FEDERAL TRADE COMMISSION

I N D E X

POM WONDERFUL, LLC

TRIAL VOLUME 13

PART 1, PUBLIC RECORD

SEPTEMBER 1, 2011

EXHIBITS	FOR ID	IN EVID	IN CAMERA	STRICKEN/REJECTED
CX				
None				
PX				
None				
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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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THURSDAY, SEPTEMBER 1, 2011

9:30 a.m.

TRIAL VOLUME 13

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR-CRR-CLR

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P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: Back on the record, Docket 9344.

Ready for the next witness?

MR. FIELDS: Yes, Your Honor. Our next witness is Dr. Burnett from Johns Hopkins.

Dr. Burnett, if you would take the witness stand. It's right over there.

Whereupon--

ARTHUR L. BURNETT, II

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

DIRECT EXAMINATION

BY MR. FIELDS:

Q. Good morning, Doctor.

A. Good morning.

Q. For the record, would you state your full name, please.

A. My name is Arthur Louis Burnett, II.

Q. And you are a medical doctor. Is that correct?

A. That is correct.

Q. And is it correct that you are a graduate of Johns Hopkins Medical School?

A. That is correct.

Q. And that you did your internship, residency, and fellowship at Johns Hopkins?

A. That is correct.

Q. And you studied under Dr. Walsh, who's a very famous man in that field?

A. That is correct.

Q. All right. Is it correct you are board certified in urology?

A. I am.

Q. Okay. And is it also correct that you are the Walsh Professor of Urology at Johns Hopkins Medical School and at Johns Hopkins Hospital?

A. I am.

Q. Thank you.

Are you also director of the Basic Science Laboratory in Neurourology at the James Buchanan Brady Urological Institute?

A. I am.

Q. And you are the director of the Male Consultation Clinic of the Sexual Medicine Division of the Johns Hopkins Department of Urology?

A. That is correct.

Q. Okay. Is it correct that you have served as the chairperson or officer of many professional organizations in the field of urology?

A. That is correct.

Q. And the examples are set forth in your CV that has been filed with the Court. Is that right?

A. That is correct.

Q. Okay. And you have had a number of visiting professorships in urology nationally and internationally; again, examples set forth in your CV.

A. That is correct.

Q. Okay. Is it correct that you have been the assistant editor of the Journal of Urology, coeditor in chief of the Journal of Andrology, reviews as associate editor of the Journal of Sexual Medicine, and assistant editor of Practical Reviews in Urology?

A. That is correct.

Q. Okay.

A. All of the above.

JUDGE CHAPPELL: Just so I'm clear, where would you go to work today if you weren't here?

THE WITNESS: I would be at Johns Hopkins. Today would be a typical surgery day for me.

JUDGE CHAPPELL: Downtown or Bayview?

THE WITNESS: At the main hospital, Johns Hopkins.

BY MR. FIELDS:

Q. I think you were taking out a prostate

yesterday.

A. That is correct.

Q. Okay.

We were trying to reschedule this witness for yesterday, Your Honor, but apparently he had something to do more important. Maybe more important for the patient.

JUDGE CHAPPELL: I was taking that as your opinion, not mine.

BY MR. FIELDS:

Q. All right. You have also been a reviewer of many peer-reviewed publications?

A. I have been.

Q. And has your work on nitric oxide and erectile function been funded continuously by the National Institutes of Health?

A. It has been.

Q. And you have been published in over 180 peer-reviewed articles. Is that correct?

A. I have.

Q. And you have written 40 book chapters in your field?

A. I have.

MR. FIELDS: Your Honor, we offer Dr. Burnett as an expert and would move that his report and CV be

accepted into evidence.

MS. DOMOND: No objection, Your Honor.

JUDGE CHAPPELL: Any opinions that meet the proper legal standard will be considered.

MR. FIELDS: Thank you, Your Honor.

BY MR. FIELDS:

Q. Doctor, have you treated patients with erectile dysfunction?

A. I have.

Q. Approximately how many patients would you say you've treated with erectile dysfunction?

A. Well, I see about 10 to 15 patients a week, among other disease states in urology, who have erectile dysfunction, and I have been doing that for more than 20 years.

Q. That's beyond my mathematics, but it sounds like a lot of patients.

A. Sure.

Q. I'd like to put up on the screen a graphic showing a cross-section of the male organ. Can we do that, please? Yes.

Can you identify what these two cross-sections are, Dr. Burnett?

A. Certainly. They are cross-sections of the penis, showing the two different contrasting physiologic

states of penile flaccidity and penile erection.

Q. The one on the left is the flaccid penis that is not erect and the one on the right is the erect penis?

A. That is correct.

Q. All right. And would you tell us, please, what the process is, that is, the biological mechanism by which the penis becomes erect or fails to become erect and how it works?

A. Absolutely. Well, we have come a long way in the science of penile erection. The penis is actually a very cleverly designed organ that has a specific structure to it that allows it to work the way that it does.

So, on the left side, to begin with, you can see that the structure of the penis involves two corporal bodies called the corpora cavernosa, which are situated on the upper side of the penis. Beneath that is the corpora spongiosum that encases the urethra, which is where the urine passes. The main erectile bodies, the corpora cavernosa, govern penile erection, although there is erectile tissue in the corpora spongiosum as well.

The vessels -- the blood vessels that supply the penis are shown in the diagram. The main vessels that supply the corporal bodies are called the cavernosal

arteries. They are bilateral structures that course centrally within each of the two long corporal bodies that comprise the penis. The vessels that are a little bit more peripheral have to do with circulation to the superficial structures, the skin and so forth, of the penis.

But what's germane for penile erection are the cavernosal arteries. These arteries then, by design, carry blood flow into the main corporal bodies. The vessels that feed from those are called helicine arteries. You may be able to see one of those depicted just beneath the main cavernosal artery for each of those structures.

Actually, these are tributaries of the cavernosal arteries that have kind of a spoke/wheel pattern or appearance that then supply blood into the penis. And then the blood finds its way into these spaces, called sinusoidal spaces, within the corporal bodies, and these are spaces as, if you will, to consider a sponge that has these spaces within it. This is where the blood then will feed these spaces or cavities.

And then the way the blood will then drain from the penis is back through these emissary veins, which are the veins that you see in the periphery of the

cavernosal bodies or the corpora cavernosa.

Q. Those are the things in blue?

A. Those are the blue structures.

Q. Right.

A. Those are called emissary veins, and they find their way to circumflex veins, which are kind of the veins that kind of run peripherally within the corporal body, almost really beneath the structure of the corporal bodies that is kind of the sheath-like encasement of the corporal bodies, called the tunica albuginea, which is a structure that has a finite elasticity to it. It can stretch, but it gets to a certain point where it can't stretch any further.

So, all of this is really carefully designed, cleverly designed, in terms of how this works now for penile erection. This is how the blood flows into the penis in the baseline state, if you will, the flaccid state, just a modest amount of blood in and out of the penis at all times.

Now, when an erection occurs, which is on the right side of the panel, what happens there is there's an increased amount of blood that comes through the cavernosal arteries that then fill these spaces, and the penis then distends, and then there's an increase in pressure within the penis that is consistent with what a

penile erection is all about.

But the design of this is actually very clever now, because what happens is the cavernosal arteries actually go from a more thin kind of shape to a wider shape; that's called dilation, okay, or we would use the word vasodilation. And, in addition, the erectile tissue -- again, this latticework of spongy material within the corporal bodies, which actually comprise a smooth muscle, and the lining of that, which I will get into in a moment -- all of that tissue has to go through what we call tissue relaxation, okay?

So, the mechanism of penile erection is really a mechanism of tissue relaxation and vasodilation of these structures that carry the blood. And in doing so now, it actually distends the corporal bodies, compresses the veins that drain blood from the penis, and basically produces an occlusion, and we call that venoocclusion -- or veins that get occluded -- and that prevents the way that blood will drain back from the penis, and the penis then expands and lengthens, develops what we call intracorporal pressure, and it is almost like a capacitance vessel, or a capacitor, that then gets full, becomes erect, and the penis develops this rigidity to it. So, that's what penile erection is all about.

So, the next step is, is how does this tissue

react? What governs its response? That's the exciting thing about how erections occur. The tissue has to be regulated, and the regulation of it involves the neurological regulation. And so, therefore, erections typically involve the nerves, that is the thoughts, or other stimulation that is nerve-regulated, for the nerve supply that feeds the penis and regulates how these vessels respond more internal in the pelvis.

And then, when blood flow comes into the penis, that also enhances the erection response. The chemical behind all of this is called nitric oxide, and nitric oxide is released from nerve endings, but also from what is called endothelium, which is the lining of these vessels and the lining of the cavernous spaces or the sinusoidal spaces. And this structure is a very dynamic structure, this endothelium, because with blood flow -- we call it sheer stress, just the blood flow coming in -- that actually makes the tissue to respond to release more nitric oxide.

So, nitric oxide for nerves and the additional propagation of the signal, if you will, by blood flow from the endothelium then is what makes the tissue respond like it does. So, nitric oxide is the key molecule that governs penile erection, and that's how erections occur. And then there's a cascade in terms of

how that turns on the tissue to become relaxed, which I can get into. But fundamentally, that's the mechanism.

Q. Now, just so we get the record clear, that's nitric oxide, not nitrous oxide?

A. Yeah. Nitrous oxide is laughing gas.

Q. Yeah, that's what I thought. This is N-I-T-R-I-C, nitric oxide.

A. That's right.

Q. And that's the fundamental thing that causes the blood flow that causes the erection. Is that correct?

A. That's correct. That's the molecule that produces the erection response.

JUDGE CHAPPELL: What's the difference between nitric versus nitrous oxide?

THE WITNESS: Well, it's a chemical formula, and so nitric oxide involves a body of nitrogen and oxygen. Nitrous oxide is nitrogen and two molecules of oxygen, NO2 in chemistry class. So, they sound almost the same, but there's actually a different chemical formula for these two different compositions of a molecule.

BY MR. FIELDS:

Q. Okay. Now, how does pomegranate juice affect this -- the sustaining of an erection or the ability of getting an erection that you just described?

A. Certainly. I will be delighted to explain that.

So, pomegranate juice has properties to it. There's polyphenols and other kinds of components to the -- to the juice that are thought to be antioxidant by way of properties. So, antioxidant, which almost by the way it sounds, is opposing oxidants. Oxidants are oxidative stress molecules, molecules that our body makes under various kinds of conditions of inflammatory changes, disease states, and so forth, that have to do with how the tissue actually becomes diseased, becomes dysfunctional.

And so these are thought to be bad things, oxidative stress molecules. And so things that oppose that generally bring about a healthful state and improved health. And then pomegranate juice actually works to help promote these kinds of signs.

Q. How does pomegranate juice affect the enhancement or production of nitric oxide, which you say is essential to proper erectile function?

A. That is correct. So, that has been studied.

Q. Explain how it works, if you will.

A. Right. So, that has been studied, and the mechanism has continued to be that of enhancing the endothelial nitric oxide formation. There's a science behind how nitric oxide is produced by either the nerve endings or endothelium. It involves enzymes, proteins

that, with a proper stimulus, then release the chemical, the nitric oxide, and the oxidative stress factors oppose this production.

So, anything that enhances the production of nitric oxide by way of suppressing the oxidative stress factors then promotes the nitric oxide effects. So, the detailed science of it is that we think that there may be various kinds of proteins in tissue that govern how the endothelial nitric oxide synthase, the enzyme that makes nitric oxide from the endothelium, how it is actually working, how it functions, and through what we call expression-level proteins that govern how these proteins work, that the pomegranate juice actually controls some of the molecules that oppose the endothelial nitric oxide synthase function.

Q. So, the bottom line is the pomegranate juice enhances the effect of nitric oxide in generating an erection?

A. Well, that's the byproduct of it, by suppressing the negative factors, the inhibitory factors for how endothelial nitric oxide is produced.

Q. Okay. Are you familiar with the work of Dr. Louis Ignarro, I-G-N-A-R-R-O?

A. I am familiar with that, yes.

Q. And you know Dr. Ignarro personally?

A. I know Dr. Ignarro personally.

Q. Yeah, all right. Now, Dr. Ignarro won the Nobel Prize for his work on nitric oxide. Is that correct?

A. He certainly did win the Nobel Prize.

Q. And he has studied both nitric oxide and the effect of pomegranate juice on nitric oxide?

A. He certainly has.

Q. Are you familiar with his studies in that regard?

A. I am familiar with those studies, yes.

Q. Okay. Can you tell us, briefly, what those studies showed?

A. Well, essentially, the studies do support what we understand about the mechanisms, just as I described it, for endothelial nitric oxide production. His team's work has involved -- has involved studies at a very basic science level, some of it with -- what we call in vitro studies, which is looking at cells in a culture dish, a Petrie dish almost, reacted to various chemical stimulants that are put across it. These have been human endothelial cells that have been studied.

He's also done some work with animal models. There's a hypercholesterolemic mouse model that is a mouse model that is induced at high cholesterol levels to mimic a cholesterol state that would be modeling for

the human condition, and he has shown that in these different models, as well in the in vitro studies, that the mechanism here of endothelial nitric oxide production does have an enhancement, as we've used that word, by opposing some of these negative factors with pomegranate juice. So, the antioxidant effect promotes the endothelial nitric oxide production in these models.

Q. And is it correct that he found that pomegranate juice contained an extraordinary amount of -- ability to enhance nitric oxide function?

A. His studies showed that very remarkably, and I think that's a very important advance.

Q. Have you seen the kind of -- perhaps famous letters from Dr. Ignarro on that subject?

A. I have seen that, yes.

Q. May we put that briefly up on the screen?

MS. DOMOND: Can we get an exhibit number, Your Honor?

JUDGE CHAPPELL: I can't hear you.

MS. DOMOND: Can we get an exhibit number?

MR. FIELDS: Yes. PX 484, I'm told by my more learned colleagues.

BY MR. FIELDS:

Q. I am just going to read it in case everybody doesn't have a screen, that Dr. Ignarro says that "Based

on studies conducted in my laboratory, pomegranate juice was 20 times better than any other fruit juice at increasing nitric oxide. It's astonishing -- I've been working in this field for 20 years and I have never seen anything like it. I drink it 3 times a day without fail. Louis J. Ignarro, Ph.D. "

Anyway, does that conform to what you understand Dr. Ignarro's study showed?

A. Yes. I mean, certainly that's an endorsement, and it sounds like he's having a great day doing it. So, I think this is consistent with his studies and that he does support the effects of pomegranate juice.

Q. Thank you.

Doctor, based on the basic science you've outlined and the laboratory studies with which you're familiar, is it likely that pomegranate juice has a beneficial effect on erectile function?

A. I do believe that it has a likely beneficial effect on erectile function.

Q. All right. Are you familiar with Dr. Padma Nathan's human study on pomegranate juice and erectile dysfunction?

A. I am familiar with it.

Q. We are going to have another doctor in your field who's going to go into detail about that study, so

I'm not going to take your time to do that, but that -- that was a double-blind, placebo-controlled study?

A. That is correct.

Q. Okay. And does that study support your opinion on the likelihood that pomegranate juice has a beneficial effect on erectile function?

A. It does support it.

MR. FIELDS: That's all I have for this witness, Your Honor.

JUDGE CHAPPELL: Cross?

MS. DOMOND: Yes, Your Honor. Thank you, Your Honor.

CROSS-EXAMINATION

BY MS. DOMOND:

Q. Good morning again, Dr. Burnett.

A. Good morning.

Q. As an expert in the field of erectile dysfunction, is it your opinion that if one uses the words "erectile dysfunction," that person or entity is talking about a clinical condition which is very different from the concept of something that has a potential beneficial effect on erectile tissue function and health?

A. The words "erectile dysfunction" has had a clinical connotation, yes.

Q. And would you say it's very different from what a potential beneficial effect on erectile tissue function and health is?

A. Well, I think that it has that distinction when we're talking about a true therapy for clinical use, yes.

Q. Okay. And do the words "erectile dysfunction" refer specifically to a clinical disorder or disease?

A. Again, we use this word "erectile dysfunction" in a global sense to refer to the inability to attain and maintain erections for sexual intercourse, and we do use that, in a clinical sense, with a terminology that refers specifically to that, yes.

Q. So, it is a clinical disorder?

A. Yes. That's why I want to be clear about my definition of it.

Q. Okay. And you mentioned erectile dysfunction therapy. Is that an intervention that would then effectively treat, improve, or allow a man who has an erectile dysfunction to function?

MR. FIELDS: Objection, Your Honor. Compound, Your Honor. Treat and improve are different things.

MS. DOMOND: Treat and improve are two different things? Okay.

BY MS. DOMOND:

Q. That would effectively treat?

A. Well, again, I think we need to dissect this a little bit so we make sure we're clear about what I'm talking about and what you're trying to infer.

Treat, in a clinical sense, has various different meanings. Treat can mean an approved pharmaceutical therapy to treat a known clinical condition. Treat can also mean, broadly, that it has a role in -- directed towards the condition that may lead to some improvement in that condition.

So, I think as a broad terminology, if you're talking about something in a true clinical sense, as in an FDA-approved pharmaceutical therapy or treatment, that's a different understanding.

Q. I guess my question is, if you have something that you said is an ED therapy, does that mean that that intervention will effectively treat, improve, or allow someone to function who has an erectile -- who has erectile dysfunction?

A. Well, there are approved FDA treatments that we use clinically and that have the role in improving the erection response, if that's what you're saying.

Q. And in your opinion, if something's defined as a treatment or therapy for erectile dysfunction, would you hold it to a higher standard of proof than something

that's been promoted as an intervention that could possibly promote some level of improvement of one's erectile health or tissues?

A. Well, again, I think that -- I don't want to quibble about what we're trying to dissect your term of treatment and mine is. A treatment can be any intervention that can improve one's erectile function. Yes, there are clinical therapies that are clinically approved for the purpose of treating erectile dysfunction, but, again, there may be a different standard for that terminology. So, I just want to be clear about what I'm describing.

Q. So, the different terminology goes to whether you're saying erectile dysfunction or improvement in erectile health? Is that the distinction?

A. I think there is still a -- there is a distinction between those two, yes.

Q. Okay. And is this because erectile dysfunction, as you stated earlier, refers to a clinical disorder, and if one claims that something treats or alleviates erectile dysfunction, then it needs to go through what -- a regular clinical trial, like the FDA-approved thing you were discussing?

A. Well, I think, taken in that context, okay -- so, making sure we all just understand what we're trying

to say here. I mean, if there is truly a therapy that is thought to be a pharmaceutical intervention, that should be FDA-vetted and then approved, in the clinical sense, to treat erectile dysfunction. That's one thing.

Q. And can you -- what do you mean, that's one thing?

A. Well, that's just -- I mean, that's one standard.

Q. Okay.

A. But there still are various interventions that I think are very acceptable for improving one's erectile health that likely have benefit that still are, I think, reasonable interventions for that purpose.

Q. Okay. And improving erectile health is -- does that always equate to improving one's erectile dysfunction, or there's other components of that erectile health as well that you're referring to when you explain that?

A. Well, just to restate it, again, I think that there may be a standard for treating erectile dysfunction --

Q. Okay.

A. -- or therapy specifically for erectile dysfunction in the clinical sense. That still may be very distinct from various interventions that I think

have helpful benefits for one's erectile function.

Q. Okay. And in your opinion, Dr. Burnett, to establish that a product treats erectile dysfunction, experts in the field would require rigorous scientific and clinical studies, which is referred to by experts as level one evidence. Is that correct?

A. Well, I think there has been a standard that has been used out there for any claims of a -- of an ED treatment now that we do look toward this level of rigor that typically has been used for pharmaceutical therapies, drug therapies, to treat erectile dysfunction. So, in that context, yes.

Q. Okay. And if it was something other than a pharmaceutical and they were making a claim -- and a claim was being made about actual erectile dysfunction treatment, would it follow that same standard as well?

A. Well, I think you have to be very careful about what we're trying to say here. If there's a claim that it is an erectile dysfunction treatment, I would like to be clear that I see that and understand that that's what's being said specifically for an intervention that you're trying to place before me. If that claim is not exactly being said, but it still may be something that has potential helpful benefits, likely to be beneficial to one's erection ability, then I still think that's

certainly something that I think clinicians could promote.

Q. Okay. And the type of scientific or clinical evidence that refers specifically to the erectile dysfunction treatment, would -- is also referred to by experts as randomized, controlled trials or RCTs. Is that correct?

A. Again, in that context, yes.

Q. And this type of scientific or clinical evidence, also known as RCTs, is what is typically achieved with Phase III studies following FDA type of standards. Is that right?

A. That is correct.

Q. And, Dr. Burnett, earlier, on direct, you had testified a bit about the Ignarro studies, and you described them as very basic -- they were at the very basic science level, and you explained that they were in vitro and animal studies.

Is it your opinion that one cannot rely on animal studies alone to conclude that a product or therapy treats erectile dysfunction in humans?

A. Again, a very broad statement. In the way I've defined "treat," okay -- which is, again, separate from what you're trying to say about an ED therapy that meets these other standards -- there are interventions that I

think have some potential benefit on the basis of animal studies or in vitro studies to likely improve one's erection physiology, and I think those are supported.

Q. To improve erectile health. Is that right?

A. That is what I'm saying.

Q. Okay, but not -- but that's different than treating erectile dysfunction. Is that right?

A. Well, let's just be clear.

Q. Okay.

A. You keep getting back to treating erectile dysfunction, and I think I've tried to explain what I thought what that means on a few occasions. So, you know, to be specific about that kind of standard is not what I'm saying here if you're trying to bring that into that definition.

Q. Okay.

A. I've already explained what that's about, and that refers to a clinical standard, okay, that has been met or at least accepted, broadly, in the field as pharmaceutical therapies that are designed specifically to treat erectile dysfunction in the clinical sense.

Q. Okay.

A. Okay? So, I -- I feel like I'm just repeating myself with that.

Q. Well, I apologize. Thank you for clarifying.

And, Dr. Burnett, is it also your opinion or is it your opinion that one cannot rely on animal studies even in combination with in vitro -- also known as test tube studies -- to conclude that a product treats erectile dysfunction in humans?

A. In the context that we said in terms of the finding of treating erectile dysfunction, for that level of discussion, I do believe that we need more than just animal studies.

Q. And would you -- if it was animal in combination with in vitro, would that be enough?

A. I think you would still need to go further than that, again, for the standard that we're speaking of.

Q. Okay. And, in fact, Dr. Burnett, is it correct that experts require -- would require two to three human randomized, controlled trials to conclude that a product treats erectile dysfunction?

A. I won't quibble with that. I think that makes sense.

Q. Okay. In fact, you've testified to that. Is that correct?

A. I have, and I would support that now.

Q. Okay. And when you say human randomized, controlled trials, you mean -- randomization, does that mean when study subjects are randomly assigned to either

the experimental or control group without any of the investigators knowing to which group that subject's assigned?

A. By definition of randomization, that's correct.

Q. Okay. And by a controlled trial, you mean a study that has a placebo control arm to distinguish positive effects resulting from the intervention from false positives that even those who might not be receiving the real intervention may experience, which is also referred to sometimes as a placebo effect?

A. So, by definition of placebo-controlled, I think you've defined that well, and I will accept that.

Q. Okay. And, Dr. Burnett, an important part of the human randomized, controlled trial would also be -- that -- that would show that a product treats erectile dysfunction is the use of proper tools to assess the outcomes. Is that correct?

A. It is customary now, for these sorts of trials to be done, to use tools that would establish the role of the therapy.

Q. Okay. And by proper tools, would -- that would mean validated measures or instruments of erectile dysfunction. Is that correct?

A. It has become the standard that those sort of tools should be included when that sort of assessment is

done.

Q. And it's important to use a measure or assessment tool that's been validated, because such tool has been established as measuring erectile dysfunction through rigorous assessments involving reliability testing, validity testing, construct validity, and other criteria. Is that correct?

A. I have said that before, and I would say that now.

Q. And one importance of using a validated assessment tool for measuring erectile dysfunction is that it's been established as reliable through testing a large number of individuals. Is that correct?

A. That is correct.

Q. And another importance to use such a tool, a validated assessment tool, is because -- for measuring erectile dysfunction is it means that the tool has specificity; in other words, it's been established as a valid test for measuring one's erectile dysfunction. Is that correct?

A. That is true.

Q. And, Dr. Burnett, can a scientist determine whether a measurement or assessment tool has been validated for measuring erectile dysfunction by reviewing published studies that demonstrate that the

tool has been tested and established for using -- for use in the measure of erectile dysfunction?

A. Could you restate that question?

Q. If I'm a scientific expert and I want to see whether a tool is validated or not, how would I go about doing that?

A. Well, there are -- there are, in clinical trials, various instruments that have undergone rigorous evaluation for their validity, and if those tools have been used in the assessment of the particular intervention being evaluated, then that would be considered a way of determining whether the therapy meets a certain efficacy level based on these tools that have validation.

Q. Okay. And so I would search through different scientific articles to see whether this specific -- this tool has been validated or tested. Is that correct?

A. That is correct. So, if that tool has been used with a particular trial and has been reported on and that's the one that you're looking at in the literature and somebody's evaluating that, that report, then looking for that kind of a tool would be helpful.

Q. Okay. And the value of using a validated assessment tool over a nonvalidated assessment tool in a study evaluating the effect of a product on erectile

dysfunction is to help establish the credibility of the work, because validated assessment tools are much stronger than nonvalidated tools in both accuracy and statistical validation. Is that correct?

A. I would support that.

Q. So, Dr. Burnett, experts would not rely solely on a nonvalidated measure to conclude that a product treats erectile dysfunction. Is that right?

A. Again, in the standard that we're talking about, treatment of erectile dysfunction, which I think I've defined, we would -- we would rely on validated tools.

Q. Okay. And, Dr. Burnett, to analyze the outcome from a human randomized, controlled trial that's testing a product's effect on erectile dysfunction, that would also require a statistical evaluation of data obtained using the validated assessment measures that we've discussed. Is that correct?

A. That is correct. Statistical evaluation is part of the analyses that occur now.

Q. Okay. And, in other words, for an expert to conclude from such a study, a randomized, controlled trial that's looking at a product's effect on erectile dysfunction, they -- the controlled trial would have to demonstrate results from those validated measures that were statistically significant. Is that correct?

A. That is correct. Again, in the context that I've described.

Q. And, Dr. Burnett, evaluating data for statistical significance is the standard of basic scientific and clinical research to demonstrate that a study's hypothesis has been proven. Is that correct?

A. Say that again. I'm sorry.

Q. Evaluating data for statistical significance is the standard -- is the standard used in basic scientific and clinical research to demonstrate that a study's hypothesis has been proven. Is that correct?

A. Yes.

Q. So, somewhat in layman's terms, to prove that a product treats erectile dysfunction, a study's results would have to show a statistically significant difference between the placebo group's effect and the treatment group's effect. Is that correct?

A. Again, in the context of a treatment for erectile dysfunction, this has been a standard that has been used with clinical trial studies.

Q. Okay. And, Dr. Burnett, if you don't have statistical significance, can you conclude that -- that the effect experienced by the test subjects was the result of a product's effectiveness versus just a result of chance?

A. Well, yes, you could make a conclusion that it has some likely benefit in terms of efficacy, but both in the standard of a true erectile dysfunction clinical trial for treatment, as well as in other interventions that we think may have some potential benefit for one's erectile health. So, in both of those contexts, I think you could still make a conclusion, even without necessarily achieving statistical significance.

Q. So, you could conclude from a study, where there's not statistical significance on a validated measure, that that product has an effect of treating erectile dysfunction?

A. If you are going to that standard, the treatment of erectile dysfunction, there may be a conclusion made that a therapy has a potential benefit in that treatment, even if it does not meet statistical significance.

Q. Right. And I'm not talking about -- I think you had mentioned potential benefit. Is that a potential benefit on erectile health?

A. Exactly.

Q. Okay. I guess my specific question is, more so, can you conclude, though -- and you discussed the distinction between erectile health and erectile dysfunction. Would you be able to conclude from such a

study that that product treats erectile dysfunction?

A. So, in that standard of a therapy that we're proposing here as being touted to treat erectile dysfunction, yes, we can still make an assessment that something has a potential benefit, although one might conclude that more studies may need to be done. You know, we would not rely on just one trial that did not meet statistical significance to discount a potential therapy, even -- even in a setting now -- even in the context now of a -- of a proposed treatment for ED.

Q. Okay. Just one moment.

And that would be a treatment in a clinical setting. Is that correct?

A. That would even be in the setting -- in the clinical setting that I'm talking about, even in that, and the point being that many times, when you will assess a trial -- and it may not even meet statistical significance, but we have to be careful in understanding whether we think it may still have some clinical importance. And just because one trial may not meet that standard, we may not automatically dismiss that therapy. We might say, "Okay, this is interesting, it might have a role here." And we may want to carry out an additional study, maybe reevaluate the criteria from which we make the assessment, maybe the patient

population that's being studied. So, I think that we would not automatically dismiss the therapy just on that basis.

Q. Okay, I see. And, Dr. Burnett, would you want such a study to have a sufficient number of men that it was powered to meet requirements of statistical significance? And, again, we're talking about the randomized, controlled trials.

A. Again, that would be an ideal, to really carry it to the highest standard of promoting something as an FDA pharmaceutical for the clinical management of erectile dysfunction.

Q. And, Dr. Burnett, in your opinion, for a product to be promoted as preventing erectile dysfunction, would experts also require the same type of human randomized, controlled trials?

A. Well, this term "prevention" I think requires some discussion. I don't think there's a therapy out there in the world of sexual medicine that we've established as of yet to be a true preventative intervention for erectile dysfunction. We do think there are various sorts of interventions that we believe likely have some potential benefit, anything from dietary changes to weight loss and perhaps things that we're still evaluating, but we're not sure really have a

role, but because they seem to be potentially beneficial and do not necessarily have harms and likely have benefits, that we feel comfortable in promoting.

So, at this point in time, I think prevention is a -- you know, kind of a little bit of a tough subject to get into. As clinicians, we may talk about therapies that we think likely have benefit and will discuss those, but at this point in time, I don't think there's anything out there that has been established to be a true prevention for erectile dysfunction.

Q. Okay. And when you said a likely potential benefit, again, you're going -- you're referring to a beneficial effect on erectile tissue and health. Is that right?

A. Exactly. So, we're talking about various things that we think likely have healthful benefits in preserving the physiology of one's erectile tissue, that I think we're going to certainly support or I'm going to tell my patients, "I think smoking should be discontinued here, sir," or "Maybe you should be a little bit more healthy" or "I think you should talk to your primary doctor and consider trying to pursue some more cardiovascular, healthful, kind of beneficial things," that I think may help one's erectile function.

So, we are going to suggest these sorts of

things, but I think the standard we're looking for -- we haven't met yet anything in terms of clinical trials for prevention, and that's just something we still need to get to. But even at this time, we are not going to discount some of the discussions with our patients and some suggestions that we think likely will be beneficial to their health, including their erectile health.

Q. And, Dr. Burnett, you see prevention as the same thing as reducing risk. Is that correct?

A. I do think that's so.

Q. So, you would have the same opinion with --

A. The same opinion.

Q. Okay. And earlier this morning, Dr. Burnett, you were testifying on direct about the very complex process of erectile function. Is that correct?

A. That is correct.

Q. And it's a very complex process because it involves many different molecules and signaling conduction pathways that lead to the er -- an erection. Is that right?

A. You are correct.

Q. And you were discussing nitric oxide as an important chemical in this process. Is that right?

A. Yes. We think that's central to the process of penile erection, but there still may be a number of

different molecules signaling pathways, the word that you're using, that may interact with this mechanism. And studying all these and figuring out how these interact, figuring out which ones promote it and try to enhance those; figure out which ones inhibit it and then suppress those, may all have dividends in terms of improving nitric oxide physiology in the penis.

Q. Okay. And you said nitric oxide is an enzyme that assists in the erectile process. It's an enzyme that actually begins the biochemical cascade of events that lead to the production of another chemical called cyclic GMP. Is that correct?

A. That's correct.

Q. And cyclic GMP is the molecule that causes the smooth muscle cells of the penis to relax. Is that right?

A. Well, it's another intermediate, if you will.

Q. Okay.

A. So, it's -- it actually carries out some additional downstream mechanisms, so we will call it an effector for how the tissue responds. Downstream, the cyclic GMP are various ion channels. There may be various contractile proteins in the smooth muscle tissue of the penis. All of these can be changed by how cyclic GMP signaling then brings about some of these other

effects. There's a cascade phenomenon, and there is various other -- multiple other components to it. But nitric oxide drives this next messenger molecule, cyclic GMP, that carries out a host of other things.

Q. Okay. And in your opinion, Dr. Burnett, proper erectile dysfunction [sic] requires more than just the production of nitric oxide. Is that right?

A. Well, I think nitric oxide is central, and without it, I think you're not going to be able to have an erection, but there is other things that I think do have roles in either promoting or inhibiting this mechanism. So, yes, we're going to consider what things might be interventions to be beneficial, that would be appropriate to promote nitric oxide function.

Q. Okay. And if a man has been diagnosed with erectile dysfunction, that does not mean that he necessarily has a nitric oxide deficiency. Is that correct?

A. Not necessarily. There may be a direct component of failed nitric oxide production, but there may also be some other conditions, other disease states that affect the way nitric oxide could be functional. So, I'll give you a case in point.

Somebody who is a diabetic, they may actually have some deterioration of the nerves or the smooth

muscle may actually become atrophied or kind of shrink down and just not respond well. So, it may actually be that the rest of the system doesn't really work well despite the nitric oxide production that may or may not be a hundred percent, but in light of the rest of the system working well and whether the nitric oxide is there or not, may interfere with the erection response.

Q. And, Dr. Burnett, you recall my having taken your deposition in this case back in April. Is that correct?

A. I do recall.

Q. And prior to that deposition, you had not reviewed any expert reports for any of POM's other experts, had you?

A. I had not.

Q. And that would mean that you had not reviewed the expert report of POM's expert, Dr. David Heber. Is that correct?

A. I had not reviewed that at that time.

Q. Okay. Since your deposition, have you reviewed Dr. Heber's report?

A. I don't recall reviewing that report. You would have to refresh me on what that report was about.

Q. Okay, we can do that. I would actually like to show you one of the statements in Dr. Heber's report on

nitric oxide and erectile dysfunction. If we could show -- this is Exhibit PX 0192, and this is Dr. Heber's report, and if we can actually turn to page 36 -- oh, I'm sorry.

MS. VISWANATHAN: Your Honor, may I?

JUDGE CHAPPELL: Go ahead.

THE WITNESS: Thank you.

BY MS. DOMOND:

Q. And, Dr. Burnett, if you could turn to page 36 of that report.

A. I think I have page 36 here.

Q. Okay. And if you look at that section, Section 6 at the top of the page, it's entitled "Mechanisms of Action and Nutritional Research Methodology -- Erectile Health."

Do you see that?

A. That's the heading of the section, you're saying?

Q. Yeah. It's Section 6 that's the heading. Yeah, it's also on the screen if you can't find the page.

A. Okay. I think I have it now.

Q. You've got it? Okay.

A. It's page 40 on one place and 36 somewhere else, so --

Q. Okay. I think there's probably two numbers

there, so --

A. Okay.

Q. -- I can go with the second one.

A. Gotcha.

Q. All right. And if you can look at the last line of the first paragraph, which reads, "Increased nitric oxide levels lead to improvement in erectile dysfunction, which is the basis of medications such as Sindenafil" -- which I think Dr. Heber meant Silenafil -- "and other inhibitors of nitric oxide breakdown."

If we could break -- just break down Dr. Heber's statement into its components. First off, Dr. Burnett, as an expert in the field of nitric oxide and erectile dysfunction, you do not find accurate Dr. Heber's statement that medications such as silenafil are inhibitors of nitric oxide breakdown, do you?

A. I think that's a broad statement, and I think I need to clarify that for you. Sildenafil is specifically a phosphodiesterase type 5 inhibitor. So, what it does is it directly inhibits the enzyme that degrades cyclic GMP. So, it doesn't directly, at least to be scientifically accurate, do anything to nitric oxide.

The downstream effector now, the messenger

molecule of cyclic GMP that carries out this tissue-relaxing effect, can be inhibited by an enzyme called PD-5, phosphodiesterase type 5. Various agents, such as sildenafil, by blocking that inhibition, then promotes cyclic GMP action.

Q. So, basically products like silenafil work by preventing the breakdown of cyclic GMP by the enzyme PD-5, not by preventing the breakdown of nitric oxide. Is that correct?

A. That's right, to be clear, as I described.

Q. Okay. And so the effect of these types of erectile dysfunction products is an influx in the amount of cyclic GMP, not an increase in nitric oxide levels. Is that correct?

A. Well, it's directly related and is proportional to the extent that the amount of nitric oxide translates into the amount of cyclic GMP. Now, the cyclic GMP will get degraded by phosphodiesterase type 5. If you inhibit that, then you are actually promoting the whole nitric oxide biochemical cascade.

Q. By promoting the -- by preventing the degradation of the cyclic GMP, correct?

A. That's exactly what it's doing.

Q. And you said earlier that cyclic GMP is what causes the smooth muscle to relax. Is that right?

A. Right, through some downstream effects -- pathway mechanisms, but really, that is thought to be key there.

Q. Okay. And if we could just go back again to the same quote we were looking at by Dr. Heber on page 40 of what you have, of Exhibit PX 0192. Okay, it's also on the screen there.

Dr. Burnett, would you agree with Dr. Heber's statement that increased nitric oxide levels is the basis of medications such as sildenafil? And my guess is you don't based off of what you just described. Is that correct?

A. Well, I think what he's saying -- I mean, the gist of what he's saying is correct, but I wanted to be accurate just so that it's clear, scientifically speaking, that it's really a matter of promoting cyclic GMP, which is really the effector of nitric oxide action, but it's not a direct effect on the nitric oxide. Are you following me?

Q. Right. Yes.

And, Dr. Burnett, actually, when Dr. Heber testified in his direct testimony earlier this week, he testified that "drugs that are out there now for erectile dysfunction are based on their ability to enhance the half-life or the survival of nitric oxide in

the penis."

As an expert, Dr. Burnett, would you also -- would you find Dr. Heber's statement, that drugs -- that these drugs are based on their ability to enhance the half-life or survival of nitric oxide in the penis, as an accurate statement?

A. I think that what he was trying to say, I would support, which is does it promote the nitric oxide biochemical pathway, and that's what it's doing. Maybe trying to translate this for a nonscientific audience, he is saying that it has a direct effect on nitric oxide. That's not quite correct. It's really on promoting cyclic GMP function.

Q. Okay. So, it doesn't -- as you say, it -- it doesn't have a direct effect on the nitric oxide.

A. But -- but, again, to be scientifically correct here, I mean, he's talking about the nitric oxide cascade, which is entirely correct. You're trying to promote this really healthful pathway, and these therapies do promote that, but not directly on nitric oxide.

So, therein is why I think it is important to think about new scientific directions, because yes, I mean, you can envision for the future maybe something that directly inhibits cyclic GMP breakdown but maybe

something else that also promotes nitric oxide physiology, and then you actually have a much more potent cascade that carries out the erection response. So, it would be great to continue to think about ways that, if something directly interferes with nitric oxide function, like oxidative stress molecules, if you can inhibit those, you promote the cascade from up front, and you have something else that interferes with the breakdown of the downstream mediator, and you have a very potent cascade that brings about better erection response.

Q. And when you're talking about the nitric oxide cascade, that's the entire process.

A. The entire process.

Q. Not just the nitric oxide molecule.

A. That's right. So, I think it has to be understood in that context now. We don't have to dissect every molecule. It's more important to understand the entire mechanism.

Q. Um-hum. And that's sometimes also referred to as the nitric oxide/cGMP cascade. Is that correct?

A. That is the way we are saying it, absolutely.

Q. And if we could return one more time to the PX 0192, Dr. Heber's report, at 36, that same section, in that same last line of the first paragraph.

Dr. Burnett, would you find accurate Dr. Heber's statement that increasing nitric oxide levels leads to improvement in erectile dysfunction in humans?

A. I think that the concept here that he's trying to say, as I understand what's here on the page you have presented to me, is that anything that promotes the nitric oxide/cyclic GMP cascade, this pathway, really is beneficial for one's erection physiology.

Now, again, he may be interchanging this term here, erectile dysfunction, which I think we've talked about before, that if we want to talk about it specifically in the context of a clinical treatment for ED, then I think that is a standard that we have kind of gone through now, perhaps has a certain level of rigor that we need to talk about.

But understand, in principle, that this cascade is important for erection health and the way erections work, I think that's what he's saying here, and I support it.

Q. Right. But the words "erectile dysfunction" that Dr. Heber used is very different from the concept of something that has a potential for being beneficial to erectile health.

A. Right. I think that the -- I guess what I'm having trouble with is I want to carry concepts forward

and not dissect apart just little words here. I mean, the concept here is that we're talking about a cascade that helps promote the erection of one's penis, okay, and I think that this is what's going on here. So, let's not overly concentrate on this word ED, erectile dysfunction. What he's trying to say is that it helps erection health, and that's correct.

Q. Okay. Dr. Burnett, you believe there is evidence to support that antioxidants promote nitric oxide production. Isn't that correct?

A. That is correct.

Q. Okay. However, you do not believe that evidence that antioxidants have an effect on the production of nitric oxide leads to the conclusion that antioxidants will treat or alleviate erectile dysfunction in humans. Is that correct?

A. I think for that specific standard of a clinical treatment for erectile dysfunction, that we think we -- I think we still have a ways to go to really make that statement.

Q. And in your opinion, to conclude that antioxidants treat erectile dysfunction would require antioxidants to be scientifically evaluated through rigorous studies as true agents. Is that correct?

A. Well, again, to qualify the statement, as a

treatment for erectile dysfunction, yes. Do antioxidants play a potential role in preserving erectile tissue health, potentially have a role to promote one's likelihood of preserving their erection function, perhaps a risk modification with regards to one's erection physiology, I would support all of that.

Q. Dr. Burnett, isn't it your opinion that rather than touting antioxidants as a treatment for erectile dysfunction, more appropriately, antioxidants can be suggested as a complementary therapy for a patient who is under a clinician or physician's advice and care? Is that correct?

A. Well, you had a pretty loaded question there. Let me see if I can tell you what I'm thinking about in responding to that.

Yeah, I think that as a clinician, we do have conventional therapies for the treatment of erectile dysfunction, and I do think that we should take care of our patients honoring those kinds of therapies.

Now, there may be some interventions that have not quite met the standard as a treatment of erectile dysfunction that may be employed to help improve that person's erection health. If I were to counsel a patient to discontinue smoking, that counts as that. If I ask them to lose some weight, that counts as that. If

I ask them to do other healthful things for his body, that counts for that. Dietary changes, that may count for that. And conceivably, pomegranate juice may be one of those sorts of things.

That doesn't mean that it replaces a standard intervention, standard therapy in the sense of a proper diagnosis and treatment for erectile dysfunction, but it may be complementary and I think may be acceptable. Again, not to replace it. It's not a substitute.

Q. Okay. And you mentioned some other interventions that might also be helpful. So, you would -- so, it's your opinion that a clinician would perhaps consider suggesting antioxidants, along with other interventions, such as dietary changes or weight loss and physical activity, to help preserve a patient's erectile health or tissue. Is that correct?

A. I would support that.

Q. And in this recommendation that a clinician might give, it might include various antioxidants from different sources, including various fruits and vegetables, whole fruits and whole vegetables that are high in antioxidants, not just pomegranate juice alone. Is that correct?

A. Oh, certainly.

Q. And this is because various antioxidants may

have potential benefits to erectile health. Is that right?

A. I would support that. Absolutely.

Q. And if a recommendation was made to a patient to consider using antioxidants to benefit their erectile health, you would want such recommendation to be made under the care of a clinician or physician who can evaluate the benefit versus the risk to the patient. Is that correct?

A. Well, that's a tough one. I certainly think that clinicians may be best able to make that sort of judgment, but I don't think they're exclusively the ones to do that.

Q. Who might else be able to make that type of judgment?

A. Well, non-M.D. type people, may be therapists, may be nutritionists who may know more than I know, and I would support what they have to say about that.

Q. Dr. Burnett, earlier, you were testifying on direct about some of the studies that you reviewed when preparing your expert report and conclusions. You reviewed a study by Dr. Azadzoi called "Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants." Is that correct?

A. I did.

Q. Okay. And if we could just show that study. That's CX 1185.

Dr. Burnett, this study did not examine the effect of POM Juice as a treatment for erectile dysfunction in humans. Is that right?

A. That is correct.

Q. Nor did this study measure the effect of POM Juice with preventing or reducing the risk of erectile dysfunction in humans, correct?

A. That is correct.

Q. Okay, you can take that down. Thank you.

And, Dr. Burnett, you also reviewed a study, when preparing your expert report and conclusions, entitled -- that was by Dr. Ignarro that you discussed this morning, entitled "Beneficial Effects of Pomegranate Juice on Oxidative-Sensitive Genes and Endothelial Nitric Oxide Synthase Activity at Sites of Perturbed Shear Stress." Is that correct?

A. Yes. I did remark on that study. Quite a mouthful.

Q. A long title.

A. I commend you.

Q. Thank you. I practiced it a little. If we could just show that study.

Dr. Burnett, this study did not examine the

effect of POM Juice on erectile dysfunction, did it?

A. It did not.

Q. Nor did this study examine the effect of POM Juice on live human subjects, did it?

A. It did not.

Q. And this study also did not measure the effect of POM Juice as treating, preventing, or reducing the risk of erectile dysfunction in humans. Is that correct?

A. It did not do that. Again, you're using this word "erectile dysfunction," but I do think that it's providing good support for the role of the nitric oxide pathway influenced by oxidative stress chemicals and pomegranate juice that promotes endothelial nitric oxide function, which I think is fundamental to the vascular process of penile erection.

Q. Okay. And this study's focus was the coronary arteries. Is that correct?

A. I think it was a study involving isolated tissue specimens, coronary artery, but the point being that the vascular function of vessels in various parts of the body do behave very similarly. So, I think the inference can be made that it would similarly impact the cardiovascular arteries, let's say, of the penis.

Q. And, Dr. Burnett, you also reviewed a study when

preparing your expert report and conclusions entitled "Effects of a Pomegranate Fruit Extract on Oxidative-Sensitive Genes and ENLS Activity at Sites of Perturbed Shear Stress and Atherogenesis." Is that correct?

A. That is correct.

Q. If we could show -- it's PX 0056, which is already up there.

Dr. Burnett, this study did not examine the effect of POM Juice on erectile dysfunction, did it?

A. Again, not specifically, nor did I discuss it -- again, I want to be clear about what I'm saying so that it globally just covers what you're trying to say. I think I'm making myself clear on that.

Q. Right. But you saw it as a benefit on erectile health.

A. That's right.

Q. And the focus of this study was the coronary arteries, is that correct, again?

A. I believe this is so, and it may also have had to do with the mouse study as well.

Q. Okay.

A. The mice didn't have high cholesterol levels.

Q. And, Dr. Burnett, this study did not measure the effect of POM Juice as treating, preventing, or reducing the risk of erectile dysfunction in humans. Is that

correct?

A. A loaded question again.

Q. I'm sorry?

A. That's a loaded question again. It specifically did not do that, but I think that, again, it provides support for this intervention on erectile health, which I think is very well supported by this article.

Q. Okay. And, Dr. Burnett, you reviewed a study when preparing your expert report and conclusions by Dr. Forest and Padma Nathan, entitled "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." Is that correct?

A. I did.

Q. And if we could just show that, that's CX 0908.

Unlike the other studies that we just went through, Dr. Burnett, this study did examine the effect of POM Juice on erectile dysfunction in live human subjects. Is that correct?

A. This one did, yes.

Q. And this study was randomized?

A. It was.

Q. And it was placebo-controlled?

A. It was.

Q. And double-blinded? Is that correct?

A. It was.

Q. And the tools used to assess the outcomes or efficacy in the study were the International Index of Erectile Function, which I will just refer to as the IIEF, and the Global Assessment Questionnaire, which I will refer to as GAQ.

A. It did have those tools in that study.

Q. And you've testified that an important element of the type of human randomized, controlled trials that would be needed to conclude that a product treats erectile dysfunction would be using an assessment tool that has been validated for measuring erectile function. Is that correct?

A. I believe such a tool would definitely support the credibility of that work. Again, not to discount studies that do not include, as part of the assessment, some nonvalidated tools, but I think they add to the strength of the proposal that something has efficacy, at least in the context of an ED treatment, you would ideally like to include some validated tools.

Q. And the IIEF is thought to be a validated tool. Is that right?

A. It is a validated tool, but it has its deficiencies, too. Speaking as a specialist in the

field, just to briefly say that this is a tool that requires patient recall, it involves patients' subjective interpretation of their erection physiology. So, it's not an ideal tool either, but this may be the best we have short of doing objective studies; that is, putting probes in people's penises and measuring responses while they're taking the therapy. So, I think at this point in time, it's a tool that we use and it's helpful, but even that is not perfect, if you will.

Q. And the GAQ that was also used in the study is not a validated assessment tool. Is that correct?

A. It is not thought to be a validated assessment tool, but I think it's informative and still valuable to use in clinical studies.

Q. Most experts would not consider the GAQ to be a primary end point, in and of itself, for evaluating a treatment for erectile dysfunction. Is that correct?

A. I think most would contend that that solely would not be enough, and perhaps other tools would be more helpful, not to say that that tool with a study couldn't inform us that something seems to have likely benefit. It may prompt us to think of additional studies to do in the future. But that solely would not hold.

Q. Okay. And this is because the GAQ is more vague

and nonspecific in its measurements for establishing whether a therapy truly has an effect on a man's ability to achieve and maintain erections. Is that right?

A. Well, that's true. It's just thought that some of the other tools that we use, they use language that's a little bit more specific for one's getting an erection and maintaining an erection, and therein, we use some other tools to perhaps complement using that tool, because that one is more, in a global sense, did it improve your response?

You see, that's kind of a little bit more vague and nonspecific, not -- but still, I wouldn't discount it as being helpful to get that kind of information.

Q. And going back to the Forest study, which used the IIEF and the GAQ, neither measurements obtained on either of those measures demonstrated statistically significant differences between the subjects who drank POM Juice from those drinking placebo beverage. Is that correct?

A. That is correct. And I think the point that is being made here is to look for that statistical rigor, but again, just to make the point, that doesn't mean that that doesn't give us something that is informative about the study, and this may still be, in a sense, clinically meaningful about what a therapy or potential

therapy may offer in treating patients.

Q. In a patient-clinician sense. Is that correct?

A. Well, again, treatment has a broad, I think, interpretation. If we're talking about treatment at the level of FDA-approved pharmaceutical therapy for ED treatment, that's really a high standard, but even broadly treating, if I use that term, of offering an intervention that has potentially helpful benefits for one's erection physiology, in that much more broad context, I still think this is a valid and important study.

Q. Um-hum. In the Forest study, in fact, the validated IIEF measurement was reported as not meeting statistical significance with a P-value of 0.72. Is that correct?

A. I would have to look exactly at the results section to --

Q. Okay. If --

A. -- to look at the number. I can't remember my locker combination right now.

Q. So, this is, again, CX 0908, and again, Dr. Burnett, if you could look at page 003 of that, and it's the second sentence of the last full paragraph before the discussion.

A. Okay.

Q. Do you see -- we can blow it up on the screen for you as well. It says, "The mean plus/minus standard deviation of change from baseline in IIEF erectile function domain score was negative 0.13, plus or minus 6.08 for POM, and negative 0.02, plus or minus 5.04 for placebo (P equals 0.72)."

Does that refresh your recollection about --

A. That's correct. I appreciate your being clear about that.

Q. Okay. And the P-value of 0.72 is nowhere near approaching statistical significance, is it?

A. That is correct.

Q. And, in fact, in the Forest study, the nonvalidated GAQ measure did not reach statistical significance with a P-value of 0.058. Is that correct? If you can't recall, I can show you where it is.

A. You'd have to show me. Again, I didn't memorize numbers.

Q. No problem. If you could look at the same page, 003 of Exhibit CX 0908, and it's the second sentence of the -- let's see, where is it? It's in that -- yeah, the first full paragraph of the 55 subjects. Do you see --

A. I do see that.

Q. And it says, "It was observed that subjects were

more likely to have improved scores if they drank POM (P equals 0.058)."

A. I do see that.

Q. And that P-value does not reach statistical significance is what you testified earlier. Is that correct?

A. That is correct.

Q. Dr. Burnett, wouldn't you want to see statistically significant results to conclude from the Forest study that POM Juice is effective in treating what we've defined as erectile dysfunction?

A. Let me preface it again by saying that if we're talking about a pharmaceutical that we think we want to show by clinical trial is going to be claimed to be a therapy for erectile dysfunction, a treatment for erectile dysfunction, then I would be concerned that we would like to see more data, not to discount this, but I would like to see more data. So, in that context, there would be concern.

In the more broad context that something could offer healthful benefits for one's erection physiology, this looks interesting and would, you know, give me at least some support in saying that this may still be an intervention that would complement conventional ED treatment, and I would support its use by patients.

Q. Okay. And, Dr. Burnett, I don't know if you recall, but at your deposition, when we met back in April, you testified that you had reviewed the expert report of Dr. Arnold Melman. Is that correct?

A. I did.

Q. And you knew Dr. Melman before you were retained for this case. Is that right?

A. I do know Dr. Melman.

Q. And how do you know him?

A. I've known him for many years. We're both in the -- we're both urologists and we're both in the field of sexual medicine as experts. So, there's interactions that would come along in those professional lines.

Q. Okay. And would you consider Dr. Melman to be an expert in the field of erectile dysfunction?

A. Certainly.

Q. And would you agree that Dr. Melman is highly respected among urologists?

A. Absolutely.

Q. And if, like yourself, Dr. Melman opined that there was insufficient scientific evidence to conclude that drinking eight ounces of POM Juice daily treats erectile dysfunction, would you agree with Dr. Melman?

A. I didn't hear all of the first part of your question.

Q. If Dr. Melman opined that there was insufficient evidence to conclude that drinking eight ounces of POM Juice daily treats erectile dysfunction, would you agree with him?

A. I would agree that if we're, again, using this language of "treatment of erectile dysfunction," then I would be concerned, and I would agree then with that statement. Again, though, I do believe that there are healthful benefits, and I do believe that there is evidence to suggest that it potentially improves one's erection health and would support it on those grounds.

Q. Okay. And if Dr. Melman also opined that there was insufficient evidence to conclude that drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction, would you also agree with Dr. Melman on that?

MR. FIELDS: Objection, Your Honor, compound. Between "prevents" and "reduces the risk" might be very different answers.

MS. DOMOND: Okay. I can break it down.

BY MS. DOMOND:

Q. If Dr. Melman opined that there was insufficient scientific evidence to conclude that drinking eight ounces of POM Juice daily prevents erectile dysfunction, would you agree with that?

A. I would agree with it, but with the additional statement to make that I don't think we have any intervention that truly prevents erectile dysfunction, in the -- kind of the concept that something that almost cures erectile dysfunction. I don't think we have anything that even meets that kind of standard out there at all. So, just trying to look at that exact terminology, I think we have to really critically look at that word and understand that.

However, if you're talking about something that potentially has a risk modification benefit, that may help preserve erectile function, if we're thinking about prevention in that context -- context, I think that there is evidence here that pomegranate juice has that potential role. So, this word "prevention" is a highly contentious, kind of tough word to get our head around, and so I want to make sure it's clear how you're using that word "prevention," what that's all about.

Maybe that's how Dr. Melman is using that term. I don't know, I can't figure out what he's trying to say, but if I have to define what I'm trying to say here, getting around the words, but what am I really trying to say? We are trying to say, does pomegranate juice have some potential role in preserving one's erection health? And I think that it does.

Q. Okay. Thank you, Dr. Burnett.

Your Honor, I have no further questions.

JUDGE CHAPPELL: Any redirect?

MR. FIELDS: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

REDIRECT EXAMINATION

BY MR. FIELDS:

Q. Doctor, I think you and counsel had a -- what seemed to be a semantic problem. Counsel kept asking you questions about the word "treatment," and you kept saying, "Well, in the context that I use it," and then you would say yes or no to her question.

Is it correct that when you were talking about treatment in response to her questions, you were talking about a clinical intervention as by a pharmaceutical?

A. That's exactly right, and, in fact, I hope I explained that, but to clarify that one step further, that, indeed, is what I was meaning by that, is a true treatment then for erectile dysfunction. That's a different context and meaning.

Q. Right. You were -- is it correct that -- you were not saying that drinking pomegranate juice is a treatment in the sense you used it in response to those questions, correct?

A. That is -- that is correct.

Q. Okay. And if a man has erectile dysfunction and he does something that improves his erectile function, he has helped his erectile dysfunction. Isn't that correct?

A. Most certainly. But, again, I guess what I'm trying to say here is if it's something that's directly associated as a treatment for erectile dysfunction, that standard I think is a little different. I still support something that could potentially have a role in preserving one's erectile health.

Q. I understand. But is it correct that in addition to helping with erectile function, that which helps erectile function may also help improve erectile dysfunction?

A. I would support that understanding.

Q. Okay. Okay. Now, you talked about -- counsel asked you a lot of questions about RCTs and double-blind tests and all that, and you kept saying, "Well, if you're talking about treatment in my context, yes, you need all of that."

Is it correct that you are not saying that RCT tests are necessary to deal with studies of drinking pomegranate juice?

A. I do not think they apply. So, you are correct.

Q. Thank you.

You talked about validated tests, and I think you said that -- you were talking about the FDA standards for dealing with pharmaceuticals. Is that correct?

A. That is true.

Q. When you say "validated tests," you're talking about validated by the FDA. Is that right?

A. Well, they're validated tests that have been established by the scientific bodies --

Q. Um-hum.

A. -- by scientific experts that develop these tools that then the FDA does accept as meaningful tools.

Q. Yes. Well, isn't the GAQ widely used in -- even in testing drugs?

A. Well, it's widely used, yes.

Q. It's used even by -- I guess it was Pfizer testing Viagra?

A. It was certainly widely used, yes.

Q. And moving away from what you call clinical treatment and talking about pomegranate juice, the GAQ is -- correct me if I'm wrong -- certainly an adequate way of testing something like pomegranate juice, isn't it?

A. I think it's certainly a very acceptable tool to use.

Q. All right. And when you're talking about pomegranate juice, rather than the clinical treatment, you don't necessarily need to reach statistical significance in order to have something important by way of information. Isn't that correct?

A. Absolutely.

Q. Okay. So, when you said, "Well, you -- if you're talking about treatment in the context that I use it, you would want statistical significance," you were talking about pharmaceuticals. Isn't that right?

A. That is correct.

Q. Okay. 0.058, which was the GAQ score in that study that we talked about -- and I said I wasn't going to get you into that study, and I guess I did -- that's the equivalent of 94 percent validity. Isn't that right?

A. Yes. That's one way of looking at it.

Q. In other words, not -- if it was 0.05, the point of statistical significance, that would mean you have 95 percent likelihood of validity rather than mere chance. Isn't that right?

A. That is one way of -- yes, that's an accurate way of understanding it.

Q. So -- so, when we're talking about 0.058, we're talking about something that is 94 percent likely to be

valid.

A. That's correct.

Q. Okay. Is there any chance in the world that something that is 94 percent valid and shows a benefit to erectile function and, thus, a likely help to erectile dysfunction, that that information shouldn't get out because it's only 94 percent valid?

A. I agree with your point, that it would seem to me that that's important information with likely benefits.

Q. Thank you.

That's all I have.

JUDGE CHAPPELL: You're a professor as well as a practicing physician?

THE WITNESS: I am.

JUDGE CHAPPELL: And you give -- do you give exams to students?

THE WITNESS: I do.

JUDGE CHAPPELL: What if one of your questions was "Define 'treatment.'" What's the answer?

THE WITNESS: Well, I think I would define treatment with a statement -- an apposition of what my definition of treatment would be. So, to be specific, then, treatment is that of any intervention that possibly confers healthful benefits.

JUDGE CHAPPELL: Would that be the standard medical definition, as far as you know?

THE WITNESS: Well, I think that a medical definition of treatment might be slightly different if we're talking about a true pharmaceutical or intervention that we would offer clinically for the treatment of a disease state, that we would use it in a different context. Treatment, I think, is used more broadly than what we might use clinician to clinician.

JUDGE CHAPPELL: What if someone presents in the ER with arterial spray? Is it a tourniquet treatment or a sutures treatment or a both treatment?

THE WITNESS: Presented with what?

JUDGE CHAPPELL: Arterial spray. Someone is cut and is spraying everywhere.

THE WITNESS: Oh, arterial spray. So, the proper treatment there, conventionally, is immediate compression, occlusion of the area, and then fixing the traumatic -- the traumatized vessel.

JUDGE CHAPPELL: If someone calls you and they say, "A window just broke in my house and I sliced an artery, how do I treat this?" Do you recommend a tourniquet?

THE WITNESS: I am going to recommend direct compression, occluding the vessel, and that's the

conventional -- the conventional treatment to be offered for that.

JUDGE CHAPPELL: So that compression, the pressure to try to stop the flow, that's considered treatment?

THE WITNESS: That's considered treatment.

JUDGE CHAPPELL: Are you familiar with the FDA at all?

THE WITNESS: Sure.

JUDGE CHAPPELL: Do you know how they would define "treatment"?

THE WITNESS: I don't know what terminology they would use, no.

JUDGE CHAPPELL: Okay. Thank you.

MR. FIELDS: All right. Can I just clarify one thing, Your Honor? In light of your questions, can I just clarify one thing?

JUDGE CHAPPELL: Yes.

FURTHER REDIRECT EXAMINATION

BY MR. FIELDS:

Q. Again, when you were answering counsel's question and talking about treatment, you were talking about treatment in the context of clinical treatment as by a pharmaceutical, correct?

A. That is exactly correct.

Q. Not pomegranate juice.

A. No. No, most certainly I'm talking about something different in that context.

JUDGE CHAPPELL: The academic question I had about treatment, let me ask you the same thing regarding prevention. If it's on an exam with your students, how do you define "prevention"?

THE WITNESS: Well, prevention, again, I think is subject to many different expert opinions. That's a very tough word. I hope that I made that point earlier.

Prevention, I think, in general means you're trying to limit the extent to which a condition will develop or progress. I think that's a fair enough way to describe it, but I think it still has a general context above that.

JUDGE CHAPPELL: Do you think there is a -- a general medical definition of the term?

THE WITNESS: If there is, I don't have it right immediately at my fingertips. I'm sure that it's probably been mentioned here and there, but I can tell you, going through medical school, I don't recall that there's a standard definition that we have to adhere to with that term.

JUDGE CHAPPELL: Does prevention imply something is definitely going to happen, and without action, it's

going to happen? So, in other words, does it include, in your mind, intervention? Is there an intervention component in prevention?

THE WITNESS: Sure. The intervention means to not let something continue without some sort of interference, but prevention in the context of something that's known to occur, yeah, that's one way of talking about prevention. But, of course, none of us on an individual basis will know what is in store maybe with one condition, one diabetic versus another diabetic, and the sort of therapy that we would offer.

We might have a general sense of what conditions would likely come about with a disease state and intervening with different kinds of practices that we think might help limit the way that disease state may progress. So, I think that you could say there's a very broad context to that term.

JUDGE CHAPPELL: As a doctor, if one were eating five Big Macs every day -- let's say ten Big Macs every day and they had been doing that for ten years and they were 60, would you say that stopping that diet would prevent heart disease, or are there too many variables involved to say that would prevent heart disease?

THE WITNESS: Well, I think that there's a lot of variables involved. I think that you may be able to

limit any further progression of the condition from where you are, but you may have already produced enough life-long exposure to the harmful elements of that many Big Macs that maybe something would not change even if you discontinued that practice.

So, as I say, it's very complicated, but certainly I would still recommend to that patient, "Hey, cease this activity, because I think it probably is better than not that you will have an outcome that is more favorable if you are not doing that practice than if you are continuing."

JUDGE CHAPPELL: Is there a continuum that contains both prevention and treatment?

THE WITNESS: I gather there could be examples of that, something that we think may help immediately stop a bad condition from occurring at the present time and as well progressing down the line. So, I think that, yeah, again, this term "prevention" is a highly charged term, but -- weight loss, physical activity, these are things that may actually confer immediate cardiovascular benefit, but at the same time may actually be potentially helpful down the line.

JUDGE CHAPPELL: Okay, thank you.

Any follow-up?

MR. FIELDS: Nothing further, Your Honor.

JUDGE CHAPPELL: Recross?

MS. DOMOND: Yes, Your Honor.

RECROSS-EXAMINATION

BY MS. DOMOND:

Q. Hi again, Dr. Burnett.

When you were discussing treatment, you meant treatment as a true agent for therapy, correct?

A. Well, I think that what I was referring to -- and if there's just -- I need to restate that and be absolutely clear. I was saying that treatment can have different meanings behind it, and treatment in the context of a pharmaceutical drug that is approved by the FDA as an intervention for a disease state, that may have a different meaning for treatment than the broad term of treatment, which is to intervene for a condition.

And so -- which I'd just automatically say there is a different synonym for what I'm trying to say. Intervention, more broadly, for a condition I think is fair enough. That still separates it from the treatment, but that's not to say that pomegranate juice is not a treatment. It could be a treatment in the sense that it offers some potential health benefits.

Q. Okay. But when we were discussing treatment, it's not limited only to just prescription drugs. Is

that correct?

A. Sure. A treatment could be more than just prescription drugs.

Q. Okay.

A. Absolutely.

Q. And you were asked and testified that RCT tests are not necessary to deal with studies of drinking pomegranate juice. Now, this is okay if these are studies and you're saying pomegranate juice is a complementary therapy for erectile health and erectile tissue. Is that correct?

A. Certainly, with the emphasis being that I am not endorsing it as a primary intervention. When somebody comes in to see me as a patient with erectile dysfunction, and I am going to otherwise proceed with my clinical judgment, that there's interventions that I think are primary interventions there.

Q. Okay.

No further questions, Your Honor.

MR. FIELDS: No further questions, Your Honor.

JUDGE CHAPPELL: Thank you, sir. You're excused.

THE WITNESS: Thank you.

JUDGE CHAPPELL: We will take a break now. We will reconvene at 11:30.

(A brief recess was taken.)

JUDGE CHAPPELL: Back on the record, Docket 9344. Next witness.

MR. FIELDS: Yes, Your Honor. The next witness is Dr. Dean Ornish, who is already up there in the witness chair.

THE WITNESS: Good morning, Your Honor.

JUDGE CHAPPELL: Good morning.

Whereupon--

DEAN ORNISH

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

DIRECT EXAMINATION

BY MR. FIELDS:

Q. Good morning, Dr. Ornish.

A. Good morning, sir.

Q. Would you spell your name for the reporter so she gets it right?

A. Yes. It's Dean, D-E-A-N, last name is O-R-N-I-S-H.

Q. Is it correct, sir, that you're a medical doctor and a clinical professor of medicine at the University of California in San Francisco?

A. Yes, sir.

Q. Okay. And you got your undergraduate degree

suma cum laude at the University of Texas?

A. Yes, sir.

Q. You are originally from Texas?

A. Yes, sir. I was born and raised in Dallas.

Q. Okay.

A. Spent my first 26 years there.

Q. All right. And you actually gave the baccalaureate address at the university. Is that right?

A. At the University of Texas in Austin, yes.

Q. And you got your medical degree at Baylor College in Houston?

A. Baylor College of Medicine in Houston.

Q. And is it correct that you studied bypass surgery with Dr. Michael DeBakey at Baylor?

A. Yes, sir, when I was a medical student.

Q. And Dr. DeBakey is the fellow who developed open heart surgery. Is that right?

A. He was one of the pioneers of open heart surgery, yes, sir.

Q. Okay. And then, on leaving Texas, you became a clinical fellow in medicine at Harvard Medical School. Is that correct?

A. Yes.

Q. And did your residency at Mass General Hospital in Boston?

A. Yes.

Q. Okay. And is it correct that for over 34 years, you've directed clinical research on the relationship between diet and lifestyle and coronary heart disease?

A. Yes, sir. We were the first to prove that by -- in a series of studies, randomized, controlled trials, that heart disease could not only be prevented but could actually be reversed simply by making changes in diet and lifestyle. We went on to do studies showing that the same lifestyle intervention that reversed heart disease could reverse Type II diabetes, which would affect half of the Americans with diabetes and prediabetes over the next five to ten years.

We also showed that the same program could stop swelling and reverse the progression of early stage prostate cancer in a study we did in collaboration with the Department of Urology at Memorial Sloan-Kettering in New York, and that a change in lifestyle could change your genes, turning on the genes that prevent disease, turning off the genes that promote heart disease, prostate cancer, and other illnesses.

And most recently, we did a study with Dr. Elizabeth Blackburn, who was awarded the Nobel Prize in medicine last year, showing that even your telomeres can get involved in the chromosomes and control genes.

So, when we tend to think of advances in medicine as a new drug or a new laser, rather than simple choices in diet and lifestyle, we use these very high-tech, expensive, state-of-the-art scientific measures to prove how powerful these very simple and low-tech and low-cost interventions like diet can be.

Q. Okay. Is it fair to call that -- the studies you've described landmark studies in the field of the relationship between diet and lifestyle and heart health?

A. I'd like to think so. Other people have called them that.

Q. Yes, okay.

A. Dr. Sacks referred to the study of reversing heart disease as a landmark study in his testimony.

Q. Is it correct that even aside from the studies you've talked about, you've been the principal investigator or are the principal investigator in several federally funded studies relating to nutrition and coronary heart disease?

A. Yes.

Q. And that's including studies funded by the Department of Defense?

A. Yes, sir.

Q. And the National Institutes of Health?

A. Yes.

Q. Okay. Now, you talked about prostate cancer. Your research included the first randomized, controlled trial on the effect of diet and lifestyle on early stage prostate cancer, and you did that in collaboration with the University of California and Memorial Sloan-Kettering in New York?

A. Yes, sir. We did that study. It was a randomized, controlled trial. We found that the same lifestyle changes that could reverse heart disease could beneficially affect the progression of prostate cancer in men. It was the first study to show that.

Q. And is it correct you've written six published books on the subject of the effect of diet and lifestyle on heart disease and other diseases?

A. Yes, sir.

Q. Okay. And you've written chapters in books by other people as well?

A. That's right, many standard medicine and cardiology textbooks.

Q. And is it correct that research by you and your colleagues have been reported in such journals as the Journal of the American Medical Association, Lancet, Lancet Oncology, the American Journal of Cardiology, the Proceedings of the National Academy of Sciences, and

other peer-reviewed journals?

A. Yes, sir.

Q. Okay. You have written numerous chapters -- pardon me, numerous articles for peer-reviewed journals, as well as a chapter on the management of coronary heart disease in Harrison's Principles of Internal Medicine. Is that correct?

A. That's right. And also, the companion to the Braunwald Cardiology textbooks as well.

Q. Thank you.

And many of your studies and articles have been on the subject of cardiovascular disease. Is that correct?

A. Yes, sir.

Q. Okay. Now, has that been the principal area of your research for over 35 years?

A. Yes.

Q. Okay.

A. Not the only area, but a principal area.

Q. That's been a principal area of your study?

A. Yes. In fact, just recently, as of January 1st of this year, Medicare made a decision to cover Dr. Ornish's Program for Reversing Heart Disease, our program, for the American people. That's the first time Medicare has done anything like that.

Q. Thank you.

All right, I am not going to list all of your awards. You got the Kellerman Award for Distinguished Contribution to the Field of Cardiovascular Disease Prevention. That was awarded by the International Academy of Cardiology. Is that correct?

A. Yes, sir.

Q. Okay. And you were awarded by the University of Texas as one of the most extraordinary alumni in the past 125 years?

A. Yes, sir.

Q. Okay. And you are listed by Life Magazine as one of the 50 most influential people in your generation?

A. Yes, sir.

Q. Okay. And by Forbes as one of the most powerful teachers -- one of the seven most powerful teachers in the world?

A. Yes, sir.

Q. Okay. We're going to wind up with this pretty soon.

And a panel of experts in U.S. News Report [sic] rated your diet number one for heart health, among all of such diets?

A. Yes, sir. Just a few months ago, the editors of

U.S. News and World Report convened a panel of leading diet experts that reviewed all of the different diets, and they rated our diet as number one for heart health and number two for diabetes.

Q. Okay. And you have given numerous lectures in such institutions as the Mayo Clinic, the Cleveland Clinic, the M.D. Anderson Center in Houston, and such -- and the like?

A. Yes.

Q. Okay. And is it -- you presently conduct a nonprofit research institute in Marin County, across the Bay from San Francisco?

A. Yes. In 1984, when I finished my medical training in Boston, I moved to San Francisco and established the nonprofit Preventive Medicine Research Institute, which is a 501(C)(3) public foundation for primarily research but also education and service.

Q. Okay.

We would offer Dr. Ornish as an expert and his report and CV in evidence.

MS. EVANS: Could I ask you to specify, an expert in what?

MR. FIELDS: Well, he's an expert in the relationship between the heart and nutrition and in cardiovascular disease and its relationship to

nutrition, nutrients, and such things.

MS. EVANS: No objection.

JUDGE CHAPPELL: Any opinions that meet the proper legal standards will be considered.

MR. FIELDS: Thank you, Your Honor.

BY MR. FIELDS:

Q. Dr. Ornish, as part of your research on diet and its effect on cardiovascular disease, have you done research on pomegranate juice sponsored by the Resnicks or by Roll International?

A. Yes, sir.

Q. All right. At present, are you on friendly terms with the Resnicks? You can speak frankly.

A. We're on reasonably good terms. I -- they created a major challenge for me when they cut our funding midway through one of the studies that actually we will be talking about later, because we weren't recruiting patients as fast as we thought we initially would.

My prime directive in doing research is always to do it right, even if it takes longer. Their attitude was, well, you said you could do it in a certain amount of time, and, you know, when you're doing research in a new area, sometimes you -- it takes you longer than you think, because in the case of this particular study, it

was harder to get patients recruited because the cardiologists were so aggressive about doing angioplasties and stents, surgeries and bypass surgeries, so it reduced much more than we had originally planned the number of patients eligible.

So, by cutting our funding, it was often more counterproductive to them, because as we'll talk about later, if one of the studies had continued with the number of patients that we initially projected we would have needed, it would likely have shown a much stronger outcome.

So, I respect the Resnicks. I appreciate them as -- for what they're doing to advance the field. We're on good -- reasonably good terms, but it -- it created a major financial issue for our institution at the time.

Q. They're not presently sponsoring anything that you're doing, are they?

A. Not for many years. Not since then, actually.

Q. Pardon me?

A. Not since that time.

Q. Okay. Still, you've come here voluntarily, and I gather your fee is a dollar an hour, or is it a dollar a day?

A. It's a dollar an hour.

Q. A dollar an hour, okay. Do you count nights as well as days?

A. No. I think I have to get paid something, right?

Q. Why have you come here essentially without pay and voluntarily for people who have cut off your funding or are no longer funding you at all?

A. Well, I am not doing this for the Resnicks. I am doing this because I think this is an historic case. I get asked to be an expert witness all the time. I've never testified as an expert witness until now, and I'm doing it because I believe in -- I think our liberties are at stake here, and that concerns me greatly.

The -- I don't think that the Government -- I think the Government is overstepping its role here. It is playing the role of big brother, and ultimately, if successful, will keep the American people from valuable information that could make a difference in the quality of their lives and possibly even be life-saving to them.

It's one thing when you're talking about the standards of a new drug, because a new drug always has toxicities and side effects, and anyone who has ever seen a magazine ad for a drug can turn it over and there are pages of side effects, known and unknown.

But we're talking about a beverage that's been

around since the Bible, for thousands of years, that the only side effects are good ones, and it concerns me that if -- you know, if you're -- let me say that it concerns me a bit, if the standard for a drug is held to a fruit or a beverage, then, in fact, no one can meet that standard, because the drug companies spend literally billions of dollars to get a new drug approved.

Pfizer got four drugs approved in the last ten years at an average cost of 1 to 4 billion dollars each. No one is going to spend that kind of money to test a fruit unless -- you know, if it's a drug and it's successful, you could make billions of dollars a year. Lipitor, Pfizer was making $10 billion a year, per year, on one drug. So, it's worth it for them to put that kind of money into it.

But when you're talking about -- and that's why I admire the Resnicks for having put tens of millions of dollars of their own money into studying pomegranate juice. I remember meeting Stewart Resnick in the late nineties, and he said, "You know, we have got some early studies showing that pomegranate juice may be more beneficial than anybody realized," and -- but rather than going public and marketing, he said, "I'd like to fund research with you and other people to see if that's true or not." And I respect that. And he's put tens of

millions of his own -- dollars of his own money into doing that, and I respect that.

But if -- if -- with all the research that's been done, if -- if simple health claims can't be made for the potential benefits of pomegranate juice, then no one will be able to make health claims except drug companies, and I don't think that's right, and I think that's to the detriment of the American people.

I'm about -- I believe in personal responsibility, I believe in freedom of choice, and I believe in empowering an individual with information so that he or she can make their own judgments, not for big brother to make that for us.

What we include in our diet is as important as what we exclude. There are literally hundreds of thousands of protective substances in predominantly fruits and vegetables and whole grains and legumes and soy products, and I think it's important for manufacturers to be able to share science-based information with the American people so that they can decide whether or not they want to purchase these products, not to overstate the claims, not to say that this is a substitute for conventional approaches, but there are things that people can do to empower themselves. And I think it's important that the

American people know about those so they can make their own choices and not have the Government do it for them.

Q. While we're on that subject, is it your opinion that when you're talking about fruit juice or vegetables or other foods like that, that in testing whether they are good for the health or whatever health claim they might make, you have to have RCT tests?

A. I think that a randomized, controlled trial is just one of many research designs. You know, when you're doing a study, any study, whether you're looking at a drug or a fruit or a device or a surgical intervention, what you're really trying to do is say, is this true or not? Is this helpful or not? That's really the bottom line in any study. Is there a real effect or is it just a chance effect?

And by convention, if that -- if the likelihood that those findings due to chance is 5 percent or less, then it's considered statistically significant, and there are different research designs that are -- that are intended to reduce the likelihood of bias or something affecting the outcome other than the intervention itself.

Now, a randomized, controlled trial is a powerful tool to do that, but it's only one of many. But it's a very simple-minded approach to say that only

randomized trials are good science and everything else is really not, because randomized trials have their own biases as well.

For example, if you're doing a study of a drug, a randomized trial can be done because, number one, you can have a placebo; if you're taking a pill, you don't know if you're getting the drug or not. But if you're studying a fruit or a food, it's very hard to do especially double-blind, randomized, placebo-controlled trials, because you know what you're getting.

In any randomized trial, what you normally do is you ask the patient who may be eligible for the study, would you be willing to volunteer for this study? There's a 50/50 chance you are going to get the intervention, but if you get the intervention, would you be willing to follow it? Would you take the pill? Would you eat the food? Would you drink the juice? Or whatever it happens to be.

So, if they then subsequently get randomly assigned to the control group, which is what happens half the time, of course, they already know what the intervention is. Now, if it's a drug, it doesn't matter, because they can't get the drug if it's an experimental drug, but if it's a food or a juice, they can.

And so you get what's called contamination, where the control group members say, hey, if they think it's good enough to do a study, maybe I'll just start taking it myself. I'll start eating the food or I'll start drinking the beverage. This is what happened with the women's health initiative study, where the Government spent a billion dollars to see whether diet affected the likelihood of getting breast cancer or heart disease in women.

And what they found is the control group patients changed almost as much as the people in the experimental group, so it didn't really show a difference, and so it appeared as though diet didn't really have an effect, but the real issue was that the control group was changing as much as the experimental group.

So, randomized trials can be beneficial, but they are not perfect, and they have their own -- especially when you are dealing in nutrition, they have their own set of limitations as well.

Q. So, is it correct that, in your opinion, RCTs would not be necessary to test and substantiate health claims of something like pomegranate juice?

A. It's important to look at the totality of the evidence and to -- you know, to keep our common sense.

In reviewing some of the transcripts -- you know, we can get into the nitty-gritty and I am sure we will today over P-values and this patient versus that patient and so on, but I think it's important to examine the totality of evidence.

In Dr. Sacks' testimony, for example, he said that if it's not a double-blind, randomized, controlled study, then it's not really -- you shouldn't be considering it in a decision like this. Well, I think that's -- that's silly. I mean, his own research, if you applied that standard, the vast majority of his own studies wouldn't meet that standard. So, clearly he doesn't think that's true in his own work.

So, I think it's important to examine the totality of evidence and to keep our common sense --

Q. Okay.

A. -- and if you're shown a series of studies that include randomized trials but are not limited to them, but there's a benefit for that, particularly if the only side effects are good ones, then I think those studies are worth considering.

Q. Well, is it correct that they are not --

JUDGE CHAPPELL: I don't think you got an answer to your question.

MR. FIELDS: Yes, that's right. I was just

going to put it to him again, Your Honor.

BY MR. FIELDS:

Q. Are you -- is it -- is it correct that when you look at the totality of the evidence, which you may include RCTs, that RCTs are not necessary when you're talking about fruit juice or broccoli or things like that?

A. Yes.

Q. Okay. Let's talk about your studies, which is what we're really here for today.

Is it correct you did a myocardial perfusion study on pomegranate juice, known as Bev 1?

A. Yes, sir.

Q. And is it correct that myocardial perfusion is blood flow to the heart?

A. Yes, sir.

Q. And I gather that blood flow to the heart is essential to life. Is that correct?

A. Well, it is, and the latest thinking about heart disease is that the most important measure of heart disease is blood flow to the heart, because that's really the bottom line. I mean, heart disease is simply -- coronary heart disease, which is the most common form of heart disease, is when the heart doesn't get enough blood to fuel itself, and blood carries the

oxygen, which is the fuel for the heart.

And so over time, arteries that feed the heart -- the heart feeds blood to the body, but it first needs blood to feed itself through the coronary arteries. If those arteries get clogged over time, then the heart may not be able to provide enough blood to sustain itself. If it's tempered, you get what's called angina or angina, which is chest pain. If that disruption of the blood supply to the heart is for more than a few hours, part of the heart muscle may die, turn to scar tissue, and that's called a heart attack.

If it's a small part of the heart, you may live; if it's a large part of the heart, you may not. It's a little like a partially clogged fuel line in a car. You may get enough gas to the engine at low speeds, but when you go out on the highway, the need for the gasoline can't keep up with the supply because of the clogging -- the partially clogging of the fuel line, and so you may have the equivalent of what would be angina in the heart.

Now, over time, our first understanding in the field of heart disease was at the autopsy table. When someone would die, you would cut open their heart, you would see blockages in their arteries, and you would think, well, that's the reason why they had a heart

attack.

But we understand now that the process is much more dynamic than we had once realized, that the blockage is only one of several factors that affect blood flow to the heart. The arteries are not like lead pipes. They are like smooth muscle that can constrict and dilate. Your body can grow new blood vessels around clogged arteries, called collateral flow. And so when you do an angiogram, which used to be the gold standard for measuring blockage, but the blockage unit that you measure is really only part of the story, because most of the blockage is inside the wall of the artery, kind of like an iceberg, where you are really just seeing literally the tip of the iceberg.

And so with a conventional angiogram, you are not even getting the most accurate information about how much blockage there is, whereas when you're measuring blood flow, it takes into account all of the mechanisms, whether it's the blockage, whether it's the amount of collateral flow, whether it's the diameter of the arteries, whatever it happens to be.

In fact, studies have shown that measures of myocardial perfusion or blood flow to the heart are actually not only as predictive but are often more predictive of who's going to get a subsequent heart

attack or die than the blockages alone. So, that's why I think it's a very -- I think it's the most important measure.

Q. In that regard, the FDA approves of HDL cholesterol as a surrogate for cardiovascular disease.

A. I think they -- actually, it's LDL cholesterol that they recognize as a surrogate.

Q. Pardon me. LDL cholesterol. You're right.

And comparing the two, myocardial perfusion and LDL cholesterol, is it correct that myocardial perfusion is much more closely connected --

A. Yes, sir.

Q. -- to the -- let me finish my question -- to coronary vascular disease than LDL cholesterol?

A. Yes, sir, that's correct, because to me, LDL cholesterol is a risk factor for heart disease, just like blood pressure is a risk factor for heart disease. It's not heart disease. So, I don't think it's a valid surrogate.

Clearly, there are a number of people who have low cholesterol levels who get heart disease. There are people who have high cholesterol levels who don't have heart disease, and the same is true for blood pressure, whereas when you're measuring myocardial perfusion or blood flow to the heart, you're actually measuring what

most matters, which is how much blood flow the heart is getting.

Q. So, if LDL cholesterol is a surrogate, isn't it clear, sir, that myocardial perfusion must be a valid surrogate?

A. It's a much better surrogate.

Q. Okay.

A. I don't even think that -- I know the FTC or the FDA use LDL and blood pressure as surrogates. I think they're wrong. I think it's -- these are risk factors. They are not surrogate measures, because a surrogate measure means if you measure LDL and it's high, that means they probably have heart disease, but we know that's not the case in many cases. And the same is true for blood pressure.

Q. Okay. Is there a difference between studying -- strike that.

In your tests, in your study, were you studying the effect of pomegranate juice on patients whose blood flow was significantly different when resting and when -- after stressful exercise?

A. Yes, because when you're measuring -- when you're doing a thallium scan, the way the test works is you do two scans. You do a scan at rest, where you inject thallium into a vein, it's a radioisotope, so it

goes where the blood goes, but it's taken up by the heart, and then you can scan it and see how much blood flow is the heart getting at rest.

Then you can put the patient under some kind of physical stress, whether -- running on the treadmill is the traditional way or giving a drug like dipyridamole that makes your heart beat fast -- D-I-P-Y-R-I-D-A-M-O-L-E -- because what you're really interested in is, like the analogy of the partially clogged fuel line in the car, the heart may be getting enough blood flow at rest but not when you're putting a greater demand on it.

And that helps you differentiate between areas of the heart that aren't getting enough blood flow that may be due to scar tissue versus areas of the heart that may not be getting enough blood flow because that heart muscle is alive but under higher demand, i.e., when it's beating fast, the supply can't keep up with the demand.

Q. So, you're measuring the difference between the patient resting, let's say sitting down, and the patient under stress, as on a treadmill or similar?

A. Yes, sir.

Q. Okay. What was the result that you found in your study?

A. What we found was that -- we gave -- it was a

randomized, double-blind, placebo-controlled study, the highest standard. One group was randomly assigned to receive pomegranate juice. One group was randomly assigned to receive a placebo, which was Gatorade as it turned out. It was done in the time before people really knew what pomegranate juice tasted like. It was unusual back then. So, it was possible to do a -- if anything, people might have thought that the Gatorade was the intervention, because it has a large -- PepsiCo owns Gatorade and was always doing studies on Gatorade, whereas people didn't really recognize what pomegranate juice was, so they might just as easily have thought we were doing a study on Gatorade as pomegranate juice, because they didn't recognize the flavor.

What we found was that after only three months of them drinking an eight-ounce glass of pomegranate juice that those patients showed an improvement in blood flow to their heart compared with the randomized control group, who actually got a little worse. Those differences were statistically significant, and we published that in the American Journal of Cardiology.

Q. Now, is it correct that the comparative benefit of the pomegranate juice to the placebo group was about 35 percent?

A. Yes. One group improved by about 18 percent and

the other group got worse by about 17 percent, so the net difference, if you will, was about 35 percent. The natural history of heart disease is to get worse over time. It's unusual for people to get better, especially in such a short time, but because we're learning that these mechanisms that affect blood flow to the heart are more dynamic than we had once realized, that we think these are real findings.

In fact, one of the very first studies that I did back in 1977, '78, we found that we could show improved blood flow to the heart after just one month when people made intensive changes in diet and lifestyle. So, we are confident that these findings are valid. What also increases our confidence is that they were blindly read by a nuclear cardiologist who had no understanding which group the patient was in, so they were blindly read by someone who was otherwise not working with the study at all.

Q. Okay. Is the improvement that you've shown in myocardial perfusion, that 35 percent improvement, something that's likely to benefit a substantial number of people in the United States?

A. Yes. If these findings were extrapolated to the entire country, absolutely. You know, coronary heart disease is the leading cause of death.

We also found, by the way, a 50 percent reduction in angina or chest pain, whereas the control group showed an increase in angina. That wasn't statistically significant, because there's so much variability in angina that it's hard to show the statistical significance in a smaller group of people when you have something that's as variable, but it certainly is consistent with the findings.

And if we go back to the common sense rule, if you show that the amount of chest pain is reduced by 50 percent and the blood flow is clearly getting better, that's a real finding.

Q. Now, the 35 percent improvement, that was statistically significant.

A. Yes, sir.

Q. While we're talking about that, is it your opinion that if something doesn't reach statistical significance -- and we're talking about testing a risk-free substance like pomegranate juice -- that you can't consider it at all?

A. The -- the -- could you ask that question in a way that I can say yes or no to it? I'm not really sure whether that's a yes or a no.

Q. Let me rephrase the question if you don't understand it.

Is it correct that you don't have to reach statistical significance to have really important information about something like pomegranate juice as opposed to a prescription drug?

A. Yes, sir, that's correct. And remember, the -- the convention that -- a statistically significant finding is one that's 5 percent or less likely due to chance is an arbitrary convention, that -- there is nothing magical about it.

Q. Yes.

A. So -- and I think just to follow the point, I do think that a new drug needs to be held to a higher standard than a juice that's been around for thousands of years.

Q. And is it correct that when you say you have got a 0.05 P-value, you're really saying there's a 95 percent probability of validity as opposed to chance?

A. That's correct.

Q. And so if you're talking about something that's, let's say, 0.058, where we have had some evidence of a study that was 0.058, that's more like 94 percent validity as opposed to chance, correct?

A. That's correct. That's why I say, it's arbitrary.

Q. Yeah. Okay.

A. There's nothing magical about that number.

Q. Let's talk a little bit about Dr. Sacks' criticisms. He -- he criticized your study because he said you were measuring what's called SDS as opposed to SRS. What do those initials stand for? Do you recall?

A. Well, there's three measures that we looked at. There's SRS, which is simply the amount of blood flow the heart is getting at rest. There's SSS, which is the amount of blood flow the heart is getting during stress, i.e., when you're running on a treadmill. And there's SDS, which is simply the difference between the two.

And as we discussed before, in this context, our primary end point measure, stated a priori, was, how much blood -- how much blood flow is the heart getting when you compare the rest versus the stress? Now, that's what the SDS measures.

One of Dr. Sacks' criticisms was, well, we didn't say in our protocol that we were measuring SDS, but we did say very clearly that we were measuring blood flow to the heart, which is what SDS measures. It would be kind of like saying, "I like Ole Blue Eyes," but you say, "Well, you didn't say that you liked Frank Sinatra." Well, yeah, but that's what we're looking at.

Q. Okay. And is SDS considered a valid surrogate for coronary heart disease?

A. Yes, it is.

Q. Okay. And SRS as well. Is that correct?

A. Well, again, you have to say, what is the question we're trying to answer? One of Dr. Sacks' comments was that in the Braunwald Cardiology textbook, they state that SRS is a -- is a good predictor of who's likely to die earlier from heart disease than someone else, and that's true, because remember, what you're measuring with SRS is how much of the heart muscle is dead, i.e., when you have a heart attack, part of that muscle turns into scar tissue. So, clearly, the more of your heart muscle that's scar tissue, the worse your prognosis is.

But that's not the question we were trying to answer in our study, because we are not going to make dead tissue come alive, you know, unless you're -- I won't even go there, but you're not going to make -- unless you're Jesus, you are not going to make dead tissue come to life.

Now, what we were trying to answer was the question of would areas of the heart that weren't getting enough blood flow during peak exercise improve, get more blood flow, after drinking pomegranate juice, because -- for whatever reason those mechanisms were, because if the heart's getting more blood flow, that

means it's getting better. And that's exactly what we found.

Q. Okay. Another criticism that Dr. Sacks made was that there was some difference at baseline, as he said, in the SRS score and perhaps in the SDS score, and that is a criticism of the study, he said.

A. There was no difference in SRS score or in SDS score, and remember, SDS was the primary end point measure. There was a difference in the SSS at baseline, but the analysis that we used, what's called analysis of variance, takes into account any baseline differences, because you're really looking at the difference in change over time.

Q. So, even if there had been a difference in SDS at baseline, it would not have made any significant difference in the improvement?

A. It could have been more of an issue, but it wouldn't have undermined the validity of the study, particularly since it wasn't our primary end point measure, and so the study is valid.

Q. Yeah. Very often, when you recruit randomly, you are going to get a difference in baseline between the placebo group and the --

A. That's right. It's not uncommon, if you look at a number of different measures, that one of them may be

statistically significant in the group, but in every way we measured between these groups, their cholesterol levels, their blood pressures, their blood sugars, their weights, their -- you know, all the number of ways, there was no differences between the groups at baseline.

Q. Now, if one of the groups, let's say the placebo group, was sicker at the beginning somewhat, at baseline, does that necessarily mean that they got a greater or lesser result?

A. You know, again, part of the value of having a randomized control group is to answer questions like that, because what we found was that the -- basically, the control group got sicker, but the group that drank the pomegranate juice got better, and the natural history of heart disease is not to get better, especially in only a three-month period.

There's a statistical phenomenon called regression to the mean, which says that outlier -- if you measure someone more than once, the outliers tend to come more towards the middle. So, if someone was sicker, all other things being equal, you would expect them -- if there was no effective intervention, you would expect the subsequent measures to show that they were a little better, not that they were necessarily worse.

Q. Okay. Dr. Sacks made some other criticisms -- and, by the way, as to some of these criticisms, he said they were not fatal, they were just demerits, but they are criticisms. He said that a few participants got unblinded, I think, toward the end of the study. How did that happen and did it have a material effect on the outcome?

A. Well, I would agree with Dr. Sacks here that that would be a demerit on the study but it doesn't affect the outcome, and the reason -- what happened was that the pomegranate juice and the Gatorade were shipped by Roll International, and six of the patients, they didn't move -- they didn't -- they opened -- they -- they took the sticker off and they could see whether they were getting the Gatorade or the pomegranate juice. So, that was six of the -- of the 41 patients. Now -- six of the 45 patients, I should say.

Now, the real question, again, is, is that likely to affect the outcome? And the answer is, in my opinion, no, and here's why. Again, this was at a time when people didn't know that pomegranate juice might even be beneficial to them, and if they found they were drinking Gatorade, it was much like -- probably to me, there was a greater likelihood that they would have thought that that was the -- because we called this the

beverage study. We didn't call this the effects of pomegranate juice study.

So, if they thought they were getting Gatorade, they might have just as well have thought that was the intervention rather than the others who didn't know what it is. And so --

Q. When you say they might have thought that was the intervention, you mean they might have thought that what was being studied was the Gatorade --

A. That's right.

Q. -- and that they were in the group that was getting that and not in the placebo group?

A. That's right, because Gatorade is always doing studies or I should say PepsiCo is always doing studies on Gatorade to see whether it's beneficial in one context or another.

So, the real issue and one reason why you go about blinding things is that the expectation that something might have a positive benefit can sometimes be self-fulfilling, but in this case, there's no reason they would have necessarily thought that, even if they knew they were drinking pomegranate juice, that that was likely to provide them a benefit, because this was before people even knew what pomegranate juice was, other than it was an exotic juice.

Q. Okay. Do you remember when this occurred during the study? I think Dr. Sacks said it was toward the end of the study.

A. I don't know the answer to that.

Q. Okay. And if they had known that --

A. It was only a three-month study anyway.

Q. Yeah, I understand. But if they had thought that you were studying something other than Gatorade, that would not necessarily affect their blood flow to the heart anyway, would it?

A. It -- it would be a stretch to say that simply thinking that they were getting something beneficial could affect blood flow to their heart, but even if one assumed that were true, as I was saying, they might just as well have thought that the Gatorade would be beneficial as the pomegranate juice would be beneficial. So, therefore, it didn't confound it. And it was only six of the 45 patients anyway.

Q. Another Dr. Sacks demerit was that initially included in the tally -- or two participants were not included in the tally, but they were ultimately included in the ultimate conclusion that you reached.

A. Yes.

Q. Is that correct?

A. I'm sorry?

Q. Is that correct?

A. That is correct. He's absolutely right about that. It was an oversight in one of the people that works with me. So, we went back and we looked at the outcomes when all 43 patients were included, and it didn't change them.

Q. All right.

A. In other words, we included them when we did our analyses, but somehow, in the actual writing up of the paper, two of the patients were left out. But when they were included, which is what they were all along --

Q. But in your conclusion that there was a 35 percent improvement in the pomegranate juice group, these people were ultimately included in that computation. Is that correct?

A. Yes, sir. And the differences were statistically significant when they were included.

Q. All right.

A. In fact, they were, if anything, more significant, because the sample size was slightly larger.

Q. Dr. Sacks -- I think it was his final demerit -- was that you had used something called the per-protocol method rather than what he called the intention-to-treat method. Can you explain the difference?

A. We used the intention-to-treat method. In other words, we reported all the data that we had. There were 45 patients initially. Two patients, one in each group, had thallium scans that for technical reasons were unreadable, and remember, these were done blindly, so the person reading them would have no knowledge of which group they were in. It happened that there was one in each group. And two other patients dropped out because they had multiple comorbidities, one in each group as well.

It wouldn't be appropriate in a study of pomegranate juice to say that those four patients -- we used the intention to treat because we reported all of the data that we had, but the -- the corollary to that that someone would say is you use the last value to carry forward, which is to say, if you don't have the last value, you would use the baseline value, which would mean there would be no change, and that would be introducing a negative bias against being able to show something, which you could argue, if you are studying a new drug, if you are studying a new chemotherapy agent that has, you know, major toxicities, that you have to be extremely careful and use the most conservative method of analysis before you release that to the American population.

But when you're talking about a juice, you don't need to go to the extreme of biasing against being able to show effect to that degree. But we did use the intention-to-treat method.

Q. But you used the per-protocol method as well?

A. Well, per-protocol simply means that you report the data that -- that you have, and so, yes, we did that, but we reported all of the data that we had.

Q. Yes. The people who dropped out simply were not included in the data. Is that correct?

A. We reported all the data that we had. Two of the patients, the data was unreadable. Two of the patients dropped out because they were so sick, one in each group, and they refused to be tested. We tried to test everyone, but they -- those two people refused to be tested.

Q. Is it correct that a published survey shows that per-protocol was the basis of at least 50 percent of the studies published by the New England Journal of Medicine and Lancet?

A. Well, it actually goes beyond that. It -- there was a study that looked at the four top-tier journals, the New England Journal of Medicine, the Journal of the American Medical Association, Lancet, and the British Medical Journal, and less than half of the studies were

even randomized, controlled trials, much less using intention-to-treat method. So, again, Dr. Sacks' assertion that it was not a randomized, controlled trial and is not good science is certainly not borne out by the top-tier journals who publish these studies all the time.

Q. I don't think he said it wasn't a randomized, controlled trial. I think he just criticized it for using -- called it a demerit to use per-protocol instead of intention to treat, and -- but you have explained that.

Given these criticisms that I've told you about from Dr. Sacks -- and I don't mean to get into anything that's pejorative -- but in your opinion, could any unbiased doctor simply throw out your positive myocardial perfusion study because of the criticisms we've discussed?

A. No.

Q. All right. Now, you did another study called Bev II. Is that the one where the funding was cut?

A. Yes, sir.

Q. Okay.

A. Well, in a sense, the funding was cut on the Bev I study as well, because our original plan was to study these patients at three months and at one year, but we

didn't have the funding to do it for one year. So, we only did it for three months.

The Bev II study was cut in terms of the total number of patients that we had -- we had projected -- well, let me back up a moment.

When you're doing a study, again, the question you are trying to answer is, is this a real finding or is this a chance finding? So, before you do a study, you estimate the number of patients that you think you'll need based on the expected change that you think you'll observe in order to have significance. It's called the power analysis.

Our power analysis, based on earlier studies in the field, was that we would need at least 200 patients to show a statistically significant difference, and that's what we budgeted for. As it turned out, our funding got cut, so we were only able to recruit 73 patients, of whom 56 we ended up having pre and post data on.

Now, what's unfortunate and perhaps a little ironic is that we did show in one of the measures in the carotid artery that there was an improvement, and it was significant to the 0.13 level as opposed to the 0.15 level. If that degree of change had occurred in the larger number of patients that we had projected, it

would have clearly been at the 0.05 or less, and it would have been a very strong study showing that pomegranate juice affected the progression of carotid disease.

We also showed similar, almost statistically significant improvements in the elasticity of the arteries, and as the arteries get more clogged, they become less elastic. So, when they become more elastic, that's another measure of improvement.

So, it was unfortunate and short-sighted for the Resnicks to cut the funding, because it prevented us from being able to do the study that we had originally planned to do that, that had it continued with the remaining patients, and we have no reason to think that it wouldn't as with the original 73, then it would have shown a statistically significant difference.

Q. Is that what underpowered means? In other words, you don't have enough people to get to statistical significance?

A. Yes, sir. And it's important that you state, a priori, in advance, what your number is so that you can't just keep adding more patients to get the number you want. These were all things that we clearly stated in our protocol at the beginning of the study.

Q. And are you confident that if you had had the

number of patients that were in the protocol, that you would have reached statistical significance?

A. I am, because there's no reason to think that the next 127 patients would have been different than the first 73.

Q. So, you -- and those 73 showed a definite benefit but didn't reach statistical significance, correct?

A. That's correct.

Q. Okay.

A. There's always the possibility, but it would have been unlikely, that those -- the next group of patients would have been somehow different than the first group.

Q. Okay. In your opinion, Doctor, do your studies constitute credible and reliable science showing that pomegranate juice lessens the risk of cardiovascular problems?

A. Yes, and it goes beyond that. We've shown, certainly in the Beverage I study, that pomegranate juice actually improves the blood flow in people who already had heart disease. So, we're not just talking about risk of heart disease in terms of preventing it in otherwise healthy people. We're talking about reversing the progression of heart disease in people who already

have severe heart disease. Clearly, if you can reverse a disease that's -- or begin to reverse a disease, it would only make sense that it would work even better to help prevent it in the first place.

Q. Thank you.

That's all I have.

JUDGE CHAPPELL: Cross?

MS. EVANS: Good morning, Your Honor.

CROSS-EXAMINATION

BY MS. EVANS:

Q. Good morning, Dr. Ornish. How are you?

A. Good morning, Ms. Evans. Thank you for asking. I'm fine.

Q. I believe that you testified in research --

A. Could I ask you a favor? Would you mind pulling the microphone down closer?

Q. Yes, because this only works for a regular-size person.

I believe you testified that -- just a minute ago that in research, you're trying to determine whether an intervention is causing the effects or whether it's coincidence.

A. Yes.

Q. Okay. And that's the case whether the intervention is a drug or a juice or a lifestyle

intervention?

A. Yes, ma'am.

Q. And the most rigorous design is called a randomized, double-blind, placebo-controlled study?

A. Well, it depends on how you define "rigorous." I think that it controls for some set of biases but it introduces others, and it's appropriate for some interventions and it's not so appropriate particularly for a nutritional intervention, because it's impossible to blind what you're consuming, which is why in Dr. Sacks' nutrition studies, he very rarely used a double-blind, placebo-controlled study.

Q. And --

A. And, by the way, that's why we wouldn't be able to do the study today that we did back then, because people know what pomegranate juice tastes like.

MS. EVANS: Excuse me one moment.

(Pause in the proceedings.)

BY MS. EVANS:

Q. Now, I just want to -- your -- you and I have talked twice, correct? You've had two depositions?

A. Yes.

Q. Okay. And the first deposition was taken in December of last year, 2010?

A. I don't remember the exact month, but I'll

presume that's true.

Q. Okay. And the second deposition was taken in April of this year.

A. Okay.

Q. The first one, I explained to you, was a fact deposition, and the second deposition was your expert deposition.

A. Yes.

Q. Okay.

Your Honor, I am going to read into the record a portion of the deposition transcript for the first deposition.

JUDGE CHAPPELL: Can we have a foundation first, some connection with his testimony today?

MS. EVANS: Yes, sir.

BY MS. EVANS:

Q. At your first deposition, did you describe a rigorous -- excuse me, did you describe the -- what a randomized, double-blind, placebo-controlled study was?

MR. FIELDS: Excuse me, Your Honor. Could we have a page and line number so we can follow along?

MS. EVANS: Yes. I am referring to deposition one and turning to page 19.

JUDGE CHAPPELL: Do you want to repeat the question or have Susanne read it?

MS. EVANS: I'm going to read a section of his testimony into the record, sir.

JUDGE CHAPPELL: I haven't heard the foundation I said I need before you start reading a deposition here in open court.

BY MS. EVANS:

Q. Did I ask you, at your testimony, what a randomized, double-blind, placebo-controlled trial was?

A. I -- I don't remember, but I presume you did or you wouldn't be asking me now.

Q. And at that deposition, did you state that a randomized -- the most rigorous design is called a randomized, double-blind, placebo-controlled study?

A. It's the most rigorous for certain things but not for others. So, let me clarify that statement.

Again, if you were trying to do a randomized, double-blind, placebo-controlled study on pomegranate juice today, you wouldn't be able to, because people know what it tastes like. It would be an impossible bar for anyone to -- to reach.

Q. And may I now read into the record a portion of the testimony? At line -- the first deposition, at line 19, where -- actually, starting at line 19:

"QUESTION: What does a randomized, double-blind study mean?

"ANSWER: In research, you're trying to answer a question, is there -- whatever the intervention is, if it's a drug, if it's a juice, if it's a lifestyle intervention, whatever it is, you are measuring effects. You are trying to determine whether the intervention is causing the effects or whether it's a coincidence. And the most rigorous design is called a randomized, double-blind, placebo-controlled study, and there are different levels of evidence in science."

MR. FIELDS: Your Honor, could we have the rest of the answer read, for example, where he says that pomegranate juice was not on the market, so most people, even if they know, wouldn't have recognized it what they're getting? Counsel is reading two or three lines out of a long, long answer.

JUDGE CHAPPELL: You need to read the entire response or indicate that you have not done so.

MS. EVANS: Yes, sir.

BY MS. EVANS:

Q. Following up from what I just read, page 20, at line 7:

"This is considered the most definitive, and the reason is that it controls to a lesser degree than any other design, known and unknown sources of bias that might give you incorrect information. So, for example,

in the study, you would identify a group of candidates based on your patient selection criteria, and if they met these criteria and they agreed to be in the study and they agreed to be randomly assigned to either group, then you would randomly divide them into two groups in this case, one group that received the pomegranate juice and one who -- that received the placebo.

"And at the time, pomegranate juice was not on the market, and so most people didn't really -- wouldn't have recognized what they were getting, and so by randomizing people, if there was some unknown factor that was biasing your outcomes, it was likely to be distributed across both groups of people. So, for example, let's say -- I don't know, the water supply in San Francisco was healthy and you -- maybe that's not the best example. Well, let's say you --"

That is the complete response.

A. Well, I appreciate the chance to clarify that.

Q. Excuse me. There is no question pending.

A. But I still would appreciate the chance to clarify that here.

Q. No, I --

A. I would like to clarify that. Since you have raised the issue, I think it's important to clarify it since we are all interested in what I said and what I

mean. Isn't that the case?

Q. There is no question pending.

JUDGE CHAPPELL: I have a question. May I ask a you a question?

MS. EVANS: Of course.

JUDGE CHAPPELL: How is what you just read inconsistent with what I heard him testify to before you read it?

MS. EVANS: I asked him whether or not the most rigorous design is called a randomized, double-blind, placebo-controlled trial, and twice he responded in that quotation that the most rigorous design is called a randomized, double-blind, placebo-controlled trial.

JUDGE CHAPPELL: But the question you just read in open court from the deposition was, "What does a randomized, blind study mean?" That's not the same question. Whether it's the most rigorous or not is not the same question as what does it mean. I would appreciate it if you would ask a similar question to the one you are attempting to read in an attempt to impeach a witness so the record will make sense.

MS. EVANS: I'm sorry, sir. Given the length of his answer, it was difficult to anticipate that.

BY MS. EVANS:

Q. And did you also say that when you have a larger

sample size, the unknown factors that confound the results are more likely to be equally distributed across the groups than is the case with a smaller size?

A. There's a common misconception that a larger study is a better study, and you can also -- as I wrote in my expert testimony, you can argue the other way around. In other words, back in the 1950s or forties when penicillin was first discovered, if you had 20 patients and you put them in two groups of ten each and they all had pneumococcal pneumonia, and you gave ten of them penicillin and all ten got better, and you didn't give that to the control group and they didn't get better, you don't need a thousand patients to know that the drug is having an effect.

You could argue that the studies on cholesterol-lowering drugs, for example, the fact that you need thousands of people to even show an effect is because the drugs aren't working nearly as powerfully as some people might imagine. So, it's only one of many factors that determine the validity and the quality of a study, is the sample size.

When you have a smaller number of patients, as we did in our studies, it just means that the treatment has to be that much more powerful and that much more consistent for it to be statistically significant, and

that's what we found.

Q. Have you previously stated that if you have a larger sample size, the unknown factors that can confound the results are more likely to be equally distributed across the groups than is the case with a smaller size?

A. It is true that a larger sample has a greater chance of distributing those values more equally. That's why, in the case of the Bev I study, for example, Table 1 compares the two groups at baseline in all of the measures that are relevant, and we found no statistically significant differences in baseline in any of the measures, which gives us the confidence that these groups are comparable, that we didn't need a thousand patients to show that.

You can also argue that in any study, there's a trade-off. So, in the women's health initiative, for example, they had thousands of women, they spent a billion dollars on the study, but because they had so many people in the study, they couldn't give very much attention to any one of those women, and so they didn't really follow the program that well.

So, whatever was gained by having a larger sample from one end was more than offset by the fact that they couldn't really give the people the attention

that they needed in order to get them to make the changes they were asking them to make.

Q. Well, isn't it true that without a randomized control group, you cannot conclude that an intervention is directly responsible for observed improvements?

A. I don't agree with that. I think you need to look at the totality of evidence. There is a -- there are a variety of experimental designs. It's very simple-minded to say that only randomized, controlled trials have validity. You need to tailor the design of the study to the other factors that we have been discussing.

As I say, you couldn't do a randomized, controlled -- double-blind, randomized, controlled trial of a food that people recognize, so how would you do that?

Q. Well, you've previously -- we were -- I was looking over your -- your publications on cardiovascular disease, and didn't you publish one in 2008 that was called "Angina Pectoris and Atherosclerotic Risk Factors in the Multistate [sic] Cardiac Lifestyle Intervention Program"?

A. You mean "in the Multisite" --

Q. Multisite, you are so right.

A. Yes. That's correct.

Q. And there, did you believe that without a randomized control group, you can't conclude that participation in the lifestyle program was directly responsible for the observed improvements in coronary risk and psychosocial factors?

A. Please read to me what -- the relevant passage you are referring to.

Q. I can actually give you a copy of it.

A. Thank you.

Q. Can you please refer to the passage you were reading?

A. Absolutely.

JUDGE CHAPPELL: Usually the boom goes down when I say go ahead. Ironsides, did you put the boom up that blocks people from approaching? I guess I have to give up on the humor.

Go ahead.

MS. EVANS: Okay.

BY MS. EVANS:

Q. I want to refer you in this article -- is this article that you've received, have you had a chance to look at it quickly?

A. I know the article, but I'm not sure of the passage you're referring to.

Q. Okay. So, if you could turn to page 917, and I

am going to use the pages that are on the document. I believe it's the second to the last page.

A. I'm sorry. What is the passage?

Q. I'm getting to it.

After footnote 23 -- do you see that? -- it says, "Finally, without a randomized control group, we cannot conclude that participation in the lifestyle program was directly responsible for the observed improvements in coronary risk and psychosocial factors."

A. Well, you know, that's just silly. Any time that you write an article, you always write the limitations of the study. You know, "Further research is needed to prove this" is a common language in a study. And so in good science, you're always trying to be your most intense critic.

Q. Um-hum.

A. And so -- but the sentence that follows that says, "However, the efficacy of this lifestyle intervention was already shown in earlier randomized, controlled trials." So, it's -- it's a limitation of the study, but it doesn't invalidate its conclusion.

And my concern with the testimony of Dr. Sacks and others is that he would say that if it's not a randomized -- and he has said on multiple occasions, that of it's not a randomized, double-blind,

placebo-controlled study, then it's -- it's of no value in considering whether a substance has effectiveness or not. And, clearly, that's just not true. It's not true of his own studies.

Q. Now, you -- just to clarify, you were one of the authors of this article?

A. I am the senior author.

Q. Thank you.

Is another rule in research that a researcher must say, in advance, how many patients will be needed, what the procedures will be, are you going to conduct measurements, and what kind of analysis you're going to use?

A. Yes.

Q. Okay. And you agree that you can't just make it up as you go along.

A. Yes. Correct.

Q. Now, in clinical trials, do you also need to control for the power of belief, because that can affect people's reactions to an intervention?

A. That's the point of having a -- a control group.

Q. Okay. And you were talking about statistical significance, and I believe you said that something is considered to be statistically significant if there's a less than 5 percent probability that it's due to chance.

A. Is there a question there?

Q. It was meant to be.

Is that correct?

A. It what correct?

Q. And you were talking about statistical significance, and I believe you said that something is considered to be statistically significance if there's less than a 5 percent probability that it's due to chance.

A. By convention, as I stated earlier today, most people have arbitrarily accepted the 5 percent cut-off as being statistically significant, but I want to clarify again, there is nothing magical about that number. It is very easy to get into very rigid, either/or, black and white thinking when it's really a continuum.

Q. Does any study need to be replicated?

A. Does every study need to be replicated?

Q. Does any study need to be replicated?

A. All studies benefit from being replicated, but that doesn't mean that until it's replicated, it's not valid.

Q. Now, the randomized, double-blind, placebo-controlled study is the same level of evidence that FDA requires for a drug trial, right?

A. Presumably.

Q. All right. Does FDA also require that clinical studies be registered so that even if a negative study is conducted, people will know about it?

A. FDA does require that, yes.

JUDGE CHAPPELL: Was there an objection or you were just stretching?

MR. FIELDS: The answer beat me to it. The objection was that there's no showing this witness is an expert on the FDA legal requirements.

JUDGE CHAPPELL: He seems to have answered it.

MR. FIELDS: He answered it, so I guess he is more expert than I thought.

THE WITNESS: I said presumably, because I don't really know -- I'm not sure what you're asking, so I don't know that that was the proper answer. So, thank you for clarifying that.

BY MS. EVANS:

Q. Are there limitations to extrapolating from studies, including animal studies or in vitro studies?

A. There are limitations on all studies, including randomized trials.

Q. And is one ability -- is one limitation to the ability to extrapolate from an animal study to humans that animal physiology is similar to but not identical

to humans?

A. There are limitations to extrapolating from all studies, including animal studies.

Q. And is that, in part, because animal physiology is similar to but not identical to humans?

A. It depends on the animal. It depends on which part of the physiology you're studying. Some animal physiology is identical to humans. In other cases, it's different. That's why it's important to not generalize too broadly.

Q. Are there many cases where animal studies were confirmed in humans and others -- and there are other examples where they were not?

A. Yes.

Q. You're not an expert in nuclear cardiology, are you?

A. I've used nuclear cardiology in several of our studies, but I wouldn't say that I'm an expert in it. But I'm qualified to discuss it.

Q. At your second deposition, do you recall that there -- we were talking earlier, there were two depositions. Do you recall that you refused to answer the question, "In your opinion, Dr. Ornish -- is it your opinion, Dr. Ornish, that competent and reliable scientific evidence substantiates the claim that

drinking eight ounces of POM Juice or taking more" --

JUDGE CHAPPELL: Hold on a second. Remember, when you are going to read from that, you need to tell everyone the page and line number so we're on the same page.

MS. EVANS: Yes, sir. I'm sorry. You're so right. And I also need to make sure that they have Depo Exhibit 2. They do? Did I give you -- did we give you Deposition Exhibit 2?

BY MS. EVANS:

Q. Referring to page 30 at line 24, Mr. Hoppock, who was conducting your deposition, asked the question:

"QUESTION: Is it your opinion, Dr. Ornish, that competent and reliable scientific evidence substantiates the claim that drinking eight ounces of POM Juice or taking one POMx Pill or teaspoon of POMx Liquid daily prevents or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and improving blood flow to the heart?"

And there was then a colloquy between counsel. Should I read that into the record, also?

MS. DIAZ: No.

BY MS. EVANS:

Q. Now, if you proceed to page 37, line 10 --

MR. FIELDS: I think there is an answer on page

33 where it asks to rephrase the question.

MS. EVANS: The actual answer is on line 37 -- is on page 37, line 10.

JUDGE CHAPPELL: Are you aware that the witness doesn't have a copy of what you're reading and doesn't see anything?

THE WITNESS: Thank you, Your Honor.

MS. EVANS: Could we provide a copy of the deposition transcript to the witness, please?

JUDGE CHAPPELL: Do we need Will?

MS. EVANS: May we approach?

JUDGE CHAPPELL: Go ahead. Ironsides, release the boom.

MS. EVANS: Will has abandoned us, Your Honor. Sorry.

BY MS. EVANS:

Q. Dr. Ornish, if you refer to page 30, line 24 --

A. I'm sorry? Page?

Q. Thirty.

A. Thirty? Okay.

Q. Line 24.

A. Page 30, line 24?

Q. Yes.

A. Okay. What was the question?

Q. And the question was, at your second deposition,

do you recall that you refused to answer the question:

"QUESTION: Is it your opinion, Dr. Ornish, that competent and reliable scientific evidence substantiates the claim that drinking eight ounces of POM Juice or taking one POMx Pill or teaspoon of POMx Liquid daily prevents or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and improving blood flow to the heart?"

And that was the question posed at that deposition at TR 30, which is the page, at line 24.

A. Okay. Would you like me to respond?

Q. And -- no, excuse me, I haven't read your answer yet.

Do you recall hearing that question?

A. I do.

Q. Okay. And do you recall the answer?

A. I do.

Q. Okay. And what was your answer at that time?

MR. FIELDS: Could we have it read from the record rather than -- this is not a memory test.

MS. EVANS: Yes, sir. No, it's not.

BY MS. EVANS:

Q. And on -- referring to line -- page 37, line 10:

"ANSWER: Okay. Based on the advice of counsel, I have been advised not to answer this question in the

way that it is phrased, and I will not do so. If you can ask it in a way that -- if you can rephrase the question, I would be happy to answer it."

Was that the answer you provided at that time?

A. The answer I provided at that time was based on the advice of my attorneys --

JUDGE CHAPPELL: Hold it, Doctor. The question is, was that the answer you provided at that time? Did she read it correctly?

THE WITNESS: The answer that I provided at the time is in part here, but there's more to it. Would you like me to explain?

BY MS. EVANS:

Q. I don't -- could you refer me to a page and a line that provides the remainder of where that --

MR. FIELDS: I think the answer is at page 42, perhaps -- excuse me, Your Honor, I shouldn't address counsel.

Your Honor, I think at page 42, he might have restated or I think it got restated, and I think he answered it at page 42, but it was a compound question and it was objectionable.

THE WITNESS: Well, my answer is on 42, and that's what I was referring to. I said that, "I guess I should state that it is my expert opinion that clinical

studies, research and trials, provide significant evidence that pomegranate juice is likely to reduce blood pressure, improve blood flow, and reduce arterial plaque. It is not a substitute for conventional treatments for heart disease, nor am I aware of anyone who's suggested that it would be. So, when you use the word 'treat,' it makes me uncomfortable, because the connotation of that is that it can be a treatment in lieu of other conventional treatments, and neither I nor anyone else that I know of has suggested that."

BY MS. EVANS:

Q. Excuse me, sir. If you could please refer to page 41 of your deposition, line 9, okay, and that -- that page precedes the answer that you gave -- just read from, correct?

A. I'm sorry. I don't understand what you're saying.

Q. Okay. You just gave an answer on page 42 at line 15, correct?

A. Well, the question that you asked at line 41 --

Q. Excuse me, sir.

A. -- was a rephrasing. I asked you -- if you ask me a question, you need to let me answer it.

Q. Excuse me.

A. You asked me earlier a question on page 39, and

I asked you to rephrase it, which you did on page 41, and that's the question that I answered.

Q. Sir, if I could please read to you the question on page 41, which was a different question entirely.

"QUESTION:" -- this is on line 9 --

JUDGE CHAPPELL: If I heard you earlier, I thought I heard the witness say at the deposition that he was advised not to answer.

MS. EVANS: Yes, sir.

JUDGE CHAPPELL: And I think that point's been made. So, do you really need to read that again?

MS. EVANS: I am reading the different question to which he provided that -- the answer he just read into the record, okay? There was one question which he refused to answer on the advice of counsel and that's the answer that he read earlier.

JUDGE CHAPPELL: All right. So, first of all, I don't have a copy of the hymnal that we're all reading from. So, you're telling me there was a different question that he answered?

MS. EVANS: Yes, sir.

JUDGE CHAPPELL: All right. Go ahead.

MS. EVANS: Thank you.

THE WITNESS: It's worth clarifying that --

JUDGE CHAPPELL: Hold on, sir. There is no

question pending right now.

THE WITNESS: Okay.

BY MS. EVANS:

Q. Okay. Do you see on page 41, line 9, where it says:

"QUESTION: Thank you. Is it your opinion that clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid daily treats heart disease, including by decreasing arterial plaque, lowering blood pressure, and improving blood flow to the heart?"

Your answer -- do you see that? Is that the question that you were asked?

A. I do see that.

Q. And the answer that you read to me a second ago on page 42, starting at line 15, that was your response to this question, correct?

A. No, actually, it was a response to both questions, because the questions really contained the same information. It was the structure of the question that I had a hard time with the first time around, but the content is really the same in both questions. So, I did answer that question.

Q. Now -- now, you believe that pomegranate juice

is not the only thing that can reduce the risk of cardiovascular disease, correct?

A. Of course not.

Q. It's one of many things that a person can do to reduce the risk of cardiovascular disease?

A. Yes, ma'am.

Q. It's an adjunct, not a replacement for those other things, right?

A. Correct.

Q. Okay. And you are not offering an opinion on whether POM's -- the Respondents' advertising represents pomegranate juice or the pomegranate extracts as an adjunct to conventional treatments or as a replacement for medical care, correct?

A. I don't understand that last question. Could you rephrase it?

Q. All right. I'll reread the question.

A. Or reread it.

Q. You are not offering an opinion on whether POM -- whether the Respondents' advertisements represent pomegranate juice or the POM extract as an adjunct to conventional treatments as opposed to a replacement for medical care, correct?

A. Well, that's what I'm having a hard time understanding. Are you asking me if I'm offering an

opinion on the marketing or the advertising of POM Wonderful or whether you're asking me whether this -- I'm saying that this can be an adjunct and not a replacement for conventional therapies? There's two separate things that you've got in there.

Q. Yes. And I'm asking you whether the Respondents' advertisements represent pomegranate juice or the POM extract as an adjunct to conventional treatments as opposed to a replacement for medical care.

MR. FIELDS: To that question, I have an objection, Your Honor, that it goes outside the scope. This witness is not an expert on the advertising we've done. He didn't testify on direct about any advertising or what the advertising said.

MS. EVANS: Excuse me, sir. I believe I asked him if he's offering an opinion on that issue.

MR. FIELDS: But the second question was different.

THE WITNESS: I am not offering an opinion on that issue.

MS. EVANS: Thank you.

JUDGE CHAPPELL: Well, that --

MR. FIELDS: Withdrawn.

MS. EVANS: That was hard work.

BY MS. EVANS:

Q. You were talking earlier about the level of evidence needed for claims. Now -- and I'm just trying to understand what you said in your report. Is it your belief that because physicians use in their medical practices procedures that have not been proven in randomized clinical trials to work, that randomized clinical trials cannot reasonably be required for pomegranate juice?

A. That's a very strange question. I'm sorry.

Q. Okay. And if you could refer to your expert report --

JUDGE CHAPPELL: Hold on a second. "That's a very strange question," you said, "I'm sorry," you said. Does that mean you cannot answer it?

THE WITNESS: Oh, I'm just trying to track what she's asking. Are you saying --

JUDGE CHAPPELL: Because she seems to be taking that as a no and she's launching into something else here.

THE WITNESS: Well, Your Honor, I'd appreciate the chance to clarify that. Thank you.

The fact that doctors use procedures not only that haven't been subjected to randomized trials but even ones that have been subjected to randomized trials, and I think in the area of cardiology, angioplasties and

stents have been extensively studied in randomized trials, and we've found that they don't work very well. Unless you're in the middle of having a heart attack, they don't prolong life and they don't even prevent heart attacks.

And you would think that if we're really practicing evidence-based medicine, the number of angioplasties and stents would have fallen precipitously when those studies came out, but they are actually doing more than ever because they are reimbursed at such a high level. So, with all the talk about evidence-based medicine, it turns out that reimbursement is in many cases is a bigger driver than the practice of science. That's the way it is.

That doesn't mean it's right. I'm certainly not defending that. I'm not saying that I agree with that, but I'm just reporting what it is.

But, again, I think it's important to point out by your question that the level of evidence for a beverage is not the same as a level of evidence for a new drug with all kinds of potential known and unknown side effects and toxicities that require a higher level of evidence than a beverage that's been around for thousands of years and has no toxicities and that the only side effects appear to be good ones.

MS. EVANS: Okay. Could we provide Dr. Ornish with a copy of his expert report?

JUDGE CHAPPELL: Yes. Go ahead.

BY MS. EVANS:

Q. On -- because you wanted me to rephrase the question, I'd like to -- I'd like to direct your attention to a portion of your expert report, which would be -- it's marked as PX 25 at page 7.

A. Okay.

Q. Okay. And if you go down to the second to the last paragraph, starting with the sentence, "It seems unreasonable." Could you read those three lines to me, those three sentences to me?

A. I said, "Indeed, much of what physicians provide patients in their clinical practices" --

Q. I'm sorry. I'm sorry. Oh, that's fine. The whole thing is fine.

A. "Indeed, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in randomized controlled trials. Outside the ivory tower, there are other standards beyond randomized controlled trials. It seems unreasonable to require that pomegranate juice meet a standard that is not met by many of the drugs and surgical procedures -- surgical treatments used every

day by physicians. For example, randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. There are other considerations."

Q. Thank you.

Now -- so, when you say, "It seems unreasonable to require that pomegranate juice meet a standard that is not met by many of the drugs and surgical treatments used every day by physicians," are you -- are you saying that because physicians, in their medical practices, procedures that have not been proven in RCTs to work, that RCTs can't reasonably be required for pomegranate juice?

A. That's a very twisted logic. That's not what I'm saying at all.

Q. Well, you have the sentence that "It seems unreasonable to require pomegranate juice to meet a standard that is not used -- not met by many of the drugs and surgical treatments used every day by physicians."

A. It is unreasonable, but that's a big leap from saying that randomized controlled trials, therefore, shouldn't be used in considering the efficacy of pomegranate juice.

Q. Okay. So, here's my question: Do physicians sometimes recommend placebo tablets to their patients?

A. Yes.

Q. Okay. And does that mean that placebo tablet manufacturers should be allowed to claim that their tablet prevents or treats a condition?

A. Of course not.

Q. Thank you.

A. But pomegranate juice is not a placebo.

Q. Now, you have done studies for Respondents that were designed as randomized clinical trials, correct?

A. I'm sorry. One more time.

Q. You have conducted studies for Respondents that were designed --

A. For Respondents?

Q. The Respondents means the Resnicks and --

A. Oh, okay. Sorry. I'm not a lawyer, so you have to use --

Q. Okay. I'm sorry.

A. I'll try not to use medical jargon if you will try not to use legal jargon.

JUDGE CHAPPELL: I'm not sure that's going to work for either side.

MS. EVANS: You are so right.

BY MS. EVANS:

Q. So, you conducted the myocardial perfusion study, which was Bev I.

A. Of course.

Q. And the IMT study, which was Bev II.

A. Correct.

Q. Okay. Now, did these studies cost Respondents hundreds of thousands of dollars?

A. They did.

Q. Okay. And did you ever tell the Respondents the trials were not necessary to explore the effect on CDD of -- coronary -- CDD? See, now I'm not supposed to use the medical jargon. Cardiovascular disease.

A. Did I tell the Resnicks that they didn't need to do research?

Q. Did you tell the Resnicks that the trials that you conducted were not necessary to explore the effect on cardiovascular disease of pomegranate juice?

A. I don't understand your -- are you asking me did I tell the Resnicks that they didn't need to do research to explore the effects of pomegranate juice on heart disease?

Q. Did you tell the Resnicks that the myocardial perfusion test or the RCTs weren't necessary to explore the effect of pomegranate juice on RCT -- on heart disease?

A. I don't recall saying that, but I'd be curious to know what you're referring to.

Q. So, are you -- so -- okay. Thank you.

Now, did you ever tell them that they didn't need to spend the money sponsoring the randomized clinical trials before they could claim that pomegranate juice helps reduce the risk of cardiovascular disease?

A. I don't recall that conversation, no.

Q. Thank you.

I am about to switch --

A. Just so you know, I'm the one who actually encouraged the Resnicks to do these studies when the Resnicks first proposed them. I thought it was a wonderful idea. I think that's the kind of behavior that the FTC should be encouraging, rather than discouraging.

Q. Thank you.

Sir, I'm about to change subjects. Would you want to take a lunch break now or --

JUDGE CHAPPELL: Oh, am I sir?

MS. EVANS: Yes, you are sir.

JUDGE CHAPPELL: How much time do you think you have left?

MS. EVANS: I have at least another hour and perhaps an hour and a half.

THE WITNESS: It's your call, Your Honor.

JUDGE CHAPPELL: Just remember, we're going to lunch, but you still have to come back.

Yeah, we'll go ahead and take a break.

MS. EVANS: Thank you, sir.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: We will reconvene at 2:05.

(Whereupon, at 1:03 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:14 p.m.)

JUDGE CHAPPELL: Back on the record, Docket 9344.

Next question.

BY MS. EVANS:

Q. Dr. Ornish, during your direct examination, you were talking about your myocardial perfusion study.

A. Yes.

Q. And I have some questions about it. Now, that was designed as a randomized, clinically controlled trial, right?

A. Yes.

Q. And 45 patients did enroll in the study?

A. Correct.

Q. And you were investigating whether daily consumption of pomegranate juice would have an effect on myocardial perfusion.

A. Yes, ma'am.

Q. Okay. And the report -- and I would ask, Nathalie, if you could bring up on the screen CX 744. Do you have that?

A. Is it possible I could just have a hard copy so I could look through it?

Q. Absolutely.

A. Thank you.

JUDGE CHAPPELL: Go ahead.

THE WITNESS: Thank you.

BY MS. EVANS:

Q. And is this Exhibit 744 the results of your myocardial perfusion testing that were published?

A. Yes.

Q. Okay. And if I could refer you to Table 2 of that report. And that's CX 744-003.

Nathalie, could you enlarge that, too?

A. I've got it. I can see it.

Q. I want the Judge to be able to see it.

A. Oh.

Q. So, I just want to clarify some of these terms. Table 2 shows the results of testing on the three measures, correct?

A. Yes.

Q. And the first one is summed rest score?

A. Yes.

Q. And the second one is summed stress score, and the third one is summed difference score.

And the way you calculated these -- this -- I mean -- excuse me. What these -- what this information represents is you did -- you did one set of myocardial perfusion testing when the patients -- at the very

baseline of the study, the very beginning of the study, and -- and you tested them first at rest, correct?

A. Correct.

Q. And then you had them either exercise or they got a drug challenge that caused their heart to accelerate, correct?

A. Correct.

Q. And then about an hour later or 30 minutes later, they had a second test, a second myocardial perfusion test?

A. Twenty-five to 30 minutes later, yes.

Q. And -- 25 to 30 minutes. Thank you.

And then they -- then they were -- then they either drank the pomegranate juice or the placebo for three months.

A. Yes.

Q. Okay. And at the end of the three months, then they again were tested at rest.

A. The same protocol.

Q. And again tested at -- at stress.

A. The same protocol.

Q. Okay. And so -- and that -- so, that's the information that's reported in Table 2, correct?

A. Yes.

Q. And Table 2 -- of the statistically significant

changes at the 0.05 level in Table 2 between the active and placebo groups at the end of the study, the only statistically significant result at three months was in the summed difference score, correct?

A. You wouldn't expect there to be a change in the others, because these reflected dead tissue, which is not going to get better.

Q. So, in response to my question, the only statistically significant result at three months was in the summed difference score, correct?

A. The only statistically significant difference in the three groups after three months was in our primary end point measure, which was the summed difference score that we stated, a priori, was what we were looking for.

Q. Now, when you do -- now, the summed rest score, that measures how much of the heart muscle is either infarcted or hybernating?

A. Yes. Mostly infarcted. In other words, dead.

Q. And the summed rest score did not change at the end of the study, correct?

A. Well, like I say, dead tissue is not going to get better.

Q. So, that's correct, the summed rest score did not change at the end of the study?

A. It would have been shocking if it did. The

answer is yes, it did not change.

Q. Thank you.

And then the summed stress score, that measures -- you said -- I believe you told me the amount of infarcted, ischemic or jeopardized --

A. What it measures -- as I stated earlier, the question we're trying to answer is --

Q. Excuse me. Can we get to that in a minute and can we -- could you let me finish my question?

A. Sure.

Q. Okay. So, the summed stress score measures the amount of infarcted, ischemic or jeopardized myocardium?

A. To put it in plain English, the summed rest score measures the amount of dead tissue --

Q. Excuse me. Can you first answer my question, sir?

A. I am answering your question. The summed rest score measures the amount of dead tissue. The summed stress score measures the amount of dead tissue plus heart tissue that's not getting enough blood flow. And the summed difference score measures the difference between the two.

Q. In your report, if I could refer you to -- do you have your report before you, sir?

A. My report?

Q. Yes.

A. Yes, ma'am.

Q. Yes. If you could refer to page 13.

A. I'm there.

Q. And, as you say, "As described in the PowerPoint presentation cited by Dr. Sacks, the summed stress score (SSS) is the sum of the segmental scores at stress," and underneath that, it says, "amount of infarcted, ischemic, or jeopardized myocardium."

Is that how you described the summed stress score in your report?

A. Yes.

Q. Thank you.

And you have -- you stated in your report, also, that the summed stress score has been validated as a predictor of natural history outcomes?

A. Yes.

Q. And --

A. There is the -- the summed stress score is a predictor -- say that again, I'm sorry -- is a valid predictor of natural history of outcomes, that's right. This is a different question that we were answering.

Q. And -- and also in your report, at page 13, the -- the -- underneath the second full paragraph, you've said that (as read): "Myocardial perfusion

abnormalities at rest and after stress are still the best predictors of cardiac-free survival in patients with known or suspected ischemic heart disease, even when compared with an extensive diagnostic work-up."

A. I didn't say that. That was quoting from a major journal article that said that.

Q. Okay. And you agree with that?

A. I do.

Q. Okay. You were talking about -- during your direct testimony about some problems that occurred during the study or with the study, right?

A. Yes.

Q. And one of them was that 41 patients completed the study, but the report only provides data on 39 of those patients.

A. That's correct.

Q. Okay. And did you ever publish an erratum to this published report?

A. No, because it didn't change the conclusions of the study.

Q. And --

A. In fact, it only made it stronger.

Q. Now, in terms of the -- the summed stress scores, you testified on direct that the -- that there was actually a difference in the --

Nathalie, could you please bring up Table 2 again?

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

Q. I'm referring back to CX 744, which is your published report, in Table 2 again. You published or you stated on direct that there was actually a difference between the baseline scores of the pomegranate juice group and the placebo group at baseline.

A. In the summed stress score -- oh, I'm sorry, not of -- no. There was a difference between the two groups in the summed stress score --

Q. At baseline.

A. -- at -- at -- well, actually, we compared both -- at baseline, okay. I'll say baseline. Keep it simple. Yes.

Q. Thank you.

And in Table 2, is that difference reported?

A. Yes, it is.

Q. And how is -- how is the difference between the baseline in the placebo group --

A. There's an asterisk there, after 10.2, plus or minus 7.9, means that the differences in summed stress score, comparing them at baseline to three months, are significantly different, but as I indicated in my

earlier statement, the analysis of variance that we used controls for baseline differences, so it doesn't affect the outcome.

Q. Well, the asterisk that you refer to there, which is presented next to the placebo group results at three months, that says, does it not, that the -- that it was significantly different -- that that was the main effect among the groups. That's the main effect among all six of these groups, isn't it?

A. No. It's actually a comparison of the two groups. We look at both the baseline and the three-month data.

Q. Okay. So, it does not simply -- there's no indication that, at baseline, there was a statistically significant difference between the active and placebo groups.

A. Well, it's implicit in there, because you wouldn't show in between groups from baseline and three months unless it was also present at baseline.

Q. Now, Dr. Michael Sumner is the first author on the myocardial perfusion study, correct?

A. Yes.

Q. And he was employed at PMRI?

A. Yes.

Q. Okay. And do you recall whether in a

communication to you Dr. Sumner ever advised you that there was a baseline difference in the summed stress score between the experimental and control groups?

A. Yes, he did.

Q. Okay. And when did that -- do you remember when that occurred?

A. Of course not.

Q. Well, if I could refresh your recollection -- could I refresh your recollection?

A. If you wish.

Q. Okay. Could you -- could someone provide him with a copy of CX 701? And, Nathalie, could you bring up CX 701 on the screen?

A. I'm familiar with this document. I don't need to see it. I know what it says.

Q. Okay. And so was Dr. Sumner's information, his statement that "There was a baseline difference in SSS between experimental and control groups (P is less than 0.04). We don't have to mention this, but we should keep this in mind," was the email where he wrote that transmitted to you on December 2, 2004?

A. It was. We don't have to mention it, because it is mentioned in here.

Q. And Dr. Gerdi Weidner, she was also an author on the myocardial perfusion study?

A. Yes, Dr. Sumner was a post-doctoral fellow and Dr. Weidner was the director of research.

Q. Thank you.

And Dr. Weidner presented information about both the myocardial perfusion study and some information on the Bev II study, I believe, at -- at the POM Medical Research Summit in June of 2006?

A. Yes.

Q. Okay. Now, were you aware that the page of the PowerPoint presentation that -- that sets forth the myocardial perfusion data expressly showed that there was a baseline difference between the active and placebo groups?

A. As I said, it doesn't affect the outcome, because the statistical values we used took that into account.

Q. But you are aware that that was expressly represented in there?

A. Yes. I'm not sure what the point is, though.

Q. Okay. Now, the December 1, 2004, draft of -- of the proposed myocardial perfusion report --

Nathalie, could you bring that up at page 17?

Dr. Ornish, are you familiar with that page?

A. What is that page from?

Q. It's from Deposition Exhibit 701. There's --

the cover letter is that December 2, 2004, letter that I just -- that --

A. Okay. I'm looking at Table 2. Is that what you're referring to?

Q. No. Could you please --

Could we approach?

JUDGE CHAPPELL: Go ahead.

MS. EVANS: Okay, I'm sorry. It's CX 701, and is it up on the screen?

Okay. Counsel, do you have that? No?

THE WITNESS: I want to make sure I'm looking at the right document. This is the one that you were just quoting from, the memo from Michael Sumner to Melanie Eller?

BY MS. EVANS:

Q. Yes. And attached to it is a draft of the myocardial -- this is CX 701, is a draft of the myocardial perfusion report, correct?

A. Okay.

Q. Okay. And if you would turn to page 17 of that report, of that document.

A. Um-hum.

Q. That's a draft of Table 2, correct?

A. No. It's a -- page 17 is a draft of Table 3.

Q. And on page 17 --

A. Is that what you're looking at, Table 3 or Table 2?

Q. I am looking at Table 2.

A. Well, Table 2 is not on page 17. Table 2 is on page 16. Oh, you know what, it's page 16 and it's page 17, because there's a cover page, so -- okay, we're on the same page.

Q. Thank you. Oh, you're right. There's too many numbers on these pages.

So, that is an early draft of Table 2, correct?

A. Yes.

Q. Okay. And that shows --

A. And it shows the identical information that's in the published report.

Q. Of the -- so, in that December 2 -- early December 2004 draft, there's a line under the main table. First, there's a line that says, "Data are represented as mean plus or minus SD." Below that it says, "At baseline, differences were not statistically significant in any measure," correct?

A. Well, that's what I'm saying. This one's a draft.

Q. But that is what it says, right?

A. It does say that, but this wasn't published. This is a working document.

Q. And -- so, this line -- this line, expressly stating that there was no statistically significant difference between -- in any of the results at baseline, that was removed from the report, correct?

A. What matters is what's in the published report, not a working draft that was for internal use only. And it's worth noting in Table 1, in the same report, looks at a variety of measures, shows no significant differences in any of them at baseline, including cholesterol, blood pressure, blood sugar, medications, LDL, body mass index, age, et cetera.

Q. I believe my question was, "So, this line, expressly stating that there was no statistically significant difference between -- in any of the groups at baseline, that was removed from the report, correct?" The final report that was published.

A. Because it's wrong, so what matters is -- when you have a draft, it's a working document, and we catch things. And we caught that, and it's not included because it was incorrect.

Q. Thank you.

Now, you also talked about some unblinding issues that happened during the myocardial perfusion study.

A. That's correct.

Q. Do you recall when this initial unblinding occurred?

A. It occurred -- it occurred in the first -- when six patients of the 45 were unblinded by mistake, because, again, they were shipped, from the Resnicks' warehouse, information that allowed them to take off the sticker and determine which group they were in.

Q. Do you recall when this initial unblinding occurred?

A. I don't recall the date. I just know it was only in six patients. That's all that really matters.

Q. Could I refresh your recollection?

A. Sure.

Q. Do you recall that at your deposition, your first deposition, we discussed the conduct of the myocardial perfusion study?

A. That we discussed it? Of course.

Q. Okay. Could -- I'd like to refresh your recollection on this topic by reading from the transcript. I am going to turn to page 141 --

JUDGE CHAPPELL: You don't actually need to read that into the record. You can let the witness read it and see if it refreshes his recollection and whether he can answer your question.

MS. EVANS: Certainly.

JUDGE CHAPPELL: If it does not, then you can pursue that.

MS. EVANS: Thank you.

JUDGE CHAPPELL: And by the way, for everyone out there, part of my job here is to make sure that the record is clear and accurate, and when I listen to questions and look at the answers and hear the answers, I don't care if it's Government or Respondent, I am going to comment. And I don't know if I've said that in this trial, I've been doing a lot of trials lately, and I just want to make you aware.

MS. EVANS: Thank you, sir.

THE WITNESS: I don't have a copy of what you're referring to.

MS. EVANS: Could somebody please give him a copy of his transcript?

THE WITNESS: Thank you.

BY MS. EVANS:

Q. Okay. Could you please turn to page -- and this is -- I always have the wrong one in front of me. If you could turn to page 141 --

A. Okay.

Q. -- of the first deposition transcript, which is marked as CX 1339.

A. Okay. What is the question?

Q. I just want to make sure I'm referring you to the right page. If you could read the -- on line 141, line 6 --

A. Um-hum.

Q. -- through -- well, just through the next two lines, that's that -- the -- would that answer your question about what -- on what date the currently enrolled patients were unblinded?

A. Yes.

Q. And what was that date?

A. It says here 9/18/2002.

Q. Okay. And did you consult with Mr. Resnick about this unblinding problem?

A. I believe I did. I'm not sure.

Q. Okay. And did that consultation --

A. It was probably not with him. It was probably with Dr. Harley Liker, who was representing him.

Q. Could I refresh your recollection on that issue?

A. Sure.

Q. Okay. Could you please refer to page 142 --

A. Um-hum.

Q. -- at line 12 through 14?

Does -- does that indicate that Mr. Resnick had instructions about what to do with the unblinding?

A. Well, it was through Dr. Liker, yes. It wasn't

with Mr. Resnick directly.

Q. Okay. Right. And you indicated in your direct testimony that six of the patients were unblinded. Could I refresh your recollection as to whether that number is correct?

A. You were asking me in the Bev 1 study, how many of those patients were unblinded, and it was six patients. The other patients were in the other -- the other study.

Q. Well, I -- if you could --

A. At the time, the initial protocol was to get people who had both heart disease and carotid artery disease, and we found that people who had heart disease, they were -- they were so aggressive in doing angioplasties, stents, and bypasses, that it was very hard to recruit patients who had both. So, we only began to recruit patients who had carotid disease.

But the bottom line that you're asking about is of the 45 patients who were in the Bev I study, only six of them were unblinded.

Q. Is it possible that you misrep -- that you misremember?

A. No, because I read this last night.

Q. Okay. So, could I -- could I attempt to refresh your recollection by referring to page 146 at line --

lines -- reading from line 8 through line -- through 147, line 3?

A. Okay. I just read it.

Q. Okay. Now, in those lines, we're talking about the treadmill stress thallium list, correct, the patient -- list of patients who at that point had had the treadmill stress thallium testing?

MR. FIELDS: Objection, Your Honor. We're talking about a document here, and I'd appreciate it if the witness could see the document.

THE WITNESS: I'm looking at the document now. You know, this -- this testing or this deposition was done before I reviewed anything.

JUDGE CHAPPELL: Hold on. Hold on. Hold it.

THE WITNESS: I'm sorry, Your Honor.

JUDGE CHAPPELL: I think he heard your objection and said never mind.

MR. FIELDS: Okay. Withdrawn again.

THE WITNESS: Well, I have the document here. That's all I'm saying.

BY MS. EVANS:

Q. Thank you.

A. But this deposition was given -- this was brought up, and I hadn't done -- I mean, it was news to me at the time. I have since reviewed that, and I stand

by what I said. It was six patients of the 45 who were unblinded.

Q. Okay. So, when we were discussing the myocardial perfusion testing and where I asked you questions on page 145, line 20, and through your answers on --

A. Like I said, there were more than six patients who were unblinded --

Q. Excuse me. Sir, could I finish my question, please?

A. Of course.

Q. Okay. Going down to page 47 --

JUDGE CHAPPELL: Are both of you talking about the same study?

THE WITNESS: Yes, sir.

MS. EVANS: Yes, sir.

THE WITNESS: Well, that's what I was trying to clarify, if I may. There were --

JUDGE CHAPPELL: Is that -- may he clarify?

MS. EVANS: No. I would actually like to ask the question first.

JUDGE CHAPPELL: I'm trying to make sure we're talking about apples to apples.

MS. EVANS: Yes.

THE WITNESS: The problem is we're not, and

that's what I want to try to clarify, with your permission or not, as you wish.

BY MS. EVANS:

Q. Okay. If I could get the full question out first, that would be great.

A. Please.

Q. Thank you.

So, I asked the question, "If this document is accurate, the three-month testing data for one, two, three, four, five, six, seven" -- and then it says either, but I believe that was supposed to be eight --

A. Which line are you on again?

Q. Okay, I was on 146, line 3, "If this document is accurate, the three-month testing for one, two, three, four, five, six, seven, either of these patients occurred subsequent to the 9/18/2002 email saying that the blinding had been broken, correct?"

And you said, "Yes."

A. Okay. As I explained before, this was at a deposition before I had had a chance to fully review the data. This was from memory. When I reviewed the data carefully last night and again this morning, only six patients of the 45 in the Bev I study were unblinded. There were other patients that were unblinded that weren't in the study, and I think that may be the source

of confusion.

Q. Okay. Now, when we were actually talking -- having that conversation, there -- there was a document in front of you, and the text of that document is reported here, correct? I believe if you refer to page 144, line 20.

A. Okay. Is that the document I have here?

Q. The page that we're referring to --

A. No. No. Which document does that page referring to?

Q. I am referring to the -- to the document you have in front of you, the first deposition exhibit transcript, page 144 --

A. No, no. But within that document, you're saying it referred to another document that I had at the time. Which document is that?

Q. Well, we -- I read it to you at the deposition.

A. Do I have a copy of that here in front of me now?

Q. I don't know that I have it immediately available to me; however --

A. Well, then, I can't really comment on it.

Q. Okay. Can I refresh your recollection?

A. By all means.

Q. Thank you.

Now, my first question is, why would there be patients not in the study that were unblinded?

A. Well, as I explained, originally, we were looking for patients who had -- that we could use in both studies. As it turned out, we had to bifurcate that, because it was too hard to find patients who had both carotid disease and coronary disease, because most patients with coronary disease, even if they had carotid disease, ended up being operated on.

Q. And if I could ask you to turn to page 145, line 11, and I said, "Okay. On the top line, the top heading of that document is entitled 'Treadmill Stress Thallium Test Baseline.'"

Would there have been treadmill test thallium test baseline data on patients that were not in this study?

A. There would have, absolutely, because they were in both studies. So, we were looking for people who had both carotid disease and who had heart disease.

Q. So, there were additional patients enrolled in the study for whom you did not include their data in the myocardial perfusion report?

A. No. Some of the patients who had thallium studies didn't have abnormal thalliums, and so we couldn't use them.

Q. Okay. Well, why would, then, there have been three-month testing on all of those patients as of --

A. All of which patients?

Q. All eight of the patients who unblinded, who are listed on the "Treadmill Stress Thallium List Baseline" document.

A. I would have to look at that, but I can just tell you that I reviewed this all last night and again this morning, and only six of the 45 patients that are reported in this paper were unblinded, knew which group they were in.

And to make the point further, it didn't matter. It's not like it would affect the outcome anyway, because the only reason that would be important is if they thought that they were getting something that was beneficial to them, and there was no reason at that time that they would have thought -- if anything, it would have worked against us, because they would have more likely thought the Gatorade was beneficial to them.

Q. Now, could I ask -- so, did you have 45 people enrolled in the thallium test or -- or 47?

A. Of course we did. That's what the report says. Are we talking about the Bev I study here?

Q. Yes. So, if you could actually -- I am pleased to say that I have found the document that we were

discussing, and it is CX 561, and if you could please bring that up on the screen, and make sure that counsel -- do you have it?

A. Could I have a copy of that, please?

Q. Absolutely.

So, the -- how many people are listed -- where it says "Treadmill Stress Thallium List 3 Months," there are a number of names listed, and they have -- does that document indicate they have testing dates after the unblinding?

A. Well, remember that --

Q. Could you answer my question first, please?

A. Well, I am answering your question. If you're asking -- not everybody that -- after that date was unblinded. Only six patients were unblinded. We continued the study, and we blinded the rest of them subsequent to that. It was just a mistake in one shipment. It wasn't a mistake in all of them.

Q. Well, the mistake happened on September -- did we just say September 18th?

A. Whenever it was, but not everybody received that shipment.

Q. Well, but all of these -- all of the individuals listed on this document were tested before September for the baseline test, correct, and after -- excuse me, and

after the unblinding, they had their second test after the unblinding, which occurred on September 18th?

A. But like I said, not everybody was unblinded. Only six patients were unblinded. Even if it occurred after that date --

JUDGE CHAPPELL: Hold on. Hold on. Clearly there were two questions there, but also, you're not answering either one of them.

THE WITNESS: Okay. Then I would appreciate the chance to clarify that. What is that, sir?

JUDGE CHAPPELL: We are going to have Susanne read it back, and pause after the first correct, and then read the second part.

(The record was read as follows:)

"QUESTION: Well, but all of the individuals listed on this document were tested before September for the baseline test, correct?"

THE WITNESS: Correct.

(The record was read as follows:)

"QUESTION: And after the unblinding, they had their second test after the unblinding, which occurred on September 18th?"

THE WITNESS: Yes, but not all of these patients were unblinded. That's the point I'm trying to make.

BY MS. EVANS:

Q. Okay. And could I refresh your recollection on that point?

A. Sure.

JUDGE CHAPPELL: I have a question. Do you know which six were unblinded?

THE WITNESS: Yes, sir, I do, but I don't have that information in front of me.

JUDGE CHAPPELL: There is no indication on this exhibit we're looking at?

THE WITNESS: No, sir.

JUDGE CHAPPELL: All right. Thank you.

BY MS. EVANS:

Q. And if you would please read pages 141, line 6 through line 9, does it indicate that there were then 22 research participants in the study?

A. I'm sorry. Page 141, line which?

Q. Line 6.

A. Line 6, uh-huh.

Q. Yes. Through line 9.

A. Okay.

Q. Does that indicate that there were then 22 research participants in the study?

A. Well, again, that includes both the Bev I patients -- you have to define what the study is. Okay, only six of those patients were in the Bev 1 study.

Q. Sir, did you then -- when I asked you the question, "Okay, it says that currently there are 22 research participants in the study, and that's as of 9/18/2002, correct?"

You answered, "Presumably," right?

A. Because, again, I hadn't reviewed the information that I have now.

Q. Okay. And on page 142, if you could please read lines 12 through 14.

A. Um-hum.

Q. It says, "The blinding for these 22 patients and all staff is now out of the barn," correct?

A. Um-hum. Not all staff, but current staff.

MR. FIELDS: Again, I have an objection, Your Honor. We are reading from a document, and I don't believe it was supplied to the witness. I mean, it says, "Last Friday's shipment was sent." I don't know what document is saying that. I don't think the witness has that document. I object to the question unless he can see the whole document, see what study we were talking about.

THE WITNESS: Well, it's very simple. There were -- the two studies were combined at that point. Of those 22 patients, only six were in the Beverage I study. So, only six of those patients were unblinded.

MS. EVANS: Thank you.

JUDGE CHAPPELL: Regarding the objection, do you have the documents you need in front of you to answer these questions?

THE WITNESS: No, sir, but I reviewed them this morning.

JUDGE CHAPPELL: When you need a document to answer a question, let the examining attorney know.

THE WITNESS: I don't know what that means, sir. When I need a document, they can provide it for me? Is that what you're saying?

JUDGE CHAPPELL: If you need a document to fully and completely answer a question, you'll need to let the person asking you the question know what document is missing.

THE WITNESS: Okay, I appreciate that.

The document that's missing is the -- the names of the patients and also which study they were in. Having reviewed that this morning, I can assure you that there were only six of those patients that were unblinded, and it wouldn't matter anyway. So, if the whole line of questioning here is to question whether the study is credible, it's irrelevant.

MS. EVANS: Nathalie, could you please bring up CX 0555?

BY MS. EVANS:

Q. And I apologize that I didn't realize I had this document here, but this is -- this was the document that was marked as Dean Ornish 69 at your deposition.

A. Can I get a hard copy of that, because this is really small print here.

Q. Now, was this the document we were discussing at page 142 of your transcript?

A. Yes, it is.

Q. Okay. And does this document indicate that while there were six patients in the cardiac arm alone, there were also four additional patients who were enrolled in both the cardiac and the carotid arms?

A. I don't know what that means.

Q. Thank you.

Well, cardiac testing, that's what you were doing on the thallium group patients?

A. That's correct.

Q. Thank you.

Now, was there --

A. Just to clarify --

Q. Excuse me --

A. -- it is my understanding that none of those four patients that were in both arms ended up as part of the 45 patients.

Q. So, were they or were they not enrolled in this study?

A. It's my understanding that those four were not enrolled in the Bev I study, but the six that were in the cardiac arm were. But I would have to double-check that to be sure.

Q. But I -- I thought you told me that the Bev I and Bev II studies were separated out and that -- and that the cardiac arm patients would have stayed in the Bev I.

A. They would have. I don't understand this, so I would have to review it.

Q. Thank you.

With regard to -- now, was there a -- on November 15th, 2002, do you recall that there was a second instance of unblinding?

A. Why don't you refresh my memory.

Q. Okay. If you could bring up -- actually, let me read --

A. I think even Dr. Sacks indicated that this didn't undermine the validity of the study.

Q. Excuse me. If you could please read, on page 149 of your first deposition transcript, from line 9, through 151, line 13.

A. Okay. What is the question?

Q. And the question was were -- were there -- was there a second instance of unblinding where two more patients were unblinded before the three-month treadmill test?

A. Two more patients?

Q. Yes.

A. Where do you see that?

Q. Okay.

A. Two of the four patients received it at three months, I see. I think they were saying that they found out just as they were -- either just after or just before they were tested, if I understand this correctly.

JUDGE CHAPPELL: Are you trying to find out what actually happened in this study or are you more concerned with what he might have said at the deposition? I'm just trying to follow this.

MS. EVANS: I'm concerned about what happened in this study, which was discussed at the deposition.

JUDGE CHAPPELL: Because it appears to me that the witness is now trying to look at what he said in the deposition, rather than answering the question as to what may or may not have happened actually in the study.

MS. EVANS: I can ask the question a different way, if that would be okay.

THE WITNESS: Thank you, Your Honor.

BY MS. EVANS:

Q. This document here is entitled "Pilot Study Cross-Over," right, CX 560?

Is CX 560 up on the screen? I'm sorry, I wasn't aware.

And does this -- and this document says, "There were four study patients who discovered that beneath their labels was a sticker that designated that they were receiving the placebo beverage." And that occurred on 11/15/02, correct?

A. I'm reading. The document is dated 11/15/02, correct.

Q. So, this indicates that there were four patients unblinded on November 15th, '02, and if you could read from -- do you know whether two of them had not yet received their two-month -- their three-month testing?

A. You know, this is eight or nine years ago. I think what you're finding is that four were unblinded earlier and two later, which makes six, as we've talked about.

Q. Well, could I refresh your recollection on that?

A. Um-hum.

Q. If you would read from page 150 to page 21 [sic], I -- question -- well, excuse me. If you could just read that.

A. I just did.

Q. Okay. And so -- you said, "So, two of the -- so, basically, it looked like" --

A. It said that two patients found it a week or so before their testing, at least this is what I said then. I would have to refresh my memory about the outcome. And I went on to say that it's unlikely that it would affect the outcome for all the reasons we've been discussing.

Q. I understand what your explanation is. I am simply trying to get to the point that an additional two patients were unblinded before they had their two-month testing -- three-month testing, which -- which happened after November 15th, 2002, correct?

A. In addition to the four? Is that your question?

Q. No. Two of these four.

A. Two of these four?

Q. Yes.

A. I would have to go back and review this. I don't know.

Q. Thank you.

A. But I'd also say, again, that I stand by my statement that I made earlier. There was only a total of six patients that were unblinded.

Q. I believe the record will -- will reflect that,

what happened.

Now -- and then in January 2003, did you hear from one of your assistants that Mr. Resnick wanted to know what had happened to the people who had been unblinded?

A. Are you referring to a memo?

Q. I'm asking you if you --

A. I don't remember. This happened eight years ago. I'm not sure of the point of it. It's entirely possible that he would want to know, but I'm not sure of the relevance here.

Q. But did you keep the Respondents up to date on what was going on with the trial?

A. As I indicated, we kept Dr. Harley Liker up to date, who was the liaison for Mr. Resnick.

Q. Okay. Thank you.

Now, is it also true that two of the patients who were assigned to the placebo group never actually received a placebo?

A. That's correct.

Q. Okay. So, they -- they entered the test -- they were -- they were entered into the study, and they got their baseline testing, and then after three months, they had their three-month testing --

A. That's correct.

Q. -- okay, but they never got a product, did they?

A. That's correct.

Q. Okay. And that data was included in the results of the study?

A. Correct.

Q. Okay. Now, you had -- you talked about the fact that your funding got cut short. Was the original plan for the myocardial perfusion study to include baseline, three-month, and 12-month results?

A. It was --

Your Honor, I hate to ask you this, but could I take a quick bathroom break? I'll be right back. I just need to --

MR. GRAUBERT: Could we approach a second?

JUDGE CHAPPELL: Sure.

(Discussion off the record.)

JUDGE CHAPPELL: We will reconvene at 3:20.

(A brief recess was taken.)

JUDGE CHAPPELL: Back on the record.

Did I hear you say food poisoning?

THE WITNESS: Yes, sir. I thank you for the break. I appreciate it.

JUDGE CHAPPELL: Is there a bit of irony here?

THE WITNESS: I hadn't thought about that. Very funny. I don't think it was from pomegranate juice.

JUDGE CHAPPELL: I was just thinking, I've heard so much about diet.

BY MS. EVANS:

Q. Are you okay, sir?

A. No, I'm okay. I was just laughing. It's nice that you can maintain a sense of humor, Your Honor.

MS. EVANS: May I proceed?

JUDGE CHAPPELL: Yes.

BY MS. EVANS:

Q. Now, you testified the myocardial perfusion study was to last for 12 months, and you just said that, right?

A. No. It was going to be -- we were going to test them at zero, three months, and 12 months.

Q. Okay. And you testified that the study terminated at three months because the Resnicks didn't provide funding for the rest of the study.

A. That's right. And as evidence of that, we actually tested seven patients at 12 months but didn't have the funding to continue.

Q. Okay. Now, on May 12th, 2003, did you write to Stewart Resnick to tell him that you would complete recruitment and testing for the 35 thallium patients since that study has not been revised?

A. I presume that I did if that's what we did.

Q. Could I refresh your recollection?

A. I believe you. I mean, clearly, we ended up recruiting 45 patients, so that would make sense.

Q. Okay. Well, did you -- did you write to Mr. Resnick on May 12th, 2003, to say that you would do testing on 35 thallium patients?

A. I presume. I don't have a photographic memory.

Q. Okay. Could I refresh your recollection?

A. If you say it's true, then I believe you.

Q. I'd like to refresh your recollection.

Could you please bring up CX 1149?

I'm on page 4. If you look at the third paragraph --

A. I'm sorry. Are you asking me to look at something? I don't have anything in front of me.

Q. It's not on the screen?

A. It's just now appeared on the screen, but if I can have a hard copy, that will make it easier for me. Thank you.

Q. Let me know when you've found page 3.

A. Okay. What page are you looking at?

Q. It's the -- if you're looking at the numbers at the top of the page, it's page 3. If you're looking at the numbers on the bottom of the page, it's CX 1149-0004.

A. Okay. So, what's the question?

Q. Okay. In the third paragraph, the second sentence, is that -- does that say, "We will complete recruitment and testing of the 35 thallium patients since the budget for that portion of the study has not been revised"?

A. Well, it had been revised but not for the three-month part of it. In other words, we had -- we could -- we could -- we could -- with the funds that he was going to leave us, we could test 35 patients at three months, but not in a year.

Q. Okay. So -- but what the sentence says is, "Also, we will complete recruitment and testing of the 35 thallium patients since the budget for that portion of the study" --

A. Well, and we actually recruited and tested 45 of them, so I'm not sure of your question.

Q. Does it say, "We will complete recruitment and testing of the 35 thallium patients since the budget for that portion of the study has not been revised"?

A. That's what it says.

Q. Thank you.

And that document, that letter to Mr. Resnick, that was dated May 12, 2003, or that memo?

A. Yes.

Q. Okay. And did you, on May 16th, write to Mr. Resnick and say that you would recruit 35 patients with coronary artery disease for the thallium testing at baseline, at three months, and one year, and that -- for that, the Resnicks would reimburse PMRI $708,000?

A. I -- I don't have a copy of that in front of me, so I can't really say, but it -- it sounds right.

Q. Would you like to have your recollection refreshed?

A. Sure.

Q. Could you please bring up CX 591?

I'll give you a moment to review this document.

A. Okay. In this memo, I said that he was going to not reimburse us $223,000, which we took a -- we just had to eat; that we would recruit a total of 35 patients and perform thallium tests; and that he would reimburse us as you indicated.

Q. Okay. Could I actually ask you -- pose a question?

A. Sure.

Q. Now, was this document dated May 16th, 2003?

A. Yes.

Q. Okay. And this document says that "PMRI will recruit a total of 35 patients with coronary artery disease and perform the thallium tests at baseline,

three months, and one year. You will reimburse PMRI a total of $708,437 (including indirect costs), as outlined in the Clinical Study Budget that you gave me on" --

A. What happened was, to answer your question --

Q. Excuse me, "on April 26th, 2003." Does that document state that?

A. It states that, but it's --

Q. Thank you.

A. -- but there's -- wait. You want to understand the answer, so let me tell you. Subsequent to that, we asked them if we could --

Q. Excuse me, sir. There is no question pending.

A. Pardon me?

Q. There is no question pending.

A. Well, actually, I am answering the question you just asked, which is is that what this says, and it is, but it is incomplete information. If you want the answer, the rest of the answer is that they said that instead of 35 patients for baseline, three months, and one year, we would do the 45 patients at three months, which would be a stronger study.

MS. EVANS: I move to strike that answer as not responsive.

JUDGE CHAPPELL: Well, I can either allow it or

that will be the first question on redirect. What's your choice?

MS. EVANS: You are so right.

JUDGE CHAPPELL: I have a question.

THE WITNESS: Yes.

JUDGE CHAPPELL: Why is there a car ad at the top of that email?

THE WITNESS: Why is there a what?

JUDGE CHAPPELL: A car advertisement.

THE WITNESS: I think it was because it was on -- let's see, probably because it was from a Yahoo! account. I don't know. I didn't -- I -- I don't have car advertisements on mine. I don't even know why this is coming up this way.

JUDGE CHAPPELL: Maybe one of those free email accounts?

THE WITNESS: Perhaps, but the email that I use is an exchange service. I'm not even sure why this is printed the way it is.

BY MS. EVANS:

Q. Now --

A. Good question. I hadn't noticed that.

Q. All right.

A. Oh, I see. This was an AOL account I was using at the time. Yeah, that's what it is.

Q. On August 4, 2003, did PMRI still anticipate that the myocardial perfusion study, which is also known as Bev I, would continue past three months?

A. We didn't have the money to do that. It wasn't an option.

Q. Could I refresh your recollection?

A. You may.

Q. Could you please bring up CX 0603?

A. Thank you. Okay.

Q. This is a document that -- is it an August 4, 2003, agenda of the PMRI research team meeting?

A. Okay.

Q. And if you look at the one, two, three, four -- the fifth heading --

A. Um-hum.

Q. -- it's entitled "Cardiovascular Beverage Study Pilot Study/Bev I."

A. Um-hum.

Q. Then the one, two, three, four, fifth bullet down says, "Beverage crossover at 3 months." Does it say that?

A. It does.

Q. Thank you.

Could I please have CX 2041? Could you bring up CX 2041 on the screen, please?

Was there, on November 8th of 2003, an exchange of documents between PMRI and Dr. Liker that indicated that the Bev I study would be completed in October of 2004?

I'm sorry. I didn't realize you didn't have it. I'll hold off for a second.

MR. GRAUBERT: Okay. Go ahead.

MS. EVANS: Okay.

BY MS. EVANS:

Q. Do you see halfway -- about halfway down the page, it says -- there's a heading that says "Beverage I"?

A. Thank you.

Q. Okay. And the last line in that section is entitled "1 Year Testing Will Be Completed October 2004"?

A. I see that, yes.

Q. Okay. Thank you.

And on September 19th, 2003, did you sign a contract with the Stewart A. Resnick -- with the Stewart A. Resnick and Lynda Ray Resnick, as Trustees of the Stewart and Lynda Resnick Revocable Trust?

A. I don't know. I would have to see that.

Q. Okay. Could you please provide him with a copy of Dean Ornish Exhibit 55? Actually, do I have that?

Oh, I do. I believe it's previously marked as -- well, let me just give you this.

And I believe the second, third -- I'd ask you to refer to the second, third, and fourth pages of that document.

A. Okay.

Q. Okay. Is that a contract that you signed with regard to the conduct of the Beverage I and Beverage II studies?

A. Yes.

Q. Okay. And it's dated September 19th, 2003?

A. Correct.

Q. And that's your signature on the last page of the -- the letter portion?

A. That's correct.

Q. And does it state in the -- it states under "Beverage Study I," it says, "PMRI agrees to conduct" -- let me ask this in the form of a question.

Does it state that "PMRI agrees to conduct a randomized, controlled clinical trial beverage study, one in accordance with the methods and requirements as set forth in the Beverage Study 1 protocol, attached hereto as Exhibit A and incorporated herein by this reference, subject to the additional terms and conditions set forth below"?

A. Yes, it does.

Q. Okay. And does it also say "PMRI shall recruit and enroll thirty-seven (37) participants for a Beverage Study I with coronary arterial atherosclerosis and reversible ischemia (as measured by exercise or pharmacological myocardial perfusion studies) who shall not be enrolled in Beverage Study II (as attached below); and further, that upon completion of the Beverage Study I, PMRI shall prepare a comprehensive write-up thereof in a form acceptable for submission to peer review journals; and lastly, the Sponsor's total donation pledged for completion of Beverage Study I, inclusive of indirect costs, shall be seven hundred eight thousand four hundred thirty-six dollars" -- and it repeats that number -- "which shall be payable as set forth below."

A. I'm not aware of anything in here that says we're going to do a one-year study in this contract, are you?

Q. I had not finished.

A. I'm sorry?

Q. I hadn't finished.

A. You hadn't finished?

Q. No, I have not. Does it say that?

A. No, it does not.

Q. No. Does it say the information I read to you in -- under the section "Beverage Study I"?

A. It does say that, but within the information you read, I don't understand anything that says that we're going to test them at one year.

Q. Now, if you could please turn -- it's Dr. Ornish's deposition --

A. It may be a part of Exhibit A. I don't have Exhibit A.

Q. If you would turn to the next -- to the Beverage I study protocol that was adopted by reference in that letter --

A. Um-hum. Thank you.

Q. -- and if you would turn to page --

A. Oh, this is a --

Q. Excuse me, sir. Can I please finish?

-- page 7. Does it indicate that all testing will be repeated using identical procedure at three- and 12-month time points at the location of the original baseline testing?

A. The intention originally was --

Q. Excuse me. Can you answer?

A. You need to let me say this, okay, because you are going down a line that is misleading, and I know the Court wants to have accurate information.

We originally planned to do the testing at baseline, three months, and one year, and even in this contract, in this protocol, we reaffirmed that, but the Resnicks cut our funding to such degree that we couldn't afford to pay for that, and that's why we didn't do it. It's as simple as that.

Q. Does this document state that all testing will be repeated using an identical procedure at three and twelve-month time points at the location of the original baseline testing?

A. It does say that, but we didn't have the money to do that.

Q. Please. And that is -- and that particular protocol, if you turn to page -- I believe this is CX 613. If you turn to the top of the Beverage I study protocol, that's -- that's dated June 5, 2003, correct?

A. Is that a question?

Q. Yes. Correct?

A. I'm sorry. What's the question again?

Q. Just strike the question.

Now, so, the cost for the Bev I study that you agreed to on September 9th, 2003, was $708,000, correct?

A. That's what we had budgeted for.

Q. Yes. And that was to conduct the study -- Beverage I study protocol, which had testing at

baseline, three months, and 12 months.

A. We can keep saying this over and over again if that would be helpful.

Q. Correct?

A. But, again, the answer would be yes, no matter how many times you ask me.

Q. Thank you.

A. And the issues will still remain the same. We didn't have the money to do it.

Q. And could you please bring up CX 2043 on the screen? Is it up?

On September -- on September 29th, 2003, did -- did PMRI write to a researcher and tell them that the Bev I study was a 12-month study?

A. Let me just inject a little common sense into this. All of these documents were created at the same time. It was our intention at the time to do 12-month testing. We didn't have the money to do it because our funding got cut. It's as simple as that.

Q. On September 29th, 2003, did PMRI write to a researcher and tell them that the Bev I study was a 12-month study?

A. We did.

Q. Thank you.

If you could bring up CX 2041, please, and

provide a copy to counsel.

A. And I would remind you that we tested nine of those patients at 12 months, because that was our intention, until we ran out of money.

Q. On October 10th, 2003, did PMRI write to Dr. Liker about when the three-month testing would be completed and indicate that that would be January 2004?

A. I presume. I don't know. You would have to show me the document. Let's assume that's true. I will accept you saying that.

Q. And --

A. But if you have a copy of that, I'll be happy to look at it.

Q. Could you provide him with a copy? He has it? You have that document before you?

A. Is this the one about -- dated October 8th?

Q. CX 12 -- 2041.

A. That's right.

Q. Okay. And so it says that -- on October 10, 2003, you -- PMRI wrote to Liker about -- Dr. Liker about when the three-month testing would be completed, and that would be in January 2004, correct?

A. Let me see here. Yes.

Q. And that same document also indicates that the one-year testing for Bev I would end in October 2004?

A. That was our intention at the time.

Q. And if you could please pull up CX 2044. Can you see that document?

On January 26th, 2004, did one of your staff members, Colleen Kemp, write to Dr. Aviram to say that the 12-month testing for Bev I would be done in November of 2004?

A. That was our intention at the time.

Q. And if you could please -- did Dr. Sumner, on February 6th, 2004, for the first time send the PMRI team a document with Bev I results?

A. I don't know the date, but I'll presume that's true.

Q. Well, could you please -- could I refresh your recollection?

A. If you have a document, I would be happy to see it.

Q. Could you please refer to CX 632?

A. Thank you. And what is the question?

Q. That -- that document, that's dated February 6th, 2004, correct?

A. Yeah. February 7th, actually.

Q. I'm so sorry.

And that's from Dr. Sumner to the Bev I team?

A. Yes.

Q. And it's entitled "Continuing Bev I Results"?

A. Yes.

Q. And does that document present the results for the Bev I study as of February 7th, 2004, for the three-month testing?

A. Correct.

Q. Okay. And I --

A. And what?

Q. Now, there was a team meeting of the PMRI Bev I study team on February 9th, 2004, correct?

A. I don't know. I presume that's true.

Q. Could you refresh -- could I refresh your recollection?

A. Please.

Q. If you could please bring up CX 633.

A. Thank you.

Q. And this is a PMRI research team meeting, dated February 9th, 2004, document, isn't it?

A. Correct.

Q. And under the item identified as "Cardiovascular Beverage Pilot Study/Bev I," moving into the middle column, where it says "Discussion," does it says, "Dean says the good news is, after reviewing the data, the research shows that ischemia is reduced with a summed difference score of 4.33 to 3.63. Dean wants to quit

while we are ahead and wants to call the Resnicks with the news."

A. That's absolutely true.

Q. Thank you.

And on March -- on or about March 12th --

A. Do you want to read the rest what I said?

Q. You may, if you wish.

A. It says, "Dean asked Erin," that was our CFO, "for budgets to use in conversations with the Resnick's, including the actual cost to date versus budget to date as well as the amount of money still due to us for the completion of the study."

What we found in those budgets was that we didn't have the money to do this for a year. It wasn't quitting while we were ahead because we wanted to quit while we were ahead. It was good that we could quit while we were ahead, but it was because we didn't have the money to finish this study.

Q. And on March 12th, 2004, did Dr. Gerdi Weidner of that team send the Bev I data files to Dr. Liker for review?

A. I don't have a photographic memory, but I'm happy to see the document.

Q. And I believe that the interrogatory responses that you submitted in this matter indicated that the

total cost for the myocardial perfusion study was $708,000.

A. I'd be happy to see the document and I can comment on it.

Q. If you could bring up CX 642. I'm so sorry. That is CX 1247.

A. Thank you. What were you --

Q. Oh, I'm sorry. Turning to page -- turning to the fourth page, the fourth and -- the fourth page of that document, and so that would be CX 1237-004, and the -- and I would like to refer you to the one, two, three, fourth paragraph there, paragraph D.

A. Yes. May I read that?

Q. Yes.

A. It says, "The total amount of funding paid to PMRI," referring to this Bev I study, "was $708,437. The cost of the study was significantly higher than that amount for reasons that are described in the documents that I previously sent to the FTC (which I'm willing to reiterate if you wish)."

That simply validates what I've been saying, that we couldn't afford to continue the study because we didn't have the funding because the Resnicks cut it. It's as simple as that.

Q. Now, you subsequently sent an abstract of the

results to the American Heart Association, correct?

A. That's correct.

Q. And could you explain to Your Honor -- could you explain for my purposes what an abstract is?

A. An abstract is a summary of the findings.

Q. Okay. And in August of 2004, did you find out that the -- that the abstract had not been accepted by the American Heart Association?

A. That's correct. So, we submitted it to the American College of Cardiology, at which it was accepted.

Q. And did you ask the president of the American Heart Association to reconsider their decision not to accept the abstract?

A. I did.

Q. Okay. And did he provide you then with his reasons? Did he write back?

A. If you have a copy of the document, I'd be happy to see it.

Q. Okay. Could you bring up CX 0699? No, it's 0699. Do you have it, Nathalie? Thank you.

Is this an exchange of comments between you and Phil Fontanarosa?

A. This is for JAMA. This isn't the American Heart Association. This is a different document.

Q. It's 680. I'm sorry, it's 680.

A. Okay. What is your question?

Q. Okay. So, is this an exchange of documents between yourself and Raymond J. Gibbons --

A. Raymond J. Gibbons, yes.

Q. -- okay, and you had asked him for -- for feedback about the abstract?

A. I had asked him to reconsider, and he replied that "The process is admittedly not perfect. I personally have had an abstract rejected 3 times that became a Circulation paper."

So, he's saying, you know, abstracts are graded very quickly, sometimes they make mistakes, and gave three examples of his own, but he said that he couldn't reconsider, because he would have to do that for everyone. So, we said fine. So, we submitted it to the other major heart association, which is the American College of Cardiology, and they accepted it.

Q. Okay. Now, the top email on this exchange of documents, on page 1, at the very top email, is that Dr. Gibbons' September 2, 2004, reply to your request for feedback?

A. Yes.

Q. And is one of the lines in this document, "As reflected in my earlier email, there were no obvious

flaws in the grading process. Multiple qualified, blinded graders scored this abstract below acceptable range."

A. Yes. And the very next sentence is, "The process is admittedly not perfect, and I have personally had an abstract rejected 3 times that became a Circulation paper," which is a major -- a lead scientific journal for the American Heart Association.

Q. Okay.

A. He goes on to say, "My lab had an excellent abstract rejected this year." So, it's an imperfect process.

Q. Yes. And on page -- and in November 2004, did you learn that the Journal of the American Medical Association also rejected an article -- a version of the article about the myocardial perfusion study that you had submitted to them?

A. That's not un -- they only accept 8 to 9 percent of the articles that are submitted to them. So, it's not at all uncommon for an article to be rejected by them and it's published by another top-tier journal. In fact, that's the norm, by definition.

Q. But you did learn on November 2004, that the Journal of the American Medical Association also rejected the article about the myocardial perfusion

study?

A. Didn't you just ask me that?

Q. I didn't get an answer.

A. The answer is yes.

Q. Thank you.

And did you also ask Dr. Phil Fontanarosa for any feedback or critical comments about the manuscript?

A. I did. I'm sorry. It is a 7 percent accepted rate is what he said. He said, "The biggest issue is our 7 percent acceptance rate for unsolicited papers, making for very keen competition for space in JAMA."

Q. And what -- and he also indicated --

A. He also indicated that the study -- he says he was concerned about the sample size baseline differences between groups, intermediate end point measures, and so on. He said, "I'm sure this paper will be published in a more specialized journal," was his conclusion.

Q. Okay. So, he said that "the study appears very preliminary, with small sample size, apparent baseline imbalances between groups, use of an intermediate endpoint as a main outcome measure, and modest differences with large variability. I'm sure this paper will be published in a more specialized journal"?

A. As it was.

Q. Okay. And that's CX 0699?

A. Yes.

Q. Okay. Thank you.

Now, you did subsequently submit a manuscript of the Bev I study to the American Journal of Cardiology, correct?

A. Correct.

Q. And did -- did the editor of the American Journal of Cardiology tell you in February of 2005 that he was not able to get any external reviews on that manuscript?

A. He did. That's not unusual.

Q. Okay.

A. It wasn't something related to the manuscript. It happens all the time. People get busy.

Q. And if you could refer to -- could you bring up CX 715 on the screen?

Is this the letter from -- from the editor of the Journal of American Cardiology saying he was not able to get an external review on your manuscript?

A. No, it's not.

Q. It's not?

A. It's a note from Michael Sumner to -- to me.

Q. Oh. Did you, on March 10, 2005, write to Dr. Michael Sumner and say, "He didn't hear back from the reviewers, so I -- so he accepted it anyway"?

A. What happened is he reviewed it himself, which is the highest form of review, because he's the editor in chief. He personally reviewed it.

Q. Okay. So, this CX 715, this is the -- that email that you sent to Dr. Sumner?

A. It's -- there's two of them on here. There's one from me to him and there's one from him to me. The one from him to me says that -- that the presentation of our findings at the annual session of the American College of Cardiology went very well. She said the attendees were very impressed by the research and did not ask critical questions about it. Rather, the questions were -- focused on the methodology and statistics rather than questions on additional information, such as the nutritional mechanisms of the juice and whether there is a dose-response relationship, et cetera.

Q. Okay. And then --

A. Then what?

Q. -- you wrote back saying, "He didn't hear back from the reviewers, so he accepted it anyway," correct?

A. After he reviewed it himself.

Q. Thank you.

A. He personally -- the editor in chief -- this is, by the way, a journal that Dr. Sacks has published many

papers in. He personally reviewed the article, which makes it even a higher bar.

Q. Now, on --

Could I have one minute?

(Pause in the proceedings.)

BY MS. EVANS:

Q. Now, you also -- PMRI also conducted a second study for Respondents, correct?

A. A second study for what?

Q. For the Respondents that was --

A. For the Resnicks, yes. Um-hum.

Q. That was an IMT study?

A. That's correct.

Q. Okay. There were a few different protocols for the pomegranate juice studies exchanged or that were circulated, correct?

A. Well, in response to the issues of recruitment and the funding we got, yes.

Q. Okay. And was there a March 2003 protocol for a combination myocardial perfusion/IMT study?

A. That was the original one.

Q. Okay. And this protocol called for enrolling 70 patients, correct?

A. I would have to look at it.

Q. Okay. Could we bring up -- could I refresh your

recollection?

A. Of course.

Q. Okay. Could you bring up CX 583?

Is CX 583 a Beverage Study Protocol I dated --

A. Well, this was revised in response to the Resnicks cutting our funding. We originally had 200 patients. We ended up with only 73, and 56 were -- we had data on.

Q. Okay. Now, this Beverage Study Protocol I that's dated -- on the third line here, it indicates it's January 13, 2002, revised March 13th, 2003.

A. March 17th.

Q. You're so right.

Does this -- and on page 4, as you indicated, it called for a target sample of 70 participants?

A. Yes.

Q. And it included both -- if you turn to page 5, it included bilateral carotid B-mode ultrasound testing --

A. That's right.

Q. -- and myocardial perfusion testing?

A. That's correct.

Q. So, that would be both IMT testing and myocardial perfusion testing, correct?

A. We were going to do both tests, that's correct.

That's essentially the Bev I and Bev II studies.

Q. And on page 8 of that document -- could you turn to that page?

A. Okay.

Q. And does that page contain a power analysis for the study?

A. It does.

Q. And does it say that the total number of study participants was N equals 70, randomly divided into either the experimental or control group?

A. That's correct, but -- can you -- I think you gave me a copy of the -- of the protocol that had 200 patients in it. Do you have a copy of that?

Q. Can we just finish this line, please?

A. Well, I need to refer to it, please. The original protocol that we had that had 200 patients, do you have a copy of that?

Q. We can get to that in a second. Can I finish this line of questioning?

A. No. No, I need to refer to that before I can answer your question.

Q. Well, the only question I asked you was, does this document, on page 8, call for a total number of study participants of 70?

A. It does, because that's all that we had the

money to do.

Q. Thank you.

Now, after this, the Bev I and Bev II studies were separated, correct?

A. Correct.

Q. And the -- there's a Beverage Study II Protocol that was attached to the contract that we discussed earlier and that you were -- you were looking at it, and it was --

A. Yes, I have it.

Q. -- CX 613.

A. Um-hum.

Q. And the protocol attached to that document, it begins with the page -- well, if you could find that. It's about in the middle of the document, the Beverage Study Protocol II, and the bottom number is -- it says Liker 00449.

A. I'm sorry. I'm having -- I don't know what -- I'm a little confused. What are you asking?

Q. Okay. Can you page -- well, this page -- no, you can't. Okay. He has it?

If you could -- well, it's a multipage document, and there's numbers -- there's two sets of numbers on the bottom, okay? And the -- if you're looking at the numbers that begin with the word "Liker," and turn to

page Liker 00449.

A. Okey-doke.

Q. Okay. Is this the Beverage Study Protocol II?

A. It's one of the versions of it, yes.

Q. Okay. And this was the one that was attached to the September 13th, 2003, contract?

A. Yes.

Q. Yes. And this protocol, if you turn to the page that's numbered Liker 00452, under "General Study Design," and let me know when you have gotten there.

A. What is the question?

Q. I said let me know when you got there.

A. I'm there.

Q. Okay. Under "General Study Design," does it say that "This design was a randomized controlled clinical trial. The target sample of 50 participants includes adult participants," and then it goes on to describe them. So that this version of the protocol called for a target sample of 50 participants for the IMT testing?

A. That's right. We recruited 73, and there were 56 we ended up testing.

Q. Okay. And now, this Beverage Study II Protocol, does it also provide that one of your responsibilities, upon completion of the study, is to prepare a copy of the write-up in a form acceptable for submission to a

peer-reviewed journal?

A. Yes.

Q. And you had talked earlier about the results of the Bev II study, and I wanted to ask you some questions about them.

Nathalie, could we bring up CX 754?

Can you see that document on the screen?

A. I have it.

Q. Thank you.

Now, this document contains the results of the IMT study, correct?

A. Yes.

Q. And this study lasted one year?

A. Yes.

Q. And that's the duration set out in the Bev II protocol?

A. Yes.

Q. Okay. And although the Bev II protocol that we just discussed --

A. I'm sorry. What was the last thing you said? I didn't hear you.

Q. And that's the duration set out in the Bev II protocol attached to the contract?

A. Yes, it is.

Q. Thank you.

And the -- and although the Bev II protocol called for recruiting 55 patients, you actually recruited 73.

A. I want to clarify that. That protocol called for recruiting 200 patients. We had to rewrite the protocol, in response to the Resnicks unilaterally cutting our funding and not providing us enough funding, to do 50 patients. That's what this is.

Q. But the one that's attached to the contract --

A. The contract was because that's the amount of money that they were going to give us, and so they basically said take it or leave it. We already were several hundred thousand dollars in the hole, so we took it. In retrospect, I shouldn't have even done the study, knowing that we would need more patients than that based on our initial power calculations, which is what the conclusion of this Bev II summary that you just gave me says, which is that further research is recommended to investigate trends in the results with sufficient power to detect distinct differences.

If we had had the 200 patients that were in the original protocol, based on these trends, they would have been statistically significant. That's the bottom line.

Q. So, the -- the report to the Bev II summary

states that "The experimental and control groups showed similar levels of carotid intima-media thickness and elasticity at baseline," right?

A. Not exactly -- at baseline, yes.

Q. And -- and the -- there were no significant changes in the experimental group, relative to the placebo, for either thickness or elastic properties?

A. As I described it earlier, it approached significance. It was to the 0.13 level in the right carotid artery, and it was a similar level of significance in the elasticity, because the numbers were too small. If we just had a few more patients, given those trends, they would have been significant. And as I indicated before, the 5 percent level is a bit arbitrary anyway.

So, it would have been totally misleading and borderline unethical to publish a study that said that there was no effect of this intervention when we knew from the beginning that we needed a larger sample size in order to detect it, and that's called a type two error, which means that there's an effect, but the sample size isn't large enough to detect it.

Now, it's important to point out that this was done a priori. We stated in advance that we would need 200 patients, and we only got funding -- I mean, and we

were promised the funding to do 200 patients. We didn't get that funding. It got cut, in part because the methodology that we were using to measure the carotid arteries at the California Pacific Medical Center turned out to not be as accurately reproducible as we wanted, so we had to start over again. And we found a doctor at the Jet Propulsion Laboratory, who is considered one of the world leaders in this area, to do it, and that further delayed us.

So, it was a classic example that no good deed goes unpunished, because we weren't willing to cut corners just for the speed of getting the results to the Resnicks.

Q. And I think my question was, there were no significant changes in the experimental group relative to the placebo for either thickness or elastic properties, and that is set forth in Table 2, correct?

A. If you define significance at the 0.5 level, that's correct. If you say the 0.1 -- there was an 87 percent likelihood that this was not due to chance as opposed to a 95 percent likelihood this was not due to chance. It would have been wrong to publish this as a null finding.

Q. If you had had positive results, would you have published it?

A. If we had positive results, would we have published? Yes, we would have published it.

Q. Okay. And you just told me, as I understand it, that if you had a sample size of 200 and if you had these same data, it would be statistically significant?

A. If these trends that we saw in this sample were seen in a larger sample, it would clearly have been statistically significant.

Q. But that's merely a hypothesis, correct?

A. We can't prove that, but there is no reason to think that those patients who we followed would have been fundamentally different.

Q. But you don't know that.

A. We don't know. That's why we didn't publish it.

Q. Now, you sent the IMT results to the Respondents on August 4, 2005, right, according to the first page of this document?

A. What was your question?

Q. Now, you sent the IMT results to the Respondents on October 4, 2005, right, according to the first page of this document?

A. That's correct.

Q. Thank you.

And after that, did you have a telephone conference with Dr. Liker and Mr. Tupper and

Mr. Resnick?

A. I don't remember, but it's entirely probable.

Q. Okay. If you could bring up CX 754, please. 757.

A. Thank you. Okay. I see that at least it was scheduled. I presume we had it.

Q. Okay. And this telephone conference was with regard to the IMT study?

A. Yes.

Q. Okay. And had you previously told your assistant, Michael Sumner, that you should publish the results of this study even if they were nonsignificant?

A. I don't recall ever telling him that, no.

Q. Could I refresh your recollection?

A. That I told him -- okay, sure.

Q. Could you please bring up CX 717?

Now, this document is dated March 24, 2005?

A. Okay.

Q. And does it indicate that --

A. Well, you know, if we had found results that were clearly not significant --

Q. Could you hold on one second? I don't have the question, apparently.

A. I thought you just asked me --

Q. I can't find -- well, I can't find my copy.

A. Oh.

Q. Does that -- is that an email from Dr. Sumner to Dr. Gerdi Weidner?

A. It is. It's not from me to her or from me to him.

Q. And in that document, does Dr. Sumner say that he had briefly discussed the Bev I and Bev II results with Dean today?

A. Yes, it does. Excuse me.

Q. And --

A. You just asked me a question, and I'd like to answer it. You asked me if I had told Michael Sumner that he should publish it even if the results were nonsignificant, and the answer to that question is if they were clearly nonsignificant, if the P-value was 0.9, then I would say definitely we should publish it. But in this case, once we actually analyzed the data, and as you can see in that document you gave me a moment ago, the one dated August 4th, 2005, you actually see in the data, it was significant to the 0.13 level, which means that it was thought that it would have been grossly misleading and I think unethical to publish a study saying that pomegranate juice had no effect when, in fact, we knew from the very beginning that we needed at least 200 patients, and that if this trend had

continued, it would have been statistically significant to the 0.5 level.

Q. Now -- but what it says here and what Dr. Sumner is telling your overall team members, "Overall, it's a mixed, but relatively disappointing bag so far. Interestingly, Dean says we should publish results, even if they are non-significant."

A. Well, I'm being quoted and that's called hearsay. You can ask me directly what I actually said, and what I said is that if they were clearly nonsignificant, if the P-value is 0.8 or 0.9, in which case having more patients wouldn't have changed it, that would be an interesting finding. That wasn't the case here.

The case was it was clearly a type two error, which means that the study was underpowered because we knew from the beginning we needed 200 patients. And the only reason we didn't, which I have to tell you is just incredibly annoying to have to kind of revisit this whole experience with the Resnicks, was that they cut us off at the knees by cutting our funding.

And if they had just let us finish what we wanted to do -- it took longer because it took longer to recruit the patients and we had to find a more accurate municipal lab to do the analyses in, and for that we

were punished. And so we ended with an indeterminant finding, not a clearly nonsignificant finding.

Q. And so you weren't going to share with the public the results of this testing you're describing there?

A. To what end? For what purpose?

Q. Thank you.

A. It would be like building a house halfway and saying, "Don't you want to go live in it?"

Q. We've been talking about pomegranate juice. That contains 31 grams of sugar. Isn't that correct?

A. That's correct.

Q. And would you call that a lot of sugar?

A. Compared to what? Compared to a Coke? No. Compared to --

Q. Would you call it a lot of sugar?

A. It's a -- it's a significant amount of sugar, but it's a naturally occurring sugar, and it's -- it's not the same as taking sucrose.

Q. Well, you've published a book called The Spectrum, correct?

A. That's correct.

Q. And in The Spectrum, do you recall describing a conversation between yourself and your son?

A. I do.

Q. And did you say in that -- did you report in that book that you recommend to your son that he should choose foods that have no more than six to eight grams of sugar per serving, unless it is a treat?

A. That's correct.

Q. Thank you.

MR. FIELDS: Objection. Way outside the scope, Your Honor. He testified only to the study he did and its results, and he didn't talk about the science of sugar or whether you should have it or not.

THE WITNESS: Let me get into that. If you are getting something that has great benefits --

MS. EVANS: Excuse me, sir.

THE WITNESS: -- despite getting sugar from that, it's worth it.

MS. EVANS: Excuse me, sir. Counsel posed an objection, and you have to give the Judge an opportunity to rule on it.

THE WITNESS: Thank you.

JUDGE CHAPPELL: He said it's outside the scope. Are you responding to that?

MS. EVANS: Yes. We have been talking about how beneficial the pomegranate juice is, and this goes to whether or not he thinks it's beneficial.

JUDGE CHAPPELL: I'll allow it. Overruled.

THE WITNESS: So, in response, the benefits of the pomegranate juice outweigh the sugar content.

BY MS. EVANS:

Q. Okay. Now, you think that the Federal Trade Commission shouldn't have sued the Resnicks, right?

A. I do.

Q. And the reason is because if the FTC came down on them the way that they are, it's going to quash anyone else from wanting to fund this kind of research?

A. As I indicated in the beginning of this conversation, the issues of personal liberty and freedom of choice are why I'm here, and I don't think the FTC has any place forbidding people from making health claims that have a science base so that the American people can make informed decisions about what they should be eating. It's not a drug. It's a juice that's been around since the Bible and has no toxic effects.

I think it's entirely appropriate for the FTC to qualify the health claims so that the ones that are made are based in science, but the level of science is different for a drug or for a chemotherapy agent.

Q. Thank you.

A. And I think there's a role -- I'm answering your question. I think there's a role for the FTC, but it's not to forbid that, and if -- and if this case shows

that the Resnicks, who have the money to do this kind of research, are not able to -- to make any health claims at all, then no one will ever be able to make any kind of health claims for any fruits or beverages or vegetables, and I think that would be to the detriment of the American people, and it's big brother at its worst.

Q. Okay. Now, prior to consuming -- excuse me, consuming.

Prior to conducting the two pomegranate juice studies for the Respondents, you've never done a study to see if a single food product is beneficial in maintaining cardiovascular health or for any other end point, correct?

A. That's correct.

Q. Okay. Your life's work has centered around developing and testing the theory that comprehensive, intensive lifestyle changes can sometimes improve medical risk factors and quality of life in people with disease, correct?

A. That's correct.

Q. Now, many of your studies focused on intensive lifestyle changes to regress cardiovascular disease, correct?

A. Not just cardiovascular disease. As I

mentioned, we found an effect in Type II diabetes, prostate cancer, gene expression, and telomeres.

Q. But I asked you, did many of your studies focus on intensive lifestyle changes to regress cardiovascular disease?

A. Yes, but not limited to that.

Q. And, for example, in your Lifestyle Heart Trial, did the program consist of nutritional changes that included a 10 percent fat diet, whole foods, and a vegetarian diet?

A. It was a diet, 10 percent -- approximately 10 percent calories from fat, fruits, vegetables, whole grains, legumes, soy products, egg whites, some nonfat dairy, yes.

Q. And in addition, it called for aerobic exercise, stress management, smoking cessation, and group psychological -- psychosocial support?

A. That's correct.

Q. And in a different study you did -- the lifestyle intervention program, that's a different study, right?

A. I'm not sure what you're asking.

Q. You have the lifestyle heart trial, but I saw that you had other publications on the lifestyle intervention program.

A. I did three cardiovascular studies. The first, in 1977, a pilot study of ten patients; the second, a randomized trial for a month using thallium scans and markers of perfusion; and the third was originally a one-year study and then we got support from the National Institutes of Health to extend it for five years, and we published the findings in Lancet and the Journal of American Medical Association.

Q. Now, in the Lifestyle Intervention Program, you asked patients to exercise for a minimum of three hours a week, including a minimum of 30 minutes per session exercising within their target heart rates, and they were encouraged to eat a very low-fat, plant-based diet and engage in strength training at least twice a week and practice stress management for an hour a day and attend group support sessions for two hours a week, for 12 weeks, correct?

A. Are we talking about my research or are we talking about pomegranate juice here?

Q. I am talking about your Lifestyle Intervention Program.

A. Why is that relevant?

Q. Could you please answer the question?

A. The answer is yes.

Q. Okay. And in your study, you said you found

that the more people change their diet and lifestyle, the more their heart disease improved?

A. It did.

Q. Okay. Now, would you say that comprehensive lifestyle and dietary changes can be a treatment for cardiovascular disease?

A. It depends on how you define "treatment," but in my books, I indicate that people need to make a decision between them and their doctors whether this is an adjunct to treatment or a -- an alternative to it.

Q. Okay. And so -- and if people use this as an alternative to treatment, you found that this comprehensive lifestyle program can cause a regression in their cardiovascular disease?

A. It can cause a regression in cardiovascular disease, whether it's an adjunct or an alternative to treatment.

Q. Okay. And so in that sense, it would be a treatment?

A. In what sense?

Q. In the sense that it causes a regression in cardiovascular disease.

A. That's correct.

Q. Okay. And --

A. Which conventional treatments generally do not.

Q. Okay. And you've -- you've carefully -- you've conducted carefully controlled human clinical studies to test the proposition that comprehensive lifestyle changes can have this effect?

A. We have, and as I mentioned earlier, these data were -- we also did three demonstration projects, one with Mutual of Omaha, one with Blue Cross/Blue Shield, one with Medicare, and after 17 years of incredibly intense internal and external review, beginning in January of this year, Medicare is now covering my program as Dr. Ornish's program, because -- we asked them to do it as a generic program, and they insisted on doing it as a branded program because they know the quality of the work that we did, and that was of concern to them.

Q. So, the use of a -- you know, the information you submitted to Medicare to get this program approved, that included some very rigorous statistical, scientific results, correct?

A. Yes, it did.

Q. Okay.

A. As well as demonstration projects showing that patients could be motivated to change, and there was no negative effect, and it was also cost-effective. We published a paper on almost 3000 patients last year in

West Virginia, Nebraska, and Pennsylvania, showing that people can make these changes, and we showed significant improvements in all metrics after both three months and after one year.

MS. EVANS: Thank you very much. I have no further questions, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. FIELDS: I have no questions, Your Honor.

JUDGE CHAPPELL: No?

MR. FIELDS: No questions.

JUDGE CHAPPELL: Thank you, sir. You're excused.

THE WITNESS: Thank you, sir.

Is it all right to leave? May I leave?

JUDGE CHAPPELL: Yes.

What are we looking at tomorrow?

MR. FIELDS: Tomorrow, we have two witnesses. We have Dr. Reibstein, as I recall, and Dr. Goldstein. Dr. Reibstein is a survey guy, and Dr. Goldstein is a urologist and will talk about ED, the actual ED study.

JUDGE CHAPPELL: And do we anticipate these two will take all day?

MR. FIELDS: I'm not sure of that, Your Honor, but they are, I think, the last witnesses before the break that counsel has talked about.

JUDGE CHAPPELL: Any input on how long they will take?

MS. HIPPSLEY: Who's first? Dr. Reibstein?

MR. FIELDS: I think Dr. Reibstein is first. He's flying in or training in.

MS. HIPPSLEY: I'm thinking -- well, I hate to guess at these things, but maybe around 3:00 we'll be done, 3:30, something like that.

JUDGE CHAPPELL: The agency is excusing everyone tomorrow early. That doesn't include us.

MR. FIELDS: Oh.

JUDGE CHAPPELL: But there is an unseen and unheard pressure that builds. That's why I'm asking.

MR. FIELDS: Yes. Well, we can shorten it up.

MS. HIPPSLEY: I have a feeling it will be this part of the agency's fault if we don't meet with the pressure.

JUDGE CHAPPELL: Okay. Do we have anything else today?

MR. FIELDS: No, Your Honor.

MS. HIPPSLEY: No, sir.

JUDGE CHAPPELL: You can sit.

We will reconvene tomorrow at 0930.

(Whereupon, at 4:31 p.m., trial was adjourned.)

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 NAME: POM WONDERFUL LLC

DATE: SEPTEMBER 1, 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: 9/7/2011

SUSANNE BERGLING, RMR-CRR-CLR

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.

SARA J. VANCE, CMRS