FEDERAL TRADE COMMISSION

I N D E X

IN RE POM WONDERFUL LLC, ET AL.

TRIAL VOLUME 17

PUBLIC RECORD

OCTOBER 12, 2011

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

UNITED STATES OF AMERICA

BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL GLOBAL LLC,	)	
as successor in interest to	)	
Roll International Corporation,	)	
companies, and	)	Docket No. 9344
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually	)	
and as officers of the	)	
companies.	)	
	)	
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Wednesday, October 12, 2011

9:33 a.m.

TRIAL VOLUME 17

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Josett F. Whalen, RMR-CRR

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P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: Back on the record Docket 9344.

MS. DIAZ: Thank you, Your Honor. We're ready when you are to call our next witness.

JUDGE CHAPPELL: The voice is ready?

MS. DIAZ: It's ready. I have some lozenges here just in case, but I'm trying to avoid using them.

JUDGE CHAPPELL: All right. Next witness.

MS. DIAZ: Respondents call Matthew Tupper.

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Whereupon --

MATTHEW TUPPER

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

DIRECT EXAMINATION

BY MS. DIAZ:

Q. Mr. Tupper, you've already testified that you are president of POM Wonderful; is that right?

A. Yes, I did.

Q. You've been employed by POM since 2003?

A. That's correct.

Q. Initially as chief operating officer?

A. Correct.

Q. And in 2005 you became president.

A. That's right.

Q. Do you have any ownership interest in the company?

A. I do not.

Q. Have you ever?

A. I have never had an ownership interest.

Q. Have you ever had an expectation of having an interest?

A. No expectation. The company is the sole property of Mr. and Mrs. Resnick.

Q. And you are leaving the company soon; is that right?

A. That is correct. I plan to leave POM by the end of this year most probably, after our annual harvest, which, as it turns out, is going to commence tomorrow. We're going to start picking our fruit tomorrow. That should be completed by the early part of December, at which time I'm going to begin transitioning my duties, and I will be leaving by the end of the year.

Q. Okay. When you gave testimony in this case previously -- I believe it was June -- you knew you would be leaving; is that right?

A. Yes, that's correct.

For actually a while now, my wife and I have

been planning to pursue an early retirement, and that plan has been in the works for a while, certainly was in place in June when I testified, although at that point I had not yet informed the Resnicks, the owners, of what the plan was. I think I told them in mid to late June.

Q. And you will not be joining any other -- any Roll or Resnick company; is that right?

A. That's correct.

Q. You're not just shifting companies or --

A. I'm not shifting companies. I'd be leaving the world of Roll altogether.

Q. Okay. Shifting gears a little bit, you currently manage the day-to-day operations of the company; is that right?

A. I do. I manage the day-to-day business on behalf of the Resnicks.

Q. And you have since -- since what time period? Handled the day-to-day operations.

A. Since 2003 when I first joined POM.

Q. Okay. Does that include POM's marketing department?

A. It does include the marketing team, yes.

Q. Okay. Do you manage POM's marketing exclusive of the Resnicks?

A. If you mean do I develop the direction that we're going to take in marketing independently and decide how we want to market the products, no. That, that say, that final say, that direction, ultimately lies with the Resnicks. My job is to carry out and implement the direction that has been decided upon.

Q. Okay. So who has ultimate decision-making authority for advertising medical benefits or medical -- you know -- yes. Who has authority for advertising the benefits of POM, the consumption of pomegranate juice?

A. Ultimately, any decisions made with respect to what do we talk about, how do we talk about it, that decision would lie with Stewart Resnick in consultation with our legal advisers, our lawyers.

Q. Okay. But you handle the day-to-day in connection with the health benefit advertising?

A. That's correct. Once a direction has been decided upon, my job then is to work with all the different parts of the team at POM to make sure that we head in that direction and execute appropriately.

Q. Okay. What role do you play specifically in connection with health benefit advertising?

A. So when it comes to any of the ads or communication that we would run or issue talking about

the medical research, I really view my job as to make sure that all of the relevant pieces of the equation come together, the science and the scientists, the marketing team, the lawyers and legal advisers. My job is ultimately to make sure that the science is correctly portrayed in the ads and to make sure that's done the right way.

Q. Okay. So are your -- you're the connecting piece between the science and the marketing; is that accurate?

A. Correct. My job is to connect the science, make sure it's interpreted correctly through the lens of the marketers and to make sure that it's done in consultation and under the watch of our legal team.

Q. Okay. And so how do you go about doing that? How do you go about ensuring that the science is, you know, connected to the advertising?

A. It all starts with the scientists and in fact the published papers that we would describe in an ad or, again, in another sort of communication. I make sure that the marketing team understands what was discovered in a particular study and make sure that that information gets, again, correctly, accurately, fairly incorporated into the marketing materials.

Q. Okay. Now, have you always played that role in

connection with health benefit advertising since you first joined POM?

A. Well, since I first joined POM, I have always been engaged in the dialogue around the science, in other words, what are we studying, what did we learn, what did the publication show, what did the study conclude. But it was -- it's really been since 2007, late 2006, early 2007, that I became more engaged in this connecting role, and that occurred at a time when we had a new head of marketing join POM.

The old head of marketing had actually been around for a while and was quite up to speed on the science, had a bit of a science background himself. When we had a new marketing head come in, however, that individual obviously didn't have the history of the science program and didn't have quite as much of a science background, and that's when I became more directly involved myself.

Q. Okay. So since that 2007 time period, has the process that you've used to connect the science with the advertising and vet through legal, has that process remained the same since 2007 to the present?

A. No. We've actually modified it, and we now have a more formalized process involved where there is a well-defined path, for lack of a better term, that an ad

would travel before it ultimately gets published, and you know, we literally have a checklist of the individuals who need to review and sign off on those ads, ultimately culminating in the legal review. And that process ensures that nothing falls through the cracks.

Q. Was there ever a time where the actual ads and advertising themselves, the ads themselves, had to be run by or approved by chief science officers, either Mark Dreher or Brad Gillespie or their predecessors?

A. The -- always the final step of vetting and approving an ad lies with our lawyers who perform the legal review. The scientists, whether it's, you know, Dr. Gillespie or Dr. Dreher or any of the outside scientists we work with, they're actually engaged in the process earlier on as we try to translate from scientific language into layperson's language what it was that we learned, what a study concluded, what the results in a particular publication showed, so they get involved at the outset of the process, and then the final review is with legal.

Q. Okay. Mr. Tupper, what was Mr. Resnick's stated policy on the relationship, on the required relationship between the scientific studies and the advertisements?

A. Very simple I suppose, the policy is that the ads had to accurately represent what the science concluded. The -- you know, I think as has been testified previously, we believe that throughout the course of the science program there's been many important learnings, which serve the public's interest to learn about. The ads are one vehicle to disseminate the information, but at all times the very clear policy and direction is to make sure that what's portrayed in the ads is consistent with what was learned in the studies themselves.

Q. Are there any areas of science where POM saw positive results in the science but where it didn't advertise those?

A. Yes. There have been a number of different areas where there's been some very encouraging research and studies that have been completed and published but where we've chosen not to discuss those in any of our advertising because we wanted to see the science progress further before we brought that information out to the public.

Q. Okay. Can you identify some of those areas?

A. Sure. A few that come to mind would be:

We've done some actually quite interesting research on immunity, cold and flu.

We have seen some interesting research on cognitive function.

We have seen some interesting research on the skin and skin care and ultraviolet damage.

And there have been others as well, but those are a few that come to mind right now.

Q. Okay. What about dental health?

A. We actually had a very encouraging study that came out of a lab at UCLA that showed the potential to -- for pomegranate extract to counteract the effects of the biofilm on your teeth, which is where bacteria essentially hide, breed and begin to form cavities. That's an area where the original publication, we didn't publicize it, again, waiting instead to see how the science pans out. That's actually not an area that we're currently pursuing, and again we really have focused the ads on a few areas where the science is far along.

Q. Okay. Well, if you haven't made claims in these areas and -- well, why are you investigating these areas? I mean, if you have positive benefits, why aren't you making claims in these areas?

A. Well, as I said, you know, there is some very encouraging initial work that's been done, and in some of those areas we are in fact continuing to pursue the

science.

We actually have -- for example, in the area of cognitive function, we have some studies that are currently under way. Another area, as I mentioned before, is urinary tract infection, and we have some studies that are actively going on.

We want to see a body of science develop, make sure we understand what are the physiological effects of pomegranate in that particular system before we go ahead and share that information with the public.

Q. Okay. Mr. Tupper, POM received an FDA warning letter; isn't that right?

A. We did. That's correct.

Q. Okay. And when was that? Do you recall?

A. My recollection is it was at the very early part of 2010.

Q. Okay. And what was the FDA letter about?

A. There were a couple of issues that they flagged in that letter, expressing concerns about some of the things that we were doing on our Web site.

The couple that I remember are, first of all, on our Web site we had essentially reprinted testimonials from consumers who had written in to us, letting us know the experiences that they've had consuming POM and how they thought that POM had

positively impacted their health. That was one of the areas outlined in the letter that the FDA had a concern with.

And then the other area was the fact that in our Web site or on our Web site we included summaries of studies that had been published on POM as well as actual reprints of those studies themselves, and that was a second area that they had highlighted in the letter of concern.

Q. What was our response?

A. Well, we -- we issued a written response to the FDA, letting them know that we respectfully disagreed with their contention that -- I believe they characterized it that we were marketing our product as a drug by virtue of having these studies on our Web site, so we told them that we disagreed with that.

We -- I think in that letter we told them, however, that we appreciated the fact that they were not taking issue with the underlying science itself. There was nothing expressed in their letter to us that questioned the validity or the depth of the science but rather the fact that we were including it on the Web site, so we said, look, you know, we don't agree.

And then having sent that letter, however, you know, out of an abundance of caution and in the spirit

of being conservative, we actually did make changes to our Web site in accordance with what was in the FDA letter.

Q. Did the FDA respond to POM's letter and actions?

A. I'm not aware of any response, and you know, I think that's the -- this all goes back almost a couple of years now.

Q. So you haven't heard back from the FDA for the last two years on this.

A. We have not, no, not that I'm aware of.

Q. Switching gears a little bit again, do you recall NAD rulings being issued at any time -- well, actually in 2005 and 2006?

A. I do recall that, yes.

Q. And there are two separate rulings; is that right?

A. That's correct.

Q. And what was POM's response to these rulings, the NAD rulings?

A. Again, it was fundamentally similar to our response to the FDA. The issues raised in, if I recall correctly, in the NAD proceedings involved, first of all, a question as to whether the images and the headlines that we had been using in our ads were in fact

puffery and used hyperbole. And to my recollection, the NAD took no issue with that, and I think it agreed that in fact those images and headlines in fact constituted puffery.

But then there was the issue as to, in the body copy of ads that would appear, for example, in magazines with these headlines and images, I think there was an issue that they raised relative to the language we would use to appropriately qualify the science that we were describing.

So our response was that we disagree that we had not appropriately described and qualified the science that we portrayed in those ads. And again, to my recollection, there was no objection on the part of the NAD as to whether the science itself was appropriately strong or valid or substantive.

Q. Now, we're talking about two different NAD -- we're talking about both -- are you speaking about both NAD rulings combined?

A. I am combining them together because I don't --

Q. Okay. Well, this -- my question is really speaking to what was the -- what was POM's response to the rulings?

A. So after responding in writing that we didn't agree with their assessment about our use of language,

we nevertheless agreed to take into account in our future ads the points that they had raised. And most fundamentally at that point in time we began to shift the focus of our ads and very simply attempted to describe the results of specific studies that had been completed, published and so, for instance, let people know, hey, there was a study done at Johns Hopkins that had 42 people, here's the results that were found, and orient our ads that way.

And that was -- that was a change that occurred at that time and in conjunction with the feedback that we received from the NAD, and obviously at the same time we took into account their views and findings about the appropriate use of language to qualify the description of the studies that we were making.

Q. Okay. And do you recall -- let me just back up here a little bit.

Do you recall also altering claims about consuming eight ounces of pomegranate juice to reduce plaque by up to 30 percent or something to that effect during -- as a response to these NAD rulings?

A. Yes. I believe we stopped using that language, again, as part of the shift to simply describing what was -- how was the study conducted, what was learned, and focusing on simply directing people back to the

Web site to read the full study if they would be interested.

Q. Okay. I'm sorry. You're going to have to speak up a little bit or move your mike. I'm having some difficulty hearing you a little bit.

Did you make any of these changes, for example, the 30 percent, in connection with the 30 percent reduction claim, for example, because you -- because POM believed that they didn't have adequate support to make those claims?

A. No. To the contrary, as we I'm sure said in the letter and as we've believed all the while, anything that we've ever said in any of our ads we believe is more than adequately backed up by published research that has been done over the past 10 to 15 years. The changes that we made were again out of an abundance of caution and, frankly, to be conservative.

Q. Okay. And you also testified just now -- and I want a little bit of clarification -- you said that you began a shift to a trend where you just simply cited, you know, specific results of a study.

Is that instead of characterizing the results of the study generally? What did you mean by that?

A. The -- starting in 2006-2007, the -- in a situation where we would want to talk about the science

behind POM in an ad, rather than making any sort of a generalizing statement, the ads would simply discuss and describe there was a study done, here's where it was done, here's what the results of that study were, and the ads focused on discussing the science in that fashion at that time.

Q. Okay. Now, let's look at some specific advertising if we can. I'd like to put up the "Cheat death" ad. I believe it was previously put up by complaint counsel. It's CX 0036-0001.

Do you have that? Okay.

A. Excuse me. On this monitor here, either my eyes are going crazy or the monitor is -- it's -- the image is shimmering, and I can't even read the body copy down below. It's quite blurry.

Q. Okay.

A. Maybe we need to reset the monitor or something.

Q. Reset the monitor or we can give you a clean copy, if the court allows.

JUDGE CHAPPELL: Can you read the enlarged portion?

THE WITNESS: I can read the enlarged portion now, yes.

JUDGE CHAPPELL: You can give him a hard copy if

you'd like or you can blow up what you're going to ask him about.

MS. DIAZ: I'm not going to ask him any specifics about the actual. I just want him to recognize the general.

THE WITNESS: Can I try turning off this monitor, because it's just going to give me a nauseous headache.

MS. DIAZ: Is that all right, Your Honor?

JUDGE CHAPPELL: Go ahead.

MS. DIAZ: Your Honor, may I --

JUDGE CHAPPELL: Go ahead.

THE WITNESS: I'm going to have to turn this off. I'm sorry. It's -- I don't know if -- is mine the only one that's like shimmering on the edges?

MS. DIAZ: Yes.

THE WITNESS: It's just me?

BY MS. DIAZ:

Q. It is just you.

Do you want some assistance turning that off or is it okay?

A. No. I turned it off myself.

Q. Okay. So, Mr. Tupper, do you recognize this "Cheat death" headline and image?

A. I do. This is a headline and an image that

we've used many times in different ads.

Q. And do you also recognize the body copy?

A. I do.

Q. Okay. The body copy no longer runs; is that correct?

A. That is correct.

Q. And it hasn't run for some time.

A. I don't believe it's run for many years in fact.

Q. Okay. Do you have an approximation of when that body copy stopped running?

A. My guess would be it probably stopped running four or five, six years ago.

Q. And was that in connection with -- was that at the same time as the NAD ruling, do you recall, or if it was in response to the NAD ruling?

A. I believe it was. Yes.

Q. Okay. But that is -- there's a distinction you're making, is that right, between running the headline "Cheat death" and running the copy?

A. That's correct. This -- again, this headline and the image is one that we've used in a number of ads over a period of several years, sometimes just on their own, other times with body copy, so yes, we continued to use this image and headline, but the -- I think this

copy again hasn't been -- we haven't used it in probably five or six years.

Q. Okay. Now, the "Cheat death" headline, that is -- is that to be interpreted literally, in your view?

A. No. Unfortunately not.

Q. Okay.

A. It's an example of what we call puffery.

Q. Okay. So what other ads, if you can recall, used puffery in the headlines like the "Cheat death" ad?

A. Well, we've had -- in fact, humor and sort of a wink to the consumer are a part of the tone that we commonly use, so we've had a number of headlines that puffer us, if that's a word: "Outlive your spouse." "Outlive your personal trainer."

We ran one that said, "Relax. You will live longer."

We ran one that I believe said "Death defying."

Those are -- I think we've run others, but those are a handful that come to mind.

Q. Okay. And so, for example -- well, let me pull up one. Let's pull up "Death defying." I think it's respondents' number 060339. Okay.

So are you saying, Mr. Tupper, that this advertisement -- Your Honor, if I may, for the purposes

of continuing to show him the ads, have our paralegal walk up and approach Mr. Tupper?

JUDGE CHAPPELL: Yes, that's fine.

MS. DIAZ: Okay.

BY MS. DIAZ:

Q. So is this ad supposed to be taken literally?

A. No, it's not. No, it's not. I don't think that -- unfortunately, POM is not going to help you be a better tightrope walker.

Q. And what's the ad meant to convey, if anything?

A. It's meant to convey what really is a common theme across all of our ads, which is, hey, this is an incredibly healthy natural product, one that if you are as a consumer interested in maintaining a healthy lifestyle through nutrition, it's a product you ought to be interested in.

Q. Okay. Well, what does "good medicine" or literally "medicine" mean then?

A. Actually the -- there's a quote from Hippocrates, who's one of the godfathers of modern medicine. I think he probably expressed it best where he said, "Our food should be our medicine, and our medicine should be our food," the concept being that, especially today in a world where everybody hears about all of the foods that you shouldn't eat and that are

bad for you, saturated fats and refined carbohydrates, et cetera, on the other hand there is overwhelming science suggesting that many foods in fact will help proactively maintain your health, that are good for you, that will help you lead a healthier life, broccoli and carrots and blueberries and whole grains, et cetera.

So in that sense there's been another quote that has been out there in the press, which is that the medicine chest of the 21st century can be found in the produce department of your local supermarket.

That's what "good medicine" I think means in this context.

Q. Okay. Did POM run early on an ad -- any ads about lowering blood pressure, to the best of your recollection?

A. I don't recall that we ever ran ads that explicitly focused on blood pressure. We did in some of our early ads mention blood pressure among a list of other health conditions, but not ads that were specifically focused on blood pressure, no.

Q. Okay. Do you recall that some point in time we stopped even mentioning blood pressure, POM stopped mentioning even blood pressure?

A. We did, yes.

Q. Okay. Do you recall about when that was?

A. Several years ago. Probably three or four, maybe more years ago. Aside from a couple of mentions of blood pressure that lingered on a few pages of our Web site, but aside from that, no, not for several years.

Q. Okay. And to the extent that there are blood pressure references remaining on the Web site or -- why was that? Was that a mistake? Was that intentional?

A. No. Those were inadvertent. That was a mistake. Those did not get removed as part of a process of updating our Web site.

Q. Why did POM halt use of the blood pressure references?

A. Well, we had had some very promising research and results from a number of early studies that pertained to blood pressure, which we and our scientists felt were quite encouraging. However, we wanted to see how that science would progress. We wanted to gather more evidence before really focusing on describing those blood pressure effects, and so, as a result, we decided to in our advertising focus on the areas of science that were further along in the process, and that's the point in time in which we stopped talking about blood

pressure.

Q. Okay. And how about Alzheimer's? The early "Cheat death" ad that I flashed that we addressed before had -- I believe it indicated a benefit regarding Alzheimer's. Isn't that right?

A. It did.

Q. But the Alzheimer's references were stopped early on as well; is that right as well?

A. Correct.

Q. And why was that?

A. It was for a fundamentally similar reason as for blood pressure, which was, again, we had some early preliminary research on Alzheimer's and the formation of plaques in the brain that are ultimately the cause of Alzheimer's, but again we decided to focus in our advertising on the areas of research that were farther along.

So despite the solid research on Alzheimer's, we -- similar to blood pressure, we focused on other areas that were farther along.

Q. Okay. I want to put up, if I could, Mr. Tupper, ask you some questions about some advertisements that were raised by complaint counsel yesterday.

Can we put up the "Drink and be healthy"

advertisement. It's CX 016.

Mr. Tupper, I only have a few questions about each of these.

This "Drink and be healthy" advertisement, can you see it?

A. I can see it here.

Q. Okay. What's the time period? When was that used?

A. This was an ad that we ran long, long ago, 2003.

Q. Okay.

A. Because that -- if you look at the picture of the bottle, it's a glass bottle. That's a bottle that we had begun discontinuing by the beginning of 2004. This was actually an ad that we used to launch POM originally when we were rolling it out in 2003.

Q. Okay. And you don't believe it has been run since 2003?

A. No, it hasn't.

Q. Okay. Can we switch gears here and put up "Floss your arteries." It's CX I think 31.

Mr. Tupper, do you recognize this advertisement?

A. I do.

Q. Okay. And can you give me the time frame where

this ad was used?

A. Again, this was --

Q. And I'm talking about the whole, you know, theme with the copy.

A. This was an ad that again was very early on, 2004, just when we had launched the plastic bottle and before we had developed the -- what became known as our dressed bottle campaign, which was kicked off in late 2004, so this is another early ad in 2004.

Q. Okay. And is it your testimony that we haven't used this ad since 2004?

A. I don't believe we have, no.

Q. Are you drawing a distinction between the -- just for sake of clarity here, are you drawing a distinction between the headline and the copy, the body copy?

A. I don't even believe that we've used the headline and image subsequent to 2004.

Q. Okay. Can we put up the next ad, "Amaze your cardiologist." It's CX 471 in my notes.

Mr. Tupper, can you put a time on this, on this ad?

A. Same time frame, 2004, at the latest 2005. This was an early-on iteration of our dressed bottle campaign, which ultimately ended up having a white --

stark white background. This was sort of a precursor to that campaign, and we walked away from the use of the color behind the bottle.

Q. Okay. Okay. I want to now review the advertisements concerning the amount of money spent on POM's research program. Do you know what ads I'm referring to?

A. I do, yes.

Q. Okay. I'm referring to the "backed by" advertisements. Is that what you have in mind?

A. Yes.

Did you say "backed by"?

Q. Backed by.

A. Yes.

Q. Okay. What does it mean to convey how much money the company has invested?

A. Well, what it means is, very simply, and what our intention has always been is to convey our commitment to the science program, the seriousness, the breadth, the depth of that science program, and to do so by illustrating that concept with the amount of funding that we've provided to the science.

And we've -- the goal was to really in many ways distinguish ourselves from most of the other food and supplement companies that do one or two simple studies

and stop there. That's very different than how we've approached our program, where, you know, over the past decade-plus we've funded and provided support for dozens upon dozens of studies with the intention of probing the frontiers of knowledge about pomegranates.

And so in those ads, by citing the aggregate amount of funding, we're trying to communicate that, hey, this is a serious science program. We care about science. We're committed to science. That's a core part of what we do.

Q. Okay. So dollars referenced, were those supposed to reference the total dollars or total approximation of dollars on -- spent on POM's research program?

A. Correct. That included the funding cumulatively since the beginning that had gone to planning, executing and analyzing and interpreting the results from the studies, as well as setting the continued direction for that program.

Q. Were you comfortable using the total dollars spent on the research program regardless of the area of health referenced in the advertisement?

A. So if you're asking do I think and do we think it's appropriate to include the total amount at any given time whether we're talking about cardiovascular or

prostate or ED in an ad, the answer is yes. We feel it's very appropriate.

Number one, again, the intention was to communicate the expanse, the depth, the breadth of the commitment to science. That's the primary objective. But more fundamentally, the science all interrelates. The learnings that we get from one study apply to other studies in different areas because we're dealing with some basic fundamentals of mechanistic action within the human physiology that are really centered around antioxidation, antimicrobial activity and antiinflammation, and those span across all the areas as these nutrients essentially have a systemic effect throughout the body.

Q. Was overhead like salaries and rent included in your total dollars?

A. No, it wasn't. We've always taken a very conservative approach to calculating those dollars, so it's just been, as I said, the dollars that have gone out the door to external parties for planning and conducting and then analyzing and interpreting studies, so it doesn't include or it hasn't included the salaries, the benefits associated with people internally, Dr. Dreher, Dr. Gillespie, any of the people who have worked on that team, the offices that

we provide to house them. We've excluded those from the numbers, again in the spirit of being conservative.

Q. Okay. Were those salaries and costs significant? That were excluded.

A. Very significant. Over the course of the last decade, they would tally into the millions of dollars.

Q. Why would you include dollars in that total figure attributable to science that was both published and unpublished?

A. Well, I would say for two reasons. One, the same logic applies as I just mentioned in terms of including dollars spent on prostate versus heart versus erectile dysfunction versus cognitive function. The science all -- all fundamentally interrelates, and whether a study ends up being published because a significant finding was noted or whether a study didn't generate knowledge that reached publication, we learned something from all of those studies. That knowledge informs the direction of future studies. It adds to our understanding of the basic mechanisms for how pomegranate works in the human body, so again, you have to take all of that into account, and it's appropriate to again demonstrate the depth and breadth of the program, so that's the first reason.

But I think secondly and perhaps even more

fundamentally, it's a reflection of how we run the program and our approach and our philosophy. Again, in contrast to companies that will go out and design a simple study that they're quite sure is going to get them a quick and easy and positive result, that's not what we've done.

We've -- we have a desire to push the boundaries of knowledge, and in so doing, there are times when, you know, in designing and conducting a rigorous study, there are times when you get results that are novel and significant and reach the statistics, and so forth, and therefore will make it through the peer review publication process and there are times when you don't.

But any way you cut it, our desire is not simply to rack up studies with lots of points, but it's to push the boundaries of the science and help us better understand what's going on. And sometimes the result of that is that the study doesn't end up being published, but nevertheless, they're all important. And again, that's what we think sets our program apart, and that's what we want to communicate to the public.

Q. Okay. And I assume that's the reason, too, that you include dollars in that total figure that are attributable to both the basic science, test tube, and

animal studies, as well as the clinical studies.

A. That's correct. The science builds upon itself. The different areas interrelate. In fact, you can't sometimes do one until you've done the other.

Q. Okay. And what about using dollars incurred from both positive studies and studies that were indeterminate that where no positive result was found?

A. Again, all appropriate and the same -- I don't think I need to repeat myself, but the same logic applies as would apply to why we include -- why we included studies that have been published and not published.

Q. Okay. There is one ad -- can we put up PX 0330a47 page 0001. There we go.

Mr. Tupper, do you recognize this advertisement?

A. I do.

Q. Okay. And do you see that it reads "the only one that's backed by $25 million in published medical research"? Do you see that?

A. I do see that.

Q. Okay. When did that run? Do you know?

A. I believe this ran in 2008.

Q. Okay.

A. Approximately.

Q. Okay. Was this a mistake or what was -- what was --

A. Yeah, this was a mistake. It should not have said "published medical research." It should simply have said "medical research."

Q. Okay. And the ad was stopped; is that right?

A. That's correct.

Q. Okay. And it hasn't run since then?

A. It has not.

Q. Okay. Let's put on CX 0459-0001, "Decompress."

Mr. Tupper, do you recognize this advertisement?

A. I do.

Q. When did you first learn that there was a survey purporting to measure the participants' response to this "Decompress" advertisement?

A. I think I was actually made aware of that during a litigation-related deposition.

Q. Okay. And the survey was the Bovitz survey; is that right?

A. That's my understanding. Yes.

Q. And that survey came out in June of 2009; isn't that right?

A. That's correct.

Q. And you previously testified at trial, however,

that this "Decompress" advertisement probably ran in 2008 and possibly 2009; isn't that right?

A. That's -- I recall that, yes.

Q. Okay. Upon further reflection, could this have run in 2009?

A. I don't think it could have, and the reason is because by late 2008 we had creatively moved in a different direction from this style of a campaign. This is the dressed bottle with a the white background. By I believe late 2008 we were running ads with a burgundy background, different look and feel. This campaign was no longer in use.

Q. Okay. Now, is it your understanding as well that the -- so this -- so this ad was gone before that survey even came out, that's right -- is that right?

A. That's correct. I believe it was.

Q. And isn't it true that the Bovitz survey only looked at the -- only looked at the picture, the image with the headline and not the text?

A. That's my understanding.

Q. Okay. Now, was a message about blood pressure intended by this advertisement at all?

A. Not at all.

Q. Okay. What was the intended meaning behind this advertisement, if you know?

A. Again, as part of our overall campaign, letting people know that, A, this is a natural and healthy product, and B, as you can read in the text toward the bottom, we were communicating that this is a product that is backed by serious science, and in particular there is some good, encouraging information and promising results on prostate and cardiovascular.

Q. Taking -- separating the body copy from the headline and the image for a moment, what does the word "decompress" mean? Is there a meaning -- I mean, I don't know if there's -- what does it mean to you? Let me ask that.

A. Sure. "Decompress" means relax, destress, in the context of an ad like this, be healthy.

Q. Okay. Why would there -- why -- why is this cuff being used in the image? If you know.

A. Well, as you can see again from the copy text down below, we're letting people know about cardiovascular research in the ad, and so the cuff serves as a visual cue, a symbol of something that, for example, you would associate with a cardiologist's office, similar to other ads we've run where there's a bottle with little EKG stickers on it.

Q. Did you learn during this trial that the POM Web site, in addition to posting all the actual studies,

actually still had a two-line reference or one or two-line reference to blood pressure?

A. I did. And that's what I mentioned earlier.

Q. Okay. And that was -- that reference was not deliberately left in; is that what you had suggested earlier?

A. It was left inadvertently, not intentionally. It -- among literally thousands of lines of our Web site that we modified, it was a couple lines that inadvertently escaped.

Q. Okay. And has it since been removed from the Web site?

A. It has, yes.

Q. Mr. Tupper, do you understand that the FTC has asked why POM has continued or why it continued to run ads about Dr. Aviram's 30-plus percent improvement in arterial plaque study after knowing about Dr. Davidson's study showing a lower percentage of improvement? Are you familiar with that story line by the FTC?

A. I'm aware of that line of argumentation.

Q. Okay. Can you explain the circumstances for this?

A. Well, the reason that we felt comfortable continuing to summarize the results of Aviram's study

were that fundamentally we and more importantly our scientists believe that the Davidson study and the results from that study were reinforcing and consistent with what was -- what we'd seen not just in the Aviram study with the 30 percent difference but moreover the entire body of cardiovascular research, so we felt that they were consistent. Even though the numbers and the percentages were different, the studies were obviously, I think as has been testified earlier, different studies, different populations, therefore not comparable one to the other, but we felt that they were entirely and consistent.

Q. Okay. Switching gears again a little bit, Mr. Tupper, is POM seeking FDA approval for any of its products?

A. Yes, we are.

Q. For what products?

A. We are seeking drug approval, botanical drug approval for POMx under two different health indications.

Q. Okay. Why not the juice?

A. Well, as far as we are aware, the FDA has no provision or process for one to obtain drug approval for a juice.

Q. Any other reasons?

A. Well, again, the overall objective for us in pursuing the drug approval for POMx is, you know, we are -- we're trying to compete in a very challenging marketplace, and we're trying to figure out how to distinguish our products in a world where other companies that sell pomegranate extracts and juices, and so forth, are typically selling product that's either adulterated, meaning, it's labeled as pomegranate and it's not -- in reality it is not 100 percent pomegranate or is misleadingly labeled to make you think that it in fact is pure pomegranate when in fact there's other stuff in there.

And so we believe that with an FDA approval for POMx as a drug, that could be an important tool for helping us to distinguish the product in this challenging marketplace. But with respect to juice, again, it just does not seem that a drug approval is necessarily going to help that objective.

Q. Okay. Are you seeking drug approval because you believe you've been advertising the product as a drug?

A. Absolutely not.

Q. Okay. Do you recall, Mr. Tupper, I think in your testimony in June, the FTC complaint counsel showed you the medical portfolio review, CX 1029?

A. I do recall that, yes.

Q. Could you tell us what your objective was in the preparation of this exhibit was.

A. This is really one example of many in which from time to time we will get together and review the science that has been completed, the science that's ongoing and the science that we are contemplating doing in the future in trying to inform ourselves as to what it is the right path going forward, given all the variables involved.

Q. What was the objective in the preparation of this particular exhibit?

A. We had a meeting scheduled with myself and Mr. Resnick, with Dr. Dreher who was our head of science at the time, with Dr. Liker, Dr. Kessler, I think Dr. Heber, a few of our other senior scientist advisers. And again, we were -- this is really getting into the period where we were beginning to seriously have dialogue about pursuing a drug application and a drug approval, again, relative to some of the circumstances going on in the marketplace, so much of this document was to help us think through the details associated with obtaining FDA approval.

Q. Okay. So in some part it was to give an FDA drug approval assessment of the science?

A. Absolutely, yes.

MR. DIAZ: Okay. If the court would excuse me just for a moment, I'm sucking on a cough or -- drop, so I can -- so I don't mean to be rude or disrespectful to the court, but I do have a cough drop in my mouth, so I'm sorry.

JUDGE CHAPPELL: Okay.

BY MS. DIAZ:

Q. Could we turn to page 3 of this exhibit. It's 1029-0003, and focusing on the bottom right-hand side where it says "lower cost/risk."

Do you have -- is your monitor still off?

A. I have a copy.

What does it say at the top of the page.

Q. It says "Heart Disease" at the top of that page.

A. Got it.

Q. And can you see where I'm focusing in, Mr. Tupper, the -- where it says "lower cost, but our research" -- do you see that?

A. Correct, I see that.

Q. Okay. Now, you've already told us that the references to 3 out of 10 and the, quote, hole in the evidence refers to a supposed score from the FDA for drug approval and refers to doctors oriented to FDA drug

requirements; is that right?

A. That's correct.

Q. Okay. Now, why -- why is that?

A. Well, very simply, if you're the FDA or in fact if you're one of the cardiologists involved in drug registrational trials, there are essentially a very small handful of measurements that the FDA will rely upon to approve a drug for heart disease. My understanding is that there are essentially four: reduced incidence of death; fewer heart attacks, two; blood pressure; and cholesterol.

And in the case of POM, obviously the research that we've pursued in the area of cardiovascular disease has been focused on a couple of different measurements or endpoints, namely, arterial plaque, as well as blood flow delivered to the heart, and obviously those two are not on that list of endpoints viewed by the FDA, so no matter what your research shows, the FDA is not going to approve you for a drug. I mean, that's the basis of this evaluation.

Q. So that's the basis for the score 3 out of 10?

A. Right.

And that's, for example, in our minds, very distinct from the viewpoint of a practicing cardiologist who's seeing patients day in and day out and simply not

worried about advanced drug registrational trials but rather working with their patients to try to figure out tools to give them to improve their odds for living a healthy life.

Q. Okay. Putting aside the strict FDA requirements for -- or the -- for drug approval or the FDA lens and eliminating the issue regarding blood pressure, which you no longer advertise, what grade would you give your science related to the heart on a scale from 1 to 10, 10 being the highest?

A. Taking into account the entire body of research that we've gathered over the past decade on cardiovascular disease and the heart, I would give the research a very strong grade, when you take into account all the mechanistic data we have, the -- what we've seen in multiple studies, including the Davidson study on arterial plaque, and so I'd put that together and I'd give it a strong grade, an 8 maybe, and over time, as we continue to collect more data, more evidence, I would expect that to hopefully reach all the way to 10, based on what we've seen so far.

Q. What about helping people with prostate cancer? What grade would you give your science?

You know, helping -- helping healthy people with regard to prostate conditions, first.

A. First of all, the question in the case of prostate cancer is, you know, what is a healthy person. I would give it a -- to answer your question quite simply, I'd give it a strong grade.

With -- you know, I presumably am a healthy person sitting here myself, but I wouldn't be surprised if we took out my prostate and poked around you'd find some cancerous cells. And I believe that given everything that we've seen from the very basic mechanistic work to the multiple clinical trials we run on prostate, I sure think that pomegranate would improve my odds of maintaining healthy prostate over time, and so I'd give similar, an 8 out of 10, and as the research unfolds, hopefully that number goes up.

Q. So that is an 8 on helping healthy people with regard to prostate conditions?

A. Yes.

Q. Okay. And what about helping people with prostate cancer? Is it the same? Is it different?

A. I would give it the same grade again given the totality of the research.

Q. Okay. And erectile health, erectile dysfunction, what grade would you give that, outside again of the lens of the FDA or, you know, the drug approval requirements?

A. Again, similar, similar concept, very strong research, give it a high grade, an 8 out of 10. And I don't think we would do that -- I don't think we would be -- we certainly wouldn't be pursuing a drug registration with the FDA if we didn't feel that our science was extraordinarily strong and positive.

Q. Okay.

A. You know, 8 out of 10 today, moving to 10 out of 10.

Q. Okay. I think I'm done with this exhibit now.

Isn't it true that your chief science officers, Brad Gillespie and Mark Dreher, were asked regularly to provide you with research summaries that included the FDA perspective?

A. Correct. That's right.

Q. And isn't it true that you are comfortable that with the exception of the -- of a few ads, that every one of your ads has been supported by reasonable and competent science?

And the few ads I'm referring to are the ones that have been singled out as mistakes, for example, the published reference.

MS. VISWANATHAN: Your Honor, I just object to the extent that it's asking for a legal or scientific conclusion, and he's neither a lawyer nor a scientist.

MS. DIAZ: I can rephrase it, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MS. DIAZ:

Q. Isn't it true that you are comfortable with -- comfortable that every one of your ads, with the exception of the couple that we've cited as being -- that you've already explained, that they're supported -- that the claims therein are supported by the science?

A. Absolutely. In fact, we believe that the ads that we've run, all of them, have been more than adequately supported by the body of science.

Q. Would you ever knowingly publish an advertisement that you didn't feel was supported by the science?

A. I would never do that, and I know that neither Mr. nor Mrs. Resnick would allow that to be done.

Q. Okay. There -- we do -- we have used, have we not, juice science to support POMx advertising? We've cited juice science in POMx advertising?

A. Yes, we have.

Q. Okay. And why is that?

A. Because fundamentally we believe that the studies that have been completed on POM juice apply equally to POMx and we -- we did so only after

completing several steps of scientific inquiry, including first assuring ourselves that the main active polyphenol ellagitannins that are present in juice are present as well in the POMx, so the fingerprints had to -- had to be compatible. That's number one.

Number two, early on in the research quest, in the research program, we did a whole number of preclinical studies on POM juice, test tube, animal, in the areas of cardiovascular, ED, prostate. When we had figured out how to commercially produce POMx, we went back and repeated those preclinical studies with POMx, and we found the results to be the same as what we had found with POM juice, so that's the second thing.

And then thirdly, we actually did some clinical research, number one, to confirm that POMx was indeed safe, which is very important, and, number two, to confirm that POMx was indeed bioavailable.

And so, for example, a study that looked at people drinking POM juice and people taking POMx and looking over a period of time to see whether the same metabolites, the same breakdown components of the polyphenols merged in both the urine and in the blood after consuming the products, and indeed they did, and so combined together, that assured us that the juice research was appropriate and applicable to POMx.

And fundamentally, from my understanding, this is the same logic that is used for proving generic drugs in the pharmaceutical world, same set of logical steps.

So that all combined is why we chose to do that.

Q. Okay. Thank you, Mr. Tupper.

Switching gears again a little bit here, did POM ever have a target audience for its products?

A. Not in the traditional demographic sense that many consumer products companies do where they go after a particular age group or gender or -- and so forth. What we have learned about our -- the people who consume POM over time is that they -- they actually span across all different levels of age and income and men and women and ethnicity, and so forth.

The common denominator in what we found is really more a state of mind, which is people who want to -- regardless of their age, they want to live a vibrant, healthy life, and they're people who want to take an active approach to health via good nutrition. And again, that applies to people who belong to many different traditional demographic groups, so it's been -- targeting in that sense has been just not something that's been possible for us.

Q. So you're saying -- I'm just looking at your testimony here.

Do you have a demographic as to who's actually buying your products, or is that what you were referencing by persons who -- who are -- who want to take an active approach to health?

A. What I'm saying is that, again, when you're trying to figure out who is buying and drinking POM, it's more defined by a state of mind and an active approach to health than it is by, you know, where the people live or what they do for a living, and so forth.

Q. Okay. Mr. Tupper, is it company policy to say or suggest that POM products are a substitute for proper medical treatment?

A. No. Absolutely not.

Q. Do you know of any instance in which any Roll employee told anyone to drink pomegranate juice instead of or as a substitute to consulting a doctor or taking his or her advice?

A. No.

Q. Complaint counsel has suggested that in answer to one or two consumer questions that a POM employee responded to the questions asked but didn't volunteer that the person calling should consult their doctor.

Is it company policy to say nothing?

A. No. Absolutely not.

The policy is, if a consumer has a question about a medical condition, their own health, then we encourage them strongly to go have a dialogue with their physician.

In this particular case, in those particular cases, if I recall the correspondences that I was shown earlier, those involve consumers not writing in with a question but rather writing in to thank us for making great products, high-quality, healthy products that they believe have had a positive effect on their health, and so are writing in to praise us. I believe that our consumer advocate didn't interpret those to be a question about what should I do but rather a thank you for making a great product and therefore no question that required an admonition to go see your physician.

Q. Okay. Do you or does POM have instructions to employees as to how to answer certain categories of consumer questions?

A. We do. And in fact, as it pertains to questions regarding medical conditions, drug interactions, and so forth, we actually have a database of written-out answers that our consumer advocate would use, and so it's part of the written instruction base that those individuals have.

Q. Okay. Can we put on the screen CX 0308.

This is -- what is this?

Can you flip to the next page. I think that's just a cover sheet. Okay. And zoom in on the top there so we can read the title.

This is Customer Care Knowledge Base.

Is this the database you're referring to?

A. That's correct. These are codified answers to various frequently asked questions.

Q. Okay. So in reference to your earlier statement that you actually instruct the persons answering these phone calls to ask the person calling to consult with their doctor in response to certain medical questions, this is -- this is that document.

A. It is.

And to clarify, this would apply not just to phone calls but also to written inquiries whether submitted via e-mail or in a traditional letter.

Q. Okay. So let's zoom in on health 14. It's the first reference on page 308. Can you find that?

Just zoom in on the first one.

Okay. So -- that's actually the second one. I think there's one earlier to that right above it.

It's called, "Is POM okay for children to drink?"

It's health 14. If it's not highlighted, it's okay. I want you to blow it up anyway.

Okay. Do you see that, Mr. Tupper?

A. I do.

Q. Okay. And it reads -- in response to the proposed question "Is POM okay for children to drink?" the sample response says, in part, "We advise that you check with your physician if you have any particular concerns about your children drinking POM Wonderful pomegranate juice" and "We know of no reason why children cannot enjoy it."

Is that one of the references you're referring to?

A. Yes, it is.

Q. Okay. So let's go to the next one. Under Pregnancy and Breast-Feeding, the highlighted piece.

Do you see what's highlighted there, Mr. Tupper?

A. I see.

Q. And is this one of the references that you are referring to in -- previously by the instructions to the -- to your employees on how to respond to these questions?

A. It is.

Q. Okay. And can you go to the next one under

Cancer.

Okay. And it says, "If you have any questions regarding this research, cancer, chemotherapy, we recommend that you speak with your physician" and "We wish you all the best with your treatment."

Is this one of the instructions that you're referring to, Mr. Tupper?

A. Yes.

Q. Okay. The next one, health number 19, where it reads, "If you have any questions regarding this research, your cholesterol, advice on lowering cholesterol or general health, we recommend that you speak with your physician," is this one of the instructions you're referring to, Mr. Tupper?

A. It is.

Q. Okay. And in connection with the glycemic index, the next one down, it says, "We always recommend speaking with your physician if you have specific questions regarding your blood sugar levels or your general health."

Is this what you're referring to, Mr. Tupper?

A. It is.

Q. And the next one down, health 21, "If you have any questions or concerns regarding specific questions about your medications and pomegranate juice, we

recommend you to speak to your doctor," you're also referring to this, Mr. Tupper?

A. I am.

Q. Okay. Now, on blood-thinning medications, the next one down, "Please be mindful that consumers have a varying diet and intake needs and we recommend speaking with your doctor if you have any additional questions regarding food and drug interaction," you're also referring to this, Mr. Tupper?

A. This is another example.

Q. Okay. And I don't know -- there may be more on this sheet, but at some point -- but you're referring to this document with the instructions; correct?

A. Correct.

MS. DIAZ: Your Honor, if I may have just a moment to gather my notes to see if there's anything else.

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MS. DIAZ: I have no more questions, Your Honor.

JUDGE CHAPPELL: Cross?

MS. VISWANATHAN: Yes.

JUDGE CHAPPELL: Before we start, I have a question for respondents. How do you pronounce the name

of the witness you're calling later today?

MS. DIAZ: DeKernion, Dr. DeKernion.

JUDGE CHAPPELL: I'm looking at your final proposed witness list, and under Proposed Testimony it says, "Respondents anticipate that Dr. DeKernion may testify on direct and/or in rebuttal." That of course doesn't tell me anything, and I don't see expert reports before the trial begins, so I'd like to know what are the topics upon which this person is supposed to testify.

MS. DIAZ: Dr. DeKernion was identified early as an expert. We provided expert reports for him.

JUDGE CHAPPELL: I'm not getting into that.

MS. DIAZ: He's prostate, prostate, prostate, prostate health.

JUDGE CHAPPELL: All right. Thank you.

Go ahead.

MR. GRAUBERT: Your Honor, I'm sorry to interrupt. Since you mentioned Dr. DeKernion, just in terms of getting him here, if we could get an estimate of how long complaint counsel anticipates, without holding them to it, this cross-examination taking, I'll see if Dr. DeKernion is available.

MS. VISWANATHAN: No more than 15 minutes.

MR. GRAUBERT: 15 minutes?

MS. VISWANATHAN: At most, yes.

JUDGE CHAPPELL: That's 1-5 or 5-0?

MS. VISWANATHAN: 1-5.

JUDGE CHAPPELL: Thank you.

MR. GRAUBERT: I believe Dr. DeKernion is on his way. We will get him here.

JUDGE CHAPPELL: Well, then when this witness is done, we'll take a break. If we need to extend it a little while, we can do that.

MR. GRAUBERT: Very good.

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CROSS-EXAMINATION

BY MS. VISWANATHAN:

Q. Good morning, Mr. Tupper.

A. Good morning.

Q. You testified that after the NAD proceedings took place, POM's policy was that there must be a completed published clinical trial on humans before advertising a particular medical benefit; is that correct?

A. I'm not sure that's what I said. No.

Q. I believe that you said that after the NAD proceedings came out, POM put in a more robust or more formal process for deciding how to describe medical benefits in ads. Is that correct?

A. I don't think that's what I said either.

Q. Is it POM's policy that there must be a completed published clinical trial on humans before advertising a medical benefit?

A. I think when you -- I mean, I guess the short answer is that -- yes, but the ads themselves, as I said, the -- over the last five years, the ads have simply sought to summarize and describe what was found or what was learned in a study, and the studies that we use in those ads are published studies, so by definition, what we're talking about in the ads is the result of a published study.

Q. Okay. And when you had mentioned cold and flu research, POM does not have a published study on humans on cold and flu; is that correct?

A. I believe there may actually be now a publication on cold and flu.

Q. A clinical trial in humans?

A. Correct. We've done two different clinicals, and I believe that one of them -- I believe that one of them has been published.

Q. Okay. When was it published?

A. At some point in the last one or two years. I can't remember.

Q. And is it a fact that there are no -- POM does

not have published human clinical trials on cognitive function?

A. Let's see. We have -- I'm trying to think of the publication on cognitive function. The clinical trial on -- the major clinical trial I don't believe has yet been published. The publications previously I believe were in vitro and animal model.

Q. And you also mentioned skin care as an area.

Is it also the case that POM does not have any published human studies on skin care?

A. I believe we may actually. I know there have been a number of studies published on skin care. I can't remember exactly which ones have been published and which haven't, but there may be -- there may be some -- some clinical work that's been published.

Q. The "Decompress" ad that respondents' counsel showed you -- it was CX 459 -- as you discussed, part of the body copy of that advertisement stated that POM is supported by $20 million of initial scientific research regarding prostate and cardiovascular health; correct?

A. Do you mind if I pull the ad up?

Q. Do you have it? Yeah. I'm sorry.

A. It's --

Q. CX 459.

Oh, thanks.

A. Got it.

Q. Okay. And as we had discussed back in June, there were many other ads that stated that POM was backed by a certain amount of money in medical research; correct?

A. Correct.

Q. Okay. And as you testified back in June, those figures also included research that had not been completed yet; is that fair to say?

A. Yes. Absolutely.

Q. You had testified today about the FDA warning letter. But just to the FDA letter, was that -- were the -- strike that.

The FDA's letter warned POM that it considered POM to be making drug claims about its product; is that correct?

A. I'm not sure if that's the language they used or different language. Again, I think what was at issue was the fact that we had testimonials and studies on the Web site, and they were equating that with marketing the product as a drug or -- I don't remember the language they used.

And as I said, we respectfully disagree with that assertion.

Q. You testified that POM is currently or has currently filed IND applications with the FDA for certain conditions; is that correct?

A. That is correct.

Q. And that stands for investigational new drug; correct?

A. I believe it does.

Q. And isn't it the case that the FDA insisted that POM file an investigational new drug application in order to complete a study that was ongoing?

A. No. I don't believe that's correct.

Q. Were you aware of correspondence from the FDA in which the FDA expressed a view that the use of POMx, in prostate cancer patients, being used to prevent the recurrence of cancer was a serious clinical claim?

A. I am vaguely aware of correspondence between -- I don't remember whether it was between the FDA and POM or between the FDA and Johns Hopkins, which was the university where the study was being completed.

Q. I'd like to show you a document, CX 1066.

Your Honor, may we approach and hand the witness a copy?

JUDGE CHAPPELL: Go ahead.

BY MS. VISWANATHAN:

Q. Although it might be easier to see it on the

screen. The print is very small.

(Pause in the proceedings.)

Okay. And on the first page of this document, that is an e-mail from you, mtupper@PomWonderful.com, to Michael Carducci at Johns Hopkins, dated Thursday, May 14, 2009; correct?

A. That's correct.

Q. And in this e-mail, is it fair to say you're discussing the issue of whether an IND -- POM feels an IND is required for a particular study, to complete a particular study?

A. I think that's fair to say.

Q. Okay. And then on the second page, this was an e-mail from Shaw T. Chen at FDA to Michael Carducci, and it was forwarded to you; correct?

A. I believe it was.

Q. Yeah. On the first -- the very first paragraph of the first page, it says, "Harley forwarded me the attached correspondence," and I assume that refers to Harley Liker, and he's attached all the -- excuse me -- forwarded the attached correspondence from Mr. Chen at FDA to you; correct?

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

Q. Okay. And so you had seen this correspondence from Mr. Chen; correct?

A. Presumably.

Q. And if you look at the third paragraph of Mr. Chen's correspondence -- actually I believe he's an M.D., so he's a doctor -- he states: "In your case, even if the company has no plan to make any claim, the objective of the study is to prevent recurrence of cancer and that is a drug use and a serious clinical claim. Thus an IND is required."

Do you see that?

A. I do see that.

Q. And so subsequent to May 14, 2009, POM at some point filed an IND; correct?

A. I don't remember the date as to when we filed. I believe it was after this.

Q. Okay.

A. But I can't be certain as to the date.

Q. And POM had discussions with the FDA regarding the filing of the IND before it was filed; correct?

A. We did. That's standard process for how one files an IND.

Q. And the IND -- excuse me. I'm sorry.

And isn't it the fact from this correspondence that there were concerns about continuing the study from -- expressed by Johns Hopkins without an IND filed?

A. There were, but the -- those questions had everything to do with safety and in fact had nothing to do with the issues expressed by Dr. Chen on the second page.

So this -- the letter is a bit out of context in the broader sequence of what was really going on at the time.

Q. Okay. And you stated you're not seeking any type of FDA approval for the juice, for POM juice; correct? This only applies to POMx?

A. Both of the INDs are for POMx, that's correct.

Q. But you are aware that there is a process by which the company could have obtained a qualified health claim for pomegranate juice from the FDA; correct?

A. That's actually an entirely different process, different outcome that has nothing to do with a drug.

Q. Yeah, I understand. I'm talking -- now I'm just moving to the juice.

So you are aware that there was a process by which the company could have obtained a qualified health claim for pomegranate juice; correct, especially since you stated you believe the science was an 8, the three areas we're talking about?

A. Well, I believe that that actually slightly

mischaracterizes the way that that process works. That's a generic process for all pomegranate juice, not just POM, so that would be a process that would have no benefit to us.

Q. When you say "no benefit," so it would have no benefit versus your competitors; is that what you mean?

A. Absolutely. If there's no benefit in a world where your competitors are selling adulterated product, undercutting you on price, but not having the consumers realize what's going on, so that would be a -- it doesn't make sense.

Q. No. I understand. But presumably the health claim would be for a hundred percent pomegranate juice.

That's what you had looked into or at least discussed as part of the medical summary; correct?

A. I'm not sure I follow the question.

Q. Well, if we could look at -- I think it's CX 1029, which is the medical summary. I think it's page 2, in the bottom.

So we've just blown up part of that on the screen.

Okay. And so in column B, where you're looking at the possibility of a health claim for juice or pills, you were referring to a claim that was generic to all pomegranate products meeting a minimum level of

polyphenol content; is that correct?

A. That's what it says here.

Q. So it wouldn't be the apple juices or the different kinds of juices that did not meet certain standards; correct?

A. Well, that's the issue of course, is that much of the product appearing on supermarket shelves that purports to be 100 percent pomegranate juice is in fact adulterated with all sorts of ingredients, including apple, white grape, et cetera. And moreover, there are other products on the supermarket shelf that make the consumer believe that what's inside is mostly pomegranate when in fact there's very little pomegranate, and that's the -- that's the backdrop to this entire discussion.

Q. Okay. And you testified that you will be leaving your employment at POM by the end of the year; correct?

A. I'm sorry. Did you say leaving my employment?

Q. Employment at POM.

A. Yes. That's the plan.

Q. And is this a voluntary decision on your part?

A. It is voluntary, yes.

Q. Are you getting any compensation or severance package from Roll or the Resnicks or anyone associated

with them as part of your separation from POM?

A. No, I'm not.

Q. Are you -- do you have any kind of indemnification agreements or will you have any upon your separation from POM?

MS. DIAZ: Objection, Your Honor. Indemnification? In connection with this litigation? I don't think that's an appropriate part of direct, and I would also argue that that could be protected as well. If she could parse out the question to remove the indemnification aspect of the question?

BY MS. VISWANATHAN:

Q. Well, what I'm trying to get at is whether there is -- you will be receiving any sort of benefits, direct or indirect, that would be continuing after your separation from POM from respondents.

I'm not sure how to state it more specifically.

MS. DIAZ: That's fine with me, Your Honor, so long as it's understood it's excluding any indemnification or legal arrangements.

JUDGE CHAPPELL: All right. Did you understand the latest question?

THE WITNESS: If the question is am I going to be getting any sort of financial benefits or anything like that, no. I'm on my own.

BY MS. VISWANATHAN:

Q. And so your current plans are -- you don't have any current plans to be employed in the future at this point.

A. I don't. I don't have a new job that I'm going to, no.

MS. VISWANATHAN: Okay. Thank you. That's all I have.

JUDGE CHAPPELL: Redirect?

MS. DIAZ: Yes, Your Honor.

- - - - -

REDIRECT EXAMINATION

BY MS. DIAZ:

Q. Working backwards a bit from the exhibits raised by complaint counsel, can we put on CX 1066 again.

And Mr. Tupper, this is the letter from Shaw Chen to Michael Carducci that complaint counsel raised with you. Okay.

And in the third paragraph that begins with the words "In your case," do you see that, "In your case, even if the company has no plan to make any claim"?

A. I do see that, yes.

Q. Okay. And the second sentence basically says an IND is required.

Isn't it correct, Mr. Tupper, that the FDA took

the position that an IND would be required regardless of what claims were made?

A. That's what this paragraph appears to say. Yes.

Q. Okay. If we can turn to Exhibit CX 0459-0001, it's the "Decompress" ad.

I think there's -- do we have it up?

Do you have that ad in front of you, Mr. Tupper? You're going to need to look at the text, so I want to make sure you can actually see the text.

A. I see it.

Q. Complaint counsel read some of the text to you and I think suggested that your opinion was -- your interpretation of this is that the ad -- is suggesting an interpretation of the ad that I think is either inaccurate or incomplete, so let me just clarify.

Isn't it true that where it says "20 million of initial scientific research from leading universities" that that's referring to the -- in your view, the totality of the science generally of the research program?

A. Absolutely. Yes.

Q. Okay. But that, in any event, all the science is interrelated and including cardiovascular and prostate science is interrelated with all the other

aspects of science that POM has done, both at the basic level and, you know, labs and test tube level; is that correct?

A. It is completely interrelated. That's right.

MS. DIAZ: Okay.

Thank you, Your Honor. I have no further questions.

MS. VISWANATHAN: No, nothing further.

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

What's the status of your next witness?

MR. FIELDS: Your Honor, he was scheduled to be here at 11:30, so we called it pretty close.

JUDGE CHAPPELL: All right. Let's take our morning break. We'll reconvene at 11:45.

(Recess)

JUDGE CHAPPELL: Back on the record.

Who's the next witness?

MR. FIELDS: Our next witness, already in the witness box, is Dr. Jean DeKernion.

- - - - -

Whereupon --

JEAN B. DeKERNION, M.D.

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

DIRECT EXAMINATION

BY MR. FIELDS:

Q. Dr. DeKernion, would you state your full name for the reporter.

A. Jean B. DeKernion.

Q. Dr. DeKernion, is it correct that you have just retired as the chairman of the Department of Urology at the UCLA School of Medicine?

A. Correct.

Q. And are you still the senior associate dean for clinical affairs at that medical school, or have you just retired from that, too?

A. From that also.

Q. From that also. Okay.

And for how many years were you the head of the Department of Urology at the UCLA medical school?

A. 26.

Q. 26 years?

A. Yes.

Q. In addition to being responsible for the clinical and research education of the students and residents, is it correct that you have a busy practice in urologic oncology primarily related to prostate cancer?

A. Correct.

Q. You still maintain that active practice; is that correct?

A. Correct.

Q. Now, is it correct that you're from New Orleans and you got your medical degree from LSU, Louisiana State University?

A. Correct.

Q. And that was in 1965?

A. Right.

Q. Okay. And you did your residencies in surgery and urology at the University Hospitals of Cleveland and the National Cancer Institute?

A. Correct.

Q. And is it correct that you're board certified in both the American Board of Surgery -- by both the American Board of Surgery and the American Board of Urology?

A. Correct.

Q. And you are a member of the National Cancer Institute Clinical Trials Advisory Committee; is that so?

A. I was appointed to the National Cancer Advisory Board by President Bush, but I've finished that tour.

Q. Oh, okay.

So you were appointed by President Bush to the National Cancer Institute advisory committee and -- but that board term is over now?

A. Actually I finished my term about two years ago.

Q. I see. Okay.

And is it correct you are a scientist researcher for the Department of Defense?

A. I was. I've retired from that, thank you, but I was the chair of the Department of Defense prostate cancer integration research panel, correct.

Q. For the Department of Defense.

A. Correct.

Q. Okay. And you have been the editor or associate editor of various publications in your field, such as the American Journal of Urology, Current Problems in Urology, Urology Times, and Urological Research; is that correct?

A. Well, I've reviewed for a lot of journals, but I was the associate editor for the Journal of Urology for about five years.

Q. I see.

And is it correct that you've been a visiting professor at 50 different medical institutions, including M.D. Anderson in Houston, Stanford,

University of Pennsylvania, the Cleveland Clinic and others?

A. I don't know the number, but -- but yes, sir, a number of them.

Q. Is it fair to say a lot of different institutions?

A. Oh, yes. Uh-huh.

Q. And do they include M.D. Anderson clinic in Houston?

A. Yes.

Q. And Stanford University?

A. Yes.

Q. And the University of Pennsylvania?

A. Yes.

Q. And the Cleveland Clinic?

A. Yes.

Q. Okay. Is it correct that you've done both basic laboratory research and clinical research and that you've coauthored a book on urologic oncology? Is that correct?

A. Yes. I -- we -- we coauthored the first book on urologic oncology. I've been involved in other books, but that -- that particular one, I was the -- a coauthor, two authors.

Q. Is it correct you've written 133 chapters in

texts in your field?

A. I don't know the number, but that sounds right.

Q. Okay. It sounds right. All right.

And you may not remember this number either, but is it correct you've published 228 papers in peer-reviewed journals? Is that correct?

A. I -- yes.

Q. Okay.

A. I'm not sure of the exact number.

Q. All right. And that you have been a reviewer for some 20 review -- peer-reviewed journals?

A. Correct.

Q. Among the awards and prizes that you have received were the Johnson prize for research awarded by the Johnson cancer foundation; is that correct?

A. Correct.

Q. And the Hugh Hampton Young Award of the American Urological Association?

A. Correct.

MR. FIELDS: Okay. Your Honor, we offer Dr. DeKernion as an expert, and I believe that his report and CV are already in evidence.

MS. DAVIS: Your Honor, we'd just ask for clarification as to the area of expertise Dr. DeKernion is being offered for.

MR. FIELDS: He's going to talk about the prostate.

JUDGE CHAPPELL: Pretty broad. That's a pretty broad category.

MR. FIELDS: Well, he's going to talk about the experiments, the studies that have been done on the prostate by -- about pomegranate juice and POM products. He's going to talk about first the in vitro studies and then the animal studies and then the clinical studies and will give his opinion on the results of those studies and where they take us.

MS. DAVIS: No objection.

JUDGE CHAPPELL: All right. To the extent any opinions offered meet the proper legal standards, those opinions will be considered.

MR. FIELDS: Thank you, Your Honor.

BY MR. FIELDS:

Q. All right. Doctor, would you tell us about the -- a summary about the in vitro studies of the effect of pomegranate juice on prostate cancer cells.

A. The -- the initial studies were involved with in vitro, growing the human tumor cells in a petri dish in the lab, adding POM and POM products and determining the effect on the human tumor cells. And those initial studies showed a significant decrease in growth,

increase in apoptosis, which is programmed tumor death, decrease in inflammation, factors which are related to cancer.

The studies were then taken to a laboratory in vivo study, which is fairly standard. The human tumor is grown in immunodeficient mice, and so it has an environment, a milieu, to which it allows it to grow and behave as though it was growing in a human.

In those studies with what was called LAPC4, a particular tumor line that our laboratories devised some years ago with one of our patient's tumors, they demonstrated that when that tumor is grown in mice and is given -- the mouse is given pomegranate extract and pomegranate products that the tumors markedly decreased.

The further step was then to identify -- and a very important step -- why it happened, whether there are really good, solid scientific reasons, and there were. It was shown that, by a number of authors, that the POM products or extracts have a specific effect on certain tumor growth issues within the prostate and prostate cancer.

For instance, it was shown that not only in LAPC4 but in another human tumor, PC3, that the products had a specific effect. The polyphenols, which

are the main antioxidants in POM, the polyphenols had a significant effect on decreasing the function of what we would call oxidative stress factors.

Now, I don't want to -- you know -- oxidative stress factors basically are related to cancer. It's one of the reasons why inflammation now is important for cancer.

So when you have an oxidative stress situation, you have increased tumor cell proliferation or growth. And what happened with the POM extracts, it decreased the oxygen stress factors, decreased tumor proliferation therefore, as measured by various proliferation factors, and increased, on the opposite side, the incidence of cell death.

Further, another mechanism that was very important is the inhibition of NF-kappaB. Now, we've known many years NF-kappaB -- well, let's see how I can put it. It's a nuclear transcription factor.

Well, NF-kappaB in this -- when it's present in tumors, it stimulates -- to short-circuit, it stimulates tumor growth. And while it was clearly demonstrated that not only in the tumors treated with the POM was the NF-kappaB decreased, therefore causing decrease of tumor growth, but further it was shown that there was an absolute linear connection. In other

words, the actual mechanism was due to the polyphenols in the POM.

Now, the third part of this was there are other growth factors like -- and growth factors simply grow -- make tumors grow normally in the body by -- you know, it's unfortunate we have those, but they're for good use normally, but in a tumor situation they cause tumor growth.

So there were several growth factors, the EGF and TGF-beta, which are -- well, they're known in prostate cancer to stimulate growth. And those were actually interfered with by the polyphenols.

In every tumor system there's a cascade pathway, which it gets to be extraordinarily complicated as we learn more about it, but all along the way there are steps that are metabolic from this to this to this that end up in many case -- in certain situations or certain pathways causing tumor growth. And it was demonstrated -- it's called the MCODE pathway. It was demonstrated that interference with this pathway was -- was -- could be -- was attributed to POM polyphenols and therefore the decrease in tumor growth.

So that kind of summarizes a lot of more complicated stuff, but that basically gives the summary of it.

JUDGE CHAPPELL: I have a question.

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: You referred to oxidative stress factors?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Are these factors a physical manifestation or are these factors something that's detected in a lab test?

THE WITNESS: No. They're detected in multiple lab tests. They're not -- you don't -- it's not something you feel. You feel the result of it.

In other words, for instance, kidney cancer on some people now a lab discovered the association with certain molecules that increase oxidative stress and increase kidney tumor growth, but you don't feel anything from it.

JUDGE CHAPPELL: Is it -- are they a type of marker or indicator that turn up in a blood test?

THE WITNESS: They're -- they're an indicator -- well, let me -- we don't use them except to measure oxidative stress. There are certain tests like nitric oxide that you can measure in the blood, which is a measure of oxidative stress, yes, but we don't have a test that we use for humans that says this measures your oxidative stress and therefore. These are

all mechanisms by which tumors grow.

JUDGE CHAPPELL: Is there a normal baseline or benchmark for, let's say, a 30-year-old male what the stress factor marker or indicator should be?

THE WITNESS: No, sir. No, there is not.

BY MR. FIELDS:

Q. All right. And when you talked about the animal studies, I just wanted to make one thing clear.

These were not studies of animal glands, they were studies of human prostate tissue put into the animal; is that correct?

A. Yes, that's correct. Except for one, whatever mechanistic studies, where it was necessary to do to see if in a prostate, in prostate tissue, if you could have interference with the same kinds of factors in prostate tissue that was not cancer. And that was done in one paper, and they used -- they used a new mouse model and they used a wild-type mouse which was not immunosuppressed and demonstrated -- it's just to demonstrate that even in non-prostate cancer these pathways are interfered with. But all the -- all the ones that showed antitumor effect essentially were in human tumors.

Q. Human tumors.

A. Correct.

Q. Okay. Now, is it correct that at that point they progressed -- the people who were doing this science progressed to human clinical studies?

A. That's correct.

Q. And one of those studies was done by Dr. Pantuck at your school; is that correct, the UCLA medical school?

A. Correct.

Q. And would you explain, before we get into detail on that, what PSA doubling time is and how that affects people who have had cancer.

A. Well, the PSA doubling time is simply an expression of -- a mathematical expression of the rapidity with which the PSA is rising, and that is an expression of the rapidity of growth of the tumor cells and the number of tumor cells.

It's -- we used something like it for years. We've used PSA velocity in people who have their prostates, but they go and get screened -- and I sure hope we don't talk about screening here today -- but they get screened and they're found to have a PSA that's a little high, and you -- for whatever reason you don't do a biopsy, but you watch their PSA. And we use PSA velocity, a change in the PSA, to tell us that indeed they have a greater or lesser probability of having

cancer cells that are growing.

Now, that's called PSA velocity. It's not doubling time for a lot of reasons. PSA doubling time, again, is simply a measure in people especially who have had treatment, who have had their prostates removed, irradiated or frozen or what, an expression of, A, that there is residual cancer and, B, the rate at which it is growing.

Q. So is the doubling time for PSA a measure of the likelihood of recurrence of the tumor after a man has had his prostate removed?

A. Well, first of all, the presence of a detectable PSA after your prostate is removed indicates cancer, well, with one qualifier. There are a very small percentage -- in our studies it was a couple, 1 percent -- where the surgeon, maybe in an attempt to save the nerves, stayed a little too close to the prostate and he left a tiny bit of normal prostate, which will produce a very tiny fraction. But it doesn't go up; it stays the same.

So other than that, presence of a detectable PSA after prostatectomy means cancer is present. And then, once the cancer is present, the important thing to know is is it going to be a threat, and the PSA doubling time gives you an expression of how those tumor

cells -- they're microscopic -- how they're going to behave.

Q. And so is it correct that the longer the PSA doubling time, the less dangerous the growth of the cancer?

A. Yes, that's correct.

Q. And what did Dr. Pantuck's study show in that regard?

A. It showed that it decreased -- excuse me -- it increased the PSA doubling time. I don't recall the exact number.

Q. Was it fourfold?

A. Yeah, fourfold, up to 50 months or so.

And then an extension study, a follow-up study, then showed that a certain -- a number of those people who had a marked decrease in PSA were kept on it and followed, and they maintained their low level for an extended period of time.

JUDGE CHAPPELL: I have a question.

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: "PSA" stands for prostate-specific antigen?

THE WITNESS: Yes.

JUDGE CHAPPELL: Did I hear you say that someone who had a cancer and had the prostate removed, that

person still has a PSA score?

THE WITNESS: No, sir. They should not.

JUDGE CHAPPELL: So no prostate, there's --

THE WITNESS: No prostate, no PSA.

JUDGE CHAPPELL: You were referring then to people who might have been treated in another way without removal.

THE WITNESS: That's correct. Or people who have it removed and have some microscopic residual cancer. But -- but if a person has their prostate completely removed, they should have a zero PSA.

PSA -- you know, PSA -- PSA genes are in every cell in our body, but only prostate tissue cancer and prostate normal tissue actually produce the protein product, the PSA that you measure in the blood, so if the prostate and the prostate cancer are gone, it should be zero.

JUDGE CHAPPELL: Did I hear you say that if there's some cancer remaining you might still have a PSA score?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Even though the prostate has been completely removed?

THE WITNESS: Yes, sir.

What happens, when -- even when you take out a

cancerous solid tumor, whether it's breast or whatever, and you examine it, the pathologist says, "Well, you got it all. It looks good. All the margins are clear. The lymph glands are fine," and then the person shows up with a metastasis years later. What happened there was that those cells had been there the entire time, but they were too small and too few in number to be detected by x-ray.

Now, in prostate cancer we have a leg up, because if those cells are left behind, they will express, they will produce a little bit of PSA, so then you know that there's tumor somewhere.

JUDGE CHAPPELL: The reason I'm asking is I've seen/heard testimony in this case relating to PSA scores for people that have been treated. Now it's making sense.

MR. FIELDS: Yes.

BY MR. FIELDS:

Q. In other words, there still can be cancer cells that are microscopic, and the PSA will show that --

A. Correct.

Q. -- even after removal.

A. Yes, sir.

Q. Then you've got to look to the PSA doubling time to see how dangerous, in lay terms, that is.

A. Yes, you do, because it's microscopic.

Now, if you -- in lung cancer we don't have that nice marker, so you keep doing x-rays and until the tumor gets big enough you can detect it, and of course by that time it has -- even something that's very tiny has a lot of cells. But in prostate cancer, these microscopic areas actually are known because they express the PSA early. We have a -- it's a very good marker. Whatever else might be wrong with PSA, it is an excellent marker in this environment.

Q. When you say "marker," you mean something that is predictive of what your outcome is going to be.

A. Yes. It's a -- well, and also an indicator of recurrence.

JUDGE CHAPPELL: Do you have experience treating patients with prostate cancer?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: And do you rely on the PSA more so after treatment or before?

THE WITNESS: Well -- yes, sir, that's a -- actually let me answer it this way.

Before, it has a lot of qualifiers. I mean, sometimes it's elevated and there's no cancer; other times it's not elevated and there's cancer. But we do rely on it. It's important. It's a qualified marker of

cancer, qualified.

Once the prostate is removed completely, there's no qualification. It shouldn't be there.

So if it is there, then there's cancer, so...

JUDGE CHAPPELL: If you were going to conduct a study with something like POM juice, would the study be more effective with someone with or without prostate cancer?

THE WITNESS: Well, if -- if you want to demonstrate it has an effect on tumor cells, you really -- first of all, you should -- you wouldn't want to substitute it for -- for the legitimately hormone treatment or surgery. You wouldn't substitute even -- you wouldn't do anything except standard treatment if you are positive there is cancer there.

JUDGE CHAPPELL: You're not going to ask the control group to do without medicine.

THE WITNESS: No. No. No. No.

Now, on the other hand, what we've found in the data -- I shouldn't say "we"; I didn't do it -- but what has been shown is that it has effect on tumor, microscopic tumor, so one could then argue that it might be good for people who have their prostates who don't have known cancer. But -- and in that sense it could make -- it is a very good idea perhaps.

But in terms of -- if you want to show an effect of POM on cancer, the best way is to do it in a pure form, where the prostate is gone, the presence of a PSA elevation is an absolute indication as cancer, and it can't be due to anything else, and that PSA that's expressed, any alteration in it could be attributable to what kind of treatment you're doing, so that's where you'd start anyway.

JUDGE CHAPPELL: Has that study been done?

THE WITNESS: The study about -- for the --

JUDGE CHAPPELL: The one you just referred to as, in your opinion, the best case.

THE WITNESS: Yes. These are the studies that Pantuck and Carducci did. They took a population of people who should have been cured by every criteria except their PSA was detectable when they came back to see their doctor, which indicated they had microscopic cancer somewhere. And yes, that's the purest kind of treatment, so that's what they did. They then treated these folks with POM, and they showed that it slowed down the growth of the tumor cells as expressed by the longer time it took for those tumor cells to double.

BY MR. FIELDS:

Q. All right. We talked about Dr. Pantuck's study.

Would you tell us briefly about Dr. Carducci's study at Johns Hopkins.

A. Well, Dr. Carducci, he tested two strengths of POM extract, I think one versus three grams. I'm not positive. He also expanded -- he used a multicenter study, so he had -- I don't know. Gosh, he must have had 15 centers contributing patients. And he also spread out the criteria. He said, well, we'll take higher-risk patients. And also the age group was older. I think a mean age of 73.

The net result of that study was that there wasn't any difference between the two doses, but there was an almost doubling of the median, of the mean PSA doubling time.

He also -- in addition, he did some of the basic lab studies which I -- the same thing I mentioned earlier about the basic science.

Q. Right.

So he got a similar result to the result that Dr. Pantuck at UCLA got?

A. No. Dr. Pantuck had a more -- more profound effect. And that isn't unusual at all, I mean, because that Pantuck study was a small population, which was still statistically significant, but it was a single institution. When you branch out a study into multiple

institutions, I mean, it's the rule rather than the exception that the results are not quite as good because you have such a mixture. No matter how you set the criteria, you have a mixture of patients coming in. And they were higher-risk patients.

Q. All right. Now, in each case, with Dr. Pantuck and Dr. Carducci, the control was the previous growth, previous doubling time prior to treatment; is that correct?

A. That's correct.

Q. And so you're measuring the doubling time before they took the POM and then the measuring time after they took the POM --

A. Correct.

Q. -- comparing one to the other?

A. Correct.

Q. That was true with both studies?

A. Yes.

Q. Okay. And that was in lieu of a separate placebo group; is that correct?

A. That's correct.

Q. Now, in the -- is it correct that the use of a placebo group is more important when you have a subjective reporting as opposed to an objective reporting?

Do you understand my question?

A. Yes, I do.

Yes. I think especially if you have a drug with toxicities it's extremely important you have a placebo because it frames the subjective effects of the drug against a group who might express some of the headache or nausea who didn't even get the drug, so it gives you a real measure of the toxicity of the drug.

Q. In other words, is it correct that when you have something subjective like pain or nausea, it's important to have a placebo group because people may be reporting something they don't really feel or -- but does that apply to prostate? Is there anything subjective about whether your prostate doubling time increases or decreases?

A. No. No. You have no -- there's no symptoms, no -- no knowledge or subjective feeling about it, no, or objective feeling.

Q. Okay. Now, in the case of something like fruit juice that has low or no toxicity at all, is it necessary to have a -- what we call an RCT, that is, a placebo-controlled kind of test?

A. Well, in my opinion, no. Well, no.

Q. Okay. It's your opinion we're looking for right now.

A. I think that -- there's a lot of reasons to that obviously.

Q. In your opinion, based on all of the science that you've talked about, is it likely that POM or POMx will improve the chances of avoiding or deferring the recurrence of prostate cancer in men who have had a radical prostatectomy?

A. Yes.

Q. And is that a matter of high probability?

A. Yes.

Q. Now, a somewhat different question. I think the court was alluding to this to some extent.

Based on all of these studies that you've told us about, is it your opinion that the same mechanisms that you've described would result in pomegranate juice inhibiting the clinical development of prostate cancer in men who have not been diagnosed with prostate cancer?

A. Yes.

Q. Is that a matter of high probability in your opinion?

A. Yes, it is.

MR. FIELDS: That's all I have.

JUDGE CHAPPELL: Will there be any cross?

MS. DAVIS: Yes.

- - - - -

CROSS-EXAMINATION

BY MS. DAVIS:

Q. Good afternoon, Dr. DeKernion.

A. Good afternoon.

Q. Dr. DeKernion, would you agree that there is no clinical study, research or trial proving that POM juice prevents prostate cancer in humans?

A. Yes.

Q. And would you agree that there is no clinical study, research or trial proving that POMx pills prevents prostate cancer in humans?

A. Correct.

Q. Would you -- you would agree that there is no clinical study, research or trial proving that POMx liquid prevents prostate cancer in humans.

A. Correct.

Q. And you would agree that there is no clinical study, research or trial proving that POM juice reduces the risk of prostate cancer in humans.

A. Correct.

Q. And you would agree that there is no clinical study, research or trial proving that POMx pills reduces the risk of prostate cancer in humans.

A. Correct.

Q. And you would agree that there is no clinical study, research or trial proving that POMx liquid reduces the risk of prostate cancer in humans.

A. Correct.

Q. And you would agree that the results of animal and in vitro studies can't always be extrapolated to a response in humans; is that correct?

A. I'm sorry. Did you say "can" or "can't"?

Q. Cannot.

A. Cannot.

Q. Cannot always be extrapolated to a response in humans.

A. I would -- my answer to that is yes, but the -- not always but most of the time, if the mechanisms are clearly defined as they are in here.

Q. And you would agree that even where the animal and in vitro evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that an agent works in humans; is that correct?

A. I'm sorry. Repeat that, will you? I'm sorry.

Q. Sure.

You would agree that even where the animal and in vitro evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove

that an agent works in humans.

A. Correct.

Q. And you are familiar with the selenium and vitamin E prostate cancer clinical trial?

A. I am.

Q. Okay. And in that instance, the animal and in vitro studies indicated that selenium and vitamin E would have an effect on prostate cancer; is that correct?

A. Correct.

Q. But the human trials failed to show a similar effect; is that correct?

A. That's correct.

Q. And you would also agree that there's no research in humans showing that POM can kill a tumor cell; is that correct?

A. Well, I would qualify that. I think in humans you -- especially in microscopic tumor you don't have a cell that you can measure and watch it die, but when you have evidence, as with the doubling time or the PSA itself, that the agent is having an effect on that, they -- that marker, the implication -- well, the extrapolation, which I think is safe, is some tumor cells are -- either their growth is being slowed or the tumor cells are being killed, either one.

Q. But again there's no clinical research demonstrating that; is that correct?

A. Well, I -- I think there really is. I think the fact that patients who are given POM and then they -- their PSA goes down, that is significant evidence that something is happening to those tumor cells.

And just to follow up on that, as you probably know, years ago, some -- I was involved in some of the research -- we found that finasteride lowered the PSA in patients like this, and that was the basis -- the assumption there was that it had an effect on tumor cells, and that was the basis for the clinical trial which then later went on to show that finasteride prevented prostate cancer.

So it's pretty darn good evidence that when the PSA goes down, some of the cells are being killed or they're put into cell arrest in some form. And as I'm sure has been talked about here, killing a tumor cell now is not always the goal. If we can arrest tumors in people for a long time with a good quality of life, which is how most of the new drugs is what they do, then we -- that's a laudatory goal.

Q. And the study showing that finasteride either prevented or reduced the risk of prostate cancer, that

was a randomized, double-blind, placebo-controlled trial was it not?

A. That was a randomized, double -- no. Excuse me. If I might say that the reason it was is that finasteride is a prescription drug, which also has side effects, and in that situation -- especially sexual side effects, and in that situation it was very important to have a placebo control.

Q. Now, Dr. Pantuck's study was a phase II trial; is that right?

A. I'm sorry -- yes, it was a phase II.

Q. And phase II trials often do not include a placebo arm or second treatment arm since they are exploratory; is that correct?

A. Since they are -- I'm sorry -- what?

Q. Since they are exploratory; is that correct?

A. Yes. Okay. Yes.

Q. And Dr. Pantuck's study lacked a placebo arm; is that correct?

A. Correct.

Q. And with only one arm, there obviously can be no randomization; is that right?

A. That's correct.

Q. And the purpose of a placebo control group in clinical studies is to limit confounding factors; is

that correct?

A. That's one, yes.

Q. And there are lots of variables which may affect prostate cancer growth; is that correct?

A. Well, I wouldn't say there are lots of them, but there are -- we -- there's been evidence that some things do affect the PSA in these patients, which, again, the extrapolation is it affects the tumor growth.

Q. And exercise may affect the cancer growth; is that right?

A. Exercise has been shown to change the PSA doubling time in some patients, right.

Q. And there's some research that indicates that a low-fat diet can reduce the growth of prostate cancer cells; is that right?

A. Correct.

Q. And without a placebo control arm, it's not possible to control for confounding factors; is that correct?

A. Yes, that's correct.

Q. Now, Dr. Pantuck's studied 46 men who had been treated for prostate cancer with either a radical prostatectomy and/or radiation therapy; right?

A. That's correct.

Q. And they had a rising PSA after treatment; right?

A. Correct.

Q. But they had no evidence of metastasis or clinical disease which could be observed on a -- or detected on an x-ray; is that right?

A. Correct. Correct.

Q. Dr. DeKernion, I'd like to show you what's been marked as PX 0172.

And if you need a hard copy --

A. No.

Q. -- we can provide that.

A. No. I'm familiar with the study.

Q. Okay. And just for the record, PX 0172 is a copy of an article reporting on a study by Smith, et al., titled Rosiglitazone versus Placebo for Men with Prostate Carcinoma and a Rising Prostate-Specific Antigen Level After Radical Prostatectomy and/or Radiation Therapy; is that right?

A. Correct.

Q. And you are familiar with this article.

A. Yes.

Q. And this was a randomized, double-blind, placebo-controlled study; correct?

A. Correct.

Q. And this was a study of 106 men who had been treated for prostate cancer with either a radical prostatectomy and/or radiation therapy; is that right?

A. That's correct.

Q. And they also had a rising PSA after treatment.

A. Correct.

Q. And they had no evidence of metastasis or clinical disease; is that correct?

A. Correct.

Q. So the population studied in the rosiglitazone study is similar to the patient population in Dr. Pantuck's study in that the patients were at the same -- were in the same disease stage; would that be correct?

A. As I recall, that's correct. They were all recurrent, PSA-recurrent.

Q. Okay. And the rosiglitazone study had two arms, a treatment arm and a placebo arm; is that right?

A. Correct.

Q. And patients were randomly assigned to either the treatment or placebo arm; is that right?

A. Correct.

Q. And the patients in the treatment arm were treated with rosiglitazone?

A. Right.

Q. And patients in the second arm received a placebo.

A. Correct.

Q. And the primary endpoint of this study was the change in PSA doubling time; is that right?

A. Correct.

Q. And a positive outcome was defined as a posttreatment PSA doubling time of greater than 150 percent of the baseline PSA doubling time with no new metastasis.

A. Correct.

Q. Okay. And that would mean that the PSA doubling time had increased. That would be the positive outcome; is that correct?

A. That's correct.

Q. And after treatment with rosiglitazone and placebo, 40 percent of the men in the placebo group had a posttreatment PSA doubling time of 150 percent; is that correct?

A. Excuse me. I don't remember the exact number, but --

Q. Okay. Well, we can blow up the results section.

A. Yes. I see it, yes. That's -- I see it now. 150 percent, correct.

Q. Okay. So 40 percent of the men in the placebo group had an improvement and 38 percent of the men in the treatment group also had a posttreatment PSA doubling time of 150 percent; is that correct?

A. Correct.

Q. So that both groups -- so for both groups the PSA doubling times improved; is that correct?

A. That's correct.

Q. And there was no statistically significant difference between the treatment and the placebo arm in the improvement of PSA doubling time; is that right?

A. That's correct.

Q. And actually the placebo group experienced a greater improvement; is that right?

A. I don't recall that there was greater improvement, but --

Q. Well, strike that.

More men in the placebo group had experienced an improvement than the men in the treatment group.

A. Okay. I think that's correct.

Q. Okay. If we could turn quickly to table 1 on page PX 0172-0004.

Sorry.

Okay. So table 1 shows the baseline characteristics for both the treatment group and the

placebo group; is that right?

A. That's correct. Yes.

Q. And if you could look down near the bottom, they give the baseline characteristics for both groups for PSA doubling time.

Do you see that?

A. Yes. Uh-huh.

Q. And the median PSA doubling time for the treatment group was 7.6 months; is that right?

A. Correct.

Q. And the median for the placebo group was 8.8 months; is that correct?

A. Correct.

Q. And the median baseline of Dr. Pantuck's study population was 15 months; is that right?

A. Correct.

Q. So the patients in the rosiglitazone study were actually at a higher risk of clinical progression; is that right?

A. Well -- yes. I think that, you know, you could probably extrapolate that.

Q. So even patients with a higher risk of clinical progression saw improvement in PSA doubling time with no intervention; is that right?

A. I'm sorry. You said what?

Q. Sure.

So even the patients with a higher risk of clinical progression saw an improvement in PSA doubling time with absolutely no intervention; isn't that correct?

A. Well, I don't know if absolutely no intervention, but yes, in the placebo group.

Q. And if we could turn to page 5.

I'm just going to blow up the paragraph I want to direct your attention to.

And the authors of the study stated that the high rate of positive PSA doubling time -- the authors, on page 5, stated that the high rate of positive PSA doubling time outcomes may reflect the limited precision of repeat PSA doubling time assessments; is that correct?

A. Yes.

Q. And they also said that alternatively, they theorized that the higher than expected rate of positive PSA doubling time outcomes may be related to the placebo effect; is that correct?

A. That's what they say, uh-huh.

Q. Dr. DeKernion, I want to show you --

A. Excuse me. Can you put that paragraph back on?

Q. There's no question pending. I'm ready to move

on to the next exhibit.

A. Okay.

Q. Now, Dr. DeKernion, I'd like to --

MR. FIELDS: Your Honor -- excuse me one second -- I think that the witness wanted to have a copy of this. He's being cross-examined about it without having it in front of him. I think we should give him a copy, Your Honor.

MS. DAVIS: Your Honor, I did offer that to Dr. DeKernion at the very beginning of the examination, and he declined. Of course we could provide him a copy, but when I asked him, he indicated to me that he could see it on the screen, so we were not trying to be difficult in not providing him with a copy. I did ask him.

MR. FIELDS: I certainly didn't mean to cast aspersions on counsel. The witness said, "Could I see that page, and counsel declined to let him see it, and he doesn't have it in front of him.

JUDGE CHAPPELL: Doctor, why did you ask to see it again?

THE WITNESS: Because I wanted to look again at the last part of the paragraph.

JUDGE CHAPPELL: Regarding the last answer you gave?

THE WITNESS: Yes.

JUDGE CHAPPELL: Let's do that.

MS. DAVIS: Okay.

(Pause in the proceedings.)

THE WITNESS: Can I comment on this?

JUDGE CHAPPELL: Why don't we have the court reporter repeat your last question and hear his response.

MS. DAVIS: Okay.

(The record was read as follows:)

"QUESTION: And they also said that alternatively, they theorized that the higher than expected rate of positive PSA doubling time outcomes may be related to the placebo effect; is that correct?

"ANSWER: That's what they say, uh-huh."

THE WITNESS: May I comment?

JUDGE CHAPPELL: Well, is that not a correct answer? Do you want to change your answer?

THE WITNESS: The answer to that -- no.

JUDGE CHAPPELL: You can only respond to a pending question.

THE WITNESS: Okay. All right. I can't -- no, I don't want to change that answer.

JUDGE CHAPPELL: Okay. Thank you.

I'm sure anything else you want to say will be

brought out by counsel representing the respondent.

THE WITNESS: Okay.

BY MS. DAVIS:

Q. Dr. DeKernion, I'd like to show you another study, that's been marked CX 2087.

Would you like a copy of it? It's up on the screen, but we will provide you a copy if you'd like one.

A. No. I can read it.

Q. And CX 2087 is a copy of an article reporting on a study by Smith, et al., titled Celecoxib versus Placebo for Men with Prostate Cancer and a Rising Serum Prostate-Specific Antigen After Radical Prostatectomy and/or Radiation Therapy; is that correct?

A. Correct.

Q. And you are familiar with the celecoxib study; is that right?

A. Yes.

Q. And again, this is another randomized, double-blind, placebo-controlled study; is that correct?

A. Correct.

Q. And here it was a study of 78 men who had been treated --

MR. FIELDS: Could we have a copy of that?

MS. DAVIS: I'm sorry. Sure.

BY MS. DAVIS:

Q. And again, this was a study of 78 men who had been treated for prostate cancer with either radical prostatectomy and/or radiation therapy; is that right?

A. Correct.

Q. And they also had a rising PSA after treatment; right?

A. Correct.

Q. And no evidence of metastasis or clinical disease which could be seen on an x-ray; is that right?

A. Correct.

Q. So again the patient population in the celecoxib study is similar to the patient population studied in Dr. Pantuck's phase II study in that the patient population was at the same disease stage; is that correct?

A. Yeah, that's correct.

Q. And the patient population in the celecoxib study is also similar to the population studied in the rosiglitazone study; is that right?

A. Correct.

Q. And again, the celecoxib study had two arms, a treatment arm and a placebo arm; right?

A. Correct.

Q. Patients were randomly assigned to either arm; is that right?

A. Correct.

Q. One arm was treated with celecoxib and the other arm received a placebo; is that right?

A. Correct.

Q. And again, the primary endpoint of this study was a change in PSA doubling time; is that right?

A. Correct.

Q. And here, a positive outcome was defined as posttreatment PSA doubling time of greater than 200 percent baseline with no new metastasis; is that correct?

A. Correct.

Q. And so that would mean that the PSA doubling time improved or got longer; is that correct?

A. Correct.

Q. And after treatment, the PSA doubling time in both the celecoxib group and the placebo group increased; isn't that correct?

A. Correct.

Q. So this is the same pattern of PSA doubling time improving in both the treatment groups and the placebo groups that we saw in the rosiglitazone study; is that correct?

A. Correct.

Q. And I'd like to direct your attention to page 4.

And again on page 4, again the authors state or theorize that the high rate of prolongation may be related to a placebo effect; is that correct?

A. That's what they say.

Q. Okay. Now, the authors of both the rosiglitazone study and the celecoxib study -- the lead author is Dr. Matthew Smith; is that correct?

A. Correct.

Q. And he's a well-respected oncologist and researcher; is that right?

A. I don't know him, but I know the other author, Dr. Kantoff.

Q. And Dr. Kantoff is also a well-respected oncologist and researcher and expert in prostate cancer; is that correct?

A. Correct.

Q. Okay. Dr. DeKernion, I want to go back to the conclusion of the rosiglitazone study just for a minute.

If you could turn to page 6 of PX 0172.

And on page 6, the authors state (as read): The discordance between baseline and posttreatment PSA

doubling time in our placebo group suggests caution... in PSA doubling time as an outcome in uncontrolled trials and reinforces the value of randomized, placebo-controlled trials in this setting.

Is that what they concluded?

A. That's what they said, yes.

Q. Okay. Dr. DeKernion, I'd like to go to the Pantuck study, which we will show you. We can provide you a copy as well. That is the CX 01 -- 0815. Sorry. Exhibit CX 0815.

A. Can you enlarge that, please?

Q. Sure, we will. I want to call out...

(Pause in the proceedings.)

Okay. Dr. DeKernion, we're going to look at page 8 of the Pantuck study. And we're going to blow up the last several lines of the first column.

And in this paragraph Dr. -- let me know when you've found it. I don't want to go ahead until you -- we're all on the same page.

A. Yeah. Okay.

Q. And if we could go -- there's a sentence there -- near the bottom, Dr. Pantuck is discussing the rosiglitazone study we just discussed; isn't that correct?

A. Correct.

Q. And about the rosiglitazone study Dr. Pantuck wrote that the study highlighted the potential limitations of PSA variables in monitoring patients and the need for confirmatory prospective studies using a blinded control arm; is that correct?

A. Correct.

Q. Now, Dr. DeKernion, based on the results of these studies, wouldn't you agree with Dr. Smith, Kantoff and Pantuck's conclusion that a placebo control arm is needed when PSA doubling time is the study endpoint to assess the efficacy of the product or therapy being studied?

A. No.

Q. Now, Dr. Pantuck testified in his deposition that the greatest limitation of the phase II study on POM juice is the lack of a blinded control arm.

Do you agree with him?

A. I think a blinded control arm is good for any study when it's necessary and/or feasible.

Q. Now, isn't it possible that given an intervention, any intervention, including placebo, can have an effect on PSA doubling time?

A. I don't think any intervention can, and the reason I say that is, first of all, that anti-inflammatory study, we know that it has an effect

on PSA -- on the cancer, and so I think that it would be expected to prolong PSA doubling time. And as far as the ros- -- it's got a trade name I'm more familiar with. It's an antidiabetic.

Do you remember that trade name?

Q. No. I'm sorry. I don't.

A. Rosiglitazone. That particular study, it is -- it is so that it would suggest that you don't always -- you can't always rely on PSA doubling time, but there's one -- one thing that still I would come back to and the reason that I would support it is that in this case of POM, backing all of this up is a whole body of undeniable basic research in human tumors which shows the mechanism of action, which shows the inhibitory effect. It isn't just taking something and giving it to somebody and then looking for other issues.

The other -- the other point of this is the population that was studied, they do look somewhat similar. But I'm not sure they weren't similar. I'm not sure that -- that those people didn't change lifestyles significantly more than others did. I mean, I would have no idea. And I think one study that calls to question a serum marker is just not sufficient to say that the other studies are -- are not valid.

Q. Now, the population that Dr. Pantuck studied,

this was a group for which there was no I guess standard of care for that -- at that particular moment in time; is that right?

A. That's correct.

Q. So correct me if I'm wrong. My understanding that it is ethical -- it would be ethical to give a placebo if you were trying to study that population, that it's -- is that correct?

A. It would certainly be acceptable. But the problem is that when you have something that's not a prescription agent and you expect people to not go to the Internet or the corner drugstore and pick up the drug off the counter, it's very hard to do those kind of trials.

People, if they -- if you say, well, we want to test this thing you can buy in your nutri-pharmacy store and we don't know if you're going to get the real thing or not, but we think it works, so we're going to do this, and you might get a placebo, they'd go out and get the real thing.

Q. Now, PSA doubling time is considered to be prognostic by experts in the field of prostate cancer; is that right?

A. Yes, it is.

Q. Okay. So if a man has been treated for prostate

cancer and then his PSA begins to rise after treatment, the clinician would use the PSA doubling time to make a risk assessment about the likelihood of clinical progression and/or death from prostate cancer; is that right?

A. Correct.

Q. Okay. And so as a clinician, when a patient has a biochemical recurrence of PSA, you would calculate his PSA doubling time at the time of recurrence, and then, depending upon the value, you would make a determination about whether to commence further treatment; is that the way it works?

A. Whether to do what? I'm sorry.

Q. Whether to commence further treatment.

A. That's correct.

Q. And experts in the field of prostate cancer would consider patients with a PSA doubling time of less than three months at the time of biochemical recurrence to have a very high-risk of clinical progression; is that right?

A. Yes.

Q. And so for that type of patient, as a clinician, you would probably initiate further treatment right away; is that right?

A. Yes. Uh-huh.

Q. Now, experts in the field of prostate cancer would consider patients with a PSA doubling time of 15 months to have a lower risk of clinical progression; is that right?

A. Correct.

Q. And for these patients you would watch and wait; is that correct?

A. Yes. You have a discussion with the patient, and you decide what you are going to do. Most of the time you would not institute toxic therapy.

Q. And it's true that few prostate cancer deaths occur in those with long PSA doubling times; is that correct?

A. There are a few, but they do occur. They've been documented many times. If you want me to review that, I could. Yes, the number is down, but it's not zero.

Q. Now, the majority of men in the Pantuck study -- I believe it might have been 68 percent -- were actually treated with a radical prostatectomy; is that right?

A. Correct.

Q. And radical prostatectomy is currently the most common treatment for prostate cancer; right?

A. Yes. In this country. Uh-huh.

Q. And a large percentage of men who actually undergo a radical prostatectomy are cured; isn't that correct?

A. Correct.

Q. Now, in your report, in the report you prepared for this case, you had referenced a study by Pound, titled Natural History of Progression After PSA Elevation Following Radical Prostatectomy; is that right?

A. Correct.

Q. And in the Pound study, they followed 1,997 men after radical prostatectomy and found that 82 percent of the men remained metastasis-free 15 years after surgery; is that right?

A. Correct.

Q. And only 15 percent of the patients that underwent a radical prostatectomy for clinically localized prostate cancer developed a biochemical recurrence or a PSA rise; is that right?

A. Correct.

Q. And only 34 percent of that 15 percent went on to develop metastatic disease or a -- or have clinical progression; is that right?

A. Correct.

Q. So isn't it true --

JUDGE CHAPPELL: How much more time do you think you'll need for your cross?

MS. DAVIS: A little bit more -- yeah, I'm probably only about halfway through, so I guess 30 to 45 minutes.

JUDGE CHAPPELL: All right. Were you finished with the line of questions you were pursuing?

MS. DAVIS: Yes. This would be a good stopping point.

JUDGE CHAPPELL: All right. We'll reconvene at 2:00 p.m.

(Whereupon, at 12:58 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(2:13 p.m.)

JUDGE CHAPPELL: Back on the record.

Are you ready?

MS. DAVIS: Before we start, our tech person had a medical emergency during the break, and we can't access TrialDirector right now. We're trying to contact her to get the password, so we didn't want to wait. We'll just proceed but just using hard copies, if that's okay, if that's permissible.

JUDGE CHAPPELL: Old school? Sure, that's permissible. Look forward to it. Go ahead.

MS. DAVIS: Okay.

BY MS. DAVIS:

Q. Dr. DeKernion, before the break, we talked about the fact that not every patient who has a biochemical or PSA recurrence will eventually develop metastatic disease or have clinical progression; correct?

A. Correct.

Q. So we can't say for certain that the patient population in the Pantuck phase II study would ever experience clinical progression; is that right?

A. In that study, correct, because they haven't been followed long enough.

Q. And you are not aware of any studies or research

proving that therapies which prolong PSA doubling time will prevent a clinical -- will prevent a clinical recurrence; is that correct?

A. Well, there are studies that have shown that a treatment that has an impact on PSA doubling time does influence the outcome, and certainly we know all the data, that if it's a very short PSA doubling time, the outcome is poor, so we start treatment earlier.

So if you extrapolate from that, from that, then a little longer PSA doubling time may not be as much of a threat, but certainly it still reflects that that person is at risk for developing recurrence once you've followed them long enough.

Q. Okay. But my question was, you are not aware of any study or research proving that therapies which prolong PSA doubling time will prevent a recurrence; is that correct?

A. Will prevent recurrence?

Q. Yes.

A. Only to the extent that in PSA with a shorter doubling time, definitely those who are treated and who have a response will do better.

MS. DAVIS: I'm sorry, Your Honor. I was trying to review Dr. DeKernion's answer to my question, but I'm having a little problem with the -- it's not working at

all? Okay.

So it's just my day with technical difficulties I guess.

BY MS. DAVIS:

Q. Dr. DeKernion, do you recall that I took your deposition in April of this year?

A. Correct.

Q. Okay. And I'm going to refer to PX 0351, transcript page 114 lines 9 through 12.

A. Page 114.

Oh, okay. Excuse me. I see the numbers now. Okay.

114 lines 1 through 10?

Q. Sorry. No. It's lines 9 through 12.

A. Okay.

Q. And at that time I asked you:

"QUESTION: Are you aware of any studies or any research which proves that therapies which have an effect or modulate PSA doubling time will prevent a recurrence?

"ANSWER: No."

Dr. DeKernion, isn't it true that there are no studies which demonstrate that a therapy which prolongs PSA doubling time results in longer survival?

A. If we're talking about prolonged -- a long PSA

doubling time, that is exactly correct.

Q. Dr. DeKernion, I'm going to refer you to page 52 of your deposition transcript.

A. Uh-huh. Okay.

Q. Starting at line 25, carrying onto the next page.

At that time I asked you:

"QUESTION: Dr. DeKernion, are there any studies which demonstrate that a therapy which affects PSA doubling time results in longer survival?"

And your answer was: "No."

A. Yes. And if we're --

Q. Now, Dr. DeKernion --

MR. FIELDS: If that was a question, the witness should be allowed to complete his answer, Your Honor. Counsel cut him off in mid-sentence.

MS. DAVIS: I thought he finished his answer.

Or, rather, I finished my impeachment of Dr. DeKernion. I didn't think there was a question pending for him to answer.

JUDGE CHAPPELL: Well, it was open-ended because you didn't ask the follow-up.

For example, you didn't say, "Is that what I asked and what you answered on that day?" I didn't hear that, so it was open-ended when the man started to

speak.

MS. DAVIS: Okay.

JUDGE CHAPPELL: So you need to let him speak or -- what were you going to say, sir?

THE WITNESS: I was going to say that during the deposition, as I -- and maybe I'm recalling -- we were really addressing the issue of these studies which showed a change in the PSA doubling time across the board, in which case certainly in people with a long PSA doubling time there's been no evidence that that is the case.

But the point I wanted to make is that people with a short PSA doubling time and -- or a shorter time, who undergo therapies with whatever, their PSA goes down, provided they have a response, so in that sense, yes, the PSA is indeed a measure of the response to treatment.

BY MS. DAVIS:

Q. Dr. DeKernion, are you talking about the -- and when you're talking about these studies that showed a change, which studies are you referring to?

A. The studies of the short term?

Q. Yes.

A. Yeah. Well, as we've talked about before, people with a short doubling time is an indication for

therapy, those people who have generally aggressive treatment with hormones, hormones plus chemotherapy, chemotherapy alone.

Now, with PSA doubling time, you can't use it in that context because they were people who respond, most of them, their PSA falls. Now, you can't measure the doubling time because it falls. You can only measure doubling time if it doubles.

So the reason I'm qualifying the answer is that if you were asking me in this context of these patients in these trials, Pantuck, Carducci, et cetera, with very long, you know, potential survival, has any treatment in those people been shown, any of the treatments we're talking about, to prolong their lives or to cure their lives, the answer to that is that evidence is not available now, correct.

Q. Okay. Thank you.

Now, Dr. Pantuck testified in his deposition that although PSA changes are thought to be prognostically important, it's based on level two evidence, and nobody has ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful.

Do you agree with him?

A. I agree that to the extent that most of the

trials that they've talked about, when -- and you know them -- when they've treated people with advanced disease, they have not shown a relationship with a PSA doubling time, which is not particularly surprising because, as I said, it's hard to measure doubling time in those people.

And furthermore, treating people with a lot of tumor burden is a great deal different than treating people with microscopic tumor.

So I hope that answers your question.

Q. Okay. Thank you.

So Dr. Pantuck studied patients who had a baseline of 15 months PSA doubling time, and we've already discussed the fact that patients with a long PSA doubling time have few cancer-related -- fewer -- few prostate cancer-related deaths, so even if POM juice had an effect on PSA doubling time, isn't it true that these patients wouldn't necessarily be benefit -- benefited by POM in terms of survival?

A. Well, I think -- I think that -- well, is it possible? I think that's so. But, again, the reason I support the concept of the POM is that even though in all the studies that have been published a small percent of people, for instance, in the Aronson and Teeter study, only about 5 to 8 percent of people with a very

long PSA doubling time died of prostate cancer.

Now, would POM have changed that? I'm not sure. But it is reasonable to assume that if it really affects behavior of the cancer, it would be helpful for those people and certainly not harmful.

Q. Dr. DeKernion, I'd like to show you -- go back to page 815 of the -- sorry. I would like to turn your attention back to CX 0815.

A. Okay.

Q. And I'd like to turn to page 8 of the Pantuck study and would like to look at the conclusion.

A. What page is that -- oh, you have it. Okay.

Q. CX 0815 and it's page 8.

A. I don't have the pages here, but it's the conclusions. That's fine. Okay.

Q. And it's also on the screen.

A. Uh-huh.

Q. Okay. And the conclusion of Dr. Pantuck's article states, in part -- states (as read):

This study shows statistically significant effects on PSA doubling time coupled with corresponding effects on prostate cancer in vivo (sic) cell growth and apoptosis. These proposed benefits, however, are in assays that are as yet unvalidated, and further research is needed to prove the validity of these tests and to

determine whether improvements in such biomarkers (including PSA doubling time) are likely to serve as surrogates for clinical benefit.

A. Uh-huh.

Q. Do you agree with Dr. Pantuck's conclusions?

A. No. Not entirely.

Q. Okay.

A. If he's talking -- I don't know what he's talking about here, but if he's talking about the use of in vitro models and human models in immunosuppressed mice, that's totally validated. I think he's probably referring to a couple of the assays that they developed looking at the ellagitannins, the polyphenol measures, so that I would believe, but all these others are well-established.

Q. And isn't it true that PSA doubling time is not accepted by experts in the field of prostate cancer as a surrogate endpoint for clinical benefit in prostate cancer treatment trials?

A. Yes. That is absolutely so because he's referring to treatment trials I referred to, the large chemotherapy trials, in which case I wouldn't expect it to be valid either. In fact, we don't use it.

Q. Now, earlier you talked about Dr. Carducci's study.

A. Uh-huh.

Q. And Dr. Carducci's study looked at the effect of POMx on rising PSA, and that was also a phase II study; is that right?

A. Correct.

Q. Okay. And it was a study of 104 men with a patient population that was similar to the patient population of the Pantuck phase II study; is that right?

A. They were only similar in the sense that they were -- in the broad sense that they were recurrent, PSA-recurrent after treatment. However, as I mentioned earlier, they were a hetero- -- more heterogeneous population. They were older. They were at a higher risk. Yeah.

Q. And there were only two arms in the study.

One armed looked at one POMx pill, and the other arm looked at three POMx pills; is that right?

A. Correct.

Q. And there was also no placebo arm in this study; is that right?

A. Correct.

Q. And the men in the Carducci study were -- strike that.

The study was designed to treat men for

18 months or until progression; is that right?

A. Correct.

Q. And only 36 percent actually completed the 18-month study; is that right?

A. Well, that, I'm not sure about. They entered a hundred-and-something, and at some point they did an interval analysis, and the interval analysis showed a significant change.

So I'm -- and -- and the fact is the idea was to treat for the full length, but at an interval analysis, if you see a significant effect, you terminate the study.

Q. Okay. But as far as we know, Dr. Carducci's study was not terminated early, do we, as far as you know?

A. Was not what?

Q. Terminated early.

A. No, not as far as -- there was no indication I saw or heard from the presentations he gave that that was -- that that was the case, I mean, that it was terminated because of any toxicity or any other reason.

Q. Actually maybe we could pull up CX 1174. And we will hand you a copy if that's -- if it's okay to approach?

JUDGE CHAPPELL: Go ahead.

THE WITNESS: Thank you.

Okay.

BY MS. DAVIS:

Q. So just to reemphasize, according to CX 1174, only 36 percent of the population completed the 18-month study; is that right?

A. That's correct.

Q. So that means that approximately two-thirds of the patients terminated the study early. Would that be a correct analysis?

A. I don't know the detail, but you terminate the study early because of one of two things, either you don't get patient accrual to meet your goal, which doesn't seem to be the problem here, or either there is -- you have reached your goal and you've proven your point and there's no need to continue, or there's been severe toxicity, which causes you to terminate the trial.

So I don't see any of those issues here.

Q. Okay. Now, Dr. Carducci's study looked at changes within the groups and found that both groups had improvement in PSA doubling time; is that right?

A. That's correct.

Q. But there was no statistically significant difference between the groups; is that right?

A. That's correct. Right.

Q. I'd like to pull up 1175.

Dr. DeKernion, I'm going to show you CX 1175.

And this is an article titled Pomegranate Extract Produces Mixed Results in Prostate Cancer from Internal Medicine News, dated February 28, 2011.

And according to the article, when Dr. Carducci presented this abstract that we just discussed at the Genitourinary Cancers Symposium, he was quoted as saying, "There is an apparent benefit across all PSA doubling times, although some shortening of PSA doubling time was seen."

Do you see that quote?

A. Yes. Uh-huh.

Q. So my question for you, Dr. DeKernion, is that for those patients who had a shortening of PSA doubling time, isn't it possible that POMx may have harmed them more than it helped?

A. No. No. The mean -- the results of the study was positive, that it did prolong the doubling times.

And -- no. No. I don't -- no. When you're doing a trial looking at a cancer, there will be people who in the process don't respond to the drug, whatever it is, and their tumors will worsen. That doesn't mean that the drug made the tumor worse. It just means that

their particular tumor doesn't respond to the treatment.

So I don't -- I don't think that follows at all.

Q. Now, Dr. DeKernion, vitamin E is a substance that is considered safe and harmless under most circumstances; isn't that correct?

A. Yes.

Q. Okay. And it's found in foods such as nuts, seeds -- isn't that correct?

A. It's been -- I'm sorry -- what?

Q. Sure.

And vitamin E is found in foods such as nuts, seeds, nuts -- isn't that correct?

A. Yes.

Q. Now, yesterday, did you see the new study that came out looking at vitamin E and its effect on prostate cancer?

A. No, I didn't see the new study.

You mean the randomized trial?

Q. Yes.

Out of the Cleveland Clinic?

A. I didn't see the report, but I know about the study.

Q. Okay. And in the study -- it was a randomized,

placebo-controlled trial looking at vitamin E, and it found that men taking a vitamin E supplement were 17 percent more likely to get prostate cancer than those in the placebo group; isn't that correct?

A. Yes. Uh-huh.

Q. So wouldn't you agree that it is not possible to conclude that a substance even normally considered to be safe will not have harmful effects unless it is extensively and rigorously studied?

A. I don't agree with that at all. I think, you know, in the case of vitamin E -- and here again, this is one study that demonstrated this, one study. The same thing has been shown in many other nutritional studies that at times there's a suggestion -- well, we read the paper every day -- of diet. You know, you're supposed to do this certain type of diet, and we go to it and we adhere to it, and then someone comes up with a study that says no, no, this doesn't work and it might be harmful because all the fruits have sugar, so cut back on that, and then later another study shows that, well, in our particular study that may be so, but the net benefit was still worthwhile.

If you're asking me do I think that proved that vitamin E causes prostate cancer, absolutely not.

Q. Dr. Carducci testified at his deposition in this

case that his study was never designed to prove POMx is a treatment for prostate cancer.

Do you agree with that?

A. If he said that, then that's what he said, yeah.

Q. And Dr. Carducci testified that it is an unanswered question in the field as to whether affecting PSA doubling time translates into a clinical benefit.

Do you agree with him?

A. As far as we know, as I said earlier, and especially in people with a long PSA doubling time, they haven't been followed long enough for me to prove that this will prolong their lives.

Q. And Dr. Carducci testified that without a placebo we can't be sure that the effect on PSA doubling time seen in his study is attributable to POMx.

Do you agree with that?

A. I do, and I think it was appropriate that he said that. And certainly I think these kind of qualifications are very important for the public to understand. And I bet you have never -- none of us have ever seen a public statement about a, quote, exciting study managing any disease, at which time -- at the end

of which someone doesn't say, Well, further studies are required.

Q. Now, Dr. DeKernion, you view POM products as a reasonable adjunct for prostate cancer patients; is that correct?

A. I do, yes.

Q. Now, POM products are not considered to be the standard of care by experts in the field of prostate cancer; is that correct?

A. A standard of care for which group of patients?

Q. For patients who have prostate cancer.

A. Patients who have prostate cancer in certain stages there are standards of care, many of which haven't been proven, but there are standards of care. In patients who have a PSA recurrence after prostatectomy, there is no standard of care.

Q. And that would -- so POM is not a standard of care; is that correct?

A. There is no standard of care for people with a low -- lowing, slowly rising PSA after prostatectomy.

Q. And you recommend POM to some of your patients; is that right?

A. Yes, I do.

Q. But POM is not the only thing you recommend to your patients to help them with their prostate cancer;

is that right?

A. That's correct.

Q. You might recommend other substances, such as lycopene; is that right?

A. No, I don't.

Q. You -- do you -- you also recommend that they exercise, do you not?

A. Yes. I -- I tell every patient, changing your lifestyle is important for your health in general. You may be able to live a long time if you exercise.

I tell them that POM is a thing that I know has the best evidence for it might help them with no harm, and they should at least think about it but that I'm not -- we haven't proven that it's going to prolong their lives. Most people are happy to take the POM, not so happy to go to the gym, as it turns out, or to cut back on their food products.

Q. And you also recommend that patients restrict their intake of fatty foods; isn't that correct?

A. I do.

Q. And you recommend that they control their weight?

A. Uh-huh. Correct.

Q. Okay. Now, you wouldn't recommend substituting POM for other standard proven therapies for prostate

cancer; is that correct?

A. That is correct.

Q. And you wouldn't want one of your patients to begin substituting a food or a supplement for treatment you prescribe without your knowledge; is that right?

A. For a treatment for which there is a standard or a proven benefit? That's correct.

Q. And if patients are trading a proven treatment that you prescribe for something that's unproven, that could be dangerous; isn't that correct?

A. Sure.

Q. And if a patient came to you and said, Dr. DeKernion, my father had prostate cancer, my brother had prostate cancer, and I'm afraid of getting it, but I can't afford $4 a bottle for POM juice, you would reassure him that there are other things that he could do to reduce his risk of getting prostate cancer; isn't that right?

A. Well, I would -- I'd have a little -- I have -- I'd do it. I have trouble here because things like exercise and diet are -- obviously we've seen them to be beneficial. But I would -- you know, I can't -- I would tell them I can't be positive that it's going to help prevent their cancer.

Q. And if a patient came to you again and said, you

know, I can't afford POM, but I'm afraid that my prostate cancer is going to come back, you would assure them that there are other things that they could do to reduce the likelihood of a clinical -- of clinical progression.

A. Yes. That's safe. Yeah, that's fair. I think if someone can't afford it, then I agree.

Q. Now, Dr. Pantuck testified at his deposition that he's not at a point where he would say that everyone who has prostate cancer or who has -- or who is at risk for prostate cancer should be drinking pomegranate juice.

Do you agree with him?

A. You say he is not at that point?

Q. Yes.

A. I agree with that.

Q. And Dr. Pantuck also testified at his deposition that pomegranate would not be appropriate for people with end-stage cancer, that are refractory to hormones, that are refractory to chemotherapy and having bone pain.

Do you agree with him?

A. I have never used it in that context, and I would -- it wouldn't hurt them probably, but I don't know if it would help them. I doubt it.

Q. Dr. Pantuck also testified that he believes it's reasonable to discuss pomegranate juice with patients who have had some primary treatment, had a recurrence of prostate cancer that is asymptomatic and no evidence of disease or -- on x-rays and that are not going to receive any other immediate treatment.

Do you agree with that?

A. Yes.

Q. Dr. Pantuck also testified that the level of scientific evidence would not support a public health statement that everyone who has prostate cancer or is at risk of prostate cancer should drink POM.

Do you agree with that?

A. I agree with that being said if you're saying they should. I think if you say "should," it is -- but if -- but if -- but what I tell my patients is that there is sufficient evidence, in my opinion, to suggest that it would be helpful to them. I wouldn't tell a patient you should or you must take it.

Q. Now, you were first contacted about submitting an expert report in this matter in March of 2011; is that right?

A. Yes.

Q. And you were asked to respond to Dr. Eastham's report; is that right?

A. Correct.

Q. You did not review the complaint in this matter before submitting your report; is that correct?

A. The complaint.

Q. Yes.

A. Can you clarify that for me?

Q. The complaint in this action, the complaint that complaint counsel filed naming -- setting forth the allegations of this case.

A. I heard basically a little bit about it. I don't think I read the initial part of it. My interest was as someone who knows the research and knows the field.

I'm -- well, okay.

Q. So you were not asked to opine on whether the claims as alleged in the complaint were supported by competent and reliable scientific evidence; is that correct?

MR. FIELDS: Your Honor, I object. The witness just testified he hasn't read it.

MS. DAVIS: That's fine. I'll withdraw the question.

JUDGE CHAPPELL: All right.

BY MS. DAVIS:

Q. And you were -- you're being compensated for

your work on this case at the rate of $250 an hour; is that right?

A. Correct.

Q. Dr. DeKernion, you were chair of urology from 1996 until this year.

A. Excuse me. No. That's misleading. I was the head of urology from 1981. We were a division in those days. Surgery was all under one. I ran urology. Then administratively, in '96, we became so large, they spun us off as a separate responsible department.

Q. Okay. Thank you for that clarification.

A. Uh-huh.

Q. Now, recently you had an article in the Canadian Journal of Urology.

The title of the article is Legends in Urology; is that right?

A. Yes.

Q. Okay. And according to that article, after taking the reins as head of urology, you became more of a research administrator and facilitator than a hands-on researcher; is that right?

A. Well, yes. And in the sense that I didn't go into the lab and do the wet lab, but I stayed in the field. I was the principal investigator of a huge Cancer Institute research and clinical grant, a SPORE

grant, Special Program of Research Excellence. I got it for the institution, I passed review and I ran it for five years, so I was very much attached, but I didn't get in the lab and do the hands-on.

Q. Okay. Now, your major contributions early -- in the early part of your career were in the area of kidney cancer; is that right?

A. Correct. Uh-huh.

Q. And most of your research dealt with immunomodulation and immunotherapy; is that right?

A. Early on, yeah. Uh-huh.

Q. And in the last five years or so you've only published probably about a dozen articles; is that right?

A. Yeah. I don't put my name on articles, unless I write them.

So all of the researchers who are in our SPORE program and in the prostate cancer program which I started in '96, I help them, I review their papers, I direct their research, but they write the papers. I don't put my name on things unless I'm primarily involved in it.

Q. And your urological practice does not focus exclusively on treating patients with prostate cancer; is that right?

A. No. But in the last 10 to 15 years it's been more so than anything else, and now it's about 80 percent prostate cancer.

Q. So you also treat patients with bladder cancer; is that right?

A. I do.

Q. And kidney cancer?

A. I do surgery for bladder and kidney cancer, correct, but not much anymore.

Q. Now, the Pantuck phase II study was conducted at your institution; is that right?

A. Yes.

Q. And Dr. Pantuck is a physician in your department?

A. Correct.

Q. Okay. And now, you were not listed as a coauthor on the Pantuck study report; is that correct?

A. That's correct.

Q. But you were listed as an investigator on the original protocol for the Pantuck phase II study; isn't that correct?

A. That's correct. Because all it meant was that I would be willing to review and participate, but in terms of the study, there again, I felt that if you put my name on it, then people assume that I'm the lead, most

senior person and the one most responsible, which is not the case.

Q. And you were listed as an investigator on the protocol because you helped identify patients for the study; isn't that correct?

A. That's correct.

Q. And you referred interested patients to the study coordinator; right?

A. That's correct.

Q. So in fact many of the patients in the Pantuck phase II study were your patients; is that correct?

A. That's correct.

Q. And you have also referred patients to the ongoing phase III study being conducted by Pantuck; is that correct?

A. Yes. Pretty much we have protocols of various kinds in the department, and if a patient comes in and they might fit the protocol, we give them the opportunity to participate and have them talk to the coordinators and decide if they want to do it, yeah.

Q. And you encouraged Dr. Pantuck and the other investigators to conduct the phase II study; is that right?

A. I did, on the basis of the preliminary research data, yeah.

Q. And the other investigators for the Pantuck II study would have included Dr. David Heber; is that right?

A. Yes.

Q. And Dr. Arie Belldegrun; is that correct?

A. Yeah. Uh-huh.

Q. And so until recently both Dr. Pantuck and Belldegrun would have reported to you as chairman of the urology department; is that right?

A. Correct. Uh-huh.

Q. And you've published approximately fifty articles with Dr. Belldegrun; is that right?

A. I don't know. But we published a lot, yeah.

Q. And you've also coauthored and published articles with Dr. Pantuck; is that right?

A. Yes.

Q. Probably about a dozen; does that sound fair?

A. I think so.

Q. And when Dr. Pantuck began the phase II study, he was a non-tenure-track professor; is that right?

A. That's correct.

Q. And at the time, only tenure-track professors at UCLA were allowed to serve as principal investigator on a grant; is that right?

A. Correct.

Q. But you wrote a letter asking that that requirement be waived to allow Dr. Pantuck to serve as principal investigator; is that right?

A. Yeah. I do that frequently. We have -- many times we'll have a visiting investigator, and by the academic center rules you -- they can't be the PI, so I write them a letter of waiver -- this isn't unusual at all -- if I'm convinced they're worthwhile and they can do the job.

Q. And so -- now, UCLA received approximately $700,000 for the Pantuck phase II study; is that correct?

A. I -- I don't know.

Q. But any funding that POM paid for the Pantuck phase II study would have been paid to your department; isn't that correct?

A. Yes. Uh-huh.

Q. And in 1996 you started a biotech company called Agensys?

A. Agensys, uh-huh.

Q. And you cofounded this company with Dr. Belldegrun; is that right?

A. And others, yeah. Yes.

Q. And Agensys performed some basic science research on POM products; is that right?

A. Yes.

Q. And the basic science research studied the effect of POM products on prostate cancer tumor cells; is that right?

A. Yes.

Q. And this basic science research provided the basis for conducting the Pantuck phase II research; is that right?

A. It wasn't -- well, yeah. First of all, I was not as closely involved with Agensys, but -- I wasn't on their board or anything. It had grown -- outgrown me.

So I knew they were thinking of doing it, and they ultimately I think did do that. But the basic was not just on what was done at Agensys. There was other work done in other labs that supported it. But the extent to which all of that Agensys part and the other part came together I'm not sure.

Q. Okay. And to your knowledge, the Agensys research was not published; is that right?

A. I don't know. But Agensys was going to do this -- this was not part of their business plan. They weren't in the business of this. They had no interest in -- in marketing POM or selling POM. They were going to do this as a contract because they had all the

facilities to do it, and it was easier for them to do it. That was the argument behind it.

So they were contracted to do some of the basic research studies.

Q. And so POM would have paid Agensys to conduct this research?

A. That was my understanding, but I don't know the details of it.

Q. And if records indicated that Agensys received approximately $1.8 million for POM for the research, you'd have no reason to dispute that?

A. I -- I was not associated with that at all. I have no idea.

Q. Now, at Mr. Resnick's deposition in the Ocean Spray litigation, he testified that you operated on him for his prostate cancer; is that correct?

A. That's correct.

Q. And he also testified that you yourself take POMx pills; is that right?

A. That's correct.

Q. And you did not disclose either of these facts in your report; isn't that correct?

A. I'm sorry.

Q. Okay.

A. What did you say?

Q. And you did not disclose either of these two facts in your report; isn't that correct?

A. Well, I don't know if anybody asked me whether I took it or not to say I did take it.

As far as Mr. Resnick, I would never mention information about a patient unless I thought it was appropriate, so I'm sure I didn't mention it.

MS. DAVIS: With the court's indulgence, I just want to check to see --

JUDGE CHAPPELL: Go ahead.

MS. DAVIS: -- if we're done.

(Pause in the proceedings.)

BY MS. DAVIS:

Q. Dr. DeKernion, just one other question.

Is it true that it's possible to have a tumor that does not produce PSA?

A. Yeah. About -- well, there's two. There's one tumor that's in the prostate that we now understand it really isn't a prostate cancer. It's called small-cell cancer.

So it is prostate cancer, but it's a different cell. They don't produce PSA.

There are prostate cancers -- and they're only a small percentage -- that do not produce PSA. It's a very small percentage, and they are extremely high grade

and usually rapidly progressive.

MS. DAVIS: Thank you, Dr. DeKernion.

I have no further questions, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. FIELDS: Thank you, Your Honor.

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REDIRECT EXAMINATION

BY MR. FIELDS:

Q. Are you okay, Dr. DeKernion?

A. Sure. Yeah, I'm fine.

Q. Okay. Good.

Counsel asked you about various things being proved, like is it proved that POM prevents cancer, and you said no, it isn't proved it prevents cancer.

Do you use "proved" in that answer to be mean a hundred percent proved?

A. That's correct.

Q. All right. And when counsel asked you if it's proved that POM products reduce the risk of prostate cancer, you meant that in the same sense?

A. Yes.

Q. And is it still your opinion that there is a high degree of probability, even though not a hundred percent proof, that POM products reduce the risk of prostate cancer?

A. Yes.

Q. Now, counsel asked you about -- and I'm paraphrasing of course -- that you can't see the cancer cells being killed in a human being. You can't actually observe the cells being killed in the -- what is the phrase you use? Is it "apple" --

A. Apoptosis.

Q. Apoptosis.

However, in the in vitro studies, don't you actually see the death of the cancer cells when people drink the pomegranate juice?

A. Yes.

I think counsel was referring to in the context of these studies of the elevated PSA you can't see cells. In the -- but in the human studies in the lab you do see it. That's what all the reports show.

When you treat the animal, a human tumor in the animal, you take it out. You look at it under microscope. The cells are dead. Apoptosis is programmed cell death, and so yes, the cells were killed.

Q. And they are dead from drinking the POM; correct?

A. Yes. Uh-huh.

Q. Okay. Now, let's talk briefly about the couple

of studies that counsel showed you.

I want to read you first what counsel didn't read you from the -- and I have trouble pronouncing this -- rosigli- --

A. Rosiglitazone.

Q. -- rosiglitazone study. All right.

And I'm reading from page 1574:

"The current results do not diminish the potential value of changes in PSADT" -- that's PSA doubling time -- "as an outcome variable for the evaluation of novel therapeutic agents."

Is that something you agree with?

A. Yes, I agree with that.

Q. All right. And another thing that I didn't understand -- and maybe you can enlighten me -- on the preceding page, it says, "The mean posttreatment PSA slope did not change significantly from baseline in the placebo group."

A. Yeah, I honestly -- I don't quite understand the math behind that because the PSA doubling time -- the slope of the PSA doubling time is another way to measure the change in the PSA doubling time. And all it does is -- and I'm certainly not a mathematician, but our mathematicians, when we did the original studies, devised this, and they explained to me that the slope of

the curve, and when you do it, it logarithmically flat -- straightens the curve instead of all the jags and ups and downs. Those should be parallel.

In other words, if you had a true lengthening of a PSA doubling time, then the slope of the curve should decrease, so I -- I don't know what was the problem with that, but it's not congruous.

Q. All right. Let's again -- the other study -- I call it the Celebrex study. Was that the --

A. Yeah.

Q. Okay. And in that case, is it correct that the baseline was measured at irregular intervals?

A. Yeah. The difficulty with that study was -- and the authors very rightly pointed this out -- when you start a study, you have -- like this, you have a baseline. Now -- and if your baseline isn't reliably established, then what comes after is difficult to interpret.

It's like having a race, but not everybody starts at the same starting line, and you don't know which is which. Then what happens at the finish line is very hard to understand.

And I think that's what they were talking about, and they're right. That's a problem, and they had to recognize it.

Q. Was that study also underpowered?

A. Yes, it was underpowered.

Q. Even so, is it correct that the test group got more favorable results than the placebo group?

A. Yes, they did. The placebo -- there was some effect of the -- in -- of the PSA doubling time in the placebo group, but the -- the effect of the Celebrex was -- was -- was significantly greater, but they had to terminate the study because of toxicity of Celebrex.

Q. All right. Now, neither of those studies involve POM or pomegranate juice; isn't that correct?

A. That's correct.

Q. Okay. Are there other studies, other than the ones that were discussed, that show that PSA doubling time is in fact a valid marker for recurrence?

A. Yes. I think -- I don't understand what everybody says about -- you haven't shown, no one has, that changing the doubling time in these people with already pretty size -- pretty good tumor status, that it ultimately changes the large population, but there's two things there.

Number one, many studies, Pound, Aronson, Teetel -- Teeter, the Mayo Clinic study, all showed that indeed some patients with a prolong -- a long, greater than 15 months in the Teeter study, a long doubling time

do die of prostate cancer, so -- now, the other side of it is that if we know, and we -- everybody accepts I think that, okay, somebody has a short PSA doubling time, six months -- you know, it might be six months, three months, nine months. It doesn't matter -- they have a short doubling time, we know that they are at high risk for very -- for early metastases.

Now, if that's the case, then someone with a slightly longer doubling time is still at risk, a little less risk, but they're at risk. Somebody with a slightly longer than that is still at risk, maybe a little less risk.

So there's significant evidence that the study does correlate with the tumor behavior.

And I always cite by the study by Giovacchini I think -- it's an Italian name; it's in the record -- and what they did -- and we've seen this -- a patient has a PSA recurrence. When they have a long PSA doubling time, there's no use doing a PET scan because the cells aren't turning over fast enough for them to pick up the PET labeler. However, when someone has a short PSA doubling time, it's a very worthwhile test because the PET will pick up those cells because they're growing fast.

So it's another measure that the PSA doubling

time, with some qualifications obviously, is a reflection of what's happening to the tumor and therefore has to be some reflection about, well, what will happen to the patient.

Q. Now, counsel referred to not -- I think it was in your answer -- that they don't use PSA doubling time in the large chemotherapy trials. Is that correct?

A. No. They -- they -- they keep -- should -- they don't. They shouldn't.

Q. Why is that?

A. Because you have -- you have other measurements. You have -- often you have bone scans to measure it. You might even have measurable soft tissue metastases. You have very strong and persuasive symptomatic markers, pain especially, weight loss. And those are things you should pay attention to there. I don't think PSA doubling time would be the main thing that you would look at. And I wouldn't expect it to be important in those people.

Q. All right. Counsel referred to Dr. Carducci as showing no difference between the control -- or she said between the two groups.

That refers to the difference in dosage; isn't that correct?

A. That's correct, yes.

Q. In other words, it didn't make any difference whether you took one bottle or three bottles; you would get the same benefit.

A. Correct.

Q. Okay. But there was a significant difference between the PSA doubling time of the various patients both before the use of POM and after the use of POM --

A. Correct.

Q. -- correct? Okay.

All right. Just I think two more questions, Doctor.

Take all the studies that were referred to by counsel and all the questions that counsel asked you.

Is it still your opinion that there is a high probability that the POM products provide a special benefit to men with PSA after radical prostatectomy?

A. Yes.

Q. And is it still your opinion that based upon the same mechanisms, there is a high degree of probability that POM products inhibit the clinical development of prostate cancer cells even in men not diagnosed with prostate cancer?

A. Yes.

MR. FIELDS: That's all I have.

JUDGE CHAPPELL: Recross?

MS. DAVIS: Just one question for clarification.

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RECROSS-EXAMINATION

BY MS. DAVIS:

Q. Dr. DeKernion, in response to questions that Mr. Fields just asked, you talked about in vitro studies. I just want to make sure we're clear.

So in in vitro studies, people are not drinking POM juice. You're looking at cells in a petri dish, and you're putting the POM juice on those cells; is that right?

A. That's correct.

MS. DAVIS: Okay. No further questions.

MR. FIELDS: No further questions, Your Honor.

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

(Pause in the proceedings.)

We have no further witnesses scheduled today?

MR. GRAUBERT: That's correct, Your Honor.

JUDGE CHAPPELL: We have one witness scheduled for Friday?

MS. HIPPSLEY: Yes, Your Honor. Our rebuttal witness, Dr. Stewart, who will be rebutting Dr. Butters' testimony, is Friday.

JUDGE CHAPPELL: All right. I intend to hear oral argument on the pending motion for the other rebuttal witness Friday morning.

MS. HIPPSLEY: Okay.

JUDGE CHAPPELL: I want both sides to be prepared for oral argument on that motion Friday morning before the witness testifies.

MS. HIPPSLEY: That's fine, Your Honor.

JUDGE CHAPPELL: How much time will be needed for this witness?

MS. HIPPSLEY: I think our direct will be roughly an hour at most.

MR. FIELDS: Oh, half an hour to an hour, Your Honor.

JUDGE CHAPPELL: Do I need to put time limits on the oral argument?

MS. HIPPSLEY: For the rebuttal witness?

JUDGE CHAPPELL: Right.

MS. HIPPSLEY: I doubt it. Right?

MR. FIELDS: I would think not, Your Honor.

MS. HIPPSLEY: No.

MR. GRAUBERT: It depends on Your Honor's patience.

JUDGE CHAPPELL: Maybe the mere mention of time limits will suffice.

MS. HIPPSLEY: I think that will, yes, Your Honor.

JUDGE CHAPPELL: If things go as planned, I will hear argument -- I've got the briefs already, the filings. We will hear the witness. We'll take a break. And I'll -- if things go as planned, I will issue a ruling from the bench Friday on that motion.

So either we'll be finished Friday or we'll be coming back.

And based on what I'm hearing, it sounds like a short day Friday?

MS. HIPPSLEY: I think so, Your Honor, yes, like -- I don't know -- two, two and a half hours total for the one witness.

JUDGE CHAPPELL: 12:00 start?

MR. FIELDS: Fine.

MS. HIPPSLEY: I think that's all right. I'd have to check -- I mean, we'll do that. Mr. Stewart is from California, and I don't know if he was hoping that he could get a late-afternoon flight.

Is the argument on the motion first at noon?

JUDGE CHAPPELL: Yes.

MS. HIPPSLEY: Or could we flip it so the witness could be first and we'd be done with him at 2:00 and then make the argument?

JUDGE CHAPPELL: If I were coming from the California time zone, I think I would prefer three hours later because 9:00 a.m. here is 6:00 a.m. for that person's body clock.

MS. HIPPSLEY: Right. I mean, we can do noon. I just don't know if -- I don't know what the last flight is.

JUDGE CHAPPELL: Why don't we do this. Let's say 11:00. I'll hear argument, and then the witness will be on the stand easily before noon.

MS. HIPPSLEY: Okay.

JUDGE CHAPPELL: Do you think that's a problem?

MS. HIPPSLEY: No. Not at all.

JUDGE CHAPPELL: All right. Anything further?

MR. GRAUBERT: No, sir.

MR. FIELDS: Nothing further, Your Honor.

JUDGE CHAPPELL: Until the day after tomorrow, Friday, at 11:00 a.m. we're in recess.

(Whereupon, the foregoing hearing was adjourned at 3:13 p.m.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9344

CASE TITLE: In Re POM Wonderful LLC, et al.

HEARING DATE: October 12, 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: OCTOBER 18, 2011

JOSETT F. WHALEN, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

ELIZABETH M. FARRELL