FEDERAL TRADE COMMISSION

IN THE MATTER OF:	)	
POM WONDERFUL LLC and ROLL GLOBAL LLC, as successor in interest to Roll International Corporation, companies, and STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER, individually and as officers of the companies.	)	Docket No. D9344

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PUBLIC ORAL ARGUMENT

THURSDAY, AUGUST 23, 2012

2:00 P.M.

BEFORE:

JON LEIBOWITZ, Chairman

EDITH RAMIREZ, Commissioner

MAUREEN K. OHLHAUSEN, Commissioner

J. THOMAS ROSCH, Commissioner

JULIE BRILL, Commissioner

Reported by: Debra L. Maheux

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P R O C E E D I N G S

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CHAIRMAN LEIBOWITZ: Good afternoon. The Commission is meeting today in open session to hear oral argument in the matter of POM Wonderful, LLC, Roll Global, Stewart A. Resnick, Lynda Rae Resnick and Matthew Tupper, Docket Number 9344, on the appeal of the respondent and the appeal of counsel supporting the complaint from the initial decision issued by the Administrative Law Judge.

The respondents are represented by Mr. Edward P. Lazarus and Mr. Bruce A. Friedman, and counsel supporting the complaint are represented by Ms. Heather Hippsley.

During this proceeding, each side will have 45 minutes to present their arguments. Counsel for the respondents will make the first presentation and will be permitted to reserve time for rebuttal. Counsel supporting the complaint will then make her presentation. Counsel for the respondents may conclude the argument of course with a rebuttal.

Mr. Lazarus, I understand that you want to reserve ten minutes for rebuttal, and that you're going to allocate five minutes of your time for Mr. Friedman. Is that correct?

MR. LAZARUS: That is correct, Mr. Chairman.

CHAIRMAN LEIBOWITZ: All right. Then you will have 30 minutes for your initial presentation, and you may begin now.

MR. LAZARUS: Thank you very much. As you noted, my name is Edward Lazarus, and I'm here representing all of the respondents other than Matthew Tupper, who is ably represented by Bruce Friedman.

The crux of respondents' argument this afternoon is to define liable and deceptive advertising, and to follow the complaint counsel's approach in this case would be to take the Commission deep into unchartered waters. It would require unprecedented decisions with regard to ad interpretation, substantiation and remedy and would put the Commission on a collision course with the past practice, legal precedent and the Constitution.

I would like to start with the issue of ad interpretation. There is no case where the Commission has taken ads that, as the ALJ found here, are literally true on their face and created so much additional meaning through implication in the absence of extrinsic evidence or, as in this case, where the extrinsic evidence in the form of expert testimony refutes the allegations in the complaint.

COMMISSIONER ROSCH: Wait, wait just a second.

You know, Counsel, I don't think that's correct, and the reason I don't think that's correct is because I think the Kraft case decided against you many, many years ago, and frankly citing Thompson Medical, which was a Commission case, but the Kraft case itself was as well, and it involved our interpretation without any extrinsic evidence at all; that is to say, the Commission's interpretation of the ads, the implied claims that were made in the ads.

And that's not to say that there were no express claims made in the ads because there were, but I just don't buy the idea that the Commission itself needs extrinsic evidence in order to interpret implied claims.

MR. LAZARUS: Commissioner Rosch, I'm very glad you framed the question just that way, because I agree with you that it is not required for the Commission to have extrinsic evidence to find implied claims, and I believe that that's what Kraft stands for, just as you said.

But what did the Seventh Circuit say in Kraft? It said that when the Commission is going to go down that road and it's going to imply meaning without extrinsic evidence, it is at the very outer edge of its Constitutional authority. It's not over the edge, but it's at the very outer edge of its Constitutional

authority. And as a result of that, the standard under those circumstances is that the ads must clearly and conspicuously have the implied meaning, and if you compare Kraft with this case, I would say there's not really a comparison.

In Kraft, as you will recall, the ad was five ounces of milk, five ounces of milk, five ounces of milk, quote, so that their little bones will get all the calcium they need, and it's right plain as the nose on your face that in that case, it was an implied claim that you had five ounces of milk source of calcium in those single slices, and the Commission found -- once it found that that was the ad's meaning, the case was over, because everybody knew --

COMMISSIONER ROSCH: Counsel, we have taken a look at the claims that the ALJ found had not made any kind of implied claims at all, and, frankly, I've got to tell you that I see a bunch of implied claims in those ads, and they are prevent or treatment claims, just as was as clear as the Kraft case.

MR. LAZARUS: Well, Commissioner, you and I will simply have to disagree on that matter, because I -- first of all, with respect -- first of all, we started out with hundreds and hundreds of ads. We got down to 43. Of those 43, more than a majority, a neutral ALJ

looking at all the testimony --

COMMISSIONER ROSCH: It doesn't make any difference whether he's neutral or not.

MR. LAZARUS: If I can just --

COMMISSIONER ROSCH: Under our rules, we get to make our decision.

MR. LAZARUS: You have the final say, that's absolutely true, Commissioner, but if you have a standard, and under that standard the meaning must be clear and conspicuous, and a neutral fact-finder has said I don't see it, that's pretty strong evidence that those are not clear and conspicuous claims.

COMMISSIONER BRILL: Mr. Lazarus?

MR. LAZARUS: Yes.

COMMISSIONER BRILL: To follow-up on what Commissioner Rosch is saying, I have to say I thoroughly agree with him. I don't see anything that's ambiguous about the cheat death ad. I'm sorry, I don't have the ability to call it up for you, but I'm sure you're very familiar with it.

MR. LAZARUS: I am, absolutely.

COMMISSIONER BRILL: And if I could just point out that what it says is POM has more antioxidants than any other drink and can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer.

There's really nothing very ambiguous about that. And I would also point out that I think what Commissioner Rosch was indicating is we look at this de novo.

The fact that one Judge overlooked what is, in my view, quite obvious in this ad doesn't mean that five of us sitting here need to overlook it as well.

MR. LAZARUS: Commissioner Brill, as I recall -- I could be wrong, but my recollection is that the ALJ found an efficacy claim in the cheat death ad. That's one of the ones where it rejected the establishment clause claim for that but found an efficacy claim. That ad is from 2004 I believe. I think you've probably chosen the ad that is at the furthest edge.

When we litigated this case, we did identify a small cadre of old ads which, while we think they're defensible, are certainly less cautious than the subsequent ads, but let me take an ad that the ALJ actually found a claim in, and let's run through it, and that's CX 0379, and I'll just describe it to you.

It starts out -- it's a description of the Pantuck PSADT study, and it says it's a pilot study, and it says how many people were in it. It says the nature of the study group, what the results were, and it quotes from Dr. Pantuck expressing enthusiasm for the results, and it says that -- then there's a reminder that the

juice is found in the produce section, and there's a reminder about the prevalence of prostate cancer, and it's linked immediately with a quote that says: "Emerging science: Emerging science suggests the importance of diet and life-style in improving prostate health," and then it says research continues.

Everything in that ad is true. The ad actually follows the NAD's suggestion of being more specific and giving more detail about the research and adding qualifiers. There's no evidence of a generalized establishment claim there, just the opposite. It's an accurate reporting of a pilot study, and under the Commission's precedence, when you have an ad like that, the question on substantiation is the level of substantiation claimed in the ad.

COMMISSIONER ROSCH: Wait just a second, Mr. Lazarus. I think you're mixing a couple of concepts. The first concept is what the ad means, and I think what Commissioner Brill is saying is that in her view, at least, she interprets this ad as making a treatment or prevent claim --

MR. LAZARUS: Yes.

COMMISSIONER ROSCH: -- with respect to both prostate cancer and with respect to also heart disease, okay? Now, that's the first question. That's the

gating question.

MR. LAZARUS: Yes.

COMMISSIONER ROSCH: The second question, however, is whether or not -- and the ALJ found this to be correct -- that this does not displace traditional therapies.

Now, take a look at that ad where the symbol of the AMA is right up there on the ad, and take a look at the later ads with respect to POM where it says POMx, which is a pill. We have never found in a liquid, for example, that a substantiation for a liquid substantiates the pill, and the reason for that is pretty clear.

MR. LAZARUS: There are tests with respect to the pill, too.

COMMISSIONER ROSCH: No, no. The problem is that with respect to the pill -- and this is raised in spades in terms of the erectile dysfunction claims that the ads make. They highlight the pill, and then they talk about the substantiation for the liquid.

Now, that's a complete misnomer. It doesn't -- we have never agreed that the fact that a liquid is substantiated substantiates the claim for a pill. We just have not done that.

MR. LAZARUS: First, Your Honor -- Commissioner

Rosch, I'm sorry, the --

COMMISSIONER ROSCH: That's okay. I like Your Honor better.

MR. LAZARUS: I vested you with life tenure, and you're welcome to it, but there are a few things about that. First of all, the falsity claim here has never been that there's a false equivalence between the juice and the pill. The ads say right on them that what the pills contain is 100 percent pomegranate juice extract that is equivalent to the eight ounces of the juice.

And the science is, and the testimony about the science is, that they are equivalent in terms of the actions inside the body, so that's why that case was not litigated on those terms.

With respect to the medical symbol, it's true. We're making healthy claims. We're just not, in this ad that I described -- now, we'll go back to cheat death in a minute.

COMMISSIONER ROSCH: You're not displacing traditional therapies at all through the use of that symbol?

MR. LAZARUS: That's correct. When you look at the other cases, people are going around and saying -- there are a million of them that you've decided, and you were absolutely right to go after these fraudsters who

go out there and say, Use my ionized bracelet and your pain will go away. That is nothing like these ads. It says it's in the grocery section of the store.

COMMISSIONER LEIBOWITZ: Well, let me just ask a question. I mean, it seems to me at least that if all the ads literally said was POM juice is healthy, I don't think we would be here today. Do you?

MR. LAZARUS: Well, the question --

CHAIRMAN LEIBOWITZ: I mean -- go ahead.

MR. LAZARUS: The question, Mr. Chairman, is not whether we have --

CHAIRMAN LEIBOWITZ: I prefer Your Honor, actually.

MR. LAZARUS: I think for these purposes, I'll call you Mr. Chief Justice.

CHAIRMAN LEIBOWITZ: That's okay.

MR. LAZARUS: Now, of course, I made a joke, and I lost my train of thought, but the point is that we're entitled to say anything that's true, and what's true about these products --

COMMISSIONER ROSCH: No, you're not. That's the problem. That is the problem with the substantiation. You're not entitled. We are not going to open the door to you, I think at least -- and I'm talking for myself, we're not going to open the door to a deceptive

substantiation claim either. We're not going to do that.

MR. LAZARUS: Well, the question, Your Honor, is where is the deception. Now, I get what you've said about the cheat death ad.

COMMISSIONER BRILL: Look at your cardiologist. I mean, I think that the implied claims here for your average consumer is quite clear, that what we're talking about is a product that will treat or prevent disease.

MR. LAZARUS: Your Honor, unless --

COMMISSIONER BRILL: It's okay, don't worry about it. Just keep going.

MR. LAZARUS: I'm so used to court. Old habits die hard.

COMMISSIONER BRILL: Just keep on going.

MR. LAZARUS: Look, Commissioner Brill, you've chosen yet again one of what we call the outlier ads. We are talking about a universe of hundreds and hundreds of ads that were over a long period of time, and yes --

COMMISSIONER BRILL: These are the ads that are being litigated. These are the ads that are part of complaint counsel's complaint.

MR. LAZARUS: They are part of the case, but if what we're really saying here is that the injunctive remedy that is being suggested here is appropriate if a

couple ads from 2004 are the problem, I don't think that that's appropriate.

COMMISSIONER ROSCH: That's another matter. We will turn to the injunction in due course.

MR. LAZARUS: Well, remedy is an important part, and I'm certainly not conceding that the ads you described are deceptive, but if that's the issue, if what we're really talking about is some ads in 2004 that went too far, what I would say is that, look, we had an NAD proceeding in 2005 and '06, and ads were changed as a result of that.

In fact, complaint counsel never takes account of this fact, but we actually thought about all of this, and we said, you know what, we're going to become more conditional. We're going to start using different language. We talk about pilots and preliminary and emerging science, and so when you look at the progression --

COMMISSIONER BRILL: What do you think all of that means to the average consumer? Do you think the average consumer understands what a pilot study is? I've deposed scientists who differ on what pilot study means. I mean, these things are not clear to your average consumer. To them it all stands for the science proves X, and here the X was treat or prevent these

three diseases.

MR. LAZARUS: We never used the word "prove."

COMMISSIONER BRILL: No, no, no. My point is when you talk about a pilot study, when you talk about the evidence demonstrate, things like that, consumers understand that to mean the science demonstrates.

MR. LAZARUS: I think one of the great things about the ad is it doesn't just -- it tells you it's only 46 people. It says here's what they found.

COMMISSIONER BRILL: Is that a lot or a little?

MR. LAZARUS: I think most people would take that as being a modest size amount. It's a pilot study with 46 people, and it then says that the research is going to continue, and then it puts it in the context of diet and life-style, and it tells you that it's in the grocery store.

These are not the things of medicine. This is not -- anybody who reads this ad and thinks, You know what, I'm going to take POM juice because that's going to be my silver bullet cure for cancer, that person is not a reasonable person.

COMMISSIONER ROSCH: It's not if it's a silver bullet cure for cancer. It's whether it treats or prevents cancer.

MR. LAZARUS: I think what these ads say is it

reduces the risk of cancer in the same sense that having -- what it says right here, "emerging science suggests that diet and life-style may significantly be able to improve prostate health." That's exactly what we tell them.

COMMISSIONER ROSCH: Again, Mr. Lazarus, I suggest you're mixing up two things. First of all, what kind of claim is made here, and second, what is the substantiation level that's necessary for that kind of claim? And if and to the extent that you are claiming that you are making a treatment or prevention claim, then I think the level of substantiation is at least as high as the ALJ found.

MR. LAZARUS: Commissioner, I am making two claims here. Now, the first claim I'm making is it doesn't make the kind of pharmaceutical/prevent/treat claim that you are describing as making, number one; and number two, if you did read this particular ad as making such a claim, it's a limited, qualified claim because it's just about one study.

And under the precedence of the Commission, what you do when you look at an ad that describes a study, that's the level of substantiation it claims, and we have that level of substantiation because that Pantuck test is a legitimate human trial that was vouched for by

eminent scientists at trial.

CHAIRMAN LEIBOWITZ: Let me ask one more question about ads, I'll go to one of two. One is drinking to be healthy, which is I think Exhibit 16. Now, I don't know if that's in -- if that's one of the earlier ads, we'll just move on beyond that.

MR. LAZARUS: It is.

CHAIRMAN LEIBOWITZ: Because it does say antioxidants guard your body against harmful free radicals. It can cause heart disease, premature aging, Alzheimer's disease, even cancer. Again, if the general message of the advertising is simply that POM is a healthy product, I don't understand why you need to have -- why you need to make those additional claims. There's also a reference to a scientific study by a doctor.

Let me go to the antioxidant super power. I think that's Exhibit 314. Are you familiar with that?

MR. LAZARUS: I can --

CHAIRMAN LEIBOWITZ: I'll just sort of walk you through it. There's a picture of POM Wonderful, POM Wonderful with a cape like a super hero, and it says it has more naturally occurring antioxidants than other drinks. Antioxidants fight free radicals, villainous little molecules that may cause premature aging, heart

disease, stroke, Alzheimer's, even cancer. All you need is eight ounces to save the day, every day.

What's the takeaway there? Isn't it reasonable to find the takeaway there that the net impression a reasonable consumer has is it reduces the risk of or it prevents all of these problems, aging, heart disease?

MR. LAZARUS: Here's the thing about that. If, let's say, I --

CHAIRMAN LEIBOWITZ: 2008, this is a 2008 ad or it ran at least in 2008. 8/25/08, as I understand it.

MR. LAZARUS: Right. Here's what it said, which is absolutely true, which is -- and I'll tell you the U.S. Government makes claims like this all the time. So does NIH and so does Sloan-Kettering and so does the Mayo Clinic. It says, Look, antioxidants are good for you because they fight free radicals, and free radicals are really bad for you. The syllogism is not completed here. This is what I think the fallacy of that interpretation is.

If I have an exercise machine and I say that my exercise machine is super good at aerobic conditioning, and aerobic conditioning fights lots of bad things that happen to you, I'm not saying that my disease (sic) fights those diseases.

CHAIRMAN LEIBOWITZ: Well, you may contend that.

It's a faulty syllogism. I saw that in your papers, and I thought you made that a very interesting argument. On the other hand, it is for the ALJ or ultimately the Commission, exercising de novo review, to make that determination.

MR. LAZARUS: Of course --

COMMISSIONER BRILL: Mr. Lazarus -- I'm so sorry.

MR. LAZARUS: Sorry. Well, I was going to say, number one, you're absolutely right. It is a de novo determination, I agree with that. But I would just reiterate the point that with respect to the ads that the ALJ did not find objectionable, that if you're talking about the high bar of clear and conspicuous, that is meaningful, but I would like to move to substantiation, if I can.

COMMISSIONER BRILL: That's exactly what I wanted to move to because I'm noticing your time.

MR. LAZARUS: There are two very important issues with respect to substantiation. The first one is whether substantiation should be under an RCT standard, and it's covered extensively in the briefs, but I would just make the following very quick points.

Number one, it's contrary to the policy of the Commission. You would be breaking dramatic new ground

if you said that that was the standard here.

Number two --

COMMISSIONER ROSCH: Well, wait a second. Thompson Medical specifically says that the standard is two RCTs.

MR. LAZARUS: Thompson Medical is not a food advertising case. It is a case about an analgesic. It's sold as a medicine.

COMMISSIONER BRILL: How does our statute define "drug"? What is the definition of drug under the FTC Act?

MR. LAZARUS: I'm not going to be able to give you --

CHAIRMAN BRILL: Let me tell you what the definition of drug is --

MR. LAZARUS: Yes.

COMMISSIONER BRILL: -- under the FTC Act because I'm sure you have it in your head. Section 15 of the FTC Act defines drug, and there's four potential definitions for drug. The second says: "Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man."

The third subpart, completely separate from the one I just read, says: "Articles other than food intended to perfect the structure or function of the

body of man or animals."

It strikes me that the definition of drug, which we need to comply with here, makes quite clear that you can be a drug under Section 15(c)(2), even though you are a food, the product is a food. Only if we're talking about a structure/function type of drug do we exclude foods. I think the ALJ got this completely wrong.

MR. LAZARUS: Well, Commissioner Brill, I just have to disagree. I just don't think that you sell drugs in the frozen juice section of the grocery store.

COMMISSIONER BRILL: Show me where that says that in the statute. Your position is that a food cannot be a drug. I don't see that in Section 15(c)(2).

MR. LAZARUS: Our position is that these products are never sold as drugs. The ALJ so found, and there was no --

COMMISSIONER BRILL: Isn't the definition of drug though what the intended use is, and the intended use is how it is being marketed? Isn't that what drives the definition or the determination of what the type of product is in this case, one of the Pfizer factors?

MR. LAZARUS: Then I guess we are going to treat water as drugs or blueberries as drugs.

COMMISSIONER BRILL: If water is marketed as a

product that will treat and prevent cancer, then, yes, it would be a drug under this definition.

MR. LAZARUS: Blueberries, broccoli. The U.S. Government says over and over again that they're all --

COMMISSIONER BRILL: Tell me which blueberry manufacturer markets its product as preventing or treating cancer.

MR. LAZARUS: This, of course, gets back to ad construction where we don't believe that we --

COMMISSIONER BRILL: But let's assume that we disagree with you on that, and now we're in the area where we think the claims at issue are that you are claiming your product prevents or treats three medical diseases.

MR. LAZARUS: I would simply go back to the fact that when you operate -- we read the policy statements with respect to health claims for food advertising, and it doesn't say anything about RCTs, and it says you can --

COMMISSIONER BRILL: You can -- I'm so sorry.

MR. LAZARUS: And you can meet the credible and reliable scientific standard, which can be done in any number of different ways, not just RCTs, and there is expert testimony by no less than -- fewer than actually eight experts, six for respondent and two for the

complaint counsel, who said in the nutrient context, RCTs is not the be-all, end-all for --

COMMISSIONER BRILL: I agree with you we need to look at what the experts actually say. I was honing in on your point, which was a point that the ALJ made that this is a food and, therefore, should be treated differently and the substantiation should be different simply because it is a food. And I'm asking you where in the statute we have that kind of a distinction, because I don't see it. In fact, I see the opposite.

MR. LAZARUS: I understand, Your Honor. So I guess I would just go back to the argument that with the exception of Thompson, which doesn't say you must have RCTs, but which established that in that particular case. You have several Court of Appeal decisions which say the opposite. You have a Supreme Court decision that says the opposite with respect to FDA standards, which are tougher than is generally observed by the FTC in this context, and you have eight experts.

Again, you have all six of the respondent's experts say RCTs are not appropriate in this context. You have Professor Stanford, who is the lead expert for complaint counsel, who had to back away from his position because all of his writings said in the nutrient context, RCTs were not appropriate.

COMMISSIONER BRILL: Did your expert -- I'm sorry.

COMMISSIONER ROSCH: Go right ahead.

COMMISSIONER BRILL: No, go ahead.

COMMISSIONER ROSCH: Counsel, let me ask you a question. Would your position be that you have substantiated the claims made here adequately?

MR. LAZARUS: Absolutely.

COMMISSIONER ROSCH: If you had claimed that they were substantiated by animal studies only --

MR. LAZARUS: We haven't made that claim, and we don't make that claim.

COMMISSIONER ROSCH: But suppose -- no, no, but some of the claims that you make with respect to substantiation in these very ads leave it open to interpretation because they say that it is a study. They don't say what kind of study. They don't say whether or not it was animals. They don't say whether or not it was a pill or a liquid.

MR. LAZARUS: Some of them actually do make that distinction, but, Commissioner, the substantiation is the substantiation you have, which is in this case 70 peer-reviewed articles, all published on the subject. With respect to heart, here's what you have: You have 15 in vitro and animal studies, and these just aren't

animal studies. These are human tissue and animal --

COMMISSIONER ROSCH: It doesn't make any difference, though.

MR. LAZARUS: -- and you have human studies.

COMMISSIONER ROSCH: We've held that animal studies never ever substantiate a claim, a prevention or treatment claim. We held that, for example, in the DCO case.

MR. LAZARUS: Standing alone, no one is asking you to say that they substantiate the claim, but they are important science, and all the scientists --

COMMISSIONER RAMIREZ: Counsel, let me jump in here, if I may. I would like to know -- I understand your position with regard to the two RCTs, but the ALJ did, in fact, take into account a number of your arguments in the order that was issued. So, tell me why the standard that the ALJ articulated is far too much in your view.

MR. LAZARUS: Actually I don't think the ALJ necessarily applied the wrong standard, with one exception, which is none of the experts testified that you needed the one clinical trial. We said look at the totality of the evidence, which could include clinical trials and, indeed, does include clinical trials in this case, and they said RCTs, and we said no.

And so he kind of fashioned that standard on his own, and we did take exception to that. But we meet -- I think what we would say is there's always been one standard, which is credible and reliable evidence, and that evidence is evidence "conducted and evaluated in an objective manner by persons qualified to do so using procedures generally accepted in the relevant profession yielding accurate and reliable results."

Here, unless you have an RCT standard, we meet that standard. We have, so there are -- let's go to the experts first. You have Dr. Heber and Dr. Ornish.

COMMISSIONER ROSCH: Is that not extrinsic evidence, Counsel?

MR. LAZARUS: As opposed to?

COMMISSIONER ROSCH: We can always take a look at extrinsic evidence if we want to, but we're not required to do so.

MR. LAZARUS: Let's talk about the studies themselves then. I'm sorry, I'm over.

COMMISSIONER OHLHAUSEN: Actually, before you move away from that point, I'm interested in your view on Thompson Medical, whether, for certain claims, extrinsic evidence is required.

MR. LAZARUS: For an ad interpretation or for --

COMMISSIONER OHLHAUSEN: Correct.

MR. LAZARUS: For ad interpretation?

COMMISSIONER OHLHAUSEN: Right.

MR. LAZARUS: I don't believe that extrinsic evidence is absolutely required. My point is because what I think Kraft says is it's not constitutionally required under the First Amendment, but the Commission is at that far edge of its authority because it becomes purely subjective if you don't have any extrinsic evidence, and so it's a very high bar you have to meet, and that's why in almost every one of these cases there is copy testing.

I mean, they called Dr. Mazis in this case, and for once they didn't have him do any testing. Why? This was an easy thing to litigate, but it would have shown that most consumers don't see the ads the way complaint counsel --

COMMISSIONER BRILL: Isn't his testimony extrinsic evidence? Isn't he able to --

MR. LAZARUS: He only came in to rebut the evidence of our witness. He did not come in to provide any affirmative evidence whatsoever, and so you don't have extrinsic evidence on these points. And so you're at the outer edge, and you can't meet the bar in this case because the ads are not susceptible to that sort of "plain as the nose on your face" type interpretation of

implied meaning. That's the interpretive argument.

On the substantiation -- and recognizing time is short -- but on the substantiation, the expert testimony is all recounted in the briefs. I'll just say that you have two experts saying so for heart, two experts saying so for prostate cancer, and two experts saying so for erectile health. All that we had credible and reliable evidence for --

COMMISSIONER BRILL: But were they asked the specific question about the substantiation required for a claim that indicates the product will treat or prevent the disease? Complaint counsel says that they answered a different question, which is how much substantiation is needed for a general health claim or health benefit claim, which is different than the claims that the ALJ found and that we may find.

MR. LAZARUS: The citations are right there in the brief. A bunch of them are collected at footnote 16 of the answering brief, if you want to look at what they actually said, and what they actually -- Dr. Heber said and Dr. Ornish said directly: "The respondents had credible and reliable evidence that POM prevents or reduces the risk of heart disease."

Dr. DeKernion and Dr. Heber said that the science showed a high likelihood of inhibiting the

development of prostate cancer even in men who haven't had prostate cancer before, and Drs. Burnett and Goldstein testified that there was credible and reliable evidence that it improves erectile dysfunction. There's some wiggle room as to whether it's function or dysfunction, but the RCT that was done to a 95.2 percent certainty with respect to erectile health on people who had erectile dysfunction showed a significant improvement.

COMMISSIONER BRILL: So an RCT was needed to demonstrate that?

MR. LAZARUS: Well, we used an RCT in that context, and it was especially appropriate in that context because RCTs generally are better when it's a subjective judgment, and erectile function is pretty subjective, so that's -- but where you have measurable -- objectively measurable things, that tends not to require the RCTs. There's expert testimony about all of this as well.

But let's get to the actual studies because that's what you asked about, Commissioner Rosch. With respect to the heart, in addition to all the animal and in vitro, you have the two Aviram studies, you have the Ornish study, and you have the Davidson study, which notwithstanding --

COMMISSIONER ROSCH: And we are required to credit all of those studies through testimony?

MR. LAZARUS: Well, I guess I would --

COMMISSIONER LEIBOWITZ: The ALJ did not.

MR. LAZARUS: I would ask you, Commissioner, of another case where there are six experts saying that the evidence is good enough, 70 peer-reviewed, published articles, and you have human studies on each one of the alleged claims. There's no case that I'm aware of, and certainly not in the food context, where this Commission has disregarded that.

What you have here is a jump ball, and under the jump ball, I must tell you, you have to look at Pearson versus Shalala on this point where you have made verifiable health claims and there was a jump ball or, in essence, a jump ball on substantiation. The First Amendment says that you cannot bar that speech --

CHAIRMAN LEIBOWITZ: Pearson versus Shalala, is that a rule or is that a case? It's a rule.

MR. LAZARUS: It's a D.C. Circuit case.

CHAIRMAN LEIBOWITZ: Very different.

MR. LAZARUS: It's a D.C. Circuit case that looks at the --

CHAIRMAN LEIBOWITZ: No, no, no, but the FDA determination was based on -- the case was about a rule

rather than a case-by-case determination. In fact, wasn't that what the D.C. Circuit found was the problem with the FDA approach?

MR. LAZARUS: Here's what the D.C. Circuit said. It says what you can't do is get around the commercial speech doctrine if you have a circumstance where you have an argument over substantiation for verifiable health claims. You must go through the Central Hudson approach, and under the Central Hudson approach, the remedy is limited to qualification or other things that could make the speech move it from potentially misleading to not leading.

CHAIRMAN LEIBOWITZ: Let me ask a question, going back to your earlier point about -- did you want to ask?

COMMISSIONER ROSCH: No, no, no.

CHAIRMAN LEIBOWITZ: -- about randomized controlled trials. You seem to have almost made the point that if we find a liability, that might be a remedy we might be interested in, but let me ask you this: I want to understand how burdensome it is to do randomly controlled trial --

MR. LAZARUS: I'm sorry, say it again.

CHAIRMAN LEIBOWITZ: How burdensome it is?

MR. LAZARUS: Yes.

CHAIRMAN LEIBOWITZ: So the record shows that you had about 200 -- is this correct, about $250 million of POM Juice sales over eight years? Is that right? Something close to that roughly?

MR. LAZARUS: Roughly speaking.

COMMISSIONER LEIBOWITZ: It also shows that the cost for the two Davidson cardiovascular studies, and those were randomized, double-blinded, placebo-controlled clinical trials, was about $2.9 million. The original budget for the Ornish study and the CIMT studies, again both randomized, placebo-controlled, double-blind studies, were $708,000 and $496,000 respectfully.

Isn't this the kind of investment that a reputable company like yours ought to be making or ought to think about making before disseminating claims to consumers?

MR. LAZARUS: Well, I think it's actually quite remarkable that they've spent $35 million on scientific studies. I think that the record shows that actually they've been incredibly responsible about it, but the complaint counsel's own expert testified that in some of these circumstances, to do the appropriate randomized, controlled testing would cost between $6 and $600 million.

CHAIRMAN LEIBOWITZ: Complaint counsel, as you know, has asked for a preclearance by the FDA as a requirement if we find liability here. Would the cost of that be exponentially greater than the cost of RCTs?

MR. LAZARUS: Well, I think the cost in time might be --

CHAIRMAN LEIBOWITZ: Well, I mean --

MR. LAZARUS: -- extraordinary.

CHAIRMAN LEIBOWITZ: I didn't necessarily mean the monetary cost, although that could be part of it, but the cost and time as well.

MR. LAZARUS: I think that that would be an extraordinarily burdensome remedy. The ALJ spent ten pages explaining why he rejected it, but there are other reasons for rejecting it, too, which is it ends up having this Commission ask its own enforcement employees to interpret the FDA Act, which it should not be doing because they have exclusive jurisdiction. And I'm sure you can understand the reciprocal problem, and in addition to that, it co-ops the resources of another agency to do the work, to do work that has not been assigned to them by the statute.

CHAIRMAN LEIBOWITZ: So, then, are you also suggesting that the FDA doesn't always move with alacrity?

MR. LAZARUS: I'm suggesting that the public record suggests --

CHAIRMAN LEIBOWITZ: Unlike, say, the FCC?

MR. LAZARUS: Well, yes. Well, we can take that to a different time and place, but what I am saying is that it would be tantamount to a prior restraint to send us to the FDA, and I think it would raise both Constitutional and legal issues if you do.

COMMISSIONER RAMIREZ: I would like you to touch on the due process arguments that you make. Can you tell me what your clients would be relying on in terms of prior guidance from the Commission that you think would prohibit us from holding that two RCTs would be required here?

MR. LAZARUS: So number one would be the dietary supplement and food policy statements, which have been in place for a long time, and which don't mention RCTs.

COMMISSIONER RAMIREZ: Can you point me to the specific language that you think governs here?

MR. LAZARUS: So, yes, those statements both cite -- first of all, they don't ever mention RCTs, and second, they say --

COMMISSIONER RAMIREZ: And was that dispositive?

MR. LAZARUS: No.

COMMISSIONER ROSCH: No, Thompson Medical says

that that's not dispositive.

MR. LAZARUS: There is one stray line in Thompson Medical which, given the facts of Thompson Medical, is complete dicta, which does say two RCTs, but I will tell you that if you look at the appellate decisions in QT, if you look at the appellate decision in Direct Marketing, they say the opposite.

COMMISSIONER RAMIREZ: Can you point to me language in the actual enforcement statement?

MR. LAZARUS: Yes, it says -- I don't have the exact language in front of me, but the paraphrase is that when it talks about credible and reliable evidence, it talks about a variety of types of testing as long as it meets the following definition, which I'll find in a second. "Evidence conducted and evaluated in an objective manner by persons qualified to do so using procedures generally accepted in the relevant profession with accurate and reliable results."

That's not RCTs, and it's especially not RCTs in the nutritional context as eight experts at trial have testified. This would be a new imposition -- look, the world is talking about this case for this reason. The world does not think that the -- the world of food advertisers don't think they've been under an RCT standard before.

They think this is surprise, just like it was a surprise in the Fox case at the FCC where the FCC imposed a fleeting expletive standard on the indecency regulations without giving -- and tried to apply it retroactively.

If you want to have a prospective rule with respect to RCTs, I think that would be bad policy for the reasons stated by the experts.

COMMISSIONER BRILL: But isn't this supposed to be driven by the nature of the claims?

COMMISSIONER ROSCH: Absolutely.

COMMISSIONER BRILL: Maybe the world is watching this not just because of the potential that we will impose a requirement of RCTs and that that will be litigated, but rather because of the nature of the claims that your client was making, which we haven't seen before, that a juice will prevent cancer or a juice will treat cancer.

MR. LAZARUS: Well --

COMMISSIONER BRILL: Those are pretty strong claims.

MR. LAZARUS: Of course, we come back to the same issue, Commissioner, which is you just don't find that language in these ads. What you find is the syllogism of, we're --

COMMISSIONER BRILL: The ALJ disagreed with you on that, so -- okay.

MR. LAZARUS: With respect to a few ads.

COMMISSIONER ROSCH: Well, with respect to the methodology you used with respect to all of the ads.

MR. LAZARUS: I'm not sure I understand, Commissioner.

COMMISSIONER ROSCH: Well, with respect to the methodology that you used to be sure, he found that certain ads contained these claims. He found that other ads which said exactly the same thing did not find these -- these claims were not implied.

MR. LAZARUS: They don't say the same thing, and he summarizes very accurately why. Some of the ads don't even refer to any of the diseases, and the attenuation is much greater, and in all the ads -- you know, it's in the brief, and I'm way over my time, and I apologize for that.

But I break down the Playboy ad, and it's broken down in the briefing. I don't think a consumer looks in Playboy for its -- for medical treatment. These things are sold --

COMMISSIONER ROSCH: I don't know that I look in Playboy for any kind of treatment.

MR. LAZARUS: Well, you and I are in agreement

on that point, Commissioner Rosch, so I'll -- I'm way over my time.

COMMISSIONER OHLHAUSEN: Actually, I have a question.

COMMISSIONER LEIBOWITZ: You don't need to apologize. This is a fairly hot bench today. Go ahead.

COMMISSIONER OHLHAUSEN: So, there's a lot of government dietary recommendations that make a link between certain nutrients and certain diseases. What kind of evidence does the government rely on to make those claims in your knowledge?

MR. LAZARUS: There is -- there is general scientific consensus that antioxidants are really good for you because they fight free radicals. POM Juice is extremely high in antioxidants and has been shown in these tests to actually have efficacy in these trials, and that's what the client is saying. If you set the standard too high, you are telling consumers that they can't have this stuff.

COMMISSIONER OHLHAUSEN: Are those recommendations always based on RCTs?

MR. LAZARUS: No.

COMMISSIONER OHLHAUSEN: Or are they based on other evidence, epidemiological or other evidence?

MR. LAZARUS: Many of them are -- well, I can't

speak to the government ones, but if you look on some of the major Mayo Clinic type web sites, some of them cite our studies. That's how convinced they are. That's what the peer-review process is about. It's about figuring this out, and if you set the bar too high, you're going to deprive consumers of information which is important.

If I can just make one point on that, which is Dr. Davidson -- complaint counsel says the Davidson study is terrible for us. That's dead wrong for reasons I will get into in rebuttal, if necessary, but the proof is in the pudding. After we did the test, what did Dr. Davidson do? He started taking POMx pills, and we should let consumers do that, too.

CHAIRMAN LEIBOWITZ: Can I ask one more question on a slightly different topic, which is how to treat media appearances?

MR. LAZARUS: Yes.

CHAIRMAN LEIBOWITZ: So, the ALJ found that the FTC Act didn't reach -- didn't reach media appearances, so I have a statutory question for you, and then I have sort of more of a Constitutional question.

So, statutorily, even if a media appearance isn't an advertisement under Section 12, which prohibits dissemination of false advertisements, couldn't it at

least statutorily be actionable under Section 5, which prohibits deceptive acts and practices?

MR. LAZARUS: I think the statutory language is irrelevant because the First Amendment would prohibit it.

COMMISSIONER LEIBOWITZ: So, let's get to the First Amendment question. Is it your sense or your contention that any statement made during a nonpaid media appearance, solicited or nonsolicited, is always completely protected by the First Amendment and immune to challenge from the FTC Act, even if it's demonstrably false and intended to promote a product?

MR. LAZARUS: Mr. Chairman, you are going to have to read that question again.

CHAIRMAN LEIBOWITZ: I won't even read it. I'll just say: If you have a nonpaid media appearance, is there blanket First Amendment protection even if the purpose of going on the Today Show or the something show is to promote a product, and even if the claim is demonstrably false?

MR. LAZARUS: Gentlemen, I think it's not commercial speech, and first of all --

CHAIRMAN LEIBOWITZ: Can it never be commercial speech?

MR. LAZARUS: I'm not going to say never,

because it's hard to say what never is. What I can say is that there are hundreds of these interviews every day, hundreds and hundreds in the cable world where people are invited on, and what are they doing? Even if it's Fox Business News, they're pitching their mutual fund, at least indirectly, or their stock, giving advice, or they're a retailer and come to Best Buy is the implicit message of all that.

CHAIRMAN LEIBOWITZ: If it's a paid-for ad or it's a paid-for Infomercial, that's totally different from your study.

MR. LAZARUS: I would give you two factors. Paid-for is really important, so most of what the case law is really about -- like Bolger. It's about you have an ad, but if you talk about public issues, does that take you out of commercial speech, not what gets you into commercial speech. So, what you've got is two things: One, the paid-for is very important, but the other is you don't control this medium.

One you go on Fox News or you go on Martha Stewart, you're not in control of that. It might be -- you could think of a scenario where you have written the script and everybody is going -- that's possible. But what if -- what if Martha Stewart had turned to Lynda Resnick and said, That's BS? I mean, you don't know

what's going to happen. That's a classic public forum.

CHAIRMAN LEIBOWITZ: What about like where you solicit the interview?

MR. LAZARUS: Solicit is another possible area, gray area.

CHAIRMAN LEIBOWITZ: We had noticed in the record I think that your client solicited --

MR. LAZARUS: But I would not suggest that here. So, this is an easy case. There might be hard cases, but this is an easy case on those interviews.

COMMISSIONER BRILL: Mr. Lazarus, I just want to follow up really quickly on something Commissioner Ohlhausen asked you with respect to nutritional guidance, and you said that that's not usually based on RCTs.

Aren't many, many of those guidances, however, based on longitudinal studies, and aren't longitudinal studies considered -- they're not RCTs. It's not randomized, it's not placebo-controlled, but a longitudinal study about eating vegetables and what vegetables do for you, isn't that considered to be pretty rigorous science as well?

MR. LAZARUS: It is rigorous science. I would simply say that this is rigorous science, too, and you had a lot of experts come in and testify that it was

rigorous science. The idea that this company has built these health claims on bogus science is wrong.

COMMISSIONER ROSCH: I hear you, Counsel, but I have to say that as a body that is interested in protecting consumers as well, there's a danger in setting the bar too high. There's also a danger in letting you set the bar too low.

MR. LAZARUS: Commissioner Rosch, I 100 percent agree with you. I think that's exactly the question before the Commission. I will simply say this, that in the context of a natural food product that is 100 percent safe, that should be drawn in a different place than in something that's untested or something that's potentially dangerous.

I agree with you. You've identified the policy question that I would 100 percent agree with, but in the context of a safe, natural food, there's a different standard, and don't take my word for it. Take Dr. Miller's word for it. He's the expert that was used in DCO. He came in and testified for us in this case. Don't set the bar too high.

COMMISSIONER ROSCH: The question that I have is, frankly, following up on my colleague's claim, Commissioner Brill's claim that our statute identifies what a drug is, and sometimes a food can be a drug.

MR. LAZARUS: I think that you would find that that definition sweeps very, very broadly if, in fact, you go down that road.

COMMISSIONER BRILL: But that's what Congress told us we had to abide by. That's the statute.

MR. LAZARUS: I do not think that a natural food sold in this way in the grocery section of your store needs to be called --

COMMISSIONER BRILL: But you can't find any place in the statute that makes that clear.

MR. LAZARUS: And you can't find anywhere in the ads that suggests this is some pharmaceutical-type drug.

Thank you very much.

CHAIRMAN LEIBOWITZ: Thank you. Mr. Friedman, we'll try to give you your five minutes and not 25 minutes.

MR. FRIEDMAN: Thank you, Mr. Chairman, Members of the Commission. I'll try to take less than the five. I want to focus on one very narrow issue, and that is the remedy with respect to my client, Matthew Tupper.

As you know, the test used by the ALJ and adopted by the circuits is basically participation or control, participating in the offending ads or control of the entity making the offending ads.

However, when you read the circuit cases, the

cases really talk both about participation and control. Rarely do they talk about participation alone, and the control tests really come down to what the Court said in the Direct Concepts Marketing case, and I think it's a good test: Could the individual have nipped the offending ads in the bud? And I think that test was adopted by the ALJ, but I believe it was misapplied by the ALJ.

Mr. Tupper is not an owner and never has been an owner of this company. He did serve in the capacity of COO and CEO. However, POM Wonderful and the Roll companies are unique companies. They are owned and run by two individuals, Mr. and Mrs. Resnick, and those two individuals do more than simply own and run the companies.

With respect to POM Wonderful, they basically were found by the ALJ as who had the ultimate say over all business functions. They set the policy. They supervised the senior executives. Ms. Resnick was found to have complete oversight over POM's business, including all branding and marketing, and she had the final word on advertising content and concepts.

The Resnicks were also found to have the final authority over advertising decisions. They set the marketing and research budget. They approved and

sponsored the research and funded it, sometimes personally out of their personal trust, and they approved the direction and content of the ads at issue in this case.

So, based on the record of the case and the ALJ's decision, I do not believe that you can find that Matthew Tupper could have nipped the offending ads in the bud.

Without any disrespect to my client, Matthew Tupper, who I like and respect, I believe we would be standing here before you -- maybe I wouldn't be, but Mr. Lazarus would even if Mr. Tupper had never worked at POM Wonderful. So, I think that that gives you added meaning to what nipping the offensive ads in the bud means.

I think you don't have to speculate about this because as the Commission is well aware, following the ALJ's decision, there was a motion made by complaint counsel to reopen the record to put into the record ads that were run after the ALJ's decision that the complaint counsel felt included the same offensive or offending ads or messages that had been litigated in the case, and they did so arguing that that was relevant to the scope of relief in this case.

Now, while the Commission -- while Your Honor,

Mr. Chairman, denied their motion, I do agree with the issue of relevance here. I think it is relevant, and I think they did Mr. Tupper a favor, to tell you the truth, because Mr. Tupper had not been at POM for a period of at least five months when those ads ran. He announced his retirement in the spring of 2011. He left at the end of 2011, and those ads were run in I think May or June of this year, so the proof is in the pudding.

The messages that the complaint counsel litigated in this case were, in their view, reiterated, and Mr. Tupper had nothing to do with it. I would ask you to refrain from including Mr. Tupper in the injunctive relief. There is no need to do so.

The cases speak about deterrence and making sure that individuals, even if they've left a company or are no longer -- the company is no longer in business, that the order should be in place to deter them from any further wrongful conduct, but Mr. Tupper, number one, has never had any history of regulatory problems. This is the first matter he's ever been in. And he has left the company. He's retired. And I don't know his intentions with respect to returning to work anywhere, but I do know the effect of this kind of an order on his ability to return to work.

CHAIRMAN LEIBOWITZ: So, can I ask you a question which is, is this more, from your perspective, about the FTC, the Commission following the case law in this area, or is it more about sort of Commission clemency or nullification?

MR. FRIEDMAN: I think you could include Mr. Tupper -- if I can get to the essence of I think what you're asking me, Mr. Chairman, I think you could include Mr. Tupper in the order. I don't think the -- the question is whether you should, so if that's responsive to your question.

CHAIRMAN LEIBOWITZ: Very responsive.

MR. FRIEDMAN: I would end, Members of the Commission, by saying the following, which I just alluded to, and that is the effect of an order like this on an individual who is not an owner of a business, who may have to seek employment in other places, who worked his life in the food industry, is basically a bar, and because the reporting -- a 20-year injunction and a 10-year reporting requirement for employment is, in essence -- no new employer would ever touch that.

It's a chilling effect on his ability to ever get a job should he want to, and I would ask that you give that very serious consideration in your deliberations. Thank you.

COMMISSIONER LEIBOWITZ: Thank you very much, Mr. Friedman.

Ms. Hippsley? Take your time. Are you sure you want the monitor off?

MS. HIPPSLEY: It's off momentarily, but thank you for asking.

CHAIRMAN LEIBOWITZ: Do you want a minute to get it back on to your program?

MS. HIPPSLEY: I'm good. It's there.

CHAIRMAN LEIBOWITZ: You may begin.

MS. HIPPSLEY: My technical wizardry back here is taking care of it, I think.

COMMISSIONER LEIBOWITZ: You may begin. You have 45 minutes, and if you want to go over a little bit, I don't think anyone will object to that.

MS. HIPPSLEY: Thank you. Good afternoon, Commissioners. This is a classic false advertising case. Respondents are not the first to argue before this Commission that they have a plethora of science to back up their claims, and they're not the first but rather one of many advertising matters where the claims got ahead of the science.

What is extraordinary is the amount of record evidence that demonstrates the principals, Mr. and Mrs. Resnick, company president Matt Tupper, overrode the

notes of caution found in the evaluation of their science by the scientific community at the time they were making the claims, and that included the published research itself, and they persisted in claiming that the POM products treated, prevented and reduced the risk of disease when they knew that the research results fell short.

To understand just how over the top respondents' ad claims were about their scientific research, I would like to walk through the prostate cancer study as an example.

In the summer of 2006, Dr. Allan Pantuck published this exploratory study examining the effect of POM juice on prostate cancer specific antigen-doubling time, PSADT, in men who had been previously treated for prostate cancer.

The published article itself acknowledges that further research is needed to address the limitations of the study, namely, the lack of a blinded control group, and then it remains controversial whether modulation of PSA levels is a valid clinical end point.

Indeed Dr. Pantuck candidly told the respondents and the press in a New York Times article discussing his study and reaffirmed at his deposition in this matter: "I'm not at the point where I would say that everyone

who has prostate cancer or who is at risk for prostate cancer should be drinking POM juice."

Ms. Resnick, however, told consumers not only that POM Juice is the magic elixir of our time, but specifically stated that every man should drink POM juice daily for prostate cancer, and I would like to show you the clip of her saying this.

(Whereupon, a clip from The Martha Stewart Show was played for the Commissioners and not transcribed.)

CHAIRMAN LEIBOWITZ: Is there any evidence in the record that she solicited this interview?

MS. HIPPSLEY: Yes. In Exhibit 1, which is her book explaining her marketing, she has a section that's in our findings where she discusses how public relations is so important, an important marketing --

CHAIRMAN LEIBOWITZ: So, she called Martha Stewart up or she had her people?

MS. HIPPSLEY: She explains that one of her goals was to get on the Martha Stewart Show. To be on the morning news shows gives you credibility.

CHAIRMAN LEIBOWITZ: To talk about POM? I mean, they have other products, don't they?

MS. HIPPSLEY: For POM. This was in relation to the POM campaign, and she explained how she sent Martha Stewart a crate of pomegranates every year.

CHAIRMAN LEIBOWITZ: So, what's your limiting principle on the reach of Section 5 with regard to statements made in media appearances, or do you have no limiting principle, none whatsoever?

MS. HIPPSLEY: I'm sorry, what was that?

CHAIRMAN LEIBOWITZ: What's your limiting principle? I mean, when is it that someone can do an interview on a TV show where they solicit it or don't solicit it, and how far does the FTC Act essentially -- how far does it reach? I'm not so sure it reaches to that situation.

Why don't you tell me why it doesn't?

MS. HIPPSLEY: It reaches the situation, and the Commission outlined very nicely the indicia as to where the line crosses from just giving a media appearance that is not commercial speech to one that is commercial speech.

That is in the R.J. Reynolds Tobacco decision, and the elements -- you had asked Mr. Lazarus, is paid advertising just a per se bar, and that is exactly what the Commission found was not true. The Commission said that there are five nondispositive indicia of commercial speech.

Paid-for advertising obviously is one of them, but the other four, which we argue in our briefs that

the media appearances that we are challenging all meet, the other four indicia were: A message promoting demand for the product; refers to the specific product or service; conveys information about the attributes of the product, that's exactly what Ms. Resnick is doing here; and is for the benefit, the economic interest of the speaker who is promoting sales of the product.

CHAIRMAN LEIBOWITZ: Now, remind me, is this the FTC decision or the appellate decision?

MS. HIPPSLEY: This is the FTC decision.

CHAIRMAN LEIBOWITZ: So, cite for me some case law on how these types of interviews or advertisements -- where it wasn't necessarily procured, it might have been, or sponsored for the purpose of promoting a product -- give me an example where we -- I mean, we don't know. It sounds to me like you read her biography. Her biography says she likes to go on television shows to promote products.

Therefore, your syllogism is that she was promoting this product deliberately, and she might have been, but if she hasn't paid for it, tell me why -- tell me why the reach of the FTC Act should encompass this situation.

MS. HIPPSLEY: Because as we developed in the record, and really what's very important for the

Commission in this day and age, is that a lot of marketing is done -- quote, unquote -- free earned media. They kept track of how much money they were saving by getting into the media and getting these touch points where their products were discussed in the media, and it meets these other indicia that the Commission has outlined, which came from the long line of the commercial speech cases by the Supreme Court, and these indicia are all found in these media appearances.

She's promoting her product. She's not saying pomegranates generally. It's all about POM Wonderful, POM Juice.

CHAIRMAN LEIBOWITZ: They own a substantial amount of the pomegranate market, production market, so there might be --

MS. HIPPSLEY: She definitely wants to keep it.

COMMISSIONER ROSCH: Counsel, would your answer be the same -- talk about limiting principles. Would your answer be the same if she had not made a treatment or prevention argument with respect to prostate cancer?

MS. HIPPSLEY: Well, one of the indicia is discussing the attributes of the product, and I think you would have to look factually at these various interviews and see how many of the indicia of commercial speech are present.

COMMISSIONER OHLHAUSEN: So, then, your point is if she went on and she was on Martha Stewart, and they made a POMtini, which they did, and she said pomegranate juice is delicious, it's wonderful, and it goes great with this, that would still be commercial speech because it's an attribute of the product?

MS. HIPPSLEY: Correct. And, of course, there would be nothing wrong with it.

COMMISSIONER OHLHAUSEN: Right. But what we're talking about is not whether it's wrong or right but whether it's commercial speech or not commercial speech.

MS. HIPPSLEY: Correct.

COMMISSIONER OHLHAUSEN: And then I have a question of the intertwining of non commercial speech with commercial speech. Like, for example, the CBS Early Show, almost all of that interview she's talking about her book.

MS. HIPPSLEY: Right.

COMMISSIONER OHLHAUSEN: She mentions very briefly the product, the POM, so I guess my question is: How do we pull those threads apart such that if there's just a little bit of talking about the product and talking about one of its attributes, that somehow that pulls the whole interview into commercial speech.

MS. HIPPSLEY: Right. I think that you do have

to look at how much of the context of the speech that we're examining does go towards a commercial element, and even in that CBS morning show, the whole thing was something about turning cash -- turning your marketing into cash or something, and then her book, of course, is focused on how she succeeded selling POM Wonderful.

And then by example, she runs through the success and the attributes of the POM Wonderful products. She also does that I believe with the Fiji and touches on a couple others. The focus though was the POM products.

CHAIRMAN LEIBOWITZ: There's no evidence that she solicited --

MS. HIPPSLEY: No.

CHAIRMAN LEIBOWITZ: Not even sort of generic?

MS. HIPPSLEY: No, there's no evidence that she directly solicited to get on that CBS Morning Show, but her -- the evidence is that they felt public relations generally and they worked hard and we had the testimony of the director of the communications -- they worked very hard to get themselves into the press.

CHAIRMAN LEIBOWITZ: So that would be a closer call from your perspective.

MS. HIPPSLEY: The CBS Morning Show is probably the closest definitely of the three, because it touches

on the book as well as the POM Wonderful. Again, the whole nature of it was commercial, but what I was going to say is what we didn't challenge, just your concern about the limiting principle, we did not challenge many, many, many, many interviews that the company conducted where it was just a fleeting question and an answer about the POM products, and the overall interview was about the history of the businesses and all their different brands and that sort of thing.

So I think it's very factually based, the determination. And then jumping --

COMMISSIONER ROSCH: Didn't we confront this same problem in DCO, that is to say, the First Amendment problem? In the case, as I recall, we distinguished the Shalala case, for example, on exactly the basis that the Chairman described, namely, that that involved a rule, and this involved an enforcement action only.

MS. HIPPSLEY: Yes. I mean, in terms of liability generally here, there is no First Amendment issue at all. It is an enforcement action, and if the speech is found deceptive, of course there's no First Amendment protection.

COMMISSIONER ROSCH: Is the commercial speech issue a First Amendment issue?

MS. HIPPSLEY: In terms of the media appearance,

I think that there is a controversy, but in terms of the liability for the remainder of the ads where respondents were trying to raise the First Amendment argument, we think that it holds no water at all because just as you found in Daniel Chapter One, it's an enforcement action. If the ads are deceptive, then there is no First Amendment protection.

Here with the media appearances, it was more of a threshold jurisdictional issue to look at the advertisements.

CHAIRMAN LEIBOWITZ: Let me follow up on the question Commissioner Rosch asked involving Daniel Chapter One but a different issue, and it relates to the proposal that you have to overturn the ALJ's decision and ask for FDA preclearance.

So two years ago in the Daniel Chapter One case, which alleged, I think everyone understands, much more egregious cancer claims, complaint counsel only pursued an order requiring competent and reliable scientific evidence, so what's changed since then?

MS. HIPPSLEY: It really was a timing issue. At the time of Daniel Chapter One, the notice sort of went out, and complaint counsel did not feel it would be appropriate to change in midstream based on the new settlements that the Commission had entertained in

Dannon and Nestle, that they would have been denied their due process basically.

And so because the notice sort of went out and had only competent reliable scientific evidence, it really is just the nature of the timing, and as Thompson Medical, the D.C. Circuit said just because something hasn't been done before doesn't mean we can't do it.

CHAIRMAN LEIBOWITZ: Sure, sure.

COMMISSIONER ROSCH: No, no, I was just curious, has this been done before in a litigated setting, with the exception of Thompson Medical? That is to say, actually we have never required preclearance by the FDA, have we, in a litigated settlement?

MS. HIPPSLEY: In a litigated settlement or --

COMMISSIONER ROSCH: In a litigated area.

MS. HIPPSLEY: There has not been a determination using that remedy.

COMMISSIONER ROSCH: Why should we rely on consent orders for a litigated judgment? I don't understand that at all. Consent orders, sometimes counsel would recommend to a client, for example, that they take a consent order requiring preclearance because they would like the certainty over the straightjacket. They value the certainty of the preclearance order by the FDA over the straightjacket of the FDA or

alternatively, counsel may decide that they just don't want to court the uncertainty and cost of litigating the matter, and it will -- it will therefore accept preclearance.

But in this setting, that is to say in a litigated setting, aren't we guessing what counsel would recommend to their client? I don't understand -- to my way of thinking, the Nestle order, it has nothing at all to do with what you're asking for here.

MS. HIPPSLEY: The order that the Commission entered in the consent context, I would agree has a modicum of information for the Commission. That is, the Commission would not even enter settlements, for example, if they felt that they were of an unconstitutional nature.

COMMISSIONER LEIBOWITZ: Sure.

MS. HIPPSLEY: Very tiny little things like that. I agree that the test here is whether or not the remedy that we're seeking in part one of the Notice Order fits the facts of this case and the fencing in that is needed to keep these respondents in line with the law, given the record we've developed, and that is the most important factor.

CHAIRMAN LEIBOWITZ: I want to just come back -- I'm sorry, go ahead.

COMMISSIONER RAMIREZ: I was just going to ask you to answer the next question: Why is that an appropriate -- why is the standard that you're proposing the appropriate standard to be imposed in this case?

MS. HIPPSLEY: Right, and here the record -- if you go through our findings, the record here is that the seriousness of what the respondents did is of a very high level. These are serious disease claims. If you find that they made these claims and they were deceptive because the science didn't come close to touching what is necessary for a treatment and prevent claim, then the problem we have here is the respondents are saying they need competent and reliable evidence.

Mr. Tupper is saying today his science is eight out of ten when the record shows that the scientific community told him it was a three. All right? So the seriousness is high and then the delivery --

COMMISSIONER RAMIREZ: Commissioner Rosch was talking about the dangers of imposing a bar that would be too high. Doesn't this impose a hurdle that is, in fact, too high, FDA preclearance? Doesn't that amount effectively to a ban, and doesn't that then mean that we do run into First Amendment issues?

MS. HIPPSLEY: No. It's a very narrow fenced in that's actually very well tailored to the situation

here. So part one, how it would operate is the respondents, when they are looking to make advertising claims for the POM product line, not any of their other products, just the POM products, which were the basis of the lawsuit, and they want to make the disease treatment, prevent, reduce risk claim, no other claims, those claims that again were at issue here and were found to have been marketed deceptively, then to do that, they have to be able to demonstrate that FDA has passed on those claims through various vehicles.

For example, let's say right now there's a health claim on the books that for a fruit and vegetable -- for a fruit and vegetable claim, that it reduces -- may reduce the risk of cancer, okay? That FDA approved and an LEA claim exists on the books today.

If respondents meet the definitions for the food that can utilize that claim, they can make a reduced risk -- may reduce the risk of certain type of cancers with the low-fat diet today. They can use that claim actually. They can use that FDA and LEA claim right now for their pomegranates.

The reason they can't use it for their POM juice is because the POM juice is stripped of its nutrients. There is no vitamin C and no fiber.

CHAIRMAN LEIBOWITZ: Why would -- let me ask you

two questions. First of all, it could also be that in the other example you just proffered, that that company wants to go to the FDA and wants their imprimatur. In this instance why wouldn't, for example, an RCT be sufficient or two RCTs?

MS. HIPPSLEY: Again --

CHAIRMAN LEIBOWITZ: Didn't one of your experts say that or suggest that?

MS. HIPPSLEY: There's two reasons that we posit the part one notice sort of over the option of randomized, controlled tests. It's definitely possible and would be an appropriate remedy here to impose a randomized, controlled trial if it was a properly defined standard.

The problem is as we have litigated mildly over this issue, and as you just heard, the respondents, in fact, still think that the largest 289-person randomized, controlled trial that was presented here is positive when the peer reviewers, the publisher and the entire scientific community knows it's negative so it won't shortcut or deter them.

CHAIRMAN LEIBOWITZ: Sure. So listen to the other side of the coin. Let's just say, let's assume hypothetically that the respondents here went back and they got significant scientific agreement, right, which

is the FDA standard, for a disease prevention, risk reduction, treatment claim.

How long does it take the FDA to process that? Is it a month? Is it a year? Is it two years? How can we conclude with any confidence that the FDA would move with any sort of alacrity even if the product is one that really does have enormous health value?

COMMISSIONER ROSCH: Put it differently: Aren't you concerned about that, about tying yourself too closely to the FDA?

MS. HIPPSLEY: In this situation, for these respondents where we know that we are going to be in instant litigation on what is a proper randomized controlled trial, if that were the section, or instant litigation on how to define competent reliable, no, we are not concerned.

As in the National Lead case, there is an out. If it turned out that they had this fantastic SSA evidence, and they were able to show us that they've been begging FDA to approve this for, I don't know what the Commission would think is reasonable, a year or two, and for whatever reason the FDA was not there, most of the time the FDA is not there because the evidence actually is not how they say it is, but let's say it was, and they were able to show us that, they can come

back and seek order modification, and that's what National Lead says.

The burden shifts. They have been found to have deceptive advertising. They have to take some burden with the order to bring them back to a level playing field.

COMMISSIONER OHLHAUSEN: But one of the things with the burden, and I think a lot of this ties back to some of the Pfizer factors, because making it more difficult to make the claims that may be true and may have a benefit for consumers when there isn't a high risk can also have a cost apart from -- have a cost in the public health.

MS. HIPPSLEY: Absolutely, and that's why the order is set out much like the food policy statement. Part one is only operative for the narrow set of unqualified health claims so it would be a prevent, treat or reduce risk. The decision is the Commission's own ad interpretation.

If the Commission agreed with respondents, that the claim is short of that, the claim is a qualified claim, giving well qualified information about emerging science, they would be into the traditional section of the order that we've used, part three, for competent and reliable scientific evidence, and we would have to work

it out with experts and everything and basically relitigate whether that claim had adequate science.

COMMISSIONER OHLHAUSEN: Actually that brings to mind a question that I have about your claim interpretation. In your briefs, you kind of make the suggestion that if you say health, that's a code word for disease so if you're making a health claim, you're really making a disease claim, and I wanted to explore a little bit how that works, and how you would be able to make a structure function claim then if it says support heart health or something like that, and if you could sort of clarify that.

MS. HIPPSLEY: Right. Just to make sure that it is clear, in the briefs, it's definitely in the context of these respondents' ads and the way they were using the term health and the record evidence showing that both Ms. Resnick and actually their linguist, too -- that health was a code word and euphemism for disease.

COMMISSIONER OHLHAUSEN: Are you basing that on the net impression of the ad or just saying the health?

MS. HIPPSLEY: It's the net impression of the ad in the facial analysis, and also there is record evidence that that indeed was what they intended to do, to use health as a euphemism for disease.

COMMISSIONER OHLHAUSEN: So for intent, I mean,

the ALJ found we shouldn't really be looking at intent that much, intent of the speaker. It should really be what consumers take from that.

MS. HIPPSLEY: Right, and with all due respect, that's definitely in error.

COMMISSIONER OHLHAUSEN: Did you ever need to take into account a lack of intent to say that a claim wasn't made?

MS. HIPPSLEY: Well, the way it works, if you look at the Telebrands case, which is fairly recent that the Commission issued, intent is not necessary to find a violation of Section 5, but intent, as Telebrands said, informs the facial analysis, and intent is powerful evidence of what is being communicated to consumers.

And as you recall, Telebrands was about implied claims, and there, like here, the company was being oh so clever, and Ms. Resnick is a very clever marketer, and they have very good legal counsel. They were trying to walk the line -- of course, we argue they didn't come close to the line; they went way over it, made disease, treatment and prevention claims.

In Telebrands, the intent evidence informed the facial analysis because there they were trying to sell the Ab Belts based on people's prior beliefs that the other advertising and the evidence of intent was,

Let's mooch off this other advertising, and the Commission said, Well, that intent informs our facial analysis.

Knowing what you were trying to pull, we're looking at these ads, and they are deceptive ads. With the facial analysis, we take exception that the ALJ or we miswrote I guess that somehow he thought we were looking at intent exclusively, which we were not.

The primary evidence is a facial analysis, but it is informed by intent.

COMMISSIONER BRILL: Ms. Hippsley, can I bring you back to the fencing in because I had some questions about that, if that's okay with my fellow Commissioners for a moment?

MS. HIPPSLEY: Yes.

COMMISSIONER BRILL: Before we get too far afield. I have a few questions. Did I hear you say that if this Commission were to find that experts in the field would require RCTs for these specific claims that we find to be in need of substantiation and that are the central focus of this claim -- if we were to require RCTs for substantiation going forward, would you need to have this fencing in relief, that is the pre-approval by the FDA?

MS. HIPPSLEY: I think in this case, I know that

in some of the structures of the settlements, both things were included. I think here, the structure that we contemplated in part one was in lieu of the randomized controlled trials again because, frankly, given the record here and the intent and the knowledge that they were making claims without substantiation, we do not want the respondents to be the judge of the science.

And a randomized controlled trial standard would still have them being the judge, even though we define randomized controlled trials.

COMMISSIONER BRILL: And let me -- I'm so sorry.

MS. HIPPSLEY: And the other point I did not make previously in thinking about this, also I do think that part one actually provides more flexibility and guidance for respondents in the future, particularly when it comes to health claims.

The FDA looks at more than randomized controlled trials. They look, as you said, at longitudinal studies, observational studies, epidemiology. Right now, for example -- and we had posited, too, that FDAMA claims could be added to part one as one of the criteria.

A FDAMA claim, by the way, for fruits and vegetables was done in six months. The FDA allowed it,

negative option, and it was done on epidemiological research for fruits and vegetables that are high in potassium.

So I think it actually offers more flexibility and is less rigid than the randomized, controlled trial situation for the unqualified health claims if they were able to find those some day to reduce risk.

COMMISSIONER BRILL: So, one of your concerns is the notion of who will judge whether it was truly a randomized controlled trial, I get that, and you're looking to the FDA to be neutral arbiter on that issue.

Do you have a plan B? Is there someone else that could serve as a neutral arbiter in the event that some Commissioners determine it was placing too much authority in another agency? Is there some other form of neutral arbitration that can be developed?

MS. HIPPSLEY: Well, I think the randomized controlled trials would be the next best approach because it would be the next best clear and bright line guidance. If the sections are well written and it states directly it has to be a valid end point, that ends the problem with the prostate cancer studies.

CHAIRMAN LEIBOWITZ: Let me just ask you this question. How would a company, let's say hypothetically POM, move from an unqualified claim to a qualified claim

because obviously you -- complaint counsel believes, and we may agree with you, that things like can help prevent premature aging, heart disease, stroke, this is in Exhibit 36 which we discussed earlier, may not qualify the claim? How do you qualify the claim?

MS. HIPPSLEY: Right. Qualifying the claims is very difficult, but if they can qualify the claim and explain that they have emerging science without triggering an impression for the consumer that the takeaway is that they reduce, prevent or treat the disease, but rather they have emerging science that may one day show this, and it's not all dressed up as here which took away --

COMMISSIONER LEIBOWITZ: I just want to understand this from complaint counsel's perspective. They could describe the results of research so long as they described it more accurately. They could reference studies.

MS. HIPPSLEY: Well, it's a possibility. As we have said in the analysis to aid public comment, the Commission in the other cases, there's a big warning to marketers that it's extremely difficult to do, and what we said in the analysis public comment though is that if they have extrinsic evidence, the right thing to do is decide how they want to present their science, copy

test.

They show the Commission that they have copy test evidence showing that consumers are getting it. They get the qualified claim, not a treat or prevent claim.

COMMISSIONER OHLHAUSEN: Doesn't that reverse the burden? I mean, don't you have the burden?

MS. HIPPSLEY: For the order? No.

COMMISSIONER OHLHAUSEN: But generally?

MS. HIPPSLEY: This is not de novo. We are not saying that a company has to figure that out in a de novo setting, but here the conundrum about the order and how the would work under the order going forward, that is the --

COMMISSIONER OHLHAUSEN: But was that your question, John? Was that your question, in the order?

MS. HIPPSLEY: But when you say qualified claims, when you think about it, in all of our orders, that question is always there, how do you qualify a claim well enough so that it's not a treat or prevent claim but rather a qualified claim about emerging science?

That issue is the same whether you're under this order or all our FTC traditional orders.

COMMISSIONER ROSCH: Counsel, you answered the

Chairman with respect to DCO, and you reported to distinguish DCO on the basis that time had passed and that this was a different time.

MS. HIPPSLEY: It was the timing to give them due process.

COMMISSIONER ROSCH: But did we not in DCO hold, hold that we should not wed ourselves to the FDA exclusively? I mean, we were very clear about that in the DCO order, were we not, because we didn't want to -- we said it's a completely different statute? It's a completely different agency? We did not want to tether ourselves to the FDA at that time?

MS. HIPPSLEY: I think the context that it came up in was the argument by respondents that the Pearson case was somehow telling.

COMMISSIONER ROSCH: No, no. It was not in that context either.

MS. HIPPSLEY: Okay. Well, there have been instances --

COMMISSIONER ROSCH: It was in the context of the argument that respondent made in that case that the -- that the FDA's regulations were binding on the FTC, which we rejected.

MS. HIPPSLEY: That has been rejected in other cases, and the context has been -- for example, in the

Sterling Drug case, where ironically -- and in Bristol-Myers, where ironically the respondents wanted us to follow the FDA and the Commission did not, and that was because the fit between in-harmonization didn't work because the claims were superiority claims which the FDA doesn't really address.

They're looking at absolute efficacy claims. That's what the Circuit Courts upheld the Commission's argument on, and that actually here is what's different. These are absolutely efficacy claims, and so the fit does harmonize as the Commission has explained in its food policy statement.

COMMISSIONER OHLHAUSEN: I have a question actually going to not to the order but the level of substantiation required for violation, and I wanted to go through the Pfizer factors with you because it seems to me that you placed a lot of emphasis on the type of claim, that there's an implied health claim here, but what the about the rest of the Pfizer factors? How do they figure into the substantiation here, the fact that it's a safe product, the fact that there's benefits to consumers and how much consumers relied on the claim, which didn't seem to be discussed?

MS. HIPPSLEY: Right. I'll back up -- I'll back into the answer and answer it. First I just want to

make sure to say that here the Pfizer factors deal with the very small minority of the ads. If the Commission agrees with us that, the way we challenged it, 85 percent of the ads made establishment claims, and meaning here, particularly, that they were touting human clinical studies in the ads, and of course that would be the level of science that is necessary, and the Pfizer analysis is not.

For the small amount of ads that do invoke Pfizer, again the most important thing, and even in some of the white papers that, for instance, Dr. Miller relied on by two of our former chairmen, it is a claim-driven analysis.

The Pfizer factors are not weighted evenly. I think it depends on the case that's in front of the Commission, and always the most important thing is the claims, what are the claims being made. If the claim is a treat, prevent, reduce risk of disease claim, then you look to the next Pfizer factor, what would the scientific community require.

Here we've posited that they would require a lot more science than what was presented, and then what is the cost of that? Well, as was pointed out earlier, the cost here is doable, and, in fact, they did randomized, controlled trials that they could do, and then what is

the cost to the consumers?

The juice is expensive, and you're telling consumers -- all these ads say drink the juice daily or take the POMx pill daily, that's all you need, that's $5 a day for the juice.

COMMISSIONER OHLHAUSEN: Compared to drinking the juice?

MS. HIPPSLEY: There's no reason for doing it if there's no basis for the claims.

COMMISSIONER OHLHAUSEN: Let's --

MS. HIPPSLEY: They're buying it for their health.

COMMISSIONER OHLHAUSEN: It seems like you are tying it back very heavily to the claim made and very much less so to the other factors such as the product required and what would be the benefits of a truthful claim.

MS. HIPPSLEY: Right. The thing is the product attributes are what drive what type of product, and the product attributes that were being sold to consumers, nobody has dealt with materiality because it's really a nonissue. The Resnicks admitted consumers buy it for the health.

COMMISSIONER OHLHAUSEN: But it's not -- right. It's the product involved, so this is the food. It's a

safe product.

MS. HIPPSLEY: But they didn't sell it to the -- if they had sold it to the consumers, I wrote down what Mr. Lazarus said, this is a safe natural food, buy it. We have no problem, and consumers are getting what they want, and then we would be wrong under Pfizer to attack that, but they weren't selling that product attribute.

COMMISSIONER OHLHAUSEN: They were selling -- this is a food that you buy in the grocery store without a prescription. You go and you buy it off the shelf, and you mix it, and you make a POMtini with it.

MS. HIPPSLEY: Of course, and if they were saying they're great POMtinis, again we wouldn't be here. Here's the way I look at it.

COMMISSIONER OHLHAUSEN: I'll let you answer, but I just want to say that it seems to me that the Pfizer factors, you can't just isolate one, that they all have to be taken as an interplay.

MS. HIPPSLEY: Correct. It's an interplay, but I do think the type of product is the product attributes, and I look at it this way. If I saw the consumer in the grocery store buying a $5 bottle of POM juice, and I was in the checkout line behind them, and they had the ad that says backed by $32 million in medical research, and these three studies are our

example, and I said to that consumer, Actually, you know, Dr. Pantuck who did that study testified that he is not the -- the science is not there to make a public health statement that all men should drink POM juice for prostate cancer, is that consumer going to buy that $4 bottle of juice.

CHAIRMAN LEIBOWITZ: Can I ask you a question? This is clearly a hypothetical? You don't actually do that in supermarkets, do you?

MS. HIPPSLEY: I stop people.

COMMISSIONER LEIBOWITZ: Let me follow up on something that Commissioner Ohlhausen asked about and you sort of responded to which is -- and I think it's true in the context of efficacy claims involving the Pfizer factors and maybe food and claim interpretation outside of the Pfizer factors. Isn't food a little bit different? In the Pfizer context or the efficacy context, from a reasonable consumer perspective, don't the factors actually tilt to some extent maybe heavily toward a lower substantiation standard for efficacy claims that involves food?

MS. HIPPSLEY: No.

CHAIRMAN LEIBOWITZ: From the perspective of a reasonable consumer?

MS. HIPPSLEY: Not if the food is also a drug,

as Commission Brill stated as listed in Section 15 of our statute. They're not in isolation, so you don't elevate the type of product over the claim.

CHAIRMAN LEIBOWITZ: I understand that, but whoa. This is a little bootstrapping here, but let me just ask a question. From the perspective of a reasonable consumer, wouldn't they be less likely to think that something like a conventional food product treats cancer than say a pill manufactured for that purpose? It seems sort of intuitive. It seems like an intuitive takeaway, right?

MS. HIPPSLEY: So there's two things in that question. For the pills, absolutely not because they were medicinal in nature. They're selling diet substitute, and that doesn't hold for the diet substitute.

For the POM juice, perhaps there's skepticism brought by the consumer, but they're going in looking at 100 percent juice. They've been told the antioxidants theory by the respondents. It's on a backdrop that you need to eat fruits and vegetables to reduce your risk of cancer; that is, fruits and vegetables that have vitamin C and fiber, not this POM juice that does not, but they have a backdrop that fruits and vegetables are healthy for them.

And then they are told that this product is special, this is all you need, it's a magic elixir, it will treat and prevent prostate cancer or heart disease.

CHAIRMAN LEIBOWITZ: Do you think a reasonable consumer believes that POM juice --

MS. HIPPSLEY: It's not the belief; it's the takeaway, with all due respect.

CHAIRMAN LEIBOWITZ: Do you think the takeaway, isn't it from the perspective of a reasonable consumer or a subsection of reasonable consumers?

MS. HIPPSLEY: Yes.

CHAIRMAN LEIBOWITZ: Is that the same with respect to a -- to the juice as it is to that pill or actually with respect to a pharmaceutical? I don't think it is. It doesn't mean these ads aren't in violation of Section 5, but do you think it's exactly -- do you think it's exactly the same? It should be treated the same? This is the argument that Commissioner Brill made, and I think it's an interesting one.

MS. HIPPSLEY: Right, but we also have evidence in this record that that was the takeaway. We have the consumer logs where a consumer wrote in and said, So it's a 30 percent reduction in arterial plaque.

CHAIRMAN LEIBOWITZ: Let me just say my

recollection it was in Telebrands, the Commission copy tested, and there might have been a net takeaway that was clear, but there was copy testing, and I think it's sort of interesting that neither side did copy testing here. I don't know that can be a part of our decision, but...

MS. HIPPSLEY: We didn't copy test because the ads are clear. They're clearly --

CHAIRMAN LEIBOWITZ: In Telebrands the ads were clear, and it was -- and the Commission copy tested as I recall.

MS. HIPPSLEY: Here we also had the intent evidence, which, again, I say is quite extraordinary for one of these cases.

CHAIRMAN LEIBOWITZ: Well, some of us who were involved in writing the Telebrands opinion, and that would be only me left over on the Commission, thought that the intent evidence of Mr. Khubani who designed the Ab Belt something or other was pretty clear also.

MS. HIPPSLEY: Right.

COMMISSIONER BRILL: Counsel, can I -- oh, I'm so sorry.

MS. HIPPSLEY: And the other evidence is we have their own business copy testing, and in Telebrands, to get that purely implied claim, it may need copy testing.

The Commission ultimately did find it a facial analysis. Here these claims are -- the functionality of the product which was studiously avoided in the ads in Telebrands, is provided in these ads.

COMMISSIONER BRILL: If I could just ask you quickly, could you address the ALJ's discussion and emphasis on whether or not a product is marketed as a replacement for medical treatment? The ALJ seemed to place some weight on the fact that there is no express claim that consumers should take these pills and avoid going to the doctor or not go to the doctor or instead of going to the doctor.

Have we ever addressed that kind of an issue in similar cases?

MS. HIPPSLEY: Well, I think there's a couple things going on in your question and how the ALJ posited it. He said there was not an express claim by the respondents, Take this in lieu of whatever, a prostate treatment or something.

But I agree with Commissioner Rosch that the net impression of the ads and all this information and prostate cancer and the fear of prostate cancer and drink this and it prolonged doubling time for men who have had prostate cancer, does give a false sense of security. Someone might delay going to their next

checkup.

The ads clearly say -- in some of them, not all of them, but in some of them they often give the message take the POM juice, that's all you need, take POMx, that's all you need. There's a false sense of security being given to the consumers. We agree they didn't expressly say use it in lieu of medical treatment.

COMMISSIONER BRILL: Do we have to show that in order to --

MS. HIPPSLEY: No.

COMMISSIONER BRILL: -- find something is a drug?

MS. HIPPSLEY: No, absolutely not.

COMMISSIONER LEIBOWITZ: Under the statute.

MS. HIPPSLEY: Under section 15.

COMMISSIONER RAMIREZ: Counsel, I have one question for you. Could you address the argument that Mr. Lazarus has made with regard to the appropriate level of substantiation that is required here, that if we do require RCTs, that that would be a substantial shift from what the Commission has done in the past and that that raises due process arguments?

According to Mr. Lazarus, the world is watching and believes that this would represent a significant shift. I think there may be a bit of hyperbole there,

but if you can address that.

MS. HIPPSLEY: It is so much a part of our tradition that I think the world was shocked by the ALJ's decision and is watching to see if we adopt it.

The dietary guidelines clearly say that the most relevant and most common evidence for a treat, reduce or prevent disease claim that has been out there for marketers to use is randomized, controlled trials.

The judicial manual -- I think the shock is because a lot of people are lawyers who are watching us, and the judicial manual clearly states the need for randomized, controlled trials when you're examining science, and that's because without a randomized, controlled trial, as Dr. Pantuck stated in messages to Mr. Resnick, you don't know if the product is the cause of the treatment effect or the biologics of the subject in this study.

It's not -- again, it's tied to the claim. The claim is a treatment claim, and so you need to be able to show a causal link, and to show a causal link, you would need randomized, controlled trials.

Before I run out of time, I did want to briefly address Mr. Tupper's liability, and this also really captures also what the company's message was to the public that's captured in everything you see in front of

you, from the websites, to the print ads, to the media appearances.

It really all is encapsulated in this Fox interview that Mr. Tupper gave.

(Whereupon, a Fox interview was played for the Commissioners and not transcribed.)

MS. HIPPSLEY: Just to follow up on a few quick points of Mr. Tupper. Obviously he participated directly in the advertising at issue, and also in the answer to the Commission's complaint, he admitted that he, along with the others, Mr. and Mrs. Resnick, did indeed control the practices of POM Wonderful.

Thank you. If there are any other questions.

CHAIRMAN LEIBOWITZ: Thank you.

MR. LAZARUS: Mr. Chairman, I know I over imposed on the Commission's time, if I can have a couple minutes.

CHAIRMAN LEIBOWITZ: You can. Absolutely.

MR. LAZARUS: Thank you very much. On the interviews, there is no evidence in the record that any of these interviews were solicited other than in the general sense that, yes, they do PR, so do a lot of companies.

On the issue of substantiation and RCTs, I just would besiege the Commission to look at the expert

testimony. The expert testimony, including the testimony of the lead expert for complaint counsel, was RCTs in the nutritional context, which is a tricky context for testing, that's a tongue twister, is very -- it's difficult.

And if you have RCTs, people stop taking the stuff after a while. They won't keep doing it, and there are ethical issues involved in this, and you still won't necessarily be able to get down to which component of what you're testing is actually the efficacious one.

You need to do a variety -- you need not to rely on RCTs in that respect. That's their testimony of their experts.

COMMISSIONER BRILL: That wouldn't be true for the pills, right? I understand what they were saying was you know whether you're drinking juice or not, and we could argue about whether you could effectively disguise the placebo, but with respect to a pill, that's just not true.

MR. LAZARUS: They weren't just talking about the question of whether you need placebos or not. They were talking about other issues as well, including just the fact that people go off the regime and including the cost issues.

COMMISSIONER BRILL: Did you all conduct

randomized, controlled trials?

MR. LAZARUS: The fact that you can in some circumstances conduct randomized, controlled trials isn't really the test, Commissioner Brill. For example, in certain circumstances, like in erectile dysfunction, it is not that hard to have a short test. When you're talking about prostate cancer, you're talking about tests that --

COMMISSIONER BRILL: That's a claim you've chosen to make. In other words -- in other words, just hang on here. What you're saying here is it takes a long time to figure that out. Absolutely, cancer as an end point is a very difficult and timely thing to develop, but if you choose to make that claim, then you have to have the substantiation to back it up.

If it requires a long time to prove it, that's because you've chosen to make that claim.

MR. LAZARUS: And if you set the standard at that level, you've set it too high because you are going to deprive the public of knowing about things that are actually really good for them where the testing is not RCT but it's very compelling.

COMMISSIONER BRILL: Knowing it prevents cancer if -- that's the point. This sort of seems like a circular argument. You're saying that consumers should

know that it prevents cancer, but they'll only know that if the tests show that.

MR. LAZARUS: That's a good thing for consumers to know that there are a lot of tests out there that suggest that this product is beneficial to cancer patients. You have two experts, world leading experts, Dr. DeKernion and Dr. Heber, both of whom said there was credible and reliable evidence that it kills cancer cells, not just in people who have held prostate cancer but others as well, and indeed they're not -- it's not just the Pantuck study.

You have the Carducci study, too, of the pills as well as a whole bunch of in vitro and animal testing. Let the standard be what it usually is, which is credible and reliable evidence. Let people argue about it -- about the rest of it.

As far as the FDA remedy, I would just -- one small point, which is just most people think that a contempt sanction is something that keeps people in line and doesn't require an independent judge for all this.

Finally I'll just say on the intent evidence, I think this is a very, very important point. There was a trial on this stuff. The ALJ didn't buy this intent argument when they made it because it's not right. The evidence is overwhelming that there was never the

intention on the part of this company to make prevention, treatment, reduction of risk claims.

The fact that Lynda Resnick may have expressed some personal opinions about the efficacy of this product doesn't mean that that's what they were attempting to put into their marketing. The evidence is actually that they've been responsive to people's concerns, whether it's the NAD, whether it's the FDA with respect to certain things on the website. This is a responsible company that's acted responsibly, and even if you find, which I would hope you wouldn't -- but even if you find that some of their ads went over the line, that does not mean that there was ever any intent to deceive consumers.

They have not accepted, as the ALJ found, the complaint counsel's view of the law or the facts of the ad, but that is a dispute they're entitled to have without being punished as malefactors of the DCO type.

Any questions?

CHAIRMAN LEIBOWITZ: Thank you, Mr. Lazarus.

MR. LAZARUS: Thank you for the generosity with my time.

CHAIRMAN LEIBOWITZ: We are adjourned.

(Whereupon, at 3:52 p.m. the hearing was concluded.)

CERTIFICATE OF REPORTER

DOCKET/FILE NUMBER: D9344

CASE TITLE: POM WONDERFUL, ET AL.

HEARING DATE: AUGUST 23, 2012

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the steno notes transcribed by me on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED AUGUST 24, 2012

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DEBRA L. MAHEUX

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

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SUSANNE BERGLING, RMR-CRR-CLR