussions with the various other individuals he's mentioned that participated in these discussions, which would have included Stewart Resnick, the medical director, I'm not asking for his discussions with lawyers and I don't think it requires a legal conclusion.

JUDGE CHAPPELL: You'll need to rephrase. I'll allow you to ask him if he's aware of certain things, but that was too broad and general.

MS. VISWANATHAN: Uh-huh.

BY MS. VISWANATHAN:

Q. Was POM aware of whether it could make claims about its products to prevent heart disease without FDA approval?

A. Yeah, I'm still not quite clear what you're getting at, but let me try my best to answer your question here.

The section around -- section A, the drug section, my understanding -- and certainly not being an FDA expert, but my understanding is that there are certain steps that are required to get an approval for a drug. And when an approval is issued by the FDA, it's always relative to a particular indication based on the endpoints that are used in the studies that lead up to the approval, and that's -- that's what this section refers to.

Q. Okay. And did you participate in drafting this section, this End Game Scenarios and Required Action for Scenario?

A. I did, yes.

Q. And so when you were drafting this section, was it your personal view that two studies with a thousand-plus patients would be required to make a claim that POM prevents heart disease?

A. Well, I guess there's again a couple parts there, so let me be clear what I'm responding to.

First of all, my personal belief and my hope was that for -- and there are other sections in this document aside from heart disease where we talk about

the possibility of entering the drug approval process. My belief was that in light of the body of science that we already had behind us, we may not in fact be required to have two additional studies, so that was my belief, number one.

And number two, the required actions are not relative to making claims. They're relative to getting an approval, which is a holistic process that, as I said, involves endpoints and indications. It very significantly involves what -- the term I've heard is "CMC," which is the process by which the FDA evaluates your manufacturing, operations and process and quality control, so there's a whole litany of things, and that's what the required actions refer to.

Q. Okay. And where it says "'Prevent Heart Disease' based on Death/Heart Attack data," what do you mean by "based on Death/Heart Attack data"?

A. My -- again, this is my understanding of the FDA, and I could be for sure off here, so take it with a grain of salt.

But my understanding is that for drug approvals, typically pharmaceutical or biotech drug approvals, in the area of heart disease, historically the FDA has looked at endpoints that are either the incidence of heart attack or I guess even further from that

mortality, so that's what this refers to. And that's my understanding.

Q. Yeah, I -- just going forward of course I'm just asking for your understanding when you were drafting this document, and so that's what I'm looking for.

Okay. And just to be clear, I mean, POM did not have data, heart attack data, in its heart disease studies at that point; correct?

A. That's correct.

Q. In the last column, Assessment, it says "not worth pursuing, too expensive, too risky."

What did you mean by "too expensive, too risky"?

A. Well, to pick up on the previous question, to do a study looking at the incidence of heart attack, because heart attacks, you know, don't occur, thankfully, with all that much frequency, you need to have quite a lot of people enrolled in the study to get enough -- to witness enough heart attacks to see if there's an effect, and the time involved can be many, many, many years to gather enough data.

For us, you know, a food product that, you know, sells for four or five dollars a bottle or a dollar a pill, that's certainly beyond our ability to undertake.

Q. Okay. Well, let's move on to the second row under End Game Scenarios. It says similarly -- at the top it says "Health Claim (Juice or Pills), two different options: 'Reduced risk of heart disease'" and "'Reduced risk of hypertension.'"

And if we look at the required actions for scenario, it appears that again it was the view of yourself or Mr. Dreher who drafted this document that it would require two studies, in total 200-plus patients, 3. -- three to five million dollars, three to five years, in order to be able to make those health claims; is that correct?

A. No, not quite. Again, this -- I believe this section refers to the on-label claims for foods, and this was our understanding of the worst-case scenario.

Again, my belief, similar to the drug path, was had we chosen to go down this road, our belief was that the body of science that preceded this point in time would be sufficient to dramatically reduce the potential requirements, although we -- this was again speculation and trying to portray the worst case, but the belief was that given the work that was out there, the requirement would be less.

Q. Under the assessment, the last line bullet point says, "Science risk: our heart disease/BP data may not

be strong enough."

So did that mean that POM felt the studies that it had would not be sufficient to meet this health claim standard on the label at the time?

A. No. I think there was some discussion here as to what endpoint would be at play. And you know, our hope, as it was listed out under the leftmost column, again, the scenarios, would be that we could convince the FDA to use IMT as an endpoint. But our understanding, my understanding was that again the endpoint that would be required would be one of heart attack, which again is just not feasible for us to undertake.

Q. And that would be even for the claims in column -- in row B, reduced risk of heart disease, reduced risk of hypertension?

A. Correct.

Q. Okay. Well, if we go to the last two rows, the third option says "Additional, targeted research for marketing/PR/medical outreach purposes," and column D -- sorry -- row D says "No more clinical research - publicize what we already have."

It sounds like from what you were just saying that essentially POM kind of decided to go with D; is that right?

A. No. We've actually -- we have continued to support a number of different cardiovascular studies.

Q. Have there been cardiovascular studies -- are these published studies?

A. Some are. Yes.

Q. Since 2009, since the Davidson study?

A. Yes.

Q. Are they in humans?

A. Some are. Yes.

Q. On row D, the assessment is: Lowest cost/risk, but our research has holes.

What does it mean by "our research has holes"?

A. Oh, I see. I was reading the bullet point here. You're talking about the underlined section.

Q. Well, yeah, and then I'll move on to the bullet point after, but what did you mean by "our research has holes"?

A. I think it referred to the fact that, you know, among other things, the gold standard in the cardiological community is heart attack, and it kind of relates to the next point. You know, when you're especially interacting with doctors whose experience is in running drug trials for pharmaceutical drugs where those are in fact the endpoints, heart attack, stroke, et cetera, that, you know, those sort of doctors that

are pharmaceutically oriented and looking for those gold-standard endpoints, when they think about foods, their level of skepticism goes up even regardless of how strong the body of evidence is beneath it, and that's what this referred to.

Q. And when we talk about the -- or when it talks about the current body of research only being viewed as a 3 on a scale of 1 to 10 by M.D.s, was that because POM had received feedback from medical doctors that its body of heart disease research was, you know, only a 3 on a scale of 1 to 10?

A. Well, we have to be more specific when, you know, we try to share our research with a whole broad group of people. And some of those people, people in the medical community, some of those folks, some of those doctors, are cardiologists involved with drug approval studies, and you know, their response is often, Well, this is interesting, but, you know, jeez, it would be nice to have some heart attack data. And that's -- I think that's really what this referred to.

Q. I mean, did you agree with the statement here that the current body of research is only viewed as a 3 on a scale of 1 to 10 by M.D.s?

A. This whole document was intended to represent all the different views of the research, including those

people who, for example, would be our critics, even if they're a small subset.

So in this case we're talking about -- this specifically I think refers to the subset of cardiologists, for example, that you might meet at a medical conference where the presentations are all about pharmaceutical trials and pharmaceutical interventions. That's the subset of doctors we're talking about here.

So do I or did we agree that our research, you know, was viewed this way or should be viewed this way? Definitely not. But we wanted to be candid with ourselves and reflect the views of all stakeholders, even if we didn't agree.

Q. Okay. So just going back up to row A, in your understanding, did POM need FDA approval to make the claim that its products prevent heart disease or lower blood pressure?

MS. DIAZ: Objection, Your Honor.

JUDGE CHAPPELL: I can't hear you.

MS. DIAZ: Same objection, Your Honor. Calls for a legal conclusion and asked and answered.

JUDGE CHAPPELL: One of the objections is asked and answered.

Have you answered that question already?

THE WITNESS: I believe I have.

JUDGE CHAPPELL: Sustained.

BY MS. VISWANATHAN:

Q. Looking again at column B where it says "Health Claim (Juice or Pills)," in that case it looks like the health claim would be for a food product, not a drug; correct?

A. Correct. An on-label food, food claim, or supplement I believe as well.

Q. So that would be to make a claim that POM juice, for example, reduces the risk of heart disease or hypertension; correct?

A. Correct. The claim actually on the product itself, on the label, similar to what you'd find with a pharmaceutical, only for a food.

JUDGE CHAPPELL: By the way, so the record is clear, your other objection -- you'll need to stand up, please. I'm addressing you.

MS. DIAZ: Yes, Your Honor.

JUDGE CHAPPELL: Thank you.

Whether it calls for a legal conclusion, that objection is overruled. It was asked if it was his understanding. If he thought or knew that FDA approval was needed, that would have been allowed.

MS. DIAZ: I understand.

JUDGE CHAPPELL: You need to stand up tall and proud and speak up because you're sounding kind of mousey, you're crouched down, and we can't hear you or see you.

MS. DIAZ: All right.

JUDGE CHAPPELL: Thank you.

BY MS. VISWANATHAN:

Q. Mr. Tupper, I'd like you to turn to page 4 of the Exhibit CX 1029, and the headline at the top says "Prostate Cancer."

And again, I'd like to focus on the human studies column. It's the third column.

Okay. And if we focus on human studies, it says there is one published study entitled Pantuck 2006/2008; correct?

A. Correct.

Q. And this was published I believe in a journal called Clinical Cancer Research; is that your recollection?

A. My recollection is actually this has been published, so to speak, multiple times, which I think is why there are two years listed here. Originally I believe Clinical Cancer Research was the journal, but then, because then he's followed these patients over a period of time, he's reported the results in other

forums when those results are available.

Q. Okay. And it says "n=46" which again I assume means there were 46 subjects?

A. Correct.

Q. And I believe we had discussed this study yesterday, maybe not in detail, but this was on subjects who had already been diagnosed and treated for prostate cancer; correct?

A. Correct.

Q. And according to the chart, it says "no placebo (patient' own baseline as control)"; correct?

A. Correct. Because of the stability of PSA, the patients served as their own controls.

Actually I should be more clear. Because of the stability of PSA doubling time and kinetics, the patients served as their own control. Unfortunately, when PSA starts rising, it tends to continue to rise in a stable fashion.

Q. And that's my next question, is that the results or the study looked at an endpoint called PSA doubling time; correct?

A. That's correct.

Q. By the way, are you aware again if Dr. Harley Liker was listed as a coauthor of this Pantuck study as well?

A. I don't recall.

Q. Okay. Let's move down to the End Game Scenarios, Where Do We Go From Here? section of this document.

Again, there's a row that says "Botanical Drug (Pills only) 'Prevent/Treat Prostate Cancer...'"

And the required actions under -- I'm sorry -- under Required Action for Each Scenario it lists two-plus (sic) studies, total 1,000 patients. And the second bullet says, "PSA will not be accepted as an endpoint."

What does it mean that PSA will not be accepted as an endpoint?

A. Well, similar to the heart disease page, the preceding page, this was a catalog, if you will, of our belief as to the worst-case scenario.

Up until this point, it was my understanding and our understanding that the FDA had not yet approved any drugs based on PSA as the endpoint. However, our belief at the time, which is beginning to be borne out, is that the FDA may in fact reevaluate it based upon growing evidence, and my understanding now is that there actually has been a drug approved with PSA as an endpoint.

Q. Okay. But at the time when you wrote this

chart, in your understanding, did POM need FDA approval to make a claim that the pills prevent or treat prostate cancer?

A. No. That's not what this says.

This is the same as before. In other words, if -- in order to get through the drug approval process with FDA, this was again a list of things that potentially we would need to have, again, as a worst case. Our belief and our hope was that through a process of dialogue with FDA, first of all, the body of science that we had already undertaken on the prostate would be sufficient to lower the amount of future research that would need to be done. And secondly, we believed that PSA in fact -- PSA doubling time -- sorry -- was in fact a very valid and appropriate endpoint.

And as we sit here today, we are actually in an investigational new drug process with the FDA and in discussions about what the right endpoint is.

Q. Well, in your view, is it -- as president of POM Wonderful, is it okay for POM to make a prevent or treat prostate cancer claim without FDA approval based on the studies you have?

A. Well, we'd certainly never market a drug without FDA approval, regardless what the indication.

Q. Okay. So your view is that if POM were making a claim that it treats or prevents prostate cancer, that would be a drug claim?

MS. DIAZ: Objection, Your Honor. Vague and ambiguous. Here, since we're talking about the FDA, I believe the questioner should indicate whether she's talking about the label or advertising, if the question is permitted.

JUDGE CHAPPELL: Well, the current question, she's asking his view, and I think that's clear enough, so I'll allow that question.

Overruled.

MS. DIAZ: Thank you, Your Honor.

BY MS. VISWANATHAN:

Q. Shall I repeat the question?

A. Yes. I'd appreciate that. Thanks.

JUDGE CHAPPELL: Or do you want Josett to read the question back?

MS. VISWANATHAN: Actually that would be great. Thank you.

JUDGE CHAPPELL: That way we don't get into a change of phrasing and another objection possibly.

(The record was read as follows:)

"QUESTION: So your view is that if POM were making a claim that it treats or prevents prostate

cancer, that would be a drug claim?"

THE WITNESS: I believe that there are -- that there are many aspects of marketing a drug, including what you put on the label, what the indication that you discuss is, how you actually bring that drug to market, and those all go into the evaluation of marketing a drug and the claims and the indications that go along with it.

BY MS. VISWANATHAN:

Q. Okay. Let's move on to row C, Additional, targeted research for marketing/PR/medical outreach purposes.

I just want to move to the Assessment column. One thing it says is that POM currently has a research gap, no data on assay cancer prevention, prior to radiation or prostatectomy.

I believe we had discussed yesterday and this is a reference to the fact that all of the prostate studies that POM has done have been on men who already have prostate cancer. Correct?

A. The four clinical studies that have either been completed or are ongoing, yes, I believe all those men have been diagnosed for prostate cancer.

Q. And the last row, No more clinical research - publicize what we have. Smart bet -- I'm sorry. Moving

to the assessment: Smart bet, given that we already have three additional studies in progress.

So that's a reference to what you just said that POM has ongoing prostate studies on humans; correct?

A. I'm sorry. I was actually just reading the bullet point that you were referring to previously --

Q. Uh-huh.

A. -- no data on prostate cancer prevention. Actually, as I read that now, I am not sure I agree with what I either edited or wrote back then.

It is true that the clinical studies, the men have been diagnosed and in some cases treated, but I think the data, when you include the in vitro and the preclinical animal studies as well as the general understanding of the biology of the prostate, I think it actually does speak to the reduction of risk of the disease, which in men who have not yet been diagnosed could be very relevant as well.

So I'm going to disagree with what I wrote here earlier, just to make the record very clear. I'm sorry.

Q. Okay. I believe we've touched on this already, but POM had discussions with medical experts regarding using PSA as an endpoint for its prostate cancer

studies; correct?

A. Correct.

Q. And POM was aware that PSA had not been validated as a surrogate endpoint for a meaningful cancer outcome; correct?

A. I think it would be more accurate or accurate to say that no drug had yet been approved by the FDA with PSA or PSA doubling time as an endpoint.

Q. Well, in Dr. Pantuck's published study at the time in 2006, did the published study itself note that further research was needed to determine whether improvements in PSADT were likely to serve as a surrogate for clinical benefit?

A. That sounds right, but I don't recall specifically.

Q. And furthermore, Dr. Pantuck's published paper said the proposed benefits are in assays that are yet -- as yet unvalidated.

Does that sound right?

A. I believe what he's referring to again is that validated meaning no drug yet having been approved by the FDA with that as an endpoint.

Q. Well, but just to be clear, the discussion in the Pantuck paper wasn't in the context of FDA approval, is it?

I mean, the Pantuck paper was just stating the results of their study and that further research was necessary to validate the test tubes; correct?

A. I believe his frame of reference when writing that was FDA drug approval.

Q. Okay. I'd like to show Exhibit CX 1080.

And this is -- I'm sorry. This is an e-mail from Harley Liker to yourself and Brad Gillespie.

I'm sorry. And it's dated July 7, 2009. The subject is Forward: update on Pantuck data.

And actually what I'd like you -- do you have it in front of you?

A. I do.

Q. Actually I want to focus your attention on the second page of that document, at the bottom. There's an e-mail from yourself to Harley Liker, cc'g Bradley Gillespie, dated July 6, 2009.

Do you see that e-mail?

A. I do.

Q. And in this e-mail is -- it's correct that you are saying that Stewart, meaning Stewart Resnick, wanted two topics addressed, one being the cancer outcomes observed and two being the concept of PSA doubling time; correct?

A. I'm sorry. I was just scanning this.

Q. Oh, sure.

The question was, is it correct that the e-mail -- in this e-mail you were saying that Stewart, meaning Stewart Resnick, wanted two topics addressed, one being cancer outcomes observed and two being more info on the concept of PSA doubling time?

A. Yes. That's what it looks like.

Q. And then you state that -- this is towards the bottom of the page -- he, meaning Stewart, seemed to want to understand this in the context of pitching FDA on the concept that not having a placebo is irrelevant.

So in this e-mail was it your understanding that Mr. Resnick was trying to persuade the FDA that a placebo control was not necessary for prostate cancer studies?

A. My recollection here was that when the study -- by "study" I mean the Dr. Pantuck study of the first published prostate cancer study with 46 men I believe -- when the study was initiated, my recollection is that the scientists explained that once a -- once a man has been treated for prostate cancer, typically the PSA goes down to zero, and then in certain cases it begins rising again. Once it begins rising again, its rate of rise is predictable, stable and doesn't change.

So in other words, if you're doubling every

twelve months, meaning going from a PSA of 3, then to 6 and then to 12, that occurs every twelve months quite reliably. And because of that stable trajectory, the -- each man would in fact serve as his own control because absent intervention that doubling time would not have changed.

So I think what the question here was around, this is what the urological community keeps telling us that's the view, what data out there exists looking at men and history and validating that point of view.

Q. Okay. And was this discussion in the context of making an application to the FDA with respect to POM juice and prostate cancer?

A. It might be helpful if I read the e-mails that preceded this. I don't think so, but let me...

(Pause in the proceedings.)

This doesn't say that I -- my recollection is that this is relative to a new drug application process with the FDA, which presumably would have been for POM pills.

Q. Okay. Okay. And at the time, in 2009, POM was aware that there was controversy in the urological community about the use of PSA; correct?

A. That's correct. We were aware that there was discussion still going on.

Q. And actually if we look at the first page, Dr. Pantuck -- there's an e-mail from Dr. Pantuck to Harley Liker. And this e-mail, as you can see at the top, was eventually forwarded to you.

And in the third paragraph, Dr. Pantuck himself says, "Regarding PSADT, there is a lot of controversy," and he sets forth various issues that have been raised; correct?

A. Yes. That's right.

Q. And if you look at the prior paragraph in Dr. Pantuck's e-mail, it appears that Dr. Pantuck also stated that it would be nearly impossible to argue for use of a PSA endpoint; correct?

JUDGE CHAPPELL: Hang on a second. You're asking this witness about an e-mail that's not from him or to him. What's your point?

MS. VISWANATHAN: I'm sorry, Your Honor. This was an e-mail that he did receive, and I'm asking whether --

JUDGE CHAPPELL: Well, that's my point. We didn't have a foundation for that question, because the way it was presented, it was just speculation.

BY MS. VISWANATHAN:

Q. Well, Mr. Tupper, did you -- were you forwarded this e-mail from Dr. Pantuck by Dr. Liker?

A. It appears so. Yes.

Q. Okay. And have you -- would you have read this e-mail at the time?

A. I assume so.

Q. And so you would have been aware of the issues that Dr. Pantuck was raising; correct?

A. I would have read the e-mail.

Q. Yeah.

And is it your understanding from this e-mail thread that Dr. Pantuck was attempting to respond to the concerns that you had raised on behalf of Stewart Resnick in your earlier e-mail?

A. I think "questions" is probably a better way to characterize what we raised versus concerns, but yes, he appears to be responding in fact to an e-mail that Dr. Liker sent him directly with a couple of questions listed out.

Q. So in essence Dr. Liker forwarded your e-mail to Dr. Pantuck; correct?

A. That is correct, yes.

Q. And so at the time you received this e-mail from Dr. Pantuck, POM was aware that Dr. Pantuck said it would be a near impossible battle to use PSA as an endpoint; correct?

A. Sure. We were aware that's what he said. We

didn't necessarily agree with him. In fact we didn't agree with him, but that's -- yes, we read the e-mail and were aware of his thoughts.

Q. Didn't Dr. Pantuck express concern about POM stating that POM juice shows promise for prostate cancer in connection with citing his study?

A. I recall something to that effect. Yes.

Q. Okay. Let's look at CX 0072.

And this is an e-mail from yourself to Lynda Resnick, dated August 6, 2006, and the subject line is prostate cancer ad; correct?

A. Correct. That's the subject of the final e-mail in the chain. It looks like it's a chain.

Q. Okay. And it appears that this is an e-mail chain and you were forwarding another e-mail that was sent from Dr. Allan Pantuck to Dr. Harley Liker; correct?

A. Correct.

Q. Below in the e-mail that Dr. Pantuck sent and that you were forwarding, in the second paragraph, the middle of that paragraph, do you see where he says, "I am not sure what it means to say PJ shows 'promise for prostate cancer.' I think the lay interpretation will be that it shows promise for the treatment of prostate cancer"?

Do you see that?

A. I see that line, yes.

Q. So it was your interpretation of this that Dr. Pantuck was concerned that saying that POM juice shows promise for prostate cancer would be interpreted as promise for the treatment of prostate cancer.

A. I think my interpretation was exactly what he said in his words, my interpretation of what his point was.

Q. And --

A. I'm not sure I understand his point, but that's a different matter.

Q. Well, and what you did was you forwarded this to Mrs. Resnick; correct?

A. That's correct.

Q. And you stated that you were "writing to alert you to a potential issue with our prostate cancer ad"; correct?

A. That's right.

Q. Did POM decide to advertise that POM juice showed promise for prostate cancer or hope for prostate cancer even after this communication with Dr. Pantuck?

A. I believe we've used wording similar to that, but I don't -- I don't recall precisely whether we used this wording or something similar.

Q. Okay. Well, we can show you an ad, CX 0120. Let's bring that up.

And this is an ad with the headline "One small pill for mankind." And the coupon expires July 7 (sic), just to give you a sense of the time frame.

I'm sorry. It may not be clear. July 2007 is the expiration date.

And do you see in the body copy it says, "An initial UCLA medical study on POM Wonderful showed hopeful results for men with prostate cancer"?

A. I do see that, yes.

Q. So does that refresh your recollection as to whether POM decided to advertise that it had shown hope for prostate cancer even after the communication with Dr. Pantuck?

A. Correct. Yeah, we're saying here "hopeful results for men with prostate cancer."

Q. Actually what I wanted to do is just -- at the bottom -- well, this line about hopeful results for prostate cancer, there's a footnote, and I just want to have -- direct your attention to the footnote quickly.

Footnote 1, can you read it? It's probably small. We'll try to bring it up.

A. I see it, yes.

Q. And footnote 1 says

"pomwonderful.com/cancer.html"?

A. Yes.

Q. Was that the URL of a Web site POM was using at this time, approximately 2007?

A. I assume it is, yes, or I assume it was.

Q. And so that would have contained -- would that Web site have included information on POM products with respect to cancer? Is that your understanding?

A. Presumably, yes.

Q. Were you also aware that Dr. Pantuck had stated publicly that he would not say that everyone who has prostate cancer or who is at risk for prostate cancer should be drinking pomegranate juice?

A. I don't recall that.

Q. Okay. Let's bring up CX 0087.

And do you have that in front of you, sir?

A. I do.

Q. And this is an e-mail from Mark Dreher to yourself as well as a number of other people, dated October 26, 2006, and the subject is CSPI - Review on Mangosteen/Noni versus POM Wonderful Juice.

And from the body of the e-mail it appears to be forwarding an article; is that correct?

A. Correct, it appears that way.

Q. And would you have read this e-mail and that

attachment at the time you received it?

A. I would probably have read it.

Q. Okay. If we turn to page 4 of this document, on the top right-hand side of the page, the first full paragraph, under where it says, "Pantuck cautions men against relying on pomegranate juice," do you see Dr. Pantuck's quote saying that "I'm not at the point where I would say that everyone who has prostate cancer or who is at risk for prostate cancer should be drinking pomegranate juice"?

Do you see that?

A. I do see that.

Q. And does that refresh your recollection as to whether you were aware of Dr. Pantuck's views at the time in --

A. No, it doesn't.

Q. Is it the position of POM that one POMx pill is equivalent to drinking eight ounces of pomegranate juice?

A. Yes. We believe that the active components, which are polyphenols, in one POMx pill, a one-gram pill, are equivalent to the active polyphenols in an eight-ounce glass of POM juice.

Q. And POM's advertisements for the POMx pills state that POMx is made from the same pomegranates that

are used to make the juice; correct?

A. Yes. I believe we say that.

Q. And don't some of the ads contain a graphic with a photo of the pill and an equal sign and a pomegranate juice bottle?

A. Yes, they do.

Q. And didn't the ads for POMx pills cite to scientific studies that had actually been performed on POM juice?

A. That's correct. Yes.

Q. So it was -- so POM believed that the studies that were done on the juice were relevant to the health benefits of the POMx pills as well; correct?

A. Yes. That's what we believe.

Q. Okay. Let's look at CX 0266.

And the first e-mail in the chain is an e-mail from Diane Kuyoomjian to various people at POM, and you are cc'd, dated January 12, 2009, and the subject is Re: New POMx Pills Ad.

Is that correct?

A. You're talking about the last e-mail in the chain?

Q. I mean -- well, yeah, I guess the most recent e-mail in the chain.

A. It appears so, yes.

Q. Actually what I'm interested in is the e-mail that starts on page 2 of this document, which I guess would be the first e-mail in the chain chronologically. It actually starts on page 2 and continues onto page 3, and it is from Diane Kuyoomjian to Lynda Resnick, and you are cc'd, January 12, 2009.

Do you see that?

A. I do see that, yes.

Q. Okay. What I'd like to do is turn to page 3 and look at the last bullet point of Ms. Kuyoomjian's e-mail to you.

Do you see where she says, "We" -- I'm sorry -- "Doing a prostate-specific ad for pills is a problem since the research to date is on juice. Matt agreed that it is too far to stretch that research to support an entire pills ad"?

Was it the case -- I'm sorry.

By "Matt" would Ms. Kuyoomjian be referring to you?

A. I would assume so.

Q. Okay. Was it the case that at the time of this e-mail you felt that it went too far to stretch juice research to support an entire pills ad?

A. No. I don't recall. And I don't believe that's true.

Q. Do you know what Ms. Kuyoomjian would mean by "an entire pills ad"?

A. I don't.

JUDGE CHAPPELL: How much more time do you think you need for direct?

MS. VISWANATHAN: Probably another hour and a half, if that.

JUDGE CHAPPELL: All right. We'll take our morning break, reconvene at 11:30.

(Recess)

JUDGE CHAPPELL: Back on the record.

Next question.

BY MS. VISWANATHAN:

Q. Mr. Tupper, we talked about -- we talked yesterday about how POM was able to, and generally, track whether particular pill ads generated more orders than others; correct?

A. That's correct.

Q. In fact did POMx pill ads that had more specific copy about medical studies generate more orders?

A. They may have. I don't recall specifically.

Q. If we could look at CX 266.

Actually if we could go to page 2 to the same e-mail we were looking at before the break. This is --

I'm looking at the bullet point at the bottom of page 2.

And Ms. Kuyoomjian do you see in the middle of that bullet point says: "We still have a choice about how copy dense/medically oriented the new ad should be. The current pills ad references the specifics of the prostate and cardio research. And you'll recall that a previous test ad with less copy did not generate as many orders"?

Do you see that?

A. I do.

Q. And does that refresh your recollection as to whether ads with more specific copy on medical studies would generate more orders?

A. Well, I take this at face value.

Q. I'd like to return to CX 1029. I have a few more questions on this document.

And I'd like to focus on page 13 of the document at this time.

And this is the section headlined Erectile Dysfunction/Sexual Function; correct?

A. Correct.

Q. And again if we focus on human studies, there is one published study, Padma-Nathan 2007 and 53 patients; correct?

A. Correct.

Q. And I think yesterday we had talked about there being one erectile dysfunction study on humans that you recall, and is this that same study?

A. This is.

Q. The results of the study are listed as POM equals 47 percent versus placebo equals 32 percent, and this represents nearly 50 percent improvement over placebo, and underneath that there is drug benchmarks which reports results for Cialis/Viagra in 200 to 500 patients, which represents nearly three times improvement over placebo; is that what that means?

A. I believe so.

Q. What was the purpose of including drug benchmarks in this chart with respect to erectile dysfunction?

A. I think the purpose was we were simply curious to see the -- a benchmark or a comparison against approved drugs for ED.

Q. And if we move to the bottom, the Where Do We Go From Here section, here there are only two end game scenarios, the first one being additional, targeted research for marketing, et cetera. And under Required Action for Each Scenario it says, "Explore one larger ED clinical study to achieve statistical significance and stronger marketing value."

What was meant by a larger ED study to achieve statistical significance and stronger marketing value?

A. I think it meant what it says here literally, that with a larger ED study, the p-value presumably would be less.

Q. Is it accurate that the Padma-Nathan study did not achieve statistical significance?

A. It just barely missed it, the p=.058. That's correct.

Q. Okay. And in row B, "No more clinical research," the assessment says "we already have a published clinical study," and then the bullet point also says, "However, the study has limitations: It was small (n=53) and just missed statistical significance."

And so that's what you're referring to when you said it was close to statistically significant but did not meet the standard?

A. Correct. A p-value of .05 or less means there's a 95 percent or greater probability of the results being not a matter of happenstance. In this study the likelihood is 94.2 percent, so just below 95 percent.

Q. And POM cited this Padma-Nathan study in its advertisements; correct?

A. I believe we did.

Q. By the way, are you aware of how the efficacy of

POM juice was measured in the Padma-Nathan study?

Well, were there questionnaires administered to the participants?

A. I believe yes.

Q. Do you know whether the authors used questionnaires that had been validated by prior research?

A. I don't.

Q. And so you don't know whether the result reported in the chart of nearly 50 percent improvement over the placebo reflects the results of a validated or unvalidated questionnaire?

A. I'm not sure.

Again, by "validated" I assume you mean the same questionnaires that would be used in -- as endpoints in approved drugs? Is that what you mean by "validated"?

Q. Well, not necessarily. I mean, it could be a valid -- validated to show -- I mean, I guess we'll have experts discuss what validation means.

Do you have an understanding of what it means to have a validated endpoint?

A. I do, but I believe it's relative to the -- again, the FDA drug approval process and whether a particular surrogate or test or measurement is used by

the FDA to approve drugs.

Q. Okay. So then based on your understanding of what "validated" means, do you know whether the result that was reported in this chart of nearly 50 percent improvement over placebo reflects the results of a validated or unvalidated questionnaire?

A. I don't know whether the questions that -- or the questionnaire that was relevant to this data -- I believe there were multiple questionnaires that were used. I don't know whether these are a questionnaire that's used by the FDA in approved drugs.

Q. Okay. Thanks. I'm actually finished with that document.

Okay. Mr. Tupper, it's fair to say that POM as a company is proud of the amount of money that it spends on its medical research; correct?

A. We believe that the amount of money that we have provided for research funding is quite unique actually in the world of foods and supplements, way beyond what anyone else that we're aware of has done. Yes.

Q. So it's one of the factors that distinguishes you from your competitors; correct?

A. Absolutely. Yes.

Q. So in addition to citing the results of specific

studies that we've seen in ads, POM has also advertised the amount of research it's funded in its advertisements; correct?

A. We have.

Q. And most recently haven't POM's ads talked about over $34 million in research?

A. I believe the actual total now is over 35. I don't remember what the last advertisement is.

Q. And in the past, have POM's ads, depending on the time frame, stated numbers like 20 million or 25 million or 32 million?

A. Correct.

Q. And POM's ads have actually used the specific phrase that its products are backed by 25 million or 32 million dollars in research, for example?

A. Yes. I believe "backed by" is a phrase that we've used.

Q. Does POM believe that the healthful products -- excuse me. Let me strike that, start again.

Does POM believe that the health properties of POM products are backed up by published research in peer-reviewed journals?

A. I'm not sure I understand your question. If you're asking -- and I think we may have talked about this yesterday. We have an entire body of science that

includes test tube, animal, clinical. It includes published research. It includes unpublished data. In its entirety, that produces the body of knowledge that informs our understanding of the benefits of POM.

Q. So you're saying when POM uses the term "backed by $32 million in medical research" in its ads, POM is referring to published research in peer-reviewed journals as well as nonpublished, nonpeer-reviewed research?

A. Yes. That's correct.

Q. Do you recall giving a testimony in a -- excuse me -- deposition testimony in a matter POM Wonderful versus Coca-Cola Company in December of 2009?

A. I do recall that.

Q. And do you recall giving the following testimony, starting at page -- I believe it starts on page 54:

"QUESTION: When you say 'backed up by science,' what do you mean by that term?

"ANSWER: Published research in peer-reviewed journals."

Do you recall that testimony?

A. I recall giving testimony. I don't recall that specific quote, but it sounds like something I might say.

Q. POM keeps a database or some kind of record tracking its cumulative medical research funding; correct?

A. We do.

Q. And would the information in that database be the source for any of the statements in advertisements that POM has funded X amount of medical research?

A. Yes.

Q. And as you just said, your understanding is, for the ads that state that POM products are backed by a certain amount of research, that all components of the research that POM has done is included in that figure.

So just to clarify, so that would mean the basic chemistry and chemical analysis research that we talked about yesterday?

A. That would be correct, yes.

Q. As well as in vitro and animal research?

A. Correct.

Q. And I guess yesterday we talked about research on livestock, I guess exploring livestock, the health of livestock.

Would that also be included in these figures?

A. Yes, it would.

Q. Is it also your understanding that the figures

used in the ads would include research studies that are still ongoing?

A. Yes. Those would be included as well.

Q. So by that I mean research that is not completed and there are no results yet. Correct?

A. That's correct.

Q. Would research that was done but that did not show an effect of POM on the study condition be included in this figure?

A. Can you be more specific what you mean by that?

Q. So, for instance, we -- earlier when we were looking at the research portfolio, we saw the Ornish study of 73 people which, according to the chart, did not show a difference in carotid IMT results.

Do you remember that?

A. That's the study where there was a difference, but the difference did not reach statistical significance.

Q. Right. And on the chart it was reported as no effect.

A. That's right.

Q. And so, for example, would the funding for that Ornish research also be included in the amount of medical research cited in the ads?

A. It would, yes.

Q. I'd like to go to CX 1276.

And this is a summary of medical research expenses that was produced to us by respondents in response to a discovery request. It's also PX 0367.

And because this was produced to us as an Excel file, the printout is going to be quite small. I apologize. But we'll enlarge sections of it on the screen, and if you need a particular section blown up, we can do that.

Do you know who Sarah Hemmati is?

A. Yes, I do. She's the chief financial officer at POM.

Q. Am I pronouncing her name correctly?

A. Yes.

It's H-E-M-M-A-T-I, first name Sarah, S-A-R-A-H.

Q. And as CFO of POM, would Ms. Hemmati have access to the financial information in the database of medical research that we've just discussed?

A. Yes, she would.

Q. And did Ms. Hemmati prepare these spreadsheets, to your knowledge?

A. That is my understanding.

Q. If we just quickly turn to page 3 of this document, at the bottom it will say "CX 1276_3."

There's three lines at the bottom that say

"sources." Do you see that?

We'll try to make it bigger for you as well.

A. Yes, I see that.

Q. And the last line says, "Comments provided by interviews with Matt Tupper and invoice reviews."

Do you see that?

A. I do see that.

Q. And so then looking at this spreadsheet, there's a column on the right that's entitled Comments.

Did you assist Ms. Hemmati in preparing the document by providing information for that comments field?

A. No. I believe the comments were actually done as a separate exercise, not in relation to this matter with the Federal Trade Commission but rather in an instance where we were doing some tallying of R&D relative to a California state R&D credit. We had to go through -- I had to go through and provide some comments on a subset of these studies.

Q. So I understand, so you're saying that it wasn't provided, it wasn't done specifically to create this spreadsheet, but at some point you had provided the information that -- to Ms. Hemmati that went into this comments field; is that correct?

A. I believe that is the case. Yes.

Q. Okay. Let's turn back to page 2, which is a -- several rows and columns of figures and the -- it's entitled POM Wonderful Medical Research Expenses. If you could to take a quick look at this.

Is it your understanding that this is a breakdown by year of medical research expenses for POM products from 1999 to 2010?

A. That is my understanding, yes.

Q. And there is a line at the -- the first line says "1988 Trust" and the second line says "POM Wonderful LLC."

Is it your understanding that the line "1988 Trust" refers to the Stewart and Lynda Resnick Revocable Trust that we talked about yesterday briefly?

A. I believe so.

Q. And that was the same trust that had entered into research agreements with some institutions; correct?

A. I think that's right. Yes.

Q. And from these figures would you agree that it appears the trust funded research from 1999 to 2007 and that POM Wonderful funded research from 2002 to 2010 on this chart, presumably until the present? Is that your understanding?

A. Yes.

Q. So at the very last column that says Total, the medical research expenses from the trust are approximately $11.4 million and the medical -- total medical research expenses from POM Wonderful is about $25.9 million; correct?

A. Correct.

Q. And so the grand total is listed as about $37.4 million; correct?

A. That's right. And just as a clarification -- make sure I don't want to -- I want to be clear on it -- this is -- there are some expenses here that this does not include.

Q. Okay. Are you referring to the additional research?

A. No. I'm referring to the costs associated with overseeing and managing the programs, so for example, the salaries of the people who, like, for example, Dr. Dreher, Dr. Gillespie, those who head it up, which had we outsourced the program we would have had to pay. To be conservative, we did not include those in these calculations, so this is a subset of the total expenditures over time.

Q. Okay. I understand.

And so this total of about $37.4 million, is that the basis for the figures in the ads that we were

talking about, whether it was 32 or 34 million dollars of medical research?

A. That's correct. What we've described in our communications is this subset that doesn't include the costs of managing the program.

Q. I see.

Okay. If you could turn to page 3 of this document.

Okay. The line at the top says "Schedule C financial developer of patentable products from agriculture (1988 Trust)."

So -- I'm sorry. Do you see that? It's very small.

A. I do, yes.

Q. Okay. Okay. So is it your understanding that this is a breakdown of the 1988 Trust's medical expenses that we just looked at in the previous chart?

A. It appears to be, yes.

Q. Okay. And so the -- it is broken down it appears by vendor, year and again the comments field that we talked about; correct?

A. That's correct.

Q. So if we focus more on the comments field, and we can just look at the first few.

For example, it says "prostate analysis and

evaluation of concentrate and seeds, product characterization and standards development."

Is this -- to your understanding, is this a description of what the particular medical research funding focused on? Is that the right term?

A. Not quite. I think this was -- again, the comments were developed in connection with an exercise to apply for some state R&D funding credits, and so they were in the context of whatever categorization was applicable at the time for that particular program.

Q. Well, in some cases the comment fields are blank.

Do you know why?

A. I don't.

Q. Okay. In some cases it just says "research" without any further elaboration.

A. Correct.

Q. Do you know why?

A. I don't recall why.

Q. Do you know whether POM's records would allow the company to specify, you know, whether -- more -- be more specificity about what those research projects were for?

A. I believe we could go back and say, you know, for any particular vendor what was the study, if that's

what you're asking me.

Q. Okay. But for some of these projects you were obviously able to provide some specificity already; correct? Like as we -- if we go further down, we can see there's some that say erectile function, cardiovascular, heart health; correct?

A. Correct.

Q. Are you the person at the company who would be most knowledgeable about the details of what these research expenses were for?

A. I would be knowledgeable on some, but for others it might be Dr. Gillespie, Dr. Liker, Dr. Dreher, whoever was closest to the study at the time.

Q. Okay. But you were knowledgeable enough to at least provide this level of information to Ms. Hemmati?

A. Correct. For the purposes of the R&D exercise.

Q. If we can turn to page 4, at the top this just says "POM Medical Research Expenses" and it goes on for two pages.

And is it correct that this is the breakdown of the medical expenses paid for by POM Wonderful as opposed to the trust?

A. Yes. It appears they both foot to 25.9 million, which is the same number.

Q. And this spreadsheet has similar breakdown by

vendor, year, grand total and comments; correct?

A. That's correct.

Q. And you provided Ms. Hemmati with information in this comments field as well; correct?

A. I think so. Yes.

Q. Do you agree that POM considered as medical research expenses overhead expenses such as research summit expenses?

A. We included research summit expenses, although those are not overhead expenses. Those are the meetings that we have with the scientific researchers to discuss data and chart a path forward, so that's a -- that is a very direct part of administering the program.

Q. Well, did POM also include trade show expenses under this?

For example, the very last row on page 4, it says "other 44,216 various including trade show expenses."

A. Correct, that's what it says. I don't -- as we sit here today, I don't know what the "other" includes.

Typically, though, we track -- if we go exhibit at a trade show, we track that in a separate category, though. That wouldn't be on this list.

Q. And I believe there's membership fees and member

contributions that's on the top half of the page. About the tenth -- I'm sorry -- the twelfth row down.

The --

A. Right. Where it says "American Herbal Products Association, American Society for Nutrition," is that --

Q. Yes, that's what I was referring to.

A. Yeah.

Q. And so those were also included in this spreadsheet of medical research expenses?

A. Yes. That's right.

Q. You just mentioned the -- you just talked about the research summits.

Are the -- and these were meetings with various scientists to discuss the state of the research on POM products; is that correct?

A. Correct. They would include researchers who had worked directly on studies that we were supporting as well as other researchers that we would bring in who weren't necessarily working on any studies, but we wanted to hear their points of view as well.

Q. And you participate -- excuse me.

You personally participated in those research summits; correct?

A. I did, yes.

Q. And did Mr. Stewart Resnick participate in those medical research summits?

A. I believe he did. Yes.

Q. And the expenses to the medical research summits would mean I guess the cost of flying in the scientists, et cetera?

A. Correct.

Q. So I guess to sum up my point, so this chart that's entitled Medical Research Expenses will include expenses that are not just directly funding a study; is that correct?

A. They include expenses which, yes, as you put it, are involved with a particular study, and they also include expenses associated with, in the case of the summit, bringing scientists together to review the research, so it's a mix of both.

Q. Okay. To the extent that there are research expenses categorized on here that have to do with specific areas or, for instance, the second one is -- it says "cold and flu," and we've already mentioned there are some that say "erectile function, heart health," et cetera, from this document can you tell whether that research that was done and funded was on humans?

A. From this document, no. It doesn't specify

whether a study was clinical or preclinical, for example.

Q. And this document also doesn't specify whether the research is ongoing or completed; is that right?

A. That's correct.

Q. And this document also doesn't specify whether the research has ended in a published paper either; correct?

A. Right. That's correct.

Q. And from this document you cannot tell whether the research results of the studies were positive, meaning that they showed that POM products had an effect; correct?

A. No. This database solely lists the recipient of the funding or the vendor, no additional details.

Q. Okay. So since this was basically an Excel spreadsheet, would you agree that one could use the comments field, use the description of comments and sort of sort all of the similar entries together?

So, for example, every entry that had a reference to heart health or cardiovascular, one could make a spreadsheet, you know, just sorting those together; correct?

A. One could, yes.

Q. Okay. And one could also use the information on

the spreadsheet to sort it by a vendor to see how much went to a particular vendor in research funding; correct?

A. Correct.

Q. Okay. So we've actually done that and we've created some demonstrative spreadsheets based on the information that POM provided to us in CX 1276.

So in the back of your book there's a tab that would say "1988 Trust Categories"; is that -- do you see that?

A. I do.

Q. Okay. That's what I want you to turn to now.

And just by way of explanation, as you take a look at it, if -- this document, Categories from 1988 Trust, we've taken information from the spreadsheet that we were just looking at entitled 1988 Trust, and we've attempted to break down the expenses per the comments field and tried to group them together.

So if we just look at the top, the first category contained all the entries we could find that referenced cardiovascular, heart health, circulation, et cetera, the second group included anything that referred to erectile dysfunction, and the third anything that referred to prostate or prostate cancer.

And do you see that the total -- and -- I'm sorry.

Do you see that? Do you understand what we've done?

A. I think so.

Q. Okay. And by breaking out these particular categories, I mean, you also agree that we can -- we've -- each one was associated with a particular total from the 1988 Trust spreadsheet, and so all we've done is added up subtotals for those three particular categories which I'm focusing on there.

A. I think I understand that.

Q. Okay. So -- and so would you agree that just based -- basing it on the comments field that you provided to Ms. Hemmati, for the 1988 Trust, the subtotal spent on research expenses related to or identified as cardiovascular is approximately $6.4 million?

Do you see that?

A. I see that.

Q. Okay. And then moving to erectile dysfunction, the subtotal for medical research expenses provided by the trust that were identified as erectile dysfunction amounts to about $516,000; is that correct? Is that what the chart says?

A. Yes, that's what it says.

Q. Okay. And finally for prostate, for medical research expenses that were from the 1988 Trust that were identified as prostate or prostate cancer, the total is approximately $2.7 million.

Would you agree that's what it says?

A. Yes.

Q. And do you have any reason to quibble with the figures?

A. No. Only to the extent that, again, the comments were done in a very different context and with a standard that was appropriate to that R&D exercise, and so there's a few things here that are uncategorized, other things that are -- may in fact have had multiple endpoints in the study and we indicated them one way or the other, but taking the comments at face value, I assume the math is correct.

Q. Okay. And just to look at this first page more specifically, the focus on the first -- the top part that says "cardiovascular heart health" -- excuse me -- "heart and circulation, heart health," on the left it says "row 34" and the subcategory vendor is Radiant Research, and the total is about $2.4 million.

Do you see that line?

A. I do, yes.

Q. Does this funding from the 1988 Trust -- is that related to the Davidson study, the IMT study that we discussed earlier?

A. I believe it would be. The dates look about right.

Q. Okay.

A. We've used Radiant for other studies as well. I don't see them here. But that sounds about right.

Q. And then moving down to the entries for erectile dysfunction, the first entry under Erectile Dysfunction, it says "Row 12, Boston VA Research Institute," and that's approximately $267,000 identified as ED.

Do you see that?

A. I do, yeah.

Q. Do you know whether that was for a human study on erectile dysfunction?

A. No. I believe that was for the preclinical work that Dr. Azadzoi and some of his colleagues did.

Q. And row 20, Essentials Group, Inc., which is $248,000 approximately, is that referring to a human study?

A. Yes. I believe that -- I believe that specifically refers to Dr. Padma-Nathan's --

Q. The published --

A. -- study.

Q. -- human study we talked about.

Okay. And then moving to the prostate section, which is row 7 -- I'm sorry -- prostate section, the first entry, row 7, the vendor is a company called Agensys, Inc.; correct?

A. "Agensys."

Q. "Agensys." Okay.

Did the Agensys research result in a published paper on prostate?

A. I don't know if there are any publications coming out of that. That was the very early-on research into prostate cancer that ultimately led us to move forward into other preclinical and clinical work.

Q. Okay. So that was preclinical; is that how you described it?

A. I believe it was. Yes.

Q. Okay. And under Prostate there are several other vendors, but I just wanted to confirm. Would one of these vendors and the amount spent represent the funding for the Pantuck prostate study that we were talking about earlier?

A. Assuming that money came from the '88 trust entity, presumably, yes.

Q. And do you know which one would it be? Would it...

A. It is probably -- well, there's two UCLA.

Q. Right, right.

A. And one or both or some combination.

Q. And so let's move on to a second demonstrative exhibit that we created, and it will probably say "Categories from POM Detail"? Is there one listed?

A. There is.

Q. Okay. And so essentially what we did was we did the same thing for POM, the POM spreadsheet, as we did for the 1988 Trust spreadsheet.

And so here, one can do a similar breakdown by category again based on the comments field that you described, and I understand that you said the comments field might not be entirely complete.

Are you -- okay. Do you see what I'm referring to on page 1?

A. I've got the exhibit, yes.

Q. Okay. Okay. And so here, if we look at the cardiovascular section, the subtotal that was funded by POM that was identified in the comments as heart health or cardiovascular amounts to approximately $2.9 million; is that fair to say?

MR. GRAUBERT: Your Honor, may I just have an objection. The witness has been doing a terrific job trying to answer these questions, but to the extent that

he's being asked to vouch for work that the Federal Trade Commission has done which he's had no opportunity to review, I object to any suggestion that he's vouching for any of the accuracy of any of that information.

JUDGE CHAPPELL: First of all, I'm going to need all you people at that table to talk about this before a witness takes the stand. I'm not going to allow tag-team objections.

MR. GRAUBERT: I understand.

JUDGE CHAPPELL: Ms. Diaz has been objecting for this witness.

MR. GRAUBERT: Yes, that's correct. I'd be happy to defer --

JUDGE CHAPPELL: So you need to talk to her and restate the objection through her. I'm just not going to allow -- it's not fair to have all of you people jumping up.

MR. GRAUBERT: I understand. That's correct.

(Pause in the proceedings.)

MS. DIAZ: Your Honor, we do object to the general line of questioning, suggesting, asking him if he quibbles with the figures, with the categorizations. There is no -- obviously on its face there's no reasonable bases for this witness to have any kind of --

I'm sure he doesn't have a calculator with him -- any kind of ability to vouch for the figures, for the categorizations, certainly not at this time, Your Honor. That's the extent of our objection.

JUDGE CHAPPELL: Lack of proper foundation?

MS. DIAZ: Lack of proper foundation.

JUDGE CHAPPELL: Any response?

MS. VISWANATHAN: Okay. We can represent that -- you know, we'll represent that this came from information they provided to us. We're not going to ask him to necessarily agree that these are correct figures.

JUDGE CHAPPELL: I believe I heard that it's FTC information.

MS. VISWANATHAN: Well, the information was created by the FTC from the spreadsheets that were provided.

JUDGE CHAPPELL: Then you're probably going to have to talk to whoever created the spreadsheet if you want evidence on a document you created.

MS. VISWANATHAN: Your Honor, this is a demonstrative exhibit that we provided to counsel on Monday, and we're not necessarily -- I mean, what we're trying to do is just take what the respondents have provided to us and show that it can be broken down.

JUDGE CHAPPELL: Then you'll need to lay a proper foundation that this witness knows what you're talking about, that this witness had anything to do with the figures you used to develop whatever this is you're referring to. The objection at this point is sustained.

MS. VISWANATHAN: Okay.

BY MS. VISWANATHAN:

Q. Well, for -- okay. Well, perhaps it would help if I would match it up with the spreadsheet that was provided to us from POM.

If we look at the POM detail, demonstrative that we were just looking at -- okay.

And do you see at the top there is -- at the cardiovascular section there's a line that says "Cargem SRL," C-A-R-G-E-M-S-R-L.

Do you see that?

A. Which exhibit are you on? I'm sorry.

Q. Actually first I was looking at the --

JUDGE CHAPPELL: Hold on a second.

Did I hear you say this is a demonstrative that FTC created?

MS. VISWANATHAN: Yes.

JUDGE CHAPPELL: You're not going to be able to use Mr. Tupper to -- I don't know -- authenticate a

demonstrative that the FTC created. That's an improper line of questioning. You need to figure out how to do this or move on.

MS. VISWANATHAN: Okay. Can I have a moment, Your Honor?

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MS. VISWANATHAN: Actually -- okay. I think I'll actually just move on.

JUDGE CHAPPELL: Thank you.

BY MS. VISWANATHAN:

Q. I want to show you an ad that's CX 0274.

This is an ad that I guess the headline is "I'm off to save prostates."

And do you see that at the -- in the body copy it says, "Powered by pure pomegranate juice... backed by $25 million in vigilant medical research"? Do you see that?

A. I do see that.

Q. And so just to be clear from the spreadsheets that were produced by POM, the $25 million in vigilant medical research did not all go to prostate health; correct?

A. Correct. The $25 million is the entirety of our research portfolio.

MS. VISWANATHAN: Okay.

Excuse me, Your Honor. May I have one moment?

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

BY MS. VISWANATHAN:

Q. Do you have any knowledge of what percentage of the total medical research expenses went to prostate specifically?

A. No. We don't track our spending in that fashion.

Q. And we've already said that when POM advertised that its research -- or that its products were backed by or supported by 32 or 34 million dollars, it did not subtract research that was negative; correct?

A. I'm not sure what you mean by the word "negative," so I'll just simply say that, as I said before, that the amount that we reported, which is intended to show our deep commitment to science, reflects the entirety of the funding that we've provided cumulatively over time.

Q. Can I show you -- I'm sorry. Can you turn to CX 0251.

And this is an ad, its copyright 2008, with the headline "Imitation may be sincere. But is it pure?" And at the bottom copy it says, and, perhaps most

importantly, the only one that's backed by $25 million in published medical research."

Do you see that?

A. I do see that.

Q. Did POM actually have $25 million in published medical research as of 2008?

A. No. I don't believe we did. I believe this was a mistake.

Q. Is it POM's belief that the medical research done on POM has been akin to that done on pharmaceuticals?

A. I believe I've used that statement before myself. Yes.

Q. And isn't it the case that you've stated that it isn't until you see an effect in humans with measurements that are medically meaningful that you know you've got a health benefit; correct?

A. That sounds familiar. Yes.

Q. Okay. And isn't it true that you've said that it's fine to say that a product works as an antioxidant in a test tube, but that's just scratching the surface?

A. I believe I provided a quote like that in connection with a comparison to some other products on the market. Yes.

Q. And did you say that was on the Web site, POM's

Web site, that quote?

A. I don't know where that appeared. I'm sorry.

Q. Okay. As president of POM, did you stay aware of what was being said about POM in the media?

A. Yes. I try to.

Q. And that would include articles written about POM products; correct?

A. Correct.

Q. And that would include things that might have been posted on the Internet like blogs; correct?

A. Correct.

Q. Okay. Let's turn to CX 0271.

And this is an e-mail from you to Jeff Rushton, dated January 26, 2009, Subject: Forward: The delicious juice that actually clears your arteries.

And who is Jeff Rushton?

A. Jeff was a member of POM's marketing team, and he headed up our Web site and online marketing group.

Q. And did you write the line at the top that says, "FYI - good blog"?

A. Looks like I did. Yes.

Q. And the e-mail text, is that some or all of the blog copy that you were referring to?

A. Yeah. It appears that I pasted both the Internet link for the blog and then all or a portion of

the -- some of the text on that blog.

Q. Okay. So this would be what the blog said at the time that you cut and pasted it; is that right?

A. Presumably.

Q. Okay. And is it fair to say that this blog is describing a well-designed placebo-controlled study about arterial plaque and POM pomegranate juice?

A. Yes. That's right.

Q. Do you know which study was being referred to in this blog?

A. I would assume it's the Aviram study, but it doesn't reference specifically, so that's just a guess on my part.

Q. Is it accurate that -- if you can see I guess the fifth paragraph of the blog, is it accurate that the Aviram study -- in the Aviram study half the patients drank a shot glass per day of pomegranate juice, 1.7 ounces to be exact?

A. I don't really know. I think it was that amount of concentrated pomegranate juice, which is the equivalent of an eight-ounce glass, but I don't believe they literally took it out of a shot glass.

Q. So they actually drank eight ounces of pomegranate juice a day; correct?

A. Actually I don't recall whether they drank

full-strength pomegranate juice or the concentrate, but regardless, it's the same, the same amount of active.

Q. And did the -- do you know whether the Aviram participants who did not drink pomegranate juice, did they drink an equal amount of pomegranate-flavored water or did they drink nothing?

A. I believe they drank placebo.

Q. By the way, the blog also makes a reference about pomegranate juice prevents arterial plaque. That's in the end of the third paragraph.

Do you see that?

A. No. Where is that again?

Q. Do you see the paragraph that starts, "That's right, pomegranate juice"?

A. Got it. I see that.

Q. Okay. And then the last line of that one and the first line of the next paragraph, do you see that?

It says "it turns out that pomegranate juice does more than just prevent arterial plaque."

Do you see that?

A. I do see that.

Q. Does POM have human studies showing that drinking the juice prevents arterial plaque?

A. Well, in -- again, go back to the Aviram study. There was actually a regression seen, so not just a

slowing of the buildup, but in that particular study the plaque actually receded.

Q. So that was -- that statement would be supported by the Aviram study; is that what you're saying?

A. Again, I assume that he's referring to the Aviram study and the -- again, there were patients in that Aviram study I think on average actually that the plaque receded.

Q. So was it the blog statement that pomegranate juice does more than just prevent arterial plaque, it actually gets rid of existing plaque is what you considered to make it a good blog?

A. I think the reference to good blog was it was good to see people getting the word out about the science behind POM.

Q. So you did not feel that the description of the study was inaccurate in any way?

A. I can't comment on that. I mean, it looks like they've restated the results of the Aviram study at least in part.

Q. Does POM get comments from consumers via mail or e-mail or phone calls?

A. We do, yes.

Q. And does POM keep track of those comments and

any responses that are sent out on behalf of the company?

A. Yes, we do.

Q. And does POM look at those consumer comments to try to understand what's on its customers' minds?

A. We do, yes.

Q. And POM actually keeps a database of these consumer comments; is that right?

A. We do file them away.

Q. As president of POM, do you have access to the records of consumer comments?

A. I can get access to them. Yes.

Q. Do you also -- strike that.

Do you get summaries of weekly correspondence activity with consumers?

A. Sometimes I do. Yes.

Q. Okay. I'm going to show you a document that's been shown. These are excerpts from the consumer correspondence and POM's responses to those consumers.

The first one is CX 0454.

And have you seen this document before in another proceeding?

A. I have, yes.

Q. Okay. What I'd like you to do is turn to page 9 of this document.

And there -- I guess there's an ID number that says "24479" which I assume corresponds to the record.

Do you see that?

A. I do.

Q. It starts on -- it starts on page 9 of this document and it continues onto page 10.

Okay. And so this is correspondence from a consumer who appears to have a concern about the -- some imagery in an ad called "Cheat death."

Are you familiar with that ad?

A. I am familiar with the ad, yes.

Q. Okay. And this -- the date on these appears to be April 6, 2010. Next to it there's a date April 7, 2010.

And the last column is a response from POM Wonderful Consumer Affairs; is that correct?

A. Correct.

Q. Okay. In response to the consumer's concern, in one of the paragraphs POM's response states that POM Wonderful has many distinct health benefits that set it apart from other products, as supported by 50 published scientific and medical research studies, many of which have focused on the cardiovascular system and prostate.

Do you see that?

A. I see it. I was trying to read the consumer's concern first just so I understand the context here.

(Pause in the proceedings.)

Thanks. I wanted to read the consumer comment.

I'm sorry. What was your question?

Q. My question is: There's a paragraph from -- a response from POM Wonderful stating, in the second paragraph, that "POM Wonderful pomegranate juice has many distinct health benefits that set it apart from other products, as supported by 50 published scientific and medical research studies, many of which have focused on the cardiovascular system and prostate," so would that answer have been provided by an employee of POM Wonderful?

A. That's correct, yes.

Q. And was there a particular person who was charged or responsible for responding to these consumer comments?

A. Yes. We have a dedicated consumer affairs person.

Q. Okay. Okay. So the -- as the -- the date on this response appears to be April 7, 2010, and there's references to 50 published scientific and medical studies.

These were not all clinical studies on humans;

correct?

A. That's correct.

Q. And do you have any sense of what percentage of those 50 studies are actually referring to cardiovascular system or prostate?

A. I would have to give you a guess. I don't know that number.

Q. I'd like to show you another consumer comment and response. It's CX 0455.

And I'd like you to turn to page 10 of this document. At the bottom it will say "CX0455_0010."

And this is -- the report number is 19712 and there's a -- I guess a consumer inquiry regarding antioxidants.

I wanted to point you to the response from POM specifically, which in the first paragraph, the last sentence -- the last two sentences, says: "Unbiased clinical trials have proven that pomegranate juice is effective in the treatment of prostate cancer, arterial plaque and many other health issues."

Do you see that?

A. Yes, I do see that.

Q. Do you know what the basis is for the POM representative to make a statement that clinical trials have proven that POM juice is effective in the treatment

of prostate cancer?

A. I believe that in this response she was referring to again the body of trials on those areas in particular.

Q. Okay. So the studies that POM had at the time as of March 6, 2009?

A. Correct. That's when the response was written.

Q. And that would be the same for the basis for the statement that POM juice is effective in the treatment of arterial plaque?

A. I'm sorry. What was your question?

Q. And the same basis -- I'm sorry.

So -- and -- let me rephrase.

Okay. So the basis for the representative's statement that clinical trials have proven that POM pomegranate juice is effective in the treatment of arterial plaque would also be the -- all the studies that had been done up until that point, March 6, 2009?

A. Correct. I think she was referring to the body of research that existed at that period of time.

Q. Okay. If you look further up in the representative's response, it says POM Wonderful has spent $25 million researching the health benefits of its juice. It says that "The findings are all available on our Web site: www.pomwonderful.com."

Would the basis for that $25 million figure have been the spreadsheets that we looked at earlier that were provided by POM?

A. The same source of data would have been used, yes, not those spreadsheets because they were from 2010, but the same methodology.

Q. The medical research database --

A. Correct.

Q. -- we talked about?

When it says, "The findings are all available on our Web site," were the findings of all research published and unpublished available on POM's Web site?

A. The -- the Web site contained the published findings. In some cases we had some unpublished data, but that was quite rare. It was mainly the published research.

Q. Okay. And just a couple of more consumer issues.

Could you please look at CX 0456.

And if we look at page 2 of this document, I'd like to direct your attention to the question and response at ID number 18493.

Okay. And it appears that the consumer's inquiry again has to do with the "Cheat death" ad, but what I'm interested in is the response from

POM Wonderful in which it says, the representative says, that it, the juice, has many distinct health benefits that set it apart from other products, and recent medical research supports an acknowledgment that drinking pomegranate juice may lessen factors that contribute to heart disease.

Do you see that?

A. I do see that, yes.

Q. And then it also goes on to say that heart disease is the number one cause of death in the United States.

Do you know what recent medical research in approximately November of 2008 that the POM representative is referring to?

A. Again, I believe she would be referring to the body of research on POM and the cardiovascular system in its entirety.

Q. And at that point in 2008 POM was aware of Dr. Davidson's results; correct?

A. Yes. Definitely.

Q. Just one more. On page 8 of this document.

Okay. I'm referring to the question and answer that starts on the bottom of page 8 and goes onto page 9. It's report number 24469 --

A. Actually just -- I'm sorry to interrupt. But

to clarify my last statement, we were definitely aware of the Davidson results and interpreted them and believed them to be supportive of the entire body of research that had gone before it, just to be clear on that.

Q. Fair enough.

And have you had a chance to look at this question and answer yet?

A. This is 24469?

Q. 24469 on page 8 and continuing onto page 9.

Actually, I'm sorry. It actually continues onto page 10, so it's a two-page --

A. It's a long one.

Q. Yeah, it's a long one.

(Pause in the proceedings.)

A. What is your question on this?

Q. Okay. Well, this is an inquiry from I guess a consumer concerned about heart health because she's had a heart attack, and the -- what I wanted to point you to is the response that's on page 9 and 10. And it appears that Ms. -- excuse me -- Dr. Gillespie himself as POM Wonderful's chief scientific officer responded to the woman's concerns; is that correct?

A. That's right, Brad responded to this.

Q. So in some cases POM Wonderful's consumer

affairs advocate would refer questions to other people at POM for response?

A. Yes. That's right.

Q. Okay. Okay. And -- gosh, if we're starting from the bottom of page 9, the response, the second to last paragraph that starts, "Regarding your question about arterial plaque," do you see that?

A. I do, yes.

Q. And it's also referring to the 2004 publication by Dr. Aviram.

Do you see that Dr. Gillespie states, to the consumer, "This study enrolled older patients with severe plaque buildup. Therefore, the results observed in this population may not represent all patients"?

Do you see that?

A. I do, yes.

Q. Do you agree that the results observed in the Aviram study population may not represent all patients?

A. I do, yes.

Q. Okay. And then the last line that Dr. Gillespie says is: "It is difficult to estimate the long-term effect of pomegranate juice based on this limited sample size."

Do you agree that from Dr. Aviram's study it is difficult to estimate the long-term effect of

pomegranate juice based on the limited sample size?

A. No. I believe that this statement from Dr. Gillespie is actually in response to -- the consumer asked the question, "If people's arterial plaque was decreased by 30 percent in one year, does that mean after about three years and four months it would be all gone and your arteries would be clean as a whistle?" I think he was responding to that statement specifically.

Q. Sure, I agree. But when he's talking about the limited sample size, in the previous section he was referring to the fact that the Aviram study followed ten patients for one year and five patients over three years; correct?

A. That's correct.

Q. But as we've discussed, POM has used the Aviram study in its advertising since it came out essentially in 2004; correct?

A. We have, yes.

Q. The consumer advocate who responds to these inquiries, does that person have access to FAQs or guidelines to use in responding to questions?

A. In a manner of speaking, they do. We have a -- we collect the responses that we've developed over time and keep those handy for the person to refer back to

when necessary.

Q. Yeah. And to be clear for the record, by "FAQs" I meant frequently asked questions.

Who prepares that set of responses that you just talked about?

A. Well, it's done on a case-by-case basis.

So in other words, a consumer inquiry will come in that we've never received before, and so it's a blank slate and we need to develop a new response, and either the consumer advocate will know the answer and be able to craft a new response because it's fairly straightforward, or if it involves information which she's not familiar with, she'll go to the correct person at POM, so Dr. Gillespie could be the example, craft the response, and then it becomes part of the historical database.

Q. And would you ever have input in terms of the responses that would be sent to consumers?

A. I very well may. And then from time to time we'll go back and do a review of responses that we've used in the past to make sure that we feel comfortable with those.

Q. Okay. Did you ever become aware that NBC broadcast network declined to accept POM ad claims because the testing was considered inadequate?

A. I am aware of an NBC TV discussion, but I thought that the issue was that we were proposing to use an ad where there was a character dressed in a white lab coat, and that's something that you can't do.

Q. Okay. Let's go to CX 0193.

A. I see the exhibit.

Q. Yeah, the -- it's an e-mail thread, but the very first e-mail is from -- or the latest e-mail is from Mark Cregar to yourself, dated May 6, 2008. The subject line is Forward: Revised POM Wonderful spot.

So was this an e-mail you received from Mr. Mark Cregar?

A. It appears so. Yes.

Q. And who was Mark Cregar?

A. Mark was the vice president of marketing at POM.

Q. At the time in 2008?

A. That's right.

Q. And so you would have received the rest of this e-mail thread as well since this was forwarded to you; correct?

A. It looks that way. Yes.

Q. If we look on page 3 of this document, it's an e-mail from Jake Sugarman to -- I guess her name is Anca Cornis, C-O-R-N-I-S, slash -- or hyphen Pop, P-O-P, at NBC Universal.

Who -- do you know who Jake Sugarman is?

A. I believe he is someone who works in the creative agency.

Q. And so since this e-mail was forwarded to you, were you aware that POM was seeking to use the line in an ad "Pomegranate contains powerful antioxidants needed to promote prostate and heart health"?

A. No. I don't recall that because we -- we did run a TV campaign in 2010, and I know we thought about running one in 2009. This is from 2008.

Q. Uh-huh.

A. So I -- this -- I don't remember what this campaign was or would have been.

Q. Okay. So if you look on page 2 of this document, in the middle of the page there's an e-mail that says 5-6-08, May 6, '08, from Ms. Cornis-Pop at NBC, and do you -- have you located that?

A. I see that. Yes.

Q. Okay. And would you agree that the NBC representative is stating that the prostate health claim is not adequately documented based on the study that was sent to her?

A. I see you're talking about the last sentence.

Q. Uh-huh. Yes.

A. I see that.

Q. And then if we go back to the first page, Mr. Cregar, who had sent you an e-mail, notes that he's calling -- he's letting you know that he's calling NBC with Mark Dreher in five minutes to provide rationale for the first choice of your ad claim, "Pomegranate contains powerful antioxidants to promote prostate and heart health," and he said he'll call afterwards to follow up.

Do you recall the follow-up from Mr. Cregar?

A. I don't.

Q. But you would have received this e-mail and read it at the time?

A. This e-mail here that -- the exhibit?

Q. From Mr. Cregar to yourself.

A. I assume so. Yes.

Q. And so at the time, you would have been aware that NBC was -- had a problem with the claim based on the science; correct?

A. I assume so. Yes.

Q. POM received a letter from the FTC in early 2008 raising questions about POMx; correct?

A. I believe that's right.

Q. And after receiving the letter from the FTC, did you have any discussions with your marketing team about changing your advertisements?

A. As I said before, we're -- we have an ongoing dialogue regarding what we advertise and how we advertise it and what our body of science looks like, so we're doing that all the time and we factor in those discussions whatever information we have at the time.

Q. Okay.

A. But I don't recall specifically that, if that's what you're asking me.

Q. And POM also received a warning letter from the FDA in February 2010 regarding health claims being made on its Web site; correct?

A. That's correct.

Q. And is it also the case that POM made no specific changes to any of its Web sites as a result of the FDA warning letter?

A. Similar to what I said before, we're always evaluating. With respect to our Web site, the Web site changes every day. We make and -- we think about changes and we make changes in response to not just one particular piece of input or information but rather the entirety of the discussion that goes on at the time.

Q. Okay. Is it -- isn't it true that you don't believe that POM was making any claims prior to receiving the FDA warning letter, which is why POM has not withdrawn any or modified any of its advertising

since receiving the FDA's letter?

A. I'm sorry. Is that a statement that I've made in the past?

Q. Yes.

Do you recall testifying to that effect at your deposition in the Tropicana matter?

A. I don't recall those specific words. Obviously I did give a deposition in that case.

Q. You said before that health is one of the top reasons, often the number one reason why consumers buy POM juice; correct?

A. Yes. We believe that people consume POM juice because it is extremely healthy. Correct.

Q. And you've been quoted in a newspaper article as saying, about POM juice, "It's not just for refreshment; it's literally medicine"; correct?

A. I think that's a statement that I've made before. Correct.

Q. And in the interview we referenced yesterday on the Fox News or the Fox Business channel, in that interview, didn't you say that with pomegranate the dose that's been shown to be effective is eight ounces a day?

A. I believe I said that in response to a very specific question, which was the anchor -- and I think

you played it at the beginning of the trial -- saying is this one of those products where you need to consume like, you know, a million pounds. I think at the time there was some research that had come out on like watermelon and watermelon rind or whatever, you know. There's a benefit, but you needed to consume eight times your body weight or something.

So my response was, you know, the research has been done -- I think I did use the word "dose" -- of eight ounces as opposed to literally tons.

Q. And POM's ads instruct consumers to drink eight ounces of juice per day or take one POMx pill a day; correct?

A. Correct. We try to be consistent with what the research studies have used.

Q. And POM's ads have referred to POM juice as "good medicine"; correct?

A. That sounds familiar.

Q. Actually we can show the ad because I have a question on it. It's CX 0471 and it's page 28.

Only one page there. Okay.

And this is an ad with the headline "Drink to prostate health," and the first line of the ad copy is: "Sometimes, good medicine can taste great"; correct?

A. Correct. That's the first sentence in the body

copy.

Q. Okay. Do you recall testifying at a trial in the matter of POM versus Tropicana juice in November 2010?

A. I do recall that testimony.

Q. And in that case while you were on the stand do you recall being shown this advertisement?

A. I don't recall that, but...

Q. Well, do you recall --

A. I have no reason to dispute it. When you're up on the stand, it's not like sitting in your own living room.

Q. Sure. I can understand. We're almost done.

A. Thank you.

Q. Do you recall your own attorney at the Tropicana trial characterizing this ad as one that deals with prostate cancer?

A. No, I don't recall that specifically.

Q. Well, do you think -- I mean, do you consider this ad to deal with prostate cancer?

A. Well, the ad discusses the results of a clinical trial in which the -- as it says here, the men in the clinical trial had been diagnosed and treated for prostate cancer.

Q. Okay. And you also testified that as president

of POM Wonderful you felt comfortable allowing this ad to be aired to the public because there's a vast body of published research that speaks to the benefits of POM juice relative to prostate. Do you recall that?

A. Absolutely. And I do believe that.

Q. Okay. And there's one published study on POM and prostate cancer in humans, as we've discussed currently; correct?

A. Yeah. In addition to many others in various preclinical models.

Q. And as we discussed, one prostate cancer study in humans that's discussed in this ad was open label and not placebo-controlled; correct?

A. That is correct.

Q. And it used an endpoint that was not accepted, according to the author, as showing a clinical benefit for prostate cancer; correct?

A. Well, as I said before, the frame of mind and the framework that he had in his mind I believe was relative to the FDA and drug approval endpoints.

Q. Okay. So we've heard some testimony in this trial about POM's ads were meant to be humorous in some ways.

Do you agree with that?

A. I do.

Q. Okay. I'd like to just show a couple more ads.

MS. DIAZ: Your Honor, if I may, I'm concerned that the witness might be getting tired. It is 1:00.

JUDGE CHAPPELL: I'm concerned that we're going to go until this direct is over. Then we'll take a break.

MS. DIAZ: Thank you, Your Honor.

JUDGE CHAPPELL: Is that okay with you, Mr. Tupper?

Proceed.

MS. VISWANATHAN: I've got less than five minutes. I'm sorry.

BY MS. VISWANATHAN:

Q. If we could look at CX 0192. And actually CX 0033. I wonder if we can put them on a split screen to make this go a little quicker.

So one of these is an ad that we've called the bikini ad, and it's obviously a POM bottle that's in a bikini top. Another one is a POM bottle that looks like it's an IV drip.

So are these ads that POM considers to have a humorous element to them?

A. Well, I think there's a bit of irreverence that I would characterize. I don't know if the word "humorous" would be a word that I would choose, but

there's certainly a personality.

Q. Okay. Okay. But I guess even if the -- I guess the imagery would be somewhat lighthearted. There's -- the description of POM's health benefits in the body copy is a serious message; correct?

A. We're discussing the health benefits of the product, the research, our commitment to the research. That's correct.

Q. Yeah.

So if we're -- some of these ads reference heart disease, Alzheimer's, cancer, I mean, these are obviously serious conditions; correct?

A. That's correct.

Q. So those discussions aren't meant -- those descriptions are not meant to be lighthearted or irreverent; correct?

A. The imagery and the headlines are the irreverence in that they grab your attention. The body copy is I guess factual.

Q. So the company wants the consumers to take the health benefits message quite seriously; correct?

A. We believe it's a serious message. It's up to the consumer to decide, but we certainly believe it's important.

MS. VISWANATHAN: Okay. I have nothing further.

Thank you.

JUDGE CHAPPELL: That concludes your direct exam?

MS. VISWANATHAN: Yes.

JUDGE CHAPPELL: Okay. We'll take our lunch break. We'll reconvene at 2:10.

(Whereupon, at 1:08 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(2:14 p.m.)

JUDGE CHAPPELL: Back on the record Docket 9344.

Cross-exam?

MS. DIAZ: Yes, Your Honor.

JUDGE CHAPPELL: Proceed when ready.

- - - - -

CROSS-EXAMINATION

BY MS. DIAZ:

Q. Mr. Tupper, I just have a few follow-up questions.

Isn't it true that most, if not all, of the science conducted by POM Wonderful is interrelated?

A. Yes, it is.

Q. So, for example, the science related to erectile health is rooted in the same basic mechanisms of action at play in prostate health; isn't that true?

A. Correct.

Q. And the basic underlying mechanisms of inflammation and oxidation apply across areas of science and different areas of human health; correct?

A. Correct.

Q. And so in connection with the cattle studies that you mentioned earlier today, the control mechanism at play in those studies -- excuse me -- the central

mechanism at play in those studies was inflammation, wasn't it?

A. Correct.

Q. And inflammation and oxidation are the same central mechanisms at play in human prostate health; correct?

A. Correct.

MS. DIAZ: Okay. Thank you, Mr. Tupper.

No further questions.

JUDGE CHAPPELL: Any redirect based on that cross?

MS. VISWANATHAN: No, Your Honor.

JUDGE CHAPPELL: Thank you, sir. You're excused.

Call your next witness.

MR. WONE: Good afternoon, Your Honor.

JUDGE CHAPPELL: Good afternoon.

- - - - -

Whereupon --

ARNOLD MELMAN, M.D.

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. WONE:

Q. Dr. Melman, could you please state and spell

your full name for the record.

A. It's Arnold Melman, M-E-L-M-A-N.

Q. And were you asked by the FTC to provide your expert opinion in this case, Dr. Melman?

A. Yes.

Q. Dr. Melman, there's a binder next to your seat. If you could please open that binder and go to what's been marked as CX 1289.

Dr. Melman, is this a copy of the expert report that you prepared in this case?

A. Yes.

Q. And if we could turn to what's been marked as CX 1290, your CV, which is within -- which was Exhibit A to your expert report.

Do you see that, Doctor?

A. Yes, I do.

Q. And is this your curriculum vitae that was part of your expert report?

A. Yes.

Q. Dr. Melman, where did you attend college?

A. At the City College of New York.

Q. And you graduated from the City College with honors, Doctor?

A. Yes.

Q. And after you graduated from college, where did

you attend medical school?

A. At the University of Rochester.

Q. And after graduating from medical school, where did you do your internship and your residency?

A. At the same institution, at the Strong Memorial Hospital in Rochester.

Q. And after completing this residency at Strong Memorial, where did you work, Dr. Melman?

A. After that, I was in the Public Health Service in the National Institutes of Health in Baltimore from 1968 to 1970.

Q. And after --

JUDGE CHAPPELL: Hold on. Hold on, please.

MR. WONE: Okay.

(Pause in the proceedings.)

BY MR. WONE:

Q. You then completed another residency, Doctor?

A. Yes. Then I did my urology residency at the UCLA Medical Center from 1970 to 1974.

Q. And do you have any board certifications, Dr. Melman?

A. In urology.

Q. And what are your areas of expertise, Dr. Melman?

A. Erectile dysfunction, perineal surgery and

urologic reconstructive surgery.

Q. And is erectile dysfunction a specialty within urology?

A. Yes.

Q. Upon finishing your residency in urology at UCLA, what was your next position, Doctor?

A. I took my first academic position as an assistant professor of urology in Indiana University at Indianapolis and as the chief of urology at the Veterans Hospital in Indianapolis.

Q. And then where did you work, Doctor?

A. And then I left Indiana, came back to New York City, and I was initially at the Beth Israel Medical Center and the Mount Sinai School of Medicine where eventually I became professor of urology at Mount Sinai and then chief of urology at Beth Israel.

Q. And you were a full professor of urology at Mount Sinai --

A. Yes.

Q. -- school of medicine?

And finally, since 1988, where have you worked, Doctor?

A. At my current position, I'm a professor and chairman of the Department of Urology at the Albert Einstein College of Medicine and the

Montefiore Medical Center.

Q. Are you a practicing urologist, Dr. Melman?

A. Yes.

Q. And how many years have you practiced as a urologist?

A. Since 1974.

Q. And approximately -- strike that.

As a practicing urologist, approximately how many patients have you treated with erectile dysfunction?

A. Many thousands.

Q. And as a practicing urologist, how do you keep up with developments in the field of urology, especially those involving erectile dysfunction?

A. Well, I'm not an ordinary practicing urologist. I also have the chairman -- I'm head of a research laboratory at the medical school. I do innovative research in trying to cure erectile dysfunction.

I was a journal editor in the review of articles and abstracts for the American Urological Association.

Q. Could you tell us a little more about the responsibilities as an editor of journals.

A. What are the responsibilities?

Q. Yes.

A. The goal is to make the journal good enough so

that you could attract manuscripts that will advance the field. And you're responsible for bringing in subeditors to help manage the various departments within the journal and then when manuscripts are submitted to the journal distribute the manuscripts to experts in the particular area that the manuscript was directed towards for peer review.

And after the peer review process is done, you have to make a decision about whether or not the article is good enough to be submitted to the journal in its present form, whether it needs improvement or modification or whether or not it should be rejected.

JUDGE CHAPPELL: Sir, you can lean back. That's a directional microphone.

THE WITNESS: Okay.

JUDGE CHAPPELL: And I think it will be easier to understand. Thank you.

BY MR. WONE:

Q. And Dr. Melman, what editor positions have you held?

A. I've been the editor of two journals. One was the Sexuality and Disability, and the other was the International Journal of Impotence Research.

Q. Have you also been a test editor of the urologic --

(Admonition by the court reporter.)

JUDGE CHAPPELL: I think what's going on is you're reading, at least partially, and most people tend to go too fast, so consciously slow down.

MR. WONE: That's fine.

JUDGE CHAPPELL: Thank you.

BY MR. WONE:

Q. Have you been a test question editor for the Urologic Clinics of North America, Doctor?

A. Yes. For a number of years I made up continuing medical education questions for each of the North American clinic volumes that would come out. I did that for about ten years I think.

Q. And through journal positions have you evaluated the design of clinical studies?

A. Of studies?

Q. Yes.

A. Yes.

Q. Does that include the data collection and reporting of clinical results?

A. Yes.

Q. Does that also include statistical analysis?

A. Yes. Although I'm not a statistician, I have some basic knowledge of statistics.

Q. Through your journal positions have you

evaluated articles involving erectile dysfunction?

A. Yes.

Q. Do you know approximately how many?

A. Several hundred.

Q. And have you also reviewed articles for the New England Journal of Medicine?

A. Yes.

Q. And the American Journal of Physiology?

A. Yes.

Q. And have you authored papers that were published in peer-reviewed scientific journals?

A. Yes.

Q. Approximately how many?

A. At the present time it's about 220.

Q. Can you list what peer-reviewed journals have published your papers.

A. The American Journal of Urology.

The International Journal of Impotence Research.

American Journal of Physiology.

The International Journal of Impotence Research.

The Journal of Sexual Medicine.

Urology and Urodynamics.

Those are the major, major ones.

Q. And how many of your papers are related to erectile dysfunction? Approximately.

A. About half. Over a hundred.

Q. And are your published articles accurately summarized on the pages 15 to 20 of your CV?

A. Yes.

Q. And Doctor, are you a member of any professional associations that relate to urology?

A. Yes.

Q. Can you name some of these associations, Doctor.

A. The American Urological Association.

The International Society of Urology.

The North American Society of Sexual Medicine.

The International Society of Sexual Medicine.

Those would be the major.

American College of Surgeons.

Those are the major.

Q. And have you been a former president of the North American Society for the Study of Impotence?

A. Yes.

Q. Have you held any consulting positions involving urology, Doctor?

A. Yes.

Q. Has one of these positions been as chairman of the FDA's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee?

A. Yes.

Q. Can you please describe your work as chairman, Doctor.

A. Yes. This is an advisory panel for the Food and Drug Administration that evaluates -- it was devices that were submitted for approval either for urology or gastroenterology. And when the FDA needed special advice, they'd call upon the advisory committee to give their opinion. As the chairman, I was responsible for coordinating the meetings and delivering the opinion.

Q. And has another one of your consulting positions been with the National Institutes of Health Urology Special Emphasis Panel?

A. Yes.

Q. Can you please describe your work on this panel, Doctor.

A. Yes. That's -- scientists throughout the United States submit grants for -- to do research that would be funded by the NIH, and from time to time I've been asked by the NIH to review certain grants and to score them and tell the NIH whether or not I thought they were worthwhile.

Q. And have you spoken at meetings of professional societies on the topic of urology?

A. Yes.

Q. And have those presentations involved erectile dysfunction?

A. Some of them have, yes.

Q. Are these meetings accurately summarized on pages 40 to 50 of your CV?

A. Well, it's not quite up-to-date. The last presentation was two weeks ago in the Washington Convention Center when I presided over a section of the American Urological Association meeting for basic research in erectile dysfunction, and that would have been in 2011, so it's not quite up-to-date.

So the last public meeting I attended was two weeks ago in Washington.

Q. Thank you, Doctor.

And have you received any research grants relating to erectile dysfunction?

A. Yes.

Q. From whom have you received these research grants from?

A. From the National Institutes of Health.

Q. Can you please describe these research grants, Doctor.

A. The grants have had two specific emphases. One was to look at the effect of -- long-term effects of

diabetes on erectile dysfunction and bladder dysfunction as part of a program, a five-year program project grant. And the others were to look at the effect of diabetes on erectile dysfunction also in rat models.

Q. Were you the principal investigator on these grants?

A. Yes, I was.

Q. Can you please describe what a principal investigator does.

A. A principal investigator is a person who writes and submits the grants to the National Institutes of Health and is legally responsible for achieving the outcome and overseeing the finances of the grant for the monies given by the government.

Q. And in reaching your opinions today, Doctor, what did you rely on?

A. I relied on the documents that you submitted to me and to results of a PubMed search that I did concerning the issue of pomegranate juice and erectile dysfunction.

Q. And you relied on your educational experiences, Doctor?

A. As a component of being able to evaluate the data, the answer would be yes.

Q. Have you also relied on your experiences as a

clinician and researcher?

A. Yes.

Q. Have you also relied on your knowledge of developments in the field of urology and erectile dysfunction?

A. Yes.

Q. Do you believe, Doctor, that you are qualified as an expert to evaluate the design and conduct of clinical trials involving erectile dysfunction?

A. Yes.

Q. Do you believe you're qualified as an expert to evaluate whether a product treats, prevents or reduces the risk of erectile dysfunction?

A. Yes.

MR. WONE: Based on Dr. Melman's education, extensive training and experience, complaint counsel wishes Dr. Melman to be accepted as an expert in urology, particularly as it relates to prevention, reduction of risk and treatment of erectile dysfunction, and in clinical testing, particularly those involving erectile dysfunction.

MR. FIELDS: No objection, Your Honor.

JUDGE CHAPPELL: To the extent any opinions offered by the witness meets the proper legal standards, they will be considered.

MR. WONE: Thank you, Your Honor.

BY MR. WONE:

Q. Dr. Melman, were you asked by the FTC to evaluate materials provided by the respondents to the FTC --

A. Yes.

Q. -- to support the claim that drinking eight ounces of POM Wonderful pomegranate juice daily prevents, reduces the risk of or treats erectile dysfunction in humans?

A. Yes, I was.

Q. And in your opinion, were the materials provided by the respondents competent and reliable scientific evidence of this claim?

A. I'm sorry. I couldn't hear your question.

Q. In your opinion, were the materials provided by the respondents competent and reliable scientific evidence to support this claim?

A. They were not.

Q. And were you asked by the FTC to evaluate materials provided by the respondents to support the claim that clinical studies, research and/or trials prove that drinking eight ounces of pomegranate -- POM Wonderful pomegranate juice daily prevents, treats or reduces the risk of erectile dysfunction in humans?

A. Were the materials sufficient? They were not sufficient.

Q. And given your experiences, Doctor, are you generally familiar with the bodies of studies on erectile dysfunction and pomegranate juice published in the English-language scientific journals?

A. Am I familiar with them, yes.

Q. And in connection with this case did you conduct a literature search, Doctor?

A. Yes.

Q. Can you please explain the search, Doctor.

A. I went online and went to the PubMed Web site. I typed in the words "pomegranate juice and erectile dysfunction" and got a list of publications that related to that subject.

Q. Can you describe what PubMed is, Doctor.

A. PubMed is a Web-based survey through the National Library of Medicine that lists all peer-reviewed journals that meet certain criteria that are then listed. The publications are listed on the Web site. And they don't list abstracts; they only list full publication.

Q. And Doctor, did you review any materials provided to you by the FTC?

A. Yes, I did.

Q. Are you familiar with the term "erectile function," Doctor?

A. Erectile function?

Q. Yes.

A. Yes, I am.

Q. Can you please what "erectile function" means, Doctor.

A. Erectile function is the ability to obtain and maintain an erection of sufficient duration and hardness so that both the individual and his partner are sexually satisfied.

For coitus, for intercourse.

Q. Was that the definition of "erectile dysfunction," Doctor?

A. No. That was function.

Q. Function. Okay.

A. That's the term that was part of the 1992 NIH special conference where they attempted to define "erectile function." I was part of that conference and was one of the contributors to the definition of the NIH.

Q. And as a background, let's first focus on the physiology of the penis.

What role does the penis play in the male's sexual function, Doctor?

A. Well, the penis is actually a conduit for the allowing of sperm to go from the inside of the body to the outside, so it's a necessary organ for the propagation of the species. And if it's functioning properly, men will achieve an erection during sexual excitement that allows them to have intercourse so that he then either impregnates his partner or has sexual pleasure.

Q. And Doctor, can you please describe the anatomy of the penis as it relates to erectile function.

A. The penis is an external organ that has -- it's covered by skin and fascial layers and has three chambers.

It has two paired corpora cavernosa that are contained within a thick, fibrous fascial covering called the tunica albuginea and then the third nonerectile structure known as the corpus spongiosum which contains the urethra, the tube through which men urinate and allows the passage of semen from the inside of the body to the outside.

At the end of the corpus spongiosum is the head of the penis or the glans penis.

The penis is the majority of the time in a flaccid position or a nonerect position. During that time, it has a very low blood flow. And then during a

phase of sexual excitement or during the rapid eye movement period of sleep, which occurs four to five times a night, the penis -- the blood flow will increase in the penis, and it will become erect at an internal pressure of the mean systolic blood pressure, and that's what a normal erection would be.

Q. Can you discuss what types of cells make up the tissue of the penile corpora cavernosa.

A. The majority of cells are smooth muscle cells, and they -- those cells are designed to maintain the tone of the penis when it's usually contracted. It also contains nerve fibers, blood vessels, both arterial blood vessels and capillaries, lymphatic vessels and endothelial cells, lining of the -- what is known as the cavernous sinuses of the corporal bodies.

Q. For what purpose do the endothelial cells have in erectile function?

A. The endothelial cells line the blood vessels in the penis as well as all the blood vessels in the body, and they create a smooth surface area over which the red blood cells and white blood cells can traverse.

In the penis they have -- another function is that some of the endothelial cells also secrete a vasodilating substance known as nitrous oxide, which may help initiate the erectile process, along with the

nitrate oxide that's released from nerve endings.

Q. And do neurons also have a role in erectile function, Doctor?

A. Does what?

Q. Neurons.

A. Neurons do, yes.

Q. And can you describe the function of neurons in the erectile process.

A. The neurons are the end organs of the brain, the spinal cord, and are necessary for transmitting neurologic impulses from the brain to the penis to help initiate -- either initiate or terminate erection.

Q. And Doctor, what's the first step of the erection process from a physiological perspective?

A. Well, the first step is the turning off of the stimulus from contractile neurotransmitters, such as norepinephrine or noradrenaline, and the release of vasodilating neurotransmitters, such as nitrous oxide.

Q. Then what happens next, Doctor?

A. Then what happens is that the -- there's a cascade of intracellular events within the smooth muscle cells of the penis. Through a series of biochemical events there's a relaxation of the smooth muscle cells that allows the inflow of blood into the penis and the eventual blockage of outflow of blood from the cavernous

bodies in order for the penis to become an erectile body.

Q. And that blood flow is what makes the penis rigid, Doctor?

A. It's the extra blood flow and the increased pressure within the penis. Yes.

Q. And that creates -- that is the erection; correct?

A. Yes, that's correct.

Q. You mentioned chemicals, Doctor.

Can you please step us through the chemicals involved in the --

A. Well, there are about 30 different biochemical events, at least 30. But to simplify it, the initial event would be the release of nitric oxide, the promotion of different kinases and the stimulation of the production of cyclic GMP and cyclic AMP, the inhibition of the entry of calcium ion into the cell, the relaxation of the contractile proteins of the cell, and the opening of the potassium channels in the cell to -- all of which go to promote relaxation of the smooth muscle cell.

Q. You mentioned nitric oxide, Doctor.

Could you please describe what nitric oxide is.

A. Nitric oxide is a gas that's produced through

an enzyme, nitric oxide synthase, and it's produced in endothelial cells and nerve endings.

It was first discovered by Robert Furchgott of -- from Brooklyn University, who first called it endothelium-derived relaxing factor, and he -- that was later renamed nitric oxide. And then in the early '90s, several investigators showed the importance of nitric oxide release on the initiation of the erectile process.

But nitric oxide is released throughout the body, and only one of its actions is that to initiate erection.

Q. And you mentioned cyclic GMP, Doctor?

A. Yes.

Q. Can you please describe what cyclic GMP is.

A. It's a small molecule which is -- has an effect on other cascades within the smooth muscle cell which cause the relaxation of the cell. There are two that are important to the smooth muscle cells of the penis. One is cyclic GMP, the other is cyclic AMP, each of which is produced by its own enzyme and necessary to initiate other enzyme activity in the cell that causes the cell to relax.

Q. And what does "cyclic GMP" stand for, Doctor?

A. Cyclic guanosine monophosphate.

Q. And after an erection is induced, does type 5 phosphodiesterase have a role in the erection process?

A. Yes.

Q. And is type 5 phosphodiesterase referred to as a PDE5?

A. Yes, it is.

Q. And can you describe what PDE5 is, Doctor.

A. It's an enzyme that causes the breakdown of the cyclic GMP and causes it to end its function. If it didn't do that, then the erection would never disappear and the individual would have a constant erection, and that would eventually become something called priapism, which is painful and a problem that no one wants to have.

Q. And can you define "erectile dysfunction," Doctor.

A. It would be the inability to obtain and maintain an erection of sufficient duration and hardness that allows the patient to have coitus and sexual satisfaction for him and his partner.

Over a continuing time, not just once but over many events.

Q. And what are the causes for erectile dysfunction, Doctor?

A. The primary causes are aging, hypertension,

diabetes mellitus, various pelvic surgeries which interfere with the nerves that go to the penis, and various medications, usually related to antihypertensive medication.

Q. And those are some of the causes of physiological or organic erectile dysfunction.

A. Correct.

Q. Are there also psychological causes for erectile dysfunction?

A. Yes. The causes of psychologically achieved ED include anxiety and depression. Those are the most common.

Q. And when you use the phrase "ED," you're referring to erectile dysfunction, Doctor?

A. Yes.

Q. You earlier discussed what PDE5 was.

Can you describe what a PDE5 inhibitor is, Doctor.

A. A PDE5 inhibitor is a drug or a chemical which blocks the action of the phosphodiesterase and inhibits its action, so it in effect prolongs the activity of the drug which the inhibitor is or the phosphodiesterase is trying to break down.

In the case of the drugs that are used in the treatment of erectile dysfunction, they're either PDE5

or in some cases PDE3 inhibitors.

Q. And is Viagra or Cialis an example of a PDE5 inhibitor?

A. Yes. Those are PDE5 inhibitors.

Q. In order to conclude that competent and reliable scientific evidence exists to support a claim that a product treats, prevents or reduces the risk of erectile dysfunction, what clinical evidence would experts in the field of erectile dysfunction require?

A. Well, you'd have to do a study in humans. Humans would be important. And the study would have to include a trial that was randomized, that was placebo-controlled, that had a sufficient number of men in the study to -- who met the inclusion and exclusion criteria. It would have to be done at independent centers and with more than one investigator. And it would have to be powered, statistically powered to meet the requirements so that a statistical significance could be achieved.

Q. Would such study also have to be double-blinded?

A. Yes.

Q. And would such study have to use an appropriate outcome measure?

A. Yes. The outcome measure would have to be

something decided in advance. That would be part of the power test, and so you use a measure that could be decided in advance so that you have to know how many people would have to be studied to achieve that significant difference to either prove or disprove the hypothesis.

Q. And in addition to statistical significance, would clinical significance be required?

A. Well, I think for the drug to be widely utilized, it would have to have clinical significance, or if not, it would not be purchased by the public.

Q. Let's go through the requirements that you mentioned, Doctor.

What did you mean by multisite or more than one investigator?

A. That is when the drug is being -- whatever is being tested, whatever the test object or drug, it would be done at sites that were under the scrutiny of the Food and Drug Administration, approved by the Food and Drug Administration, where a protocol was submitted and approved by an independent, an institutional review board.

So there would be more than one site to do the testing.

Q. And when you use the word "drug," what are you

referring to, Doctor?

A. A drug would be a chemical.

Q. So not just a pharmaceutical?

A. No. It could be any, any type of chemical.

Q. For example, a chemical in a food or a supplement?

A. That's correct.

Q. Why is it important to have multiple sites, Doctor?

A. Well, I think it reduces the possibility of bias. If only one person is doing -- is responsible for an outcome, there's a possibility of some bias, and I think that the results of the study would be more believable if more than one person were responsible for the outcome.

Q. And when you use the word "drug," Doctor, you mean any chemical agent.

A. Any chemical.

Q. And can you describe what a placebo-controlled group is, Doctor.

A. "Placebo-controlled" means that not only the drug which is the actual drug that's being tested but the -- a product that doesn't have the drug which would be given to a randomly decided group of men or in this case men to eliminate the possibility that the response

that's being sought after was caused by the drug itself and not by chance.

Q. Should the control group meet the same criteria in terms of participants as the treatment group?

A. The control group should be identical. And in many cases in studies that are done, the control group and the experimental group could be the same, but they're given either the placebo or the control or the drug at different times, but they would otherwise be identical. And in fact, the placebo should be identical in all manners to that of the drug that's being tested, except it wouldn't have the drug itself in it.

Q. Can you describe what kind of placebo should be used?

A. What type?

Q. What kind of placebo.

A. It should be a product that's identical in taste, color, size, all of the parameters to the test agent so that the double-blinded nature of the trial would be kept. If it were not the same, then it would no longer be double-blinded. Either the investigator or the participant of the trial might be able to differentiate whether they were being given the placebo or the experimental product.

Q. When you say "identical," you mean the placebo is identical to the treatment product.

A. Yes.

Q. Can you describe what randomization is, Doctor.

A. Randomization is the -- the way it's done or should be done is that a computer generates a list of numbers, and an independent person outside of the clinical trial center randomly assigns a person who's met the inclusion criteria as to whether they be put into the experimental or control group, and neither the investigator or the clinical investigator nor the participant would know then what they're receiving.

So a computer would independently generate the randomization code.

Q. And why is randomization important, Doctor?

A. Because if it's not done in an independent way, there's a possibility of a selection bias on the part of the investigatory site. Even inadvertently one is more -- is likely to put someone who's able to give a better outcome into one group versus another, or there may be other reasons why the participant would be put in one group or another. And when it's done randomly, it excludes that possibility, so it gives the best chance for a correct outcome.

Q. And what is meant by "double-blinded," Doctor?

A. "Double-blinded" means that neither the clinical investigator nor the participant in the trial know what they're being given as part of the -- for the trial drug.

JUDGE CHAPPELL: Hold on a second.

You're still leaning too close to the microphone.

THE WITNESS: What?

JUDGE CHAPPELL: You're still leaning too close to the microphone.

THE WITNESS: Okay. I'll tilt to the left.

JUDGE CHAPPELL: It's roaring through the room.

I have a question based on what you just said about double-blinded.

Neither the investigator nor the participant in the trial know what they're being given; meaning, the investigator doesn't know if it's a placebo or not, or does the investigator not even know what the trial is about?

THE WITNESS: Oh, no. The investigator has to sign a document in advance to both the FDA and the internal review board, so they know what the trial is about. They just don't know for any particular person whether they're given the -- if it's a -- if it's not a crossover trial, they don't know what's being given to

any individual at any one time. They don't know.

JUDGE CHAPPELL: And they also don't know what group any individual is in; correct, whether they're control or otherwise?

THE WITNESS: They wouldn't.

In fact, in most trials, the clinical investigator isn't the one giving out the drug. It's usually a study monitor. But in groups where the patient of a particular physician might be responsible, he shouldn't really know whether they're given placebo or the actual drug in any one time.

JUDGE CHAPPELL: So is it common for the study monitor to know?

THE WITNESS: No one knows. There's a code that's not broken until the trial is complete. No one should know.

JUDGE CHAPPELL: All right. Thank you.

BY MR. WONE:

Q. And double-blinding also prevents participants from knowing or being influenced by which treatment they receive; correct?

A. Yes.

Q. And it also prevents the investigators or their staff from subconsciously providing different levels of care to different participants; correct?

A. Yes.

Q. Earlier you mentioned outcome measures, Doctor.

What did you mean by "outcome measure"?

A. An outcome measure is a -- some type of assessment as to what it is you're looking to prove.

So in the case of treatment of erectile dysfunction one would look for an outcome measure that proved or disproved whether or not the particular product you were testing actually had an effect on erection.

Q. And are there validated instruments for measuring change in erectile function?

A. Yes.

Q. Could you please name some of these validated instruments, Doctor.

A. Well, the one that's used most commonly is the International Index of Erectile Function. This is a test that was developed in the -- in the late 1990s by Ray Rosen, who developed a test for Pfizer Corporation to test the outcome or the effect of Viagra on producing erection.

And as a component of that there's a 15-part questionnaire. Six of the questions were designed to actually look at erection, and that's -- that is the test that's most utilized by the Food and Drug

Administration to approve or disapprove the acceptance of a product for use in the general public. It's been used the most. People have the most experience with it. And it's been validated by statisticians and used throughout the world.

And there are several spin-offs on that test, another one that's called the TSS, which looks at outcome measures of people who have been treated both before and after and as well as their sexual partners to see if the response of the sexual partner to a drug that's purported to effect erection, whether the partner has the same view as the participant in whether the drug had an effect or not.

Q. You used the word "validated," Doctor.

What did you mean by a validated measure?

A. "Validated" is a statistical term which shows that the test -- statistically it shows that the test that's being used has a -- both an internal and external reliability, and that is, if you give the test over and over again to the same individual or to a group of individuals, that you'll have a statistical reliability that the test is giving the correct answer.

So the statisticians have developed these indices of reliability, and the test -- in order to test a drug, if you're going to use an outcome measure, the

outcome measure should be one that has been validated by statisticians.

Q. And can I refer to the International Index of Erectile Function as the IIEF?

A. Yes.

Q. And the IIEF is an example of a validated measure; correct?

A. Yes.

Q. Does the IIEF have multiple domains?

A. Yes.

Q. Can you explain what the domains are, Doctor.

A. The primary domain is for measuring erectile function, but it also measures ejaculation, orgasm and satisfaction, nonerectile measures.

Q. So different questions on the IIEF are for each domain.

A. Yes.

Q. And would experts in the field rely on data from an unvalidated measure alone to show efficacy?

A. They would not.

Q. And why is an unvalidated measure alone insufficient to show efficacy of a product in, say, treating erectile dysfunction?

A. Well, "nonvalidated" means not tested, and one could not or should not trust the results of a test

that's hasn't been shown to be up to snuff.

Q. In other words, is it unreliable, Doctor?

A. Well, it could be unreliable because it hasn't been validated, so you don't know one way or the other.

Q. You also mentioned that experts would require statistical significance.

Can you describe what you meant by "statistical significance."

A. Statistical significance is a -- is a mathematical test -- it could be done in many ways -- to show that the -- when one attempts to prove or disprove a hypothesis that the likelihood of the answer that you've gotten is not by chance but by the effect of whatever it is that you're looking for. And the number that's been picked in biological literature to test that assumption is point -- less than .05, a 95 percent degree of reliability. That's the number that's generally used.

It's a number that I would use as a journal editor. Someone submitting a journal -- a paper to my journal, I would use that number to say whether or not I thought that the outcome of a specific study met the criteria of significance before they could make a claim.

Q. Is statistical significance often expressed as a

p-value?

A. Yes. P stands for probability, so it's the probability that the outcome occurred less than 0.5 or one in 5 percent of the time. Yes.

Q. And would experts in the field conclude that efficacy were proven in a clinical study where the p-value was not less than .05?

A. If the value didn't meet that -- if the outcome didn't meet that criteria, then the outcome would be that it didn't meet the criteria. It would not be accepted.

Q. And earlier, Doctor, we discussed clinical significance.

Can you please define what you mean by "clinical significance."

A. Clinical significance is -- means that it really makes a difference. You could have statistical significance; that is, if you take a large number of patients and you get a number that was slightly different than what the control value was, it may not make any difference in the patient's life.

So clinical significance is that you actually see a change in the outcome that makes a difference to the patient.

For example, there are drugs that are used to

treat prostatism and urine flow, so if the -- if a drug were given to make it easier to urinate and it made a change of only one milliliter per second, in a large number of people that might be statistically significant, but to the -- the person wouldn't be able to recognize that change. It would have to be four milliliters a second before you could see the difference to be clinically significant.

Q. And what would clinical significance be in the treatment of erectile dysfunction?

A. Clinical significance for ED would be where the erection that were achieved were hard enough so that the person could effect intercourse so that both he and his partner could have sexual satisfaction.

Q. So even though the results may be statistically significant, that doesn't mean you necessarily have clinical significance; correct?

A. That's correct.

Q. And why do experts in the field require clinical significance?

A. Well, I think for a drug or a product to be accepted, that is, approved by both the FDA and by the purchasing public, unless it had a real effect on the outcome, that is, that it did what it was designed to do, it would fail and it would fail to be passed by the

FDA and it would not be purchased by the consuming population.

Q. And would experts also require a clinical study to be conducted over a sufficient duration of time?

A. Yes.

Q. And how is the duration of a study relevant to measuring the treatment of -- change in erectile function?

A. Well, I think it depends upon the -- what the drug was trying to do.

So in a drug such as a Viagra -- a PDE5 inhibitor like Viagra, where the drug was given each episode, that is, you weren't trying to cure anything, just trying to create an erection, I think the duration of the study could be shorter, perhaps a month or three months.

If the purpose of the trial were to correct a disease or to permanently cause changes in erection, not once or each time the drug were taken but over an extended period of time, then the duration of the study would have to be much longer, three months, six months, a year or even longer.

Q. And would experts also require verification of erectile function by the participants' partners?

A. Yes. I think the trend by the Food and Drug

Administration in the last several years is to get independent validation by the patients' partners, so all of the drug studies that are used to treat erectile dysfunction tend to be done in heterosexual couples who have been together for some period of time, at least six months. And the sexual partners are given -- the female -- the partner component of the -- either the IIEF or the TSS test to get independent validation. It just makes the outcome data stronger if both members of the couple actually give the same response.

Q. And you mentioned TSS.

What does "TSS" stand for, Doctor?

A. Actually I forgot. Treatment satisfaction outcome. I forgot --

Q. Scale?

Scale?

A. Scale, yes.

It's another independent validated pen-and-pencil test that's used -- it's kind of the next generation after the IIEF because it was actually designed to look at drug outcome, treatment outcome of a specific drug, so it's a little bit better than the IIEF. It's a treatment outcome validated test. And it includes the partner.

Q. If we could go back to duration for a second,

what would be the appropriate duration of a study investigating the prevention of erectile dysfunction?

A. Well, prevention would have to be many months to years, because if you're talking about preventing something from happening, diseases that cause ED happen over lifetimes or -- so, for example, if you were going to try and treat the prevention of ED in people who had diabetes, you would have to know what the incidence of diabetes is in a population or prevalence in any one year in a known population of diabetics. Then you'd have to study that whether or not over a period of, say, five years you could prevent or reduce the incidence of erectile dysfunction in that group, so this would be a very long-term study.

I think the -- to expand on that, there was a trial sponsored by the NIH looking to see whether or not prostate cancer could be reduced in men taking a drug, a 5-alpha-reductase drug, to treat benign prostatic hyperplasia, and I think that was a ten-year trial that was just opened, so these trials are done over many years.

Q. And earlier you mentioned exclusion or inclusion criteria. Can you describe what that is, Doctor.

A. Yes. So you want to -- inclusion criteria would

be one that where you set up an age range and a sexual status. You know, in an ED trial you'd want to include men who are usually between the ages of 20 and 80, who could read and write and give an informed consent and are willing to participate in the trial and would have to meet some of the obligations set up by either the company or the Food and Drug Administration.

And then you would want to exclude people from the trial who might be taking a certain drug or have a defibrillator, for example, something that would confound the outcome of the trial, or if they had a catheter in place or they had had a penile prosthesis in place where you couldn't really measure the outcome properly. Or if they had diabetes or their diabetes was out of control and they would confound the outcome, you wouldn't want to include them in such a trial.

Also you would have -- if it's an ED trial, you would want to make sure that they actually had erectile dysfunction, and so you would have to use the criteria that you set up to include them as a certain score on your -- either the IIEF or whatever test that you're using, so you want them to be between a certain range of test scores in order to include them or exclude them from the trial.

Q. And experts in the ED field would require

appropriate inclusion and exclusion criteria?

A. Yes.

Q. And would experts also require an appropriate sample size?

A. Yes.

Q. And why is that, Doctor?

A. Because you have to -- as I mentioned earlier about doing appropriate power, statisticians have designed a way of obtaining the -- looking for the change that you need to say whether a drug works or not or whatever it is you're looking for and then determine statistically how many participants in the trial you would need in order to reliably obtain that outcome. And those -- in a good trial, those numbers have to be set up in advance before the trial is done, so you do a prospective power test, say this is what I'm looking for and this is how many people I need to statistically prove that.

Q. Can you define what you mean by "power," Doctor.

A. A power analysis is one that tells the number of subjects that are needed in order to obtain statistical reliability, so it's the -- it's a statistical number, and the number that's usually used is .8. I don't remember the mathematics of what power

stands for, but it's a mathematical equation.

Q. And other than the ones we've discussed, is there anything else that experts would require in the study as part of being well-designed?

A. No. It would have to be -- the other thing is it would have to be a test that was approved by an institutional review board and a biohazards committee, so there would be independent approval. And also, if one were testing a drug, there would have to be a biomedical committee that decided, if there were any serious adverse events, they would oversee the adverse events and decide whether or not the trial should be halted before the end of the trial. And those are all independent bodies.

Q. And would experts also require reliable data collection procedures?

A. Yes.

Q. And the use of appropriate statistical analysis methods?

A. Yes.

Q. We're going to move from talking about human clinical evidence to other types of evidence, Doctor.

Doctor, can you describe what is meant by "anecdotal evidence."

A. Anecdotal evidence is one where someone has

said, Well, gee, that -- I took that product or I used that whatever and it worked great and -- but there's no -- it was not done in a blinded way. It was not done in a trial. It's just kind of a -- it's a testimonial on the part of the individual saying it's good or not, but...

Q. And in determining efficacy --

A. Let me just add, the reason that it's important not to use testimonial evidence is that, if you use testimonial evidence, that may not be reliable differentiation from a placebo.

There's something in science known as cognitive dissonance. Cognitive dissonance is that when people are put into a trial and they're willing to be subjected to a trial, they want to both please their doctor or whoever is doing the trial and not look foolish, so they may give a response that may not be true just to make it look good. And it's a known phenomenon in the field of medicine.

So testimonial or anecdotal evidence are -- could be generated by cognitive dissonance and are not reliable.

Q. So in determining efficacy, experts in the erectile dysfunction field wouldn't rely on anecdotal evidence.

A. They would not.

Q. Can you describe what an in vitro study is, Doctor.

A. An in vitro study is something that's done in a test tube or in a glass dish, not in a living -- not in a living organism.

Q. And would experts rely on an in vitro study to show a product's efficacy in treating, preventing or reducing the risk of erectile dysfunction?

A. No. You can't -- you can't equate the outcome from an in vitro study to its effect on human beings.

Q. And what is an animal study, Doctor?

A. An animal study is a trial that's done in an animal model of disease process that you have under investigation.

So in this case if the disease were erectile dysfunction, one would do a study in a model that -- in an animal in which the animal had erectile dysfunction.

Q. And would experts in the field rely on animal studies to show efficacy in treating, preventing or reducing the risk of erectile dysfunction in humans?

A. It could not.

Q. And why would animal studies be insufficient, Doctor?

A. Well, the obvious answer is that animals are not

humans and humans function physiologically different than all other animal species, even those that are close to us. And there may be other confounding factors why a particular product might either work or not work or have adverse events in humans that would not be found in animal models.

For example, the taking of a drug might cause profound nausea that a rat couldn't tell you it had but in a human cause dizziness and nausea. There was such a drug that was nearly approved by the FDA but because of nausea and syncopal episodes in humans was not allowed for the treatment of erectile dysfunction.

So the final testing has to be done in humans, not in animals, even though it worked in one or more species in animals.

Q. And to your knowledge, Doctor, is your opinion of what is required to conclude that competent and reliable scientific evidence exists to support a claim shared by experts in the erectile dysfunction field?

A. Yes.

Q. What is your basis for knowing what experts in the erectile dysfunction field would require?

A. About two years ago I was part of a group from a national -- an international consortium that actually defined the requirements of a clinical trial, so I was

part of that group and actually wrote one component of the requirements, so I think that's the last major publication that kind of summarized what the requirements should be. It's known by most of us, but here it was put into a specific summary document. And that's part of my CV.

So that would be the short answer as to why I know, other than the fact that I've designed and run clinical studies myself and as part of my editor responsibilities I've been responsible for overseeing whether or not trials that were done were -- you know, met the criteria that I thought were necessary and also as part of the FDA responsibility.

Q. Thank you, Doctor.

When you say "FDA responsibility," do you mean your involvement with the FDA committee?

A. Yes.

Q. And that's --

A. I should expand. Both when I was -- and also I've devised clinical trials that -- for testing of a product that I'm responsible for, so from both sides, both designing them and overseeing them. Yes.

Q. Thank you, Doctor.

And as part of your work in this case, did you evaluate the study published -- or sorry. Strike that.

As part of your work in this case, did you evaluate a published study by Christopher Forest, Dr. Harin Padma-Nathan and Dr. Harley Liker?

A. Yes.

Q. And was that study titled Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study?

A. Yes.

Q. And I'm going to refer to that study, Doctor, as the Forest study.

I'd like to show you, Doctor, a document that was Exhibit C to your expert report and it's part of CX 1290.

Doctor, is this the Forest study that you reviewed?

A. Yes.

Q. Can you explain how you conducted your review of the Forest study, Doctor.

A. Well, I read the paper several times, and I actually looked in the reference section, and through the Web I collected some of the papers that were used as references in the Forest study.

Q. And did you review some of the underlying data

from the Forest study, Doctor?

A. Yes. That you supplied to me.

Q. And was the Forest study a pilot study, Doctor?

A. Was it a what?

Q. A pilot study.

A. It was a pilot study, yes.

Q. And what is meant by "pilot study," Doctor?

A. A pilot study is one that's done -- it would mean -- a pilot really means small or exploratory study, so it would be done to see whether -- in a small group of people whether or not it had both safety and some efficacy before a larger study would be done, so it's basically an exploratory study.

Q. And did the Forest study authors identify their study as a pilot study?

A. I believe it did.

(Pause in the proceedings.)

Actually I don't see the word "pilot," so I'm not sure where the word -- I know it's there somewhere, but I don't see it right now.

Q. Could it have been --

A. It says, in the last paragraph, "Although the results of this pilot study did not achieve statistical significance..."

Q. Thank you.

A. They identified it as a pilot study.

Q. And would experts in the erectile dysfunction field rely on a pilot study as proof of the efficacy in treating, preventing or reducing the risk of erectile dysfunction?

A. No.

Q. Can you describe what the Forest study examined, Doctor.

A. The study used an eight-ounce glass a day of drinking either a control liquid, placebo liquid, or pomegranate juice to see if it could cause an improvement in the IIEF in a small group of men with moderate erectile dysfunction, mild to moderate erectile dysfunction.

Q. And how was the Forest study designed, Doctor?

A. It was designed as a crossover study where the men took either the product or the placebo for 28 days, and then there was a 14-day washout period, and then the other product was given to the participants in the trial. And then at the end of that, each period, outcome measures were measured either with the IIEF or with the GAQ, the other test that was given, the nonvalidated test, to measure outcome.

Q. Could you explain what a crossover study is, Doctor.

A. In a crossover study, the participant gets both the test substance, the drug, and a placebo at two separate time periods.

Q. So if the first group got the placebo in the first period, after the washout period they would receive the -- group one would receive the treatment product?

A. Yes.

Q. And you mentioned the IIEF as one measure in the Forest study. You also mentioned the GAQ?

A. Yes.

Q. What does "GAQ" stand for, Doctor?

A. It's a quality-of-life question, a single question asking whether or not there was improvement in erection, not -- a nonvalidated, very nonspecific question.

Q. And does "GAQ" stand for Global Assessment Questionnaire?

A. Yes.

Q. And the IIEF in the Forest study included the erectile function domain questions?

A. It included all of the 15 questions in the test, yes.

Q. And Doctor, does the Forest study support the claim that drinking eight ounces of pomegranate juice

daily treats, prevents or reduces the risk of erectile dysfunction?

A. No, it does not.

Q. And you testified earlier that participants in the Forest study had mild to moderate erectile dysfunction.

Does the Forest study support the claim that drinking eight ounces of pomegranate juice daily prevents erectile dysfunction?

A. No, it does not.

Q. And how about reduces the risk?

A. It does not support that claim.

Q. Let's first focus on the measures used by the Forest study. If we could go to Exhibit D of your expert report, Doctor, which is part of CX 1290.

A. Yes.

Q. Exhibit D states: While using the study beverage, did you feel that your erections improved? Yes or no.

Is this the GAQ question you referred -- you reviewed in connection with the Forest study, Doctor?

A. Yes.

Q. And is the GAQ a validated measure for erectile function, Doctor?

A. It is not.

Q. And can you explain what you mean when you say the GAQ is not a validated measure.

A. Well, it's not -- it's not been tested by any group and where the results have been published that show that this test when given has a statistical reliability to prove that the outcome is meaningful. That's what it means.

In addition to that, the question is so nonspecific as to be clinically useless, so when it says did your erections improve, did it mean that it improved 5 percent, 10 percent, 50 percent, a hundred percent, did it happen once or every time the person -- so there's no -- nothing -- no response that could be given in this question for which you could make any clinical -- meaningful clinical outcome.

Q. Was the GAQ the primary measure in the Forest study?

A. It was their primary measure, yes.

Q. And the erectile function domain in the IIEF was the secondary measure?

A. Yes.

Q. In comparing the GAQ results for the treatment group versus the placebo group, did the Forest study have statistically significant results?

A. There were no significant results reported by

the Forest study in either the GAQ or in the IIEF or in the erectile function domain in the IIEF, none.

Q. And do you know what the p-value was for the GAQ measure --

A. It was .058.

Q. Doctor, the Forest study authors described -- strike that.

Doctor, the Forest study authors described the p-value as nearly achieved statistical significance.

Why is nearly achieving statistical significance insufficient?

A. Well, nearly is not, so "nearly" means that it didn't achieve statistical significance.

So they proved that the drug didn't have an effect even using this very nonspecific questionnaire which wasn't valid to start with, so even with that, they didn't show that it was statistically significant.

Q. And aside from statistical significance, Doctor, did the GAQ in the Forest study measure whether there was any change in clinical significance?

A. Well, the GAQ is one component of -- one of the tables of the GAQ that showed the outcome of the GAQ, table 1 on page 427, showed that when one analyzed a change in the GAQ score, approved GAQ score, that the outcome was better in the group who received the drink

first and the placebo second.

And in a properly designed study there really should not be any difference between whether the drug were given first or second, so there's some internal unreliability in the way the test was given, further impugning the outcome of the study, so that -- and I believe that part of the reason for that was that the participant -- that the placebo and the test substance were not identical, and it may be that the participants were able to say whether or not they were given the product versus the placebo.

So it's another major defect in the study. And even despite that, they didn't show a statistical difference between the two.

Q. Can the GAQ question used in the Forest study show the amount of improvement by participants?

A. I couldn't hear your question.

Q. I'm sorry.

Could the GAQ in the Forest study show the amount or level of improvement by the participants?

A. No. It couldn't because the GAQ itself is so nonspecific that one couldn't use that to say what the degree of improvement was, so it did not.

Q. Thank you, Doctor.

And if we could turn to the IIEF, which is page

2 of Exhibit D, CX 1290.

Is this the IIEF measure that you reviewed in connection with the Forest study, Doctor?

A. Yes.

Q. And if we could turn to page 3 of Exhibit D, CX 1290.

A. I'm sorry. Which page?

Q. Page 3. Of Exhibit D.

Do you see question 4 on page 3 of Exhibit D, Doctor?

A. Yes.

Q. And is question 4 an example of an IIEF question that is part of the erectile function domain?

A. Yes.

Q. And how is a question like question 4 relevant in measuring a change in erectile function?

A. Yeah. Well, it does it in a couple of ways.

One is that, as part of the way the test is given, the participants are asked to try and have intercourse at least once a week and recount/recall when they answer the question what their erection was like, and then it looks like by giving more of a grading as to the actual results, so from they never attempted to have intercourse, presumably because they didn't get erections, to whether or not they were able to maintain

an erection after the onset of intercourse so they could effect intercourse, and that would be the almost always or always response, so it would be from never to always.

And this question is and question 3 before it are the two questions that are used most often to decide whether the testing of a product is efficacious in effecting erection.

Q. Can you identify the other erectile function domain questions in the Forest study's IIEF, Doctor.

A. I'm sorry. I couldn't --

Q. Can you identify the other erectile function domain questions used in the Forest study's I --

A. That should be questions 1, 2, 3, 4 and 5. I don't know if they used 15. I don't think it says.

It's not clear. Sometimes when people are using the IIEF erectile domain you use questions 1 through 5 and question 15 or not. It could be five or six, so it would be that one and maybe question 15.

Q. Okay. And when you say that the IIEF is more specific, you mean specific in measuring a change in erectile function?

A. Yes.

Q. In comparing the IIEF results for the treatment group versus the control group, did the Forest study have a statistically significant result?

A. It did not.

Q. And was that for all domains of the IIEF?

A. I'm sorry?

Q. Was that for all the domains of the IIEF?

A. It's for both all domains and the erectile function component.

Q. And aside from your conclusions about the GAQ and the IIEF, do you have any conclusions about the length of the treatment period used in the Forest study?

A. Well, I thought the treatment period was too short for a group that was trying to show that it would prevent or treat chronic disease.

Q. And did the Forest study authors also express concern that the study period may not be long enough to allow for a clinical response?

A. They did, yes.

Q. And did you reach any conclusion about the placebo that was used in the Forest study, Doctor?

A. Yes. As I alluded to earlier, because the placebo was not identical to the test substance and the fact that the participants who received the POM test substance first had a better response, that there was really not a clear -- there was no identicality between the placebo and the test substance, so clearly the

participants were able to tell the difference, and that would further make the reliability of this study unreliable.

Q. If we could go to CX 1290 at page 4 of the Forest study.

And Doctor, is that the section of the Forest study that you based your opinion on about the placebo beverage?

A. Yes. Well, that and the outcome, which was that there was a difference in the people who took POM first. I think that's evidence to show that there was a difference, and I think the authors recognized that.

Q. And how would participants knowing which beverage they were consuming affect the results of the Forest study?

A. Well, it would bias the outcome. And it might do it in the manner that I suggested earlier, and that is that the people that are willing to spend the time and the effort to participate in a study might give a -- have more of a positive outcome to make themselves look better, to make the product look better, if they could tell the difference between the placebo and the test substance.

So it eliminates the nonbiased nature of a properly done placebo-controlled study, so it eliminates

the results or it negates the results. And the results were negative anyhow, so it further negates the negative results.

Q. So the placebo used should be identical in taste and appearance to the treatment product?

A. Taste, appearance, color, if it's a liquid, yes.

Q. And did you reach any other conclusions about the design of the Forest study, Doctor?

A. Well, the study should have been done over a longer period of time. And the other -- the other problem was that they had a fair number of people who dropped out, so they would have needed a larger N in order to achieve the outcome that they were researching.

Q. You can feel free to refer to your report, Doctor, paragraph 30.

A. Yeah, there was one other.

The other was that they used a nonvalidated questionnaire.

And they also did not include a partner verification, which would be -- I think in a study done today it would include partner verification.

The two other issues are that the participants that were included were relatively young, were 46 -- the

mean age was 46 years. And the incidence of organic or nonreversible erectile dysfunction really begins and increases dramatically after the age of 50. That would be a problem as well.

And -- those would be the major things. They really didn't have significant ED, highly significant, and they were relatively young.

Q. Thank you, Doctor.

In conducting your literature search did you find any article reviewing the Forest study, Doctor?

A. I found one. Yes.

Q. I'd like to show you CX 1290.

Is this the review that you found concerning the Forest study, Doctor?

A. Yes.

Q. And this is a review by Dr. Rajfer?

A. Yes, it is.

Q. And what did Dr. Rajfer's review conclude, Doctor?

A. Well, he concluded that -- he actually congratulated the authors on publishing a study that didn't show a positive outcome. He concluded that this was a negative study. They did a study looking to see if they had a drug that corrected erectile dysfunction, and they showed that it did not, and he thanked them for

publishing it.

Dr. Rajfer is the person who was actually the first urologic investigator in the U.S. to show the importance of nitric oxide on the erectile mechanism, so he's quite a knowledgeable person.

Q. And other than the Forest study, Doctor, did you find any other human clinical study on the efficacy of POM Wonderful pomegranate juice in preventing, reducing the risk of or treating erectile dysfunction?

A. That were published or nonpublished?

Q. Published.

A. No other published studies, no.

Q. And did you find any other human clinical studies involving any other pomegranate product on the treatment, prevention or reducing the risk of erectile dysfunction?

A. Not published. I did nonpublished, yes, from the literature I reviewed.

Q. And as part of your work in this case, were you given data to review by the FTC from a cardiovascular study by Dr. Davidson?

A. Yes.

Q. And did you review this data, Doctor?

A. I did.

Q. And was this data published, Doctor?

A. It was not.

Q. Can you describe Dr. Davidson's study in relation to erectile dysfunction.

A. It was a trial that was done where people took eight ounces of pomegranate juice a day to actually change the thickness of I believe the carotid artery and in a series of patients who received either placebo or pomegranate juice. At the end of the trial they were given the IIEF -- before and after given the IIEF. And again in that trial there was no statistical difference in the outcome in the men who had cardiovascular disease -- that was one of the inclusion criteria -- on a positive effect on their erectile function. It was a nonsignificant study, so it's another negative study.

Q. And in your report, Doctor, you wrote that 52 participants completed the IIEF in Dr. Davidson's study.

Should that have been 27 participants --

A. Yes.

Q. -- in the intent to treat population?

A. There was an error. There's 27 men in that trial.

Q. And when comparing participants in the intent to treat population who received POM Wonderful pomegranate

juice versus a placebo, what were the IIEF results from Dr. Davidson's study?

A. It's hard to hear.

Q. Were the results from Dr. Davidson's study positive?

A. No. They were negative. Again, they showed no effect on erectile function.

Q. And did you also review a published study by Dr. Azadzoi titled Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants?

A. Yes, I did.

Q. And did Dr. Azadzoi's study prove that POM Wonderful pomegranate juice treats, prevents or reduces the risk of erectile dysfunction in humans?

A. It does not.

Q. And why is that, Doctor?

A. This was an animal study in an atherosclerotic ED model in rabbits, and it's in rabbits. And even in that study it didn't show a positive effect on changing blood flow in the animals that had erectile dysfunction, so it was a negative study even in the animal study, and it certainly had no effect on -- could not be implied to have any effect on outcome in the giving of the pomegranate juice to human beings.

JUDGE CHAPPELL: Hold on for a second.

(Pause in the proceedings.)

Go ahead.

MR. WONE: Thank you, Your Honor.

BY MR. WONE:

Q. Doctor, did you also review a published study by Dr. Ignarro?

A. Yes, I did.

Q. Was this study titled Pomegranate Juice Protects Nitric Oxide Against Oxidative Destruction and Enhances the Biological Actions of Nitric Oxide?

A. Yes.

Q. And does Dr. Ignarro's study on nitric oxide prove that POM Wonderful pomegranate juice treats, prevents or reduces the risk of erectile dysfunction in humans?

A. It does not.

Q. And why not, Doctor?

A. This was an in vitro study, a study done in a test tube, to show that pomegranate juice has more antioxidants than red wine or grape juice or blueberries, and they showed that it did in the test tube and has nothing at all to do with the treatment of erectile dysfunction in people. And there's certainly no human beings tested in this trial and it has -- no conclusions could be drawn from this very limited

in vitro study towards the use of pomegranate juice in the treatment of men with erectile function or dysfunction.

Q. Thank you, Doctor.

So in your expert opinion, Doctor, did the respondents provide competent and reliable scientific evidence showing that drinking eight ounces of POM Wonderful pomegranate juice daily prevents, reduces the risk or treats erectile dysfunction?

A. They have not.

Q. And in your expert opinion, did the respondents show that clinical studies, research and/or trials prove that drinking eight ounces of POM Wonderful pomegranate juice daily prevents, reduces the risk of or treats erectile dysfunction?

A. No. I think they've shown the opposite. I think in one published and one unpublished study they showed that it has no effect, so it's actually shown the opposite.

MR. WONE: Thank you, Doctor.

No further questions.

JUDGE CHAPPELL: Cross-exam?

MR. FIELDS: Yes, Your Honor.

JUDGE CHAPPELL: How much time do you think you'll need?

MR. FIELDS: I would say an hour and a half.

JUDGE CHAPPELL: All right. Let's get started, and then we'll take a short break.

MR. FIELDS: Do you want to take a break now or do you want me to get started?

JUDGE CHAPPELL: I didn't hear the last thing you said.

MR. FIELDS: I said I'm prepared to go either way the court directs.

JUDGE CHAPPELL: It looks like we may go past 5:30 tonight.

Go ahead and start.

MR. FIELDS: Okay.

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CROSS-EXAMINATION

BY MR. FIELDS:

Q. Good afternoon, Doctor.

Let's begin by reviewing some of the things you said were necessary to make a claim with reference to effecting erectile function.

Do you know the term "RCT study"?

RCT study?

A. RTC?

Q. RCT.

A. I don't know what that is.

Q. Okay. Well, it's a study term. It's a term commonly used by researchers to indicate a randomized, double-blind, placebo-based trial, and they call it for short "RCT." A number of experts in this case have used the term.

A. I don't know who "they" are. You'll have to tell me who "they" are.

Q. Yes. A number of experts in this case have used that term. You can assume that. But if you prefer, I'll say the whole thing each time.

A. I'd prefer that.

Q. Okay. So you have indicated in your testimony and in your report that the only kind of science that could justify claims to help erectile dysfunction are double-blind, placebo-based, randomized trials; right?

A. Yes.

Q. Okay. And you shouldn't be making a claim of helping erectile dysfunction unless you have that kind of trial; right?

A. Well, I think if you have a product that you're looking to have approval from the Food and Drug Administration, the Food and Drug Administration would require that as a --

Q. Well, is it -- I'm sorry.

A. That they would require that in order for the

drug to be approved, yes.

Q. Well, we're not really here today to -- I think to talk about what the Food and Drug Administration requires but what you say is required before somebody can make a claim, a public claim, of a product that helps with erectile dysfunction.

And in that regard, sir, as I understand it, you were saying one should not make that kind of public claim, in fact it's improper to do so, unless you have a placebo-controlled, randomized, double-blinded test; correct?

A. Yeah. Well, let me be perfectly clear, that in order to market a product, a drug, in the United States, if you want to market the drug under the auspices of the Food and Drug Administration, that's the requirement of the Food and Drug Administration.

Q. Yes. I'm asking --

A. And we're talking about the United States, not, you know, North Korea.

Q. Yes, sir. But I'm not really asking you about the Food and Drug Administration or marketing a drug. We're here today to talk about pomegranate juice and we're here today to talk about your opinions.

And I'm asking you if it isn't your opinion, sir -- putting aside what the FDA might require, isn't

it your opinion that one should not properly make a public claim of a product that helps erectile dysfunction in the absence of having had what I call an RCT test but what you call a randomized, double-blind, placebo-controlled test?

A. That's correct.

Q. Thank you.

Now, if I understand, you also require that the test, the study, be held at two separate locations; right?

A. I think I used the word "multiple."

Q. More than two.

A. Correct.

Q. So if, let's say, Dr. Burnett at Johns Hopkins did this test and another man on the faculty of Johns Hopkins did this test, even if they were double-blind, placebo-based, randomized tests, that wouldn't be sufficient in your opinion; correct?

A. I think you -- what I would like you to do is to define the terms under which you want the product to be marketed, so you're being very vague.

If you want the product to be marketed in the United States and you want approval by the United States government, those are what the requirements are. If you're not looking for that, if

you don't care, then you can do whatever you want to do, which is in fact what you've done.

So the requirements in order to have something approved by the government are what I said.

Q. When you say "the government," you're talking about the FDA; correct?

A. I'm talking about the United States government, a component of which is the FDA.

Q. Would you tell me the other government agencies that have to approve health claims for a product.

A. Well, I think this is the Federal Trade Commission here, not the FDA.

Q. Your understanding is the Federal Trade Commission has to give approval in advance to market a product?

A. Well, isn't that why we're here today?

Q. No.

A. Oh. I thought it was.

Q. Putting aside what government approvals might be and the FDA -- I thought my question was clear. Let me put it again.

You have said that in order to make a public claim for benefit to erectile function one must have a double-blind, placebo-based, randomized trial, and you've also said it has to be a trial done in two

separate institutions at least; correct?

A. It should be, yes.

Q. Well, you said it has to be; isn't that correct?

A. Yes.

Q. Okay. And so my question was, if Dr. Burnett -- by the way, Dr. Burnett at Johns Hopkins is a very distinguished man in the field, isn't he?

A. He is. He's a good friend of mine, so yes.

Q. And if he did this at Johns Hopkins, he ran the double-blind, placebo-based, randomized test, and it came out positive, you would say that's still not enough to support making a public claim on behalf of this product; right?

A. That's correct.

Q. Okay. And you say that in addition, this has to be a very large group to make sense. It has to reach statistical significance. Isn't that what you said?

A. Yes.

Q. And you also say that to be competent and reliable evidence to support a public claim of benefit to erectile dysfunction the wives have to confirm what the husbands say.

A. See, the tendency today in clinical trials looking at erectile dysfunction include not necessarily

the wife but the sexual partner.

Q. Yes. You have said that the -- let's call it the sexual partner -- must confirm what the male partner says in this test in order to justify making a public claim about helping --

A. Right.

Q. -- erectile function.

A. That gives the most reliable information. That's correct.

Q. But you've said it's required, haven't you, sir?

A. Yes. I used the word "required" for drugs that are being submitted to Food and Drug Administration. If you want to take a lesser standard -- I don't know what standard you're looking for. I'm talking about the use of drugs that are submitted to the Food and Drug Administration so they can be marketed in the United States.

JUDGE CHAPPELL: Hold on a second. I don't want to derail the cross-exam, but you're like two ships passing in the night.

Doctor, you keep talking about drugs. I'm not sure he's talking about drugs.

THE WITNESS: He is talking about drugs, Your Honor. This --

JUDGE CHAPPELL: So you're only prepared to talk about a drug the claim has made, not any other juice or springwater or anything else?

THE WITNESS: Your Honor, water is water. It has H2O, a product. The active ingredient of the product is not water. Otherwise, they'd be selling Evian springwater. They're selling a product that is composed of drugs. In this case the drugs are polyphenol agents that have a specific biologic effect, or they claim that they do, so it's a product, even though they're calling it a juice, but it's a product with drugs in it.

JUDGE CHAPPELL: So let me make sure I understand you.

In your opinion, pomegranate juice is a drug.

THE WITNESS: Correct.

JUDGE CHAPPELL: Thank you.

BY MR. FIELDS:

Q. I think that tells us a lot, Doctor.

Now, you also said that in order to satisfy your test for what's required to make a public claim of helping erectile dysfunction, the man's -- the man's erection must allow him to complete intercourse; isn't that correct?

A. It would allow him to complete it to sexual

satisfaction.

Q. Yes.

And by that you mean he must have an orgasm; right?

A. Well, that would be sexual -- for most people it would be, yes.

Q. Well, that's what you've said, isn't it, that what you meant by sexual satisfaction was having an orgasm?

Right?

A. Yes.

Q. Okay. And not only must he have an orgasm in order to allow this public claim, but his wife must have -- oh, his sexual partner -- sorry -- must have an orgasm; right?

A. I'm not sure that's true.

Q. Well, didn't you say that?

A. I don't remember saying that.

Q. Didn't you say that both must have sexual satisfaction?

A. Yeah. But I don't know sexual satisfaction of the female partner includes orgasm. Maybe it means that for you in your relationship, but I'm not sure that's true for the general population.

Q. I'm not talking about the general population,

Doctor; I'm talking about what you testified to in your deposition.

A. I didn't say that in my testimony.

Q. You did not say that the man must reach orgasm.

A. No. I think the definition of the NIH is sexual satisfaction, and that includes orgasm. In the NIH definition, that was not -- the female component was not considered, just the male component.

Q. Well, what did you mean when you said the female must reach sexual satisfaction?

A. That she should be satisfied with the sexual event.

Q. So the man must reach orgasm, but the woman just has to be somehow satisfied with the sexual event whether she reaches orgasm or not; right?

A. That's correct.

Q. Okay. Now -- so you're saying that even if I market a product and make public claims about that product and I run a test and the test shows that a man's erection -- having been unable to get an erection, let's say, for five years, now he takes my product and he can get an erection, he can penetrate his wife, he can bring her to satisfaction, but he can't have an orgasm himself, that doesn't count, does it?

A. I don't know. Is this some hypothetical

question? This has nothing to do with the data. The data didn't show and even in the published data that in fact there was no statistical difference. I don't know where you're -- where are you asking me this question from?

Q. Sir, I'm asking you this question from your own report and from your own deposition testimony. You said that it doesn't really count as efficacious --

JUDGE CHAPPELL: Hold on a second. He's asking you to clarify exactly where this is coming from. Is it what he said today? Is it a deposition? Is it an expert report? He deserves to know that.

MR. FIELDS: I'll be glad to do that, Your Honor.

JUDGE CHAPPELL: Thank you.

MR. FIELDS: Yes. I thought he testified, that he did say in his deposition that the man must reach orgasm, but let's look and see.

Page -- I've got my glasses somewhere. Thank you.

Mr. Graubert handed me my glasses.

BY MR. FIELDS:

Q. Page 53.

You have testified about the requirement of sexual satisfaction, and you say -- the question

(as read): I'll back up here because maybe I'm still not understanding completion of intercourse. What point is the completion of intercourse?

That was your term, Doctor, completion of intercourse.

"Well, the normal standard of the completion of intercourse is orgasm and ejaculation."

A. Well, that's --

Q. So you did say that.

A. No. I think you would agree with that. I think that's the general standard of what completion of intercourse is.

Q. Yes.

So my question that I asked you after that was: Are you saying that if a man hasn't been able to have an erection for five years, then he tries my product and he now has an erection and he can penetrate his wife and bring her to sexual satisfaction, but he doesn't have an orgasm himself, that doesn't count, I can't tell the public about what I've done?

A. Well, I don't know what you're basing your question on. What are you asking me about? Are you asking me about the results of the Davidson study? Are you asking me the results of the Forest study? What is the basis of your question?

Q. The basis of my question is to test your standard and what you've told this court.

A. I can't answer the question the way you're asking me because it's not based on any reliable information.

Q. I'll try to rephrase it again.

JUDGE CHAPPELL: Maybe you should ask him to assume.

MR. FIELDS: Yes, I will, Your Honor. Thank you.

THE WITNESS: Oh, a hypothetical question.

MR. FIELDS: We can do it that way.

THE WITNESS: Okay. And then I'll understand what you mean.

MR. FIELDS: I see. Thank you.

JUDGE CHAPPELL: Do you want Josett to read the question back as an assumption or do you want to --

MR. FIELDS: No. Read it back. And just make it your assumption, Doctor.

Thank you, Your Honor.

(The record was read as follows:)

"QUESTION: So my question that I asked you after that was: Are you saying that if a man hasn't been able to have an erection for five years, then he tries my product and he now has an erection and he can

penetrate his wife and bring her to sexual satisfaction, but he doesn't have an orgasm himself, that doesn't count, I can't tell the public about what I've done?"

THE WITNESS: No, he can't, he cannot.

BY MR. FIELDS:

Q. Okay. Now -- is this a good time to take our recess, Your Honor? I'm about to go into a slightly different subject, but I'll be glad to go on.

JUDGE CHAPPELL: No. Let's go ahead and break.

MR. FIELDS: Okay.

JUDGE CHAPPELL: We'll reconvene at 4:30.

(Recess)

JUDGE CHAPPELL: Back on the record Docket 9344.

MR. FIELDS: Thank you, Your Honor.

BY MR. FIELDS:

Q. You have -- you have the opinion that before you make a claim of the ability to help erectile dysfunction, your product, you have to prove it; isn't that right?

A. Yes.

Q. And you have to prove it by going through these various steps that you've told us were required; right?

A. Yes.

Q. Okay. But, Doctor, you don't apply that

standard consistently, do you?

A. I don't know what the implication of your question is.

Q. The implication is that you don't apply it consistently. Correct me if I'm wrong.

A. I'm correcting you.

I'm correcting him. I don't know what he's talking about.

Q. Okay. We'll get to it.

Are you the CEO and cofounder of a company called Ion Channel Innovations?

A. Yes, I am.

Q. That company makes a therapy for erectile dysfunction called hMaxi-K; is that correct?

A. That's correct.

Q. That's a form of gene transfer therapy for erectile dysfunction.

A. Yes.

Q. Potentially a competitive product with pomegranate juice; correct?

A. I don't know if it is or it isn't.

Q. By the way, isn't it correct that the standards in your mind for substantiating a claim for fruit juice are the same as for substantiating a claim for gene transfer therapy?

A. For what?

Q. Gene transfer therapy?

A. No, no. A claim for what?

Q. Oh. The claim to help erectile dysfunction.

A. It should be, yes.

Q. It should be the same. All right.

Do you recall, sir, an interview you gave with somebody named Lizzy Ratner of The New York Observer, a paper of general circulation in New York?

A. No.

Q. All right. Let me read you statements and see if you recognize them.

By the way, I refer to what we have marked as Exhibit RX 5010, which has a handsome picture of Dr. Melman (indicating).

A. Thank you.

Q. Do you recall, without regard to the name of the reporter, giving an interview about hMaxi-K, your ED product, on July 30 --

JUDGE CHAPPELL: Do you have an objection?

MR. WONE: Yes, Your Honor.

Complaint counsel requests that respondents provide a copy to --

MR. GRAUBERT: It's on your right-hand side.

MR. FIELDS: You can give it to the witness as

far as I'm concerned, sure.

JUDGE CHAPPELL: Did you mean a copy to complaint counsel or to the witness?

MR. WONE: A copy to the witness.

JUDGE CHAPPELL: Go ahead.

BY MR. FIELDS:

Q. All right. That's your picture on the cover, sir?

A. It's not the cover, but it's my picture in the article, yes.

Q. Okay. And does it now -- does this now refresh your recollection that indeed you did have an interview with Ms. Ratner?

A. If I did, it was a telephone interview. I probably did.

Q. Okay. And in that interview about hMaxi-K you told her that your product would not only help erectile dysfunction, but it also conceivably could benefit asthma, hypertension and diabetes.

A. Let me correct you, and that is that we do not have a product. There's no product. There's nothing being sold. This is in the testing phase.

So there's no product.

Q. Sir, you have something called hMaxi-K that you hope to market; correct?

A. I would like to if it goes through the testing process of the FDA and it's proved to be successful, that's correct, but there's no product.

Q. You hope to market hMaxi-K?

A. Yes.

Q. And you think the word "product" is incorrect because it wasn't actually on the market; is that --

A. There's nothing on the market.

Q. I see.

A. No sales. This is in the testing process.

Q. Yes.

But in the testing process you made these public statements about --

A. I didn't -- what public statements?

Q. Well, how about that the men who tried hMaxi-K had spontaneous, normal erections? How about that they were like young men again? How about calling your product the fountain of youth?

Did you call your product the fountain of youth, sir?

A. We did a phase I ED trial which was a nonplacebo-controlled phase I safety trial, and during the phase I safety trial, which was done on 20 men, several of the men got erections. This is just the response to a phase I trial. This trial -- this product

now has to go through phase II and III, phase III testing. hMaxi-K is not on the market. It's just gone through phase I testing.

Q. But despite that, despite the no RCTs, no double-blind, placebo-based, randomized tests, despite the fact that the wives were not interrogated, despite the fact --

A. Well, the wives were interrogated.

Q. Despite the fact --

A. And just --

JUDGE CHAPPELL: Hold it, hold it, both of you. One at a time. Is that clear?

MR. FIELDS: Yes, sir.

JUDGE CHAPPELL: Is that clear to you, Doctor?

THE WITNESS: Yes.

JUDGE CHAPPELL: Proceed.

MR. FIELDS: I'm sorry, Your Honor.

BY MR. FIELDS:

Q. In any event, you felt in the absence of the tests that you told us were required to make a public claim, you made these public claims; isn't that correct?

A. No, no, no. Let me correct you. What you asked me about is to market a product. You were asking about marketing and selling a product, and I said that to sell

a product you had to go through a testing process, and this is not -- we're not selling a product. These are the results of the phase I trial.

Q. I think, Doctor, if you go back to my questions, you'll find that I asked you about making a public claim --

A. I did not --

JUDGE CHAPPELL: Hold on. You need to let this gentleman finish his question.

Go ahead.

BY MR. FIELDS:

Q. My questions were about making a public claim -- the record will show that -- not about selling a product.

Now, without regard to whether we're selling a product or not, you have a product you hope to market; correct?

A. No. I have a gene transfer therapy which I eventually would like to market, that's correct.

Q. You hope to market.

A. Yes.

Q. Okay. And indeed you have something like 17 patents on it; correct?

A. That's correct.

Q. And you hope to make money from it.

A. I would like to, yes.

Q. And without having the tests you told us were required, you made all of these statements to The New York Observer, to the public; correct?

A. They called us and asked us the result of the trial after a scientific presentation and publication.

Q. Sir, did you --

A. I didn't say anything -- anything to her that was not published or given in a public presentation, the same thing.

Q. Sir, did you tell The New York Observer that the men that you had tested had spontaneous, normal erections?

A. Correct.

Q. Did you tell them that it was like they were young again?

A. Correct.

Q. Did you tell them that -- did you tell her that you called your erectile dysfunction product the fountain of youth?

A. I said that would be the equivalent. Yes.

Q. Well, you called it the fountain of youth, didn't you?

A. I said it could be like that. That's correct.

Q. Did you say it was the fountain youth or it

could be like the fountain of youth?

A. It could be -- it wasn't -- it could be like. I don't know.

Q. You don't remember.

A. No.

Q. Okay. Did you say that you were talking about modifying the aging process?

A. Yes. And that was based upon the result of an animal study which we published.

Q. An animal study --

A. Yes.

Q. -- was the basis for your making this public claim.

A. I gave the results of an animal study. That's correct.

Q. The animal -- just the kind of animal study that you say couldn't be the basis for this kind of claim?

A. No. The question that was asked of me this morning was could POM, your company, make the claim that it corrected, precluded and improved or prevented erectile dysfunction in humans based upon an animal study, and the answer is it could not. And she asked me about the results of an animal study, and I gave her the results of an animal study. That's what we were talking

about.

Q. Sir, you made the claim that --

A. I didn't make a claim.

Q. You didn't make a claim.

A. No.

Q. Well, you said to the public that these gentlemen had spontaneous, normal erections, that they were like being young again, that you were talking about modifying the aging process, that it was the fountain of youth, and you don't call that making a public claim?

A. I didn't make a public claim.

Q. You didn't make a public claim.

A. No.

Q. I guess His Honor will have to decide.

Sir, in fact you only had 11 men in the study you did; right?

A. No.

Q. That isn't true?

A. No, it's not true.

Q. How many men did you have?

A. Twenty.

Q. Twenty men in the study you told Ms. Ratner about?

A. I couldn't hear what you said.

Q. In the study you told Ms. Ratner that the --

A. She called me at a particular time before we had done the second component of the phase I trial, so we've now tested in phase I testing 20 men.

Q. Yes. But I'm not asking you what you have now done. You've now tested the large number of 20 men. I'm asking you about when you talked to Ms. Ratner and made all of these claims.

A. I didn't make any claims. Ms. Ratner called me and asked me about the results of the study.

Q. And that's --

A. I didn't call Ms. Ratner.

So I think you're mischaracterizing what this interview was about. I know why you're mischaracterizing it, but I didn't call her. She called me.

Q. Okay. And that means you didn't make a claim because she called you; is that what you want --

A. No. She called me and asked me about the result of the phase I trial.

JUDGE CHAPPELL: Let's use a word other than "claims" to reduce the blood pressure on both sides.

MR. FIELDS: My blood pressure is pretty low.

JUDGE CHAPPELL: Thank you.

MR. FIELDS: But I'll move on anyway.

BY MR. FIELDS:

Q. Isn't it a fact that gene transfer therapy is considered by some in the science field to be risky?

A. You have to explain to me the origin of your question.

Q. Well, isn't it true that people have died and gotten very sick from gene transfer therapy?

A. Yes. The people who have been sick have all -- I'm sure that you know that the people who have died have died using viral vectors as a means of inducing the transfer, you do know that, and you know of course the type of vector that we're using; is that correct?

Q. I didn't understand anything you said, sir.

A. That's correct. I know you did not.

Q. Let me read you a statement from the article and see if you agree with it.

"Ever since an 18-year-old boy with a rare metabolic disorder died in a gene therapy trial in 1999, the bold new biotechnology has been tainted with the risk of deadly, unintended consequences."

Is that true?

A. When using viral vectors, that's correct.

Q. All right. Now, as far as you know, you know of no instance of anybody reporting being harmed by eating pomegranates or drinking pomegranate juice --

A. What does that have to do with gene transfer?

Q. Well, my point is, gene transfer is risky and pomegranate juice isn't.

A. I'm sorry. I can't -- you have to speak up. I can't hear you.

Q. I'm very sorry. I have a soft voice.

My point was that --

(Admonition by the court reporter.)

BY MR. FIELDS:

Q. I think the reporter was having trouble hearing you, but let me go ahead.

JUDGE CHAPPELL: Let's start with a new question.

MR. FIELDS: Yes.

JUDGE CHAPPELL: And I'm directing the court reporter that the previous couple seconds of banter need not be on the record since it's unintelligible.

MR. FIELDS: I'm sorry, Your Honor.

BY MR. FIELDS:

Q. You induced a school teacher named John Otto to invest in your product a million dollars; isn't that correct?

A. I'm sorry. I don't know what the word "induced" means.

Q. "Induced" means you talked him into it.

A. I what?

Q. You talked him into it.

A. No. That's not true. That's not correct.

Q. He just voluntarily gave you a million dollars; you didn't tell him how good the product was?

A. No. This was at the onset of the company. He knew about the product, and he invested in the product.

Q. How did he know about the product --

A. Because I told him about it.

Q. You told him about the product, and he gave you a million dollars. You told him --

A. No, he didn't give me a million dollars.

Q. Did he invest a million dollars?

A. He invested a million dollars.

Q. I see.

And that was based upon your telling him pretty much the same things you told Ms. Ratner; isn't that correct?

A. You know, that's not correct because what Ms. Ratner was told was after the trials were begun. What Mr. Otto did was invest in the company before anything was done, so that's absolutely not correct, although your attempted mischaracterization is well-taken.

Q. Sir, you got your medical education at the Rochester School of Medicine and Dentistry?

A. Yes.

Q. And you've been involved with I think six different institutions since you started; correct?

A. I haven't counted them, but I'll accept your number.

Q. Thank you.

You testified as an expert witness for the FTC in three or four previous cases; correct?

A. Yes.

Q. And each time you have testified for the FTC you testified the respondents' claims were not substantiated; isn't that correct?

A. Probably.

Q. Well, you don't recall ever coming into court and saying they were substantiated.

A. No. One of -- the claims of some of the products that were used were not only not substantiated but also caused injury to the -- had the potential of causing injury to people who took the drug, so it was more than not being substantiated.

Q. And this time you were actually hoping to testify in this case; correct?

A. Why would you say that?

Q. Well, I thought you said that in your deposition.

If you'd look at page 85 of your deposition.

Question at line 13: "You're planning on testifying in the trial in this case, though, aren't you?

"ANSWER: I would hope so."

A. Yeah, that's correct. This was at the deposition two months ago.

Q. Yes.

A. Yes.

Q. Okay.

A. I was hoping to meet you.

Q. You also have been retained many times as a defense expert in malpractice cases; correct?

A. I'm sorry. I don't understand your question.

Q. Have you been retained --

JUDGE CHAPPELL: Hang on a second.

Do you mean medical malpractice, legal malpractice? Let's be clear.

MR. FIELDS: I'm sorry, Your Honor.

BY MR. FIELDS:

Q. Medical malpractice cases?

A. You have to be more specific.

Q. Well, about 18 times a year don't you consult

with lawyers in the defense of medical --

A. People call me and ask them to give me -- me to give them my opinion about specific cases, that's correct.

Q. And you review documents in those cases about 18 times a year for the defense?

A. Those are the numbers that I gave, yeah.

Q. Yes.

And you're a paid lecturer at various drug companies?

A. Not any longer, no.

Q. When did you stop doing that? Before your deposition?

A. About ten years ago.

Q. Ten years ago.

A. Yes.

Q. And actually drug companies sponsored some of your work on hMaxi-K; correct?

A. That's not correct, no.

Q. It's not?

A. No, it's not.

Q. Well, I could be wrong, but is there a company called VIVUS?

A. There is a company called VIVUS.

Q. And did it sponsor the preclinical work you did

on your hMaxi --

A. Right. But your implication is that they -- the way you're asking the question implies that it sponsored Ion Channel's work, which is not true, because at the time that VIVUS sponsored the work there was no Ion Channel Innovations. This was before the company.

Q. I just asked you if you --

A. I'm just --

JUDGE CHAPPELL: Hold it, hold it.

THE WITNESS: I'm just clarifying --

JUDGE CHAPPELL: Am I going to need to have you two say "over" at the end of each statement like you're on some army field radio or can you stop talking over each other?

MR. FIELDS: I'll try my best, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MR. FIELDS:

Q. Is it correct you've never done any testing of any kind on pomegranate juice?

A. Have I tested pomegranate juice? No.

Q. And you haven't done very much writing on the oral treatment of ED, have you?

A. Have I written about the oral treatment, I have not.

Q. Most of your current research is on gene

transfer therapy and overactive bladder condition; isn't that right?

A. Yes.

Q. The only research you've ever done on a food product was on alcohol, a substance called yohimbine; correct?

A. Yes.

Q. That was twenty years ago.

A. Right.

Q. You've never done a clinical trial on any food product; is that correct?

A. Well, by "food product" do you mean drugs? Drugs? I don't know what you -- you'd have to define a food product for me.

Q. On your definition everything is a drug, but --

A. Well, that's true.

Q. -- have you -- you've never done any clinical work on something that ordinary people would call a food?

A. You mean like mushrooms and hemlock?

Q. Like mushrooms or like broccoli or carrots.

A. No.

Q. Thank you.

JUDGE CHAPPELL: Was that -- what's that you're asking? What ordinary people would call a food?

Go ahead.

MR. FIELDS: Well, you know, I come from the west, so we talk like that.

BY MR. FIELDS:

Q. Okay. Now, I think you already told us you recognize that Dr. Burnett at Johns Hopkins is highly respected in his field; correct?

A. I couldn't hear your question. Speak up, please.

Q. Yeah. I'm sorry.

That Dr. Burnett of Johns Hopkins is a man highly respected in his field?

A. Yes.

Q. Okay. And you said that Dr. Goldstein of the UCLA Medical Center is highly regarded as well?

A. No. I said Dr. Rajfer at the UCLA Medical Center. I don't think Dr. Goldstein is at UCLA. He's in San Diego.

Q. I have Dr. Goldstein of San Diego is highly regarded --

A. Well, he's your expert, so I assume that's who you mean.

Q. Is he highly regarded?

A. I don't think I said that. I think your lawyer said that.

Q. Pardon me?

A. Your attorney said that during the deposition.

Q. I see. You didn't say it.

A. No.

Q. Let's look at 135.

A. Could I see the page, please.

Q. Okay.

"QUESTION: And you would agree that Dr. Goldstein is highly regarded among urologists?

"ANSWER: Well, you used a different word then. You said 'respected' for Burnett and 'regarded' for Goldstein. But I'd agree with that."

Right?

A. Right. I'd agree with that he characterized one as respected and one as highly regarded, yes. I agree with what he said.

Q. All right. Dr. Ignarro, who is a Nobel Prize laureate, is he highly respected also?

A. Yes.

Q. And if these three distinguished scientists opined that drinking pomegranate juice is likely to produce a significant benefit for erectile dysfunction, would you accept that?

A. Is this a hypothetical question?

Q. Yes.

A. Well, if they said it and it was based upon evidence and proof, I would accept it. If it were not, then I would not accept it.

Q. You wouldn't expect them to say something that wasn't based upon what they considered --

A. I can't answer for them.

Q. -- sufficient evidence --

A. I couldn't answer for them.

Q. You can't answer that. All right.

A. No.

Q. UCLA Medical Center has a good reputation, doesn't it?

A. Yes, it does.

Q. And do you know Dr. Aviram with the Technion Israel Institute?

A. No, I do not.

Q. You know the institute, though; right?

A. Yes, I do.

Q. And you called it a terrific institution; isn't that correct?

A. That's correct.

Q. Now -- Your Honor can see I'm leaving parts out. Maybe even more.

Blood vessels and the flow of blood are important to ED; right? I think you testified to that.

A. Could you repeat your question.

Q. Yes.

Are blood vessels and the flow of blood to the penis important to ED?

A. They're important to erectile function. Yes.

Q. Yes. Sure. Okay.

And if a therapy helps cardiovascular disease by increasing the blood flow in the human body, isn't that likely to help with ED as well?

A. Not necessarily. It would have to increase blood flow to the penis.

Q. I said isn't it likely to have a beneficial effect, not --

A. I don't know the answer.

Q. You don't know the answer.

A. No. Unless you give me the data, I can't answer you.

Q. All right. Nitric oxide also employs a critical role in the erectile process I think you told us; correct?

A. Yes.

Q. All right. And some erectile dysfunction is caused by nitric oxide; is that right?

A. I can't understand the -- I can't answer the question the way you're asking me the question.

Q. Is some erectile dysfunction caused by an insufficient supply of nitric oxide?

A. It's theorized that it does, but in fact no one knows exactly how much nitric oxide has to be produced or not be produced to cause ED. That number is not known.

Q. I'm not asking you about the number or the amount.

My question is: Is a shortage of nitric oxide one of the causes of erectile dysfunction?

A. It may be. We don't know the exact number.

Q. Again, I'm not asking you the exact number.

A. I'm answering your question. I'm answering the question.

Q. Is your answer you don't know?

A. I'm telling you I don't know the exact number, that's correct.

Q. But, sir, I'm not asking you the exact number. I'm saying, isn't it -- without regard to the number, isn't an insufficiency of nitric oxide one of the causes of erectile dysfunction?

A. I've given you my answer.

Q. Sir?

A. I gave you my answer.

JUDGE CHAPPELL: He said, "It may be."

MR. FIELDS: Okay.

JUDGE CHAPPELL: When it was phrased slightly differently, rather, from shortage to insufficiency, his answer was: "It may be."

MR. FIELDS: Okay.

BY MR. FIELDS:

Q. All right. Let's talk about a Forest study.

You in your deposition, and you said it again in the trial, you said the Forest study showed that pomegranate juice just didn't work; isn't that right?

A. Yes.

Q. You kept insisting on it at your deposition. Do you remember that?

A. I certainly do.

Q. Do you remember you said you just hope that the urologists would be smart enough to know that the study showed it didn't work? Right?

A. Yes.

Q. All right. Now, in fact, sir, it really did work, but it -- the probability was only 94 instead of 95; isn't that correct?

A. No, it really didn't work. It did not. You could stand on your head and tell me it worked, but it didn't work. It did not work. It did not work.

Q. There was an improvement, wasn't there --

A. In what?

Q. -- it didn't reach statistical significance?

A. It did not work. The test -- the reliable, validated test that was used in both the Forest study and in the Davidson study, the IIEF, showed no statistical difference between the men taking pomegranate juice and placebo. The two trials showed that it did not work.

Q. Sir, the fact that something doesn't reach statistical significance doesn't mean it didn't work, does it?

A. The whole point, sir, in doing a test is to rely upon statistical data. And if the statistical data showed it did not work, it did not work.

If your concept is to say that when you prove something doesn't work that it really did work, you could do that. You're free to do that.

But if you ask me the question did the test -- did the study show that it worked, the answer is it did not work, and it didn't do it in two studies, one of which you chose not to publish and the other one that you did publish, and in both of them it showed it gave no statistical difference.

Q. Sir, I just want to get it clear.

When you say something didn't work, you mean it

didn't reach statistical significance; isn't that correct?

A. The test, sir, was to see if there was an improvement in erection when pomegranate juice was given in two studies. The outcome, the validated IIEF, was used in two studies, and the conclusion in both studies, one which was published and the other which was not, showed there was no difference. There was no difference.

Q. On one --

A. Not that it didn't approach. There was no difference. There was no difference in either the Davidson study or in the Forest study.

Q. Your --

A. Not that it came close or approached it, there was no difference.

Q. And that's your testimony under oath, that there was no --

A. It's my testimony under oath --

Q. Let me finish the question.

A. -- to a supreme being. Yes.

Q. -- between -- there was no difference between the placebo group and the pomegranate juice group.

A. Yes. That's the data.

Q. None at all, not just that it didn't reach

statistical significance --

A. Actually I think that the trial showed that there was more improvement in the placebo group than in the pomegranate juice.

Q. Are you sure of that, sir?

A. Yes.

Q. Okay.

A. But in either case it didn't reach statistical significance.

Q. It certainly didn't reach statistical significance. We're agreeing on that. I want your testimony clear.

A. It's clear. There was no improvement.

Q. There was no improvement at all.

A. No. The IIEF was the same in both studies.

Q. And how about the GOP -- GAQ? Pardon me.

A. The GAP is a nonvalidated test that is of no value. It shouldn't be used. It was used as the primary endpoint, and even when it was used, it didn't show a difference. And in addition to that, there was no significant difference, and the data that was used was flawed because it was given -- more of the people who responded got the POM first before the -- they got the placebo. It was flawed data which was said by the authors of the paper.

Q. We'll get to all of that. All I want to do is find out if there was an improvement --

A. I know what you're trying to do. The answer is no. I'm being very specific. There was no improvement.

Q. In the GAQ questionnaire there was no improvement; that's your sworn testimony.

A. Yes.

Q. Okay. Not --

A. No statistically improved improvement.

Q. No. I'm not talking about statistically --

A. Well, I'm talking about statistical improvement.

Q. Well, that's what I'm trying to get to, sir.

There was an improvement, wasn't there? It just didn't reach statistical significance; isn't that correct?

A. It's not correct.

Q. So if you're saying that there was literally no --

A. Either you use real data and statistics or you use rhetoric. If you want to use rhetoric, which is what you seem to want to do, you can say whatever you want, but in the real world there's no significant difference.

Q. Significant difference is a little different from difference, isn't it?

A. I can't answer your question.

Q. Well, I just want to be clear because you're trying to --

A. I'm being very clear, sir.

Q. Are you saying there was no difference at all or are you saying there was no statistically significant --

A. There was no significant difference.

Q. Okay. I thought --

A. You can have -- let me just educate you for a second or the judge. You can have a difference, but if that difference does not reach a level of significance, then it's not different. It shouldn't be considered different.

So even though the numbers may change, if it doesn't reach the predetermined level of significance, then it's not different. Whether it goes up or down, you don't consider it different.

Now, your goal is to try and make-believe that it is, but it's not. It's not different.

Q. I think we now have clarity, and I just want to make sure.

There was a difference, but it didn't reach --

A. No, no, no, sir, there was no difference. There's no difference.

JUDGE CHAPPELL: Wait a minute. What about an ordinary person?

THE WITNESS: An ordinary person -- what do you mean, "an ordinary person"?

JUDGE CHAPPELL: Would they consider it different if it wasn't statistically --

THE WITNESS: Well, you know, the reason we have comment in the world, sir, is that people try and convince ordinary people that something that's not different is different. People who do scientific studies have to have some basis for comparison, and the basis for comparison is to achieve statistical reliability. If you don't get it, then you don't get it, and it's not different. And the numbers can go in either direction.

JUDGE CHAPPELL: The problem we have is the record is all over the place, and I can see why he's asking you these questions because I heard you say earlier absolutely no difference, and then based on what I'm also hearing you say, what you meant was absolutely no statistically -- or no significantly statistical difference.

THE WITNESS: That's correct. There's no

difference in the same number. It doesn't matter what the numbers are. There's no difference.

JUDGE CHAPPELL: And to you, when you say "no difference," you don't mean no difference whatsoever; you mean statistically significant difference.

THE WITNESS: That's correct.

MR. FIELDS: Thank you.

THE WITNESS: Your Honor, that's the whole basis of science. If you forgo the basis of science, then you might not as well do any of the scientific studies.

BY MR. FIELDS:

Q. Let me read you something and you tell me if you agree with it or not:

Medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence.

Do you agree with that statement?

A. No. It's so nonspecific, I can't. You have to go on from there. What do you mean?

Q. Well, do you agree that medical professionals and researchers do not limit the data they consider to statistically significant evidence?

A. No. What I think the implication of that is and what I testified to earlier in the day is that, in addition to statistical difference, there has to be a meaningful change in addition to that so that the person, the participant, the individual, can appreciate the actual change.

So as I testified to earlier -- and I'm sure you were listening -- if a person had a one milliliter per second increase in their urinary flow while they were voiding, they wouldn't notice a difference even though the drug made a statistical difference; but if that change were five milliliters a second, he would notice a difference, and that would be clinically significant.

Q. Isn't it true that even differences that are not statistically significant are considered and should be considered by medical professionals and researchers?

A. No.

Q. And if the statement I just made was correct, then the answer is yes.

A. No. The answer to your question is no.

Q. I understand.

But if the answer should be yes and if that statement I've made has validity, then your opinion goes out the window, doesn't it, sir?

A. No. The answer to your question is no, so I don't know why you're going on. The answer is no.

Q. Well, we'll get to that in this case.

You say that there are two kinds of questionnaires for ED, GAQ and IIEF; correct?

A. Did I say that -- I'm sorry. Did I say what?

Q. That there are two kinds of questionnaires that --

A. There are several questionnaires.

Q. Okay.

A. Validated questionnaires.

Q. There were two used by Dr. Forest; right?

A. Correct.

Q. And one was the GAQ, which stands for global assessment question; is that right?

A. Yeah. Questionnaire.

Q. Questionnaire.

And sometimes it's called global or global improvement questions?

A. I don't know.

Q. You don't know.

And isn't it correct that the first time you heard about the GAQ was in this case?

A. Yes.

Q. And your opinions about the GAQ were formed only

in this case; right?

A. My opinions are formed what?

Q. About the GAQ were formed in this case.

A. Well, I didn't know about it, so I formed my opinion after I learned about it, that's correct.

Q. You've done no research on the GAQ; isn't that correct?

A. Yes, I did.

Q. When did you do that?

A. Well, I did it after I was asked to examine the Forest study and I tried to find out about the GAQ and I found out it was not a validated test that's accepted by statisticians.

Q. Was it after your deposition that you did the research?

A. No, no. I did that before.

Q. Didn't you testify you had done no research on that subject?

A. If I did, I don't remember.

Q. If you did what?

I didn't hear your answer. I'm sorry.

A. No. It's my recollection as I sit here today that I looked it up after I was looking at the GAQ, not after the deposition.

Q. I'm looking at page 140:

"Did you do any research about the GAQ?

"Well, I tried to, but I actually couldn't find much about it because it's not a validated test" --

A. Right. That's exactly my answer.

Q. -- "so I tried but failed."

A. Yes. Correct.

So that was done after I got it before the deposition, you're correct.

Q. Now, when you told us repeatedly that the GAQ has been invalidated I think you said --

A. I'm sorry. I can't understand you.

Q. Did you say the GAQ has been invalidated?

A. No. I said it's not validated. It's not a valid test.

Q. And didn't you testify that it had been invalidated?

A. No.

Q. You didn't?

A. No.

Q. Okay. Did you -- you also said --

A. How can you invalidate something that's not validated?

Q. Did you say it was lousy?

A. A nonvalidated test is a lousy test. Yes.

Q. And inept?

A. That's correct.

Q. Let's see if I can find where you said it's invalidated.

JUDGE CHAPPELL: I think we're clear where he stands on that test, if that's where you're continuing to go.

MR. FIELDS: Yes.

JUDGE CHAPPELL: I'm not sure we need anything after inept and lousy, but...

MR. FIELDS: Okay.

JUDGE CHAPPELL: I think he wants to speak to you about something (indicating).

MR. GRAUBERT: Did you hear what the judge said?

MR. FIELDS: I must not have heard you, Your Honor. It must be my ears.

JUDGE CHAPPELL: That was a preemptive strike in case you were going to continue to ask him for what he thought about that test. I think we're clear.

MR. FIELDS: All right.

BY MR. FIELDS:

Q. When you use the word "unvalidated," who unvalidates something like this?

A. I don't recall ever using "unvalidated." This is not a validated test, not validated, not

unvalidated.

JUDGE CHAPPELL: Hold on. You actually used "nonvalidated" about three minutes ago.

THE WITNESS: Not validated.

JUDGE CHAPPELL: No. I heard you say "nonvalidated."

THE WITNESS: Nonvalidated. He's saying "unvalidated." I didn't say that. It's not a validated test.

JUDGE CHAPPELL: How about you define "unvalidated" and "nonvalidated"?

THE WITNESS: Nonvalidated -- there are tests that are validated statistically by statisticians, and there are tests that are not validated by statisticians, so the GAQ is not a test that's been validated by statisticians.

JUDGE CHAPPELL: And there's another option. What about invalidated?

THE WITNESS: I don't think you can invalidate a -- I mean, unless you do other studies, that's not what we're talking about here. We're talking about an unvalidated test or a nonvalidated test, something that's not been statistically validated by statisticians.

JUDGE CHAPPELL: All right. So it's your

position that "nonvalidated" and "unvalidated" are the same thing.

THE WITNESS: That's the same thing.

JUDGE CHAPPELL: All right.

BY MR. FIELDS:

Q. I just wanted to, just before we leave this, read you your answer from page 66 of your deposition.

A. Could I see it on the screen, please.

Q. He can actually look at it if you guys have a copy of the deposition (indicating).

A. No. We could all look at it.

MR. GRAUBERT: He's working on it.

BY MR. FIELDS:

Q. We'll get it on the screen.

All right. I'll read it and then --

A. No, no. I want to see it.

JUDGE CHAPPELL: He wants to read along, so hold on.

MR. FIELDS: Okay.

It's on the screen, Your Honor, I'm told.

BY MR. FIELDS:

Q. Okay. So I'm reading from page 66 (as read):

"And what are the two criticisms? Statistical significance and?"

And your answer: "And it's an inept,

unvalidated, meaningless test."

JUDGE CHAPPELL: You know, it's clear that even in the deposition you guys were talking over each other based on this excerpt.

MR. FIELDS: Well, it could be, but I wasn't there, and it's entirely possible. The word is "unvalidated." I won't ask if the reporter got it right. In any event...

BY MR. FIELDS:

Q. You said that statisticians have either not validated it or unvalidated it.

Is there some publication by these statisticians listing those tests that are unvalidated or valid, not validated?

A. Yes.

Q. And what is that called?

A. What is what called?

Q. The listing that you've referred to.

A. No. You go to PubMed and you look up a specific test and you get a series of articles that describe the statistical validation of the test. It's not any one specific journal.

Q. So there isn't any list of validated tests, is there?

A. Yes, there is. You go -- there are papers -- if

you look through the IIEF, there are publications that publish the validation statistics for the IIEF. Ray Rosen did that. That's true for all the tests that are done.

So the answer to your question is, you're not correct, and there is a list of publications.

Q. And what is that list called?

A. I just explained it to you.

Why don't you read the answer that I gave him.

Q. Is there a single list, sir, of --

A. I answered you already.

Q. Is there a single list of validated questionnaires?

A. No. I answered the question. I'm not going to answer you again.

Q. Is it correct that the GAQ has been widely used?

A. I don't know the answer. I don't know how widely it's been used. It's not a validated test. I would hope it's not widely used. I don't know.

Q. You don't know whether it's widely used or not.

A. No.

Q. Did Pfizer use it in their studies on Viagra?

A. I don't know.

Q. So it could have been used by many, many

companies over the years and --

A. I think --

Q. -- you don't know one way or the other.

A. I think it's not likely.

I know all of the studies that are submitted to the FDA that look at the outcome of drug data to effect erection use the IIEF or one of its variants. That's the primary outcome study for statistical significance to show if it's -- a drug is useful or not, not the GAQ. The IIEF has been used in thousands of publications.

Q. And --

JUDGE CHAPPELL: Hold on a second.

MR. FIELDS: I'm sorry, Your Honor.

JUDGE CHAPPELL: I'm going to give the doctor a chance to clarify or correct his testimony.

The first time you were asked if there was a single list, you said yes, and then you went on to explain it. The next time you were asked, you said no.

THE WITNESS: No. It's not like you could go to --

JUDGE CHAPPELL: And then you kept insisting you had already answered the question. In fact you had answered the question yes and then no.

THE WITNESS: So let me answer it. There's a --

there's no list of tests that are validated.

If you want to know if a test is valid, you put it into a query, a search, whatever engine that you want, Web-based engine you want to use, and you put it in and it will show -- a publication will show whether or not it's been validated or not by a series of statisticians.

I don't think you can go to a list that says "validated tests." If there is, I don't know what they are unless it's in a publication that I'm not aware of. But if you wanted to find out if a test has been statistically validated, that's how you go about it.

JUDGE CHAPPELL: So --

THE WITNESS: And in fact I tried to do that for the GAQ. I went to PubMed, I put in the GAQ, and I could find no publication that valid -- that showed that it was statistically validated.

JUDGE CHAPPELL: So according to you, there is no list -- excuse me. I believe I will talk now if that's okay?

THE WITNESS: I'm sorry.

JUDGE CHAPPELL: Would you mind holding while I speak?

THE WITNESS: Sure.

JUDGE CHAPPELL: Thank you.

If I understand you, there is no list, but there's a method for discovering whether a study is validated?

THE WITNESS: Correct.

JUDGE CHAPPELL: Thank you.

BY MR. FIELDS:

Q. In fact, Dr. Forest used both the IIEF and the GAQ; correct?

A. Yes.

Q. Now, you criticized the Forest study because you say the placebo wasn't identical to the pomegranate juice.

Do you know of any other testaments of whether they realized or revealed that they knew they were drinking a placebo as opposed to --

A. I have no idea.

Q. So it may not have had any effect at all on the study; correct?

A. We don't know.

Q. Okay. You also criticized Dr. Forest for choosing too young a group. And you said the median age was 46 and that was too young.

A. I said that was younger than the population of most men with ED. That's correct.

Q. Well, your test, according to your article,

which is RX 5017, by you and Dr. Fogarty and Hafron, says that your median age was 40 years; correct?

A. What test are you talking about?

Q. Well, the test that you refer to in your article called Can Self-Administered Questionnaires Supplant Objective Testing in Erectile Function?

If you'll look on page 2 at the bottom of the page of your results, it says the median age of the study group was 40 years.

A. Yes. And you're comparing an apple and so what? What's the point.

Q. Well, the "so what" is you criticized him for having too young --

A. No.

Q. Let me finish. You asked me "so what?" I'm answering you, sir.

And you criticized him for having a 46-year-old as the mean age or median age, and you had 40 years old in your test --

A. Right.

Q. -- right?

A. Well, would you like me to answer your question?

Q. Yes.

Did you have 40 years --

A. This was a study of young men, young men, who came in complaining of total erectile dysfunction, young men, and we evaluated those young men to see whether their claims were valid, so this basically was a study of young men.

Q. Well, sir, I --

A. That's not the same as the trial that Forest did, which was testing a drug in a series of men with ED.

Q. All right. It's probably not a good question for me to ask at my age, but, sir, you went up to 61 years in your test; right?

A. Right.

Q. Do you consider that to be young men?

A. These were a series of people who all of them came in saying they had ED. Most of them were young.

Q. Okay.

A. And we were not testing a drug.

Q. Doctor, your product hMaxi-K is injected in the penis; isn't that correct?

A. I don't have a product.

Q. Your potential product hMaxi-K is injected into the penis; isn't that correct?

A. Yes.

Q. Okay. Let's assume that Viagra, Cialis and

PDE5 inhibitors of that type don't work for a patient. And let's assume the patient doesn't want an injection into his penis or a penile implant.

Your testimony is that you still wouldn't suggest pomegranate juice; isn't that true?

A. I wouldn't suggest it because your data has shown that it does not work, so if you want to sell a product that's worthless, that's your choice. My goal would be to try and sell something that worked.

Q. Well, we've already gone over your definition of what "doesn't work" means, but in any event, you would not under any circumstances suggest pomegranate juice.

A. I wouldn't suggest something that was shown to not work.

Q. In that case, do you recall in your deposition what you said you would say to the patient if he didn't want those other things that --

A. No. But I'm sure you'll tell me.

Q. Did you say, "Well, you should just stop having intercourse"?

A. I would never say that to a --

Q. You would never say that.

Let's look at your deposition at page 31.

"QUESTION: And if they don't want to do either

of those two things?"

Those are the things that I just referred to.

"Then they should (sic) stop having intercourse."

A. No, that's not what it says.

Q. "Then they stop having intercourse."

A. Right. That's what they do. I didn't say that's what they should do. What I said was, my answer is, if they don't want to use any form of treatment, then they stop having intercourse.

Q. So before you would recommend they even try pomegranate juice, they ought to just stop having intercourse; correct?

A. I would not recommend -- I'll say it again -- I would not recommend a product which the data from the company purporting to use the product showed that the product did not work. I would not recommend that.

MR. FIELDS: That's all I have, Doctor.

JUDGE CHAPPELL: Redirect?

MR. WONE: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

- - - - -

REDIRECT EXAMINATION

BY MR. WONE:

Q. Hello, Dr. Melman.

A. Hello, Mr. Wone.

Q. Do you have RX 5017 in front of you?

A. No.

This is the Forest?

Q. No. It's the study that Mr. Fields asked you about.

A. Yes.

Q. And in this study in Exhibit --

A. This is the newspaper article you're talking about?

Q. Oh, no. Exhibit RX 5017.

A. Yes.

Q. It's titled Can Self-Administered Questionnaires Supplant Objective Testing of Erectile Function: A Comparison Between the International Index of Erectile Function and Objective Studies.

A. Yes.

Q. And in this study, Doctor, you weren't assessing the efficacy of a product in treating erectile dysfunction, were you?

A. I was not.

Q. And in fact in this study you were determining whether the results of the self-reported IIEF in assessing erectile function could overestimate the degree of erectile impairment; correct?

A. That's correct.

Q. And when you use the word "drug," Doctor, you're referring to any product with an active ingredient?

A. Yes.

Q. And in this case, Doctor, the pomegranate juice's polyphenol agents were the purported mechanism of effect on erectile dysfunction.

A. That's correct. Five different polyphenols, right.

Q. And to your knowledge, Doctor, is erectile dysfunction a disease?

A. Yes.

Q. And to your understanding, Doctor, if a marketer claims its products will prevent, reduce the risk of or treat a disease, is that claim subject to FDA regulation?

A. Yes.

Q. Doctor, is the fact that the claim you were asked to evaluate was that taking eight ounces of POM -- taking eight ounces of POM Wonderful pomegranate juice daily prevents, reduces the risk or treats erectile dysfunction the reason you equate your analysis to what the FDA would require?

A. That's correct.

MR. WONE: No further questions, Your Honor.

MR. FIELDS: No questions, Your Honor.

JUDGE CHAPPELL: Thank you, sir. You're excused.

THE WITNESS: Thank you.

JUDGE CHAPPELL: How are we looking on the timing for the witnesses for the remainder of the week?

MS. HIPPSLEY: Your Honor, tomorrow we have two witnesses, Dr. Eastham -- we'll be starting with Dr. Eastham. He's our doctor expert on prostate cancer. And then that will be followed by Mr. Rushton, who's an ex-employee.

JUDGE CHAPPELL: Do you anticipate that being a full day?

MS. HIPPSLEY: Probably given what has been happening with the experts, I suspect so.

JUDGE CHAPPELL: And who is Jeffrey Rushton?

MS. HIPPSLEY: He's an ex-employee. He was director of their online advertising. He's coming in from Kentucky to testify.

JUDGE CHAPPELL: Okay. I think maybe by the end of the day tomorrow we can talk about the following week and whether we're going to need every day or -- I don't know who's scheduled to be here from out of town or whatever. You had told me earlier you thought you would

be finished the 15th. Is that still correct?

MS. HIPPSLEY: Yes, that's still correct.

JUDGE CHAPPELL: All right.

That's all. Thank you.

Normally if we go late I start later the next day, but it sounds like we're going to need all the time tomorrow.

Do I hear 10:00 from anyone?

MR. GRAUBERT: That would be fine, Your Honor.

MR. WONE: That's fine, Your Honor.

JUDGE CHAPPELL: All right. We'll reconvene at 10:00 in the morning.

(Whereupon, the foregoing hearing was adjourned at 5:38 p.m.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9344

CASE TITLE: In Re POM Wonderful LLC, et al.

HEARING DATE: June 8, 2011

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: JUNE 14, 2011

JOSETT F. WHALEN, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

ELIZABETH M. FARRELL