UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL GLOBAL LLC,	)	
as successor in interest to	)	
Roll International Corporation,	)	
companies, and	)	Docket No. 9344
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually	)	
and as officers of the	)	
companies.	)	
	)	
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Tuesday, March 6, 2012
1:01 p.m.
CLOSING ARGUMENTS
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C.

Reported by: Josett F. Whalen, RMR-CRR

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P R O C E E D I N G S

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JUDGE CHAPPELL: Let's call to order Docket 9344, In Re POM, et al.

We're reconvening today to hear closing arguments in this case.

I'll start with the appearances of the parties.

For the government?

MS. HIPPSLEY: Your Honor, Heather Hippsley, and I will be presenting our closing argument. And with me are Mary Johnson and Tawana Davis.

JUDGE CHAPPELL: All right. For respondents.

MR. FIELDS: Your Honor, Bert Fields, and I will deliver our closing argument. I have John Graubert here and Kris Diaz on my other side.

JUDGE CHAPPELL: Okay. Thank you.

I'd like to hear from the parties as to how much time each of you think you'll need.

For the government?

MS. HIPPSLEY: Your Honor, I'm expecting to take about 45 minutes and hold 5 or 10 minutes for rebuttal.

JUDGE CHAPPELL: Okay. We need to be -- have you let Ironsides, our bailiff, know how much time you want for rebuttal?

MS. HIPPSLEY: Yes.

JUDGE CHAPPELL: Okay. Thank you.

MR. FIELDS: I'm afraid I'm going to be a little longer, Your Honor, I would say a total of an hour and a half to two hours. I didn't time it exactly.

JUDGE CHAPPELL: Okay.

MS. HIPPSLEY: Your Honor, excuse me. My understanding was, under the rules, each party is provided an hour for their closing argument.

JUDGE CHAPPELL: No. Unfortunately, the rule says up to two. My comments were ignored on that.

MS. HIPPSLEY: All right.

JUDGE CHAPPELL: Not that I would hold that against anyone, sir, if they take the full allotted time, because you have been advised of the full allotted time.

MR. FIELDS: Thank you.

JUDGE CHAPPELL: Also, since up to two hours is allowed by the rule for closing, time will not be added for any questions I may ask. Unless I advise you of that fact that I have added time, you're to end at your time limit.

We're going to be using the warning lights today. A warning light will come on five minutes

before the red light. When the red light comes on, if you're in the middle of a point or a sentence, you may finish it, but then you need to yield the floor.

And everyone was previously instructed not to present in camera information. Is that going to be a problem for today?

MR. FIELDS: Not for our side, Your Honor.

JUDGE CHAPPELL: Thank you.

Complaint counsel, proceed when ready.

Since you're not planning to take the entire allotted time, the warning lights are set to the time you gave to Ironsides, our bailiff. If you decide you'll need more time for rebuttal, within the limit, let Ironsides know, and he'll adjust the warning light accordingly.

MS. HIPPSLEY: That's fine. I may actually take a little more at the beginning depending on the amount of questions, and I'm comfortable with the rough estimate.

JUDGE CHAPPELL: All right. Go ahead.

MS. HIPPSLEY: Your Honor, today I'm going to apply the record evidence in this matter to the four-step advertising analysis to outline our position that respondents' advertising representations are deceptive and that the appropriate remedy in this matter

is the notice order that was issued by the commission with the complaint.

The complaint challenges claims that --

JUDGE CHAPPELL: Do you intend to go over the notice order and the components of the notice order?

MS. HIPPSLEY: Yes, I do, Your Honor.

JUDGE CHAPPELL: Thank you.

MS. HIPPSLEY: The complaint challenges claims that POM juice and POMx supplements prevent, treat and reduce the risk of cardiovascular disease, prostate cancer and erectile dysfunction and claims that clinical studies establish these benefits.

While POM's products are certainly recognized as fruit juice and dietary supplements, they are also drugs, under the FTC Act, based on the advertising claims. Under section 15 of the FTC Act, a drug is not defined as a pharmaceutical or limited to a pharmaceutical drug; drugs are defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.

Here, respondents' ads --

JUDGE CHAPPELL: How do you think health claims fit in there? What if an ad says, "Orange juice is good for your health"?

MS. HIPPSLEY: "Orange juice is good for your

health" would not be a drug claim. It would be, under section 12, a food making a health claim, and then the issue would be, if orange juice is good for your health, what level of substantiation is needed for that kind of vague, nonspecific health claim.

JUDGE CHAPPELL: So there's clearly a difference between a health claim, which you would say is a food claim in the example I gave you, versus a disease claim?

MS. HIPPSLEY: Correct.

JUDGE CHAPPELL: Okay.

MS. HIPPSLEY: And POM ads conveyed specific disease benefit claims through the use of dominating headlines, prominent medical imagery, specific disease benefit analysis of their studies, references to clinical studies and quotes from researchers.

Here, given the common-sense, conspicuous claims that are in the advertisements, the challenged claims can be found through a facial analysis without the need for extrinsic evidence.

JUDGE CHAPPELL: Let's talk about that.

MS. HIPPSLEY: Okay.

JUDGE CHAPPELL: Part of your claim and in the complaint includes the entire Web site. How do you suggest I judge the net impression of the entire

Web site?

MS. HIPPSLEY: Well, the Web site in its entirety is what a consumer would browse through. We have highlighted the specific pages which we think together for the Web site provide the ad claims that are challenged here, in other words, that the Web site starting at the home page with one of the Web sites had -- right when you got to the home page, it said "32 million in medical research, published studies, click here." Okay. That starts the ad representation.

You click, as we walked through in our findings, to the Health Benefits page. There's all sorts of information there that we have gone through and explained in our findings provide further information. And then there's published studies and graphs on these health pages, growing, for example, a graph on blood pressure benefits.

And as we worked through in our findings, each of these screen captures put together for the POM Wonderful Web site, as an example, make the challenged claims that POM juice and POMx treat or prevent cardiovascular disease, prostate cancer and ED. All of those diseases are touched on in the health benefit page of the Web site.

JUDGE CHAPPELL: So you would suggest that I

limit my analysis to the pages that you have set forth in your proposed findings.

MS. HIPPSLEY: You can limit it to that, and we are comfortable that those pages combined would lead a consumer to these challenged claims as the takeaway from the Web site. But our view is that the whole Web site, as you click through it the way that Mrs. Resnick set it up with her marketing people, is actually beneficial to look at it in its entirety as a consumer might click through it, because she has a lot of click-throughs on various pages, all leading back to the health benefit pages, where the express claims about treatment and prevention are found.

All right.

So as I was saying, that the court could use a facial analysis here to ascertain the ad --

JUDGE CHAPPELL: And by that you mean net impression analysis.

MS. HIPPSLEY: That's correct. A net impression of the -- overall net impression of the ads. And in the findings we've set forth each of the print ads, what the net impression -- the overall net impression would be for those ads, and then each Web site -- there are four -- and the press releases that we've challenged and the press interviews, each

one providing the net impression of the challenged claims.

And I do want to just briefly explain about the claims that we have challenged here.

Respondents seem to make a lot of effort to pigeonhole the claims -- excuse me -- pigeonhole the challenged ads as being very old. And I just want to set the record that of the 43 challenged ads, 9 were disseminated in the years 2003 through 2006, 34 were disseminated in the years 2007 through 2010, and so the vast majority of the ads that are being challenged are in this 2007 to 2010 time period.

This is important for two reasons.

Respondents say that Mr. Tupper was really not intimately involved in the linking of the science to the ad copy until 2007, and so even if that is true, he is intimately involved in these 34 challenged ads.

Also respondents say, well, in the later years, sometime in 2008, we established a much better ad review process, leading to a claim that the remedy is not needed here. And again, this argument is hollow when you see that 34 of the ads that are being challenged are being disseminated by respondents during the time they say they have a much better ad review process in place.

JUDGE CHAPPELL: But even you say that you're not proving that anything has run beyond 2010; is that correct?

MS. HIPPSLEY: That's correct. We filed our complaint I believe in September of 2010, and although a few ads trickled out after that for POMx diet supplements, obviously the complaint challenged ads through early 2010 when the complaint was prepared to be reviewed by the commission.

JUDGE CHAPPELL: Would it change your position if respondent were to demonstrate that they no longer run any of the challenged ads, nor will they ever run them again?

MS. HIPPSLEY: No. Because this is a common statement by our respondents and defendants. Obviously once we file a complaint, it's common that respondents and defendants stop, and the law is clear that stopping in the face of the litigation is not a stopping of the ads long before the government came along to challenge the ads to show some sort of remedial efforts being taken short of the government telling them that the claims that we were challenging violated the law.

JUDGE CHAPPELL: But surely you're aware there are consent decrees, and these consent agreements, which the government is a party to, basically say that, I

haven't done anything wrong, I'm not doing it now and I won't do it again, and the government is --

MS. HIPPSLEY: Oh, I'm sorry. You mean the admissions that are not made in a consent decree. That's right. I thought your question was, if they had stopped the advertising at the time we brought the litigation, would that change the need for a remedy, and our answer is no.

JUDGE CHAPPELL: No. And I added to that and there was an agreement never to run the ads again, the challenged ads.

MS. HIPPSLEY: Well, if they entered into a consent decree with us and agreed not to run the challenged ads again, that might be one thing, but right now --

JUDGE CHAPPELL: That's what I was getting at. These are the things consent agreements are made of, and if everybody walked in the hallway during a break and agreed to that, you would consider that; is that correct?

MS. HIPPSLEY: Oh, yes. And we tried very, very hard to settle this matter before the commission issued the complaint, and we could not reach agreement.

And then going on with the ad meaning analysis, here, respondents' ads -- 85 percent of the challenged

ads convey establishment claims; that is, the ads reference specific human clinical trials demonstrating that the products treat heart disease, prostate cancer and ED. They use medical imagery and nomenclature. The ads claim that the benefits are backed by tens of millions in medical research. All of these techniques that are routinely found in the ads that we've challenged lend credibility to the efficacy claims and give consumers a reason to believe the purported benefits, and that is an establishment claim.

JUDGE CHAPPELL: I'm trying to establish if you have a bright line here.

Is it the government's position that POM cannot publish its research results in connection with advertising without that being an establishment claim? Research results.

MS. HIPPSLEY: I think it's a complex -- a complex question. We have no issue with respondents publishing their research results. FTC has no stake in that. The question is whether the published results are then utilized by respondents in advertising to expressly or impliedly make a false or unsubstantiated advertising claim to consumers.

So we don't have any problem with all the research that respondents have done. Their ability to

publish that research is great. They're trying to enter a lot of non-record evidence where different hospitals and organizations, you know, repeat in newsletters, hey, there's a new study on POM juice. No problem with that at all.

But the problem here is that they took their published studies, imported them into advertisements to give consumers a reason to believe that POM juice could treat or prevent, let's say, cardiovascular disease. And their science, the published science, even though it's published, cannot support the claim that scientific studies establish a cardiovascular disease treatment benefit for the consumer.

JUDGE CHAPPELL: So if I understood you, you're saying they cannot publish research results in connection with advertising without proper substantiation?

MS. HIPPSLEY: It depends how they talk about the study in the ad.

If they had an ad where they said: Drink POM juice as part of Dr. Sacks' DASH diet, an overall diet of fruits and vegetables, low fat, less meat intake. We suggest POM juice as one of those fruit servings. We have a very preliminary, small pilot study, single arm, where ten patients drank POM juice, and we saw a signal

of benefit. There was some possibility of a cardiovascular disease benefit.

JUDGE CHAPPELL: Or like we see -- or like we see in these ads, has phrasing like "results are promising"?

MS. HIPPSLEY: Pardon? Well, the "results are promising" -- and I'm going to show a couple examples -- in the context of the ads at issue, highlight that we have studies with promising results to treat your cardiovascular disease, and not only do we have this one study that we're highlighting, we have 25 million in additional research backing up this example of the cardiovascular disease benefit that we found in this one study.

JUDGE CHAPPELL: Okay. In your example, the ad said "reduce cardiovascular disease." What if the ad said "reduce arterial plaque," period?

MS. HIPPSLEY: Our view is that that's even worse under the law. A higher level of substantiation is when you quote statistics and very specific results, and there's not enough explanation of how preliminary and qualified and -- consumers don't understand the difference between a rigorous test, as Mrs. Resnick says they're telling consumers they have, which would be a randomized controlled trial, and a teeny, little

preliminary test that Dr. Aviram says his tests are mechanistic, basic research, a starting point for determining benefit.

So if the quote, which is common in the ads, reduce plaque by 30 percent -- that's a very specific treatment benefit that's being given to consumers, and that specific information, rather than vaguely, you know, treat cardiovascular disease, but a very specific benefit, reduce the plaque in your arteries by 30 percent, increases the credibility that they must actually have something here that treats cardiovascular disease.

JUDGE CHAPPELL: Well, let's go back to your example, and what if the ad copy said, "Results are promising that drinking one glass of POM every day promotes heart health"?

MS. HIPPSLEY: If that was it, no studies even enhancing that word choice, and hopefully if they put it in the perspective that they claim they are, one glass of POM juice, like other fruits and vegetables, may help maintain heart health, we probably wouldn't be here.

JUDGE CHAPPELL: They could have an ad that says, "Please drink POM, we make money, and it sure is good for you." They could do that?

MS. HIPPSLEY: Probably. We'd have to see how they use the medical imagery and the headlines and whatnot, but probably we wouldn't be here.

JUDGE CHAPPELL: Well, again, I want to make sure you understand, when I was using your example and I referred to plaque in the arteries, it didn't say anything about disease. You didn't say that anywhere in this ad that we're talking about that plaque in the artery builds up and is considered heart disease. That part is missing. It just refers to reducing arterial plaque.

MS. HIPPSLEY: Right. But in the ads at issue there's a specific percentage, so "reduces arterial plaque by 30 percent" was the common nomenclature and term used.

JUDGE CHAPPELL: But even with a percent, if it doesn't refer to heart disease, doesn't use the D word, there's no "disease" anywhere, in your opinion, that's enough to be an unlawful ad.

MS. HIPPSLEY: Yes. Because reduce -- this product, taking POM juice daily, reduces arterial plaque by 30 percent, consumers know that that benefit is related to reducing or preventing heart disease. Remember, you have to view it from the perspective of the target audience.

JUDGE CHAPPELL: I thought it was a reasonable consumer.

MS. HIPPSLEY: Here, we know who the target audience is, and under the commission law, if you know who the target is, you have to view it from the perspective of the target audience.

JUDGE CHAPPELL: Well, let me back you up. That's a good point.

Is your position that every net impression analysis needs to be from the perspective of this target audience? Is that your position?

MS. HIPPSLEY: In this case, yes, because we know exactly who the target audience is.

JUDGE CHAPPELL: What do you mean by "this case"? This case or the arterial plaque example?

MS. HIPPSLEY: Oh. In presuming POM Wonderful was doing it and we know POM Wonderful's target audience, yes, you have to view it from the target audience. What I meant was that --

JUDGE CHAPPELL: Can you point to -- do you point to evidence of this target audience in your posttrial brief? Remind me.

MS. HIPPSLEY: Yes. There is a whole section in our findings outlining the target audience for the POM Wonderful ads. And the target audience is found in

Exhibit 409, which is the series of creative briefs that were developed, the marketing strategy plans, if you will, of the company. And every single creative brief identifies the target audience.

And the vast majority of the creative briefs describe the target audience, and Mrs. Resnick admitted this, that the target audience is consumers who are concerned about their health. It's men over 40 scared to get prostate cancer. It's women who are concerned about cardiovascular disease or who have family members, in other words, they have a history in their family of cardiovascular disease.

And so yes, in this case the ads must be viewed as what those consumers would take away from the message.

JUDGE CHAPPELL: So if you're going to drill down to that level, only someone who cares about prostate health is going to look at the prostate -- I mean, someone who cares about prostate health is only going to look at the prostate portion of any ad. Someone who cares about heart health is only going to look at the heart portion. Because you can't tell me it's a target audience and yet tell me that that target audience is looking at all three, ED, prostate cancer and heart disease. That doesn't seem to add up.

MS. HIPPSLEY: Well, I could go through some examples, but I think Mrs. Resnick even stated -- let's take the prostate health, for example. Her -- her interviews and some of her deposition testimony was, in her one ad campaign, she was primarily reaching for middle-aged men who are scared about prostate cancer.

JUDGE CHAPPELL: So you're bringing in intent now.

MS. HIPPSLEY: Well, no. The target audience. She was testifying that her target audience for the prostate health ads were middle-aged men who are scared to get prostate cancer, but she also said or their family members who are worried for the middle-aged men in their family who are worried about getting prostate cancer.

She was trying to reach out and send a message that if you or a family member that you love, you're worried about them getting prostate cancer -- this is basically what she said in some of those press interviews that we have at issue -- you know, I'm telling you that my POM juice is the only thing that will prevent or treat prostate cancer for you or a family member that you might be concerned about getting prostate cancer.

JUDGE CHAPPELL: Okay. So in your opinion, if

you are required to be objective, not if you're complaint counsel, if you're required to be objective, who are you, looking at the ads?

MS. HIPPSLEY: Under commission law, objectively you are to look at the ads as -- from the perspective of the target audience.

So you're right, for an ad that discusses prostate health, it should be looked at from the perspective of someone who is scared, a middle-aged man who's scared of getting prostate cancer or their loved ones who want to protect them.

JUDGE CHAPPELL: But you understand that means that the person looking at the ad, in your opinion, that person has the ability to connect a lot more dots than the average person looking at the ad.

MS. HIPPSLEY: That's the point of the case law, that besides looking objectively at what the ad claims say, marketers absolutely target their advertising to certain audiences, and they're trying to connect with that target audience with their message. And yes, that's right.

So myself looking at a prostate -- "off to save prostate" ad, I might see some reduced risk claim, but I might -- basically I might not pay attention to it as you're standing at the grocery store.

But a middle-aged man who's scared to get prostate cancer and sees that "off to save prostate" ad, it can only mean one thing, that it's going to protect him from getting prostate cancer.

JUDGE CHAPPELL: So in your opinion, the person doing the net impression analysis needs to throw out the consumer who is, let's say, somewhat more gullible and also throw out, on the other end, the highly educated person who knows everything there is to know about a condition.

MS. HIPPSLEY: Right. I mean -- that's right. Really you're just focusing on and here we have excellent evidence of who the target audience was for these ads. Sometimes we don't have the detailed evidence that we do here.

JUDGE CHAPPELL: So it sounds like you're talking about speculation.

MS. HIPPSLEY: No, not speculation. Here we have concrete evidence of the target audience for these ads. I'm saying that in other advertising cases we have less evidence sometimes of who the target audience is. But here, in this case, we have a lot of evidence about the target audience for these ads, and by commission law, when a facial analysis is done by the fact-finder, they should view the ads from the

perspective of that target audience.

JUDGE CHAPPELL: If this were a jury trial down the street in federal district court, you would be making the same argument to a jury?

MS. HIPPSLEY: Yes.

Okay. And maybe what I'll do is run through a couple of the ads just very quickly. Maybe it will help frame some of the questions.

In 2007, POM disseminated this ad in Health magazine, Prevention magazine and New York magazine. Here, the different pieces that make the challenged claims are connected. We have a headline with medical nomenclature, "Decompress." We have the POM juice bottle dressed in a blood pressure cuff. We have body copy that talks about amaze your cardiologist, helping to guard your body against free radicals, providing the consumer with a mechanism of action to believe the benefits, we can do something, we can stop the free radicals that cause disease, and then a statement that the juice is supported by 20 million in initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health.

Now, the interesting thing with this ad is that Mr. Tupper actually testified about this ad at a jury

trial in a case that POM Wonderful brought against one of its competitors, Tropicana Products. And when he testified about this ad, he stated, "Well, this ad is talking about the fairly vast body of published medical research. Many of those studies are, in fact, on various elements of the cardiovascular system, including blood pressure, but many others as well."

He also stated that "It's very obviously a blood pressure cuff. That's typically the first thing that your doctor will do when you go in for a physical, is check your blood pressure as a means of getting an overall picture on your health."

So Mr. Tupper was explaining to the jury that, indeed, this ad is telling consumers they have a great benefit here, they have a heart health benefit that is about lowering blood pressure, and they have a vast body of published medical research to back up these claims, in fact in this ad $20 million worth.

Another example is the antioxidant superpill, the POMx.

JUDGE CHAPPELL: Let's go back to the other ad.

So what you're telling me is that was Mr. Tupper's net impression of the ad that he ran?

MS. HIPPSLEY: That was what he was, yes, telling the jury in a trial against one of their

competitors when he testified, describing what the ad was about.

JUDGE CHAPPELL: But this ad, as I'm reading it, talks about prostate and cardiovascular health. I don't see it talk about disease anywhere.

MS. HIPPSLEY: That's right. Because there is a euphemism here, prostate and cardiovascular health. But as Dr. Butters, who's the linguist expert that respondents brought to trial, testified, in his view, any American speaker of the English language would interpret "prostate health and cardiovascular health" as discussing the absence of disease. This is in our findings, and respondents had no response in their reply to that finding.

JUDGE CHAPPELL: And to be clear, a reference to prostate health or any health to you is a disease claim.

MS. HIPPSLEY: In the context of the other components, the mosaic that's being built here by the ad, having the "Decompress," having the POM juice bottle in the blood pressure cuff, stating that there's $20 million in scientific research which has uncovered encouraging results.

Honestly, I think a consumer, if they quickly read this, $20 million of medical research for maintain

heart health, it just doesn't even really make common sense, so a consumer is going to say, "20 million in medical research, blood pressure cuff, decompress, wow, this product must lower my blood pressure."

JUDGE CHAPPELL: Okay. Blood pressure, let's go with that. You were talking about the target audience.

You're telling me you have evidence of who the audience is, but are you telling me you have evidence on how that audience will see the ad, how they will interpret the ad?

MS. HIPPSLEY: We do not have copy test evidence, except actually in this particular ad there is copy test evidence about the "Decompress" headline and the blood pressure cuff that was conducted by respondents in the course of their regular business that did show consumers interpret just that part alone to mean a lower blood pressure claim.

JUDGE CHAPPELL: Should one assume that the government didn't put forth copy test evidence because they didn't feel they needed it?

MS. HIPPSLEY: That's correct. Here, a facial analysis --

JUDGE CHAPPELL: So that's not an assumption; that's a fact.

MS. HIPPSLEY: Pardon?

JUDGE CHAPPELL: That's a fact.

MS. HIPPSLEY: That we did not?

JUDGE CHAPPELL: Because you didn't think you needed it.

MS. HIPPSLEY: Right. Because a facial analysis would yield the express and virtually implied claims. And in addition, in this case, because we did a precomplaint investigation, we knew the evidence -- the other evidence that we've put forth, what the target audience is and the overwhelming evidence of respondents' intent to make these disease benefit claims, which does go into the mix in finding the ad meaning.

JUDGE CHAPPELL: Okay. Let's talk about your target audience.

Someone concerned about prostate health, what do they care about the "Decompress" and blood pressure cuff? What do they care about that?

MS. HIPPSLEY: You're right. This ad is not targeted for prostate health. This ad is primarily targeted and in fact we only challenged it for the heart benefit claims, Your Honor.

JUDGE CHAPPELL: But it does say "results in prostate and cardiovascular health."

MS. HIPPSLEY: That's right. But the main focus

of this ad is the heart benefits, and that's what we used this ad for, and what we challenged in this specific ad were the heart -- the cardiovascular disease claims that are at issue.

JUDGE CHAPPELL: And again, you would submit that a claim that talks about lowering blood pressure is making a disease claim.

MS. HIPPSLEY: Oh, yes. Lowering blood pressure is a symptom of disease and, yes, would be making a disease claim.

So this ad is making a claim that POM juice prevents or treats cardiovascular disease through lowering blood pressure, and so here probably --

JUDGE CHAPPELL: But that's not in the ad.

MS. HIPPSLEY: Pardon me?

JUDGE CHAPPELL: Show me that in the ad.

The formula you just went over, A plus B equals C, where does this ad tell you that lowering blood pressure prevents, treats or affects heart disease? Where's that in the ad?

MS. HIPPSLEY: It's the takeaway that a consumer knows, a consumer concerned about cardiovascular disease knows. They go to the doctor. They know that high blood pressure can lead to cardiovascular disease.

And respondents are playing off consumers who are concerned about cardiovascular disease, what they bring to the table when they see this ad. They know -- in fact, as Mr. Tupper said, somebody has gone to the doctor. They've gotten a checkup. The first thing that happens is their blood pressure is taken. They're told it's high or low. If it's high, that's a danger sign for cardiovascular disease. If you can lower blood pressure, that's going to prevent cardiovascular disease.

JUDGE CHAPPELL: I'm not saying that's not a fact. I'm saying it's not in the ad.

MS. HIPPSLEY: It's not express in the ad, you're right.

JUDGE CHAPPELL: And is it your position then that POM only advertised to the target audience? They didn't advertise to the whole group of people out there, maybe millions, who think POM might taste good in club soda, maybe I'll buy it because it tastes good. They're ignoring those people? They're not part of the target audience?

MS. HIPPSLEY: No, they're not ignoring those people, but the issue is, this ad is not about taste. The core message of the respondents' ad campaigns were specific health benefits, and they tried to figure out

advertising that would resonate with consumers who had concerns about these specific heart benefits -- I mean -- I'm sorry -- health benefits.

Of course it's on the grocery shelf and anyone can buy it. But the question is, when they created their ads, created the ad campaigns, any marketer decides, as we can see in the creative briefs in this case, who's my target audience. Well -- and we'll see in some of these ads they set up the premise, you, even general audience, who maybe you don't even know you're worried about heart disease, you should know that heart disease is the most commonly diagnosed disease in this country. Okay. Now, I've been told I should worry. I'm now part of the target audience.

I can -- we can skip, if you want, to the brochure because it sort of illustrates the point.

JUDGE CHAPPELL: Well, would you admit there is no evidence in our record that consumers know anything about blood pressure means automatically heart disease? Are you telling me there's evidence of that in the record?

MS. HIPPSLEY: Evidence --

JUDGE CHAPPELL: That consumers know blood pressure references also refer to heart disease.

MS. HIPPSLEY: I would have to go through the

creative briefs again. There may be some indication of that again when they were setting up the marketing plan and strategy.

JUDGE CHAPPELL: But just let me make sure I'm clear. Your position is every challenged ad should be reviewed only from the perspective of the target audience.

MS. HIPPSLEY: Well, not only, but I would say with an eye towards the target audience. And I can show you an example of what I mean. I'm not trying to be cagey. But there are a bunch of their ads where they set up the problem.

So me, I didn't know I had a concern about cardiovascular disease, but I read the brochure, and it tells me, wow, cardiovascular disease is one of the most common diseases in this country, one out of three people is going to get it at some point in their life, blah, blah, blah. They've now convinced me that I should be part of the audience concerned about heart disease, and then they provide the solution: So POM juice, we've done two studies on heart disease that's shown these specific benefits, you know, drink it as a preventative.

A lot of their target audience documents talked about just consumers who are generally concerned about

their health. They're open to hearing about natural cures for their ailments. I've got that on a couple slides here.

JUDGE CHAPPELL: I'm seeing a lot of reference to antioxidants when I look at these ads.

MS. HIPPSLEY: Uh-huh.

JUDGE CHAPPELL: What if antioxidants are what you need? What if POM is chockful of them? What if it's good for you? Is that a problem? Can they say just that?

MS. HIPPSLEY: They could say just that.

So here, for example, is the POMx brochure, and this is a good example of what I was talking about, how the pieces are put together to make the consumer who may not know they're worried about prostate cancer become worried about prostate cancer, and then the ad goes on to explain --

JUDGE CHAPPELL: You seem to be making the jump to "worried about." What about awareness? Is there a difference to you in making someone aware versus making them worried?

MS. HIPPSLEY: No, not really. I'm thinking about the creative briefs that said it was men who were scared.

JUDGE CHAPPELL: But remember, consumers aren't

seeing the creative briefs.

MS. HIPPSLEY: Right.

So I think a general awareness of prostate cancer is also the target audience. This is what really this ad is doing, prostate health equated to prostate cancer, telling you it's the most diagnosed cancer among men in the United States and the second leading cause of cancer death in men after lung cancer. Okay. Any man that sees this ad all of a sudden is part of the target audience. They just basically scared every man in America into thinking they'd better be concerned about their general prostate health and concerned about and have a general awareness of prostate cancer and how prevalent it is.

Then the ad says, well, don't worry, according to a UCLA study that we have done on our juice, we showed PSA doubling time by nearly 350 percent improvement, a solution for those general awareness or concerned about prostate cancer.

And I just want to point out that this is somewhat similar to the ad copy in Daniel Chapter One, where many of the advertised products did something similar, through testimonials, but still making a claim, lowering PSA, a testimonial explaining how PSA was lowered, and of course this led to a finding that this,

among other claims, make a treat or prevent cancer claim.

JUDGE CHAPPELL: You understand in DCO we also had people advising someone with cancer not to go to their doctor and have surgery but take this product.

MS. HIPPSLEY: Uh-huh.

And here, on the heart page again a similar setup, heart health, an explanation that there are two studies showing a benefit and linking heart health to atherosclerosis, clogged arteries, and that there was a benefit, decreased 30 percent arterial plaque for those who participated in the studies. They go on to explain a second study that they had and the claims on this page, again, saying that we have science to prove that we have a solution for cardiovascular disease, science, not fiction, backed by 20 million in medical research, again promoting heart and prostate health, watchwords for absence of disease, clinically tested on adults.

Here, we have another -- this is a Time magazine wrap that was disseminated in 2008, using the same formula to convey to consumers that the POM juice is going to treat or prevent prostate cancer, highlighting the study, explaining the study results, PSA doubling time, a fourfold improvement, a quote from the researcher, medical imagery with a caduceus. This is a

medical solution for your medical concern.

The next page, "proof is in the POM," again highlighting that we say we have a solution and our solution is backed by science. Clinical studies have documented the benefits of drinking POM Wonderful POM juice.

There is nothing qualified about that claim. This is not a claim that we have a teeny-tiny, little open-label study, not rigorous but a beginning point to see whether or not POM juice assists someone who is concerned about getting prostate cancer or has it. This is a statement, an express statement that clinical studies have documented the benefit of drinking POM juice.

JUDGE CHAPPELL: It does say "clinical studies," but do you agree that the benefit -- a benefit could be increasing your antioxidant intake?

MS. HIPPSLEY: Well, it's in the context, if I can get back, of this ad, which was a magazine wrap distributed in urologists' offices.

JUDGE CHAPPELL: Neurologists, brain, or urologists?

MS. HIPPSLEY: Urologists. I think I need some water.

And the front page, before the "backed by

science," you know, sets the context. They're talking about treatment for prostate cancer.

JUDGE CHAPPELL: What if it said "backed by science" and ended there?

MS. HIPPSLEY: I guess the -- you know, I'm not trying to evade the answer. In this ad, with all the other strong components, I don't think it would make a difference. In some of the print ads, where they just said "maintain prostate health," if that were the claim --

JUDGE CHAPPELL: Well, some of the ads have "backed by science" as a heading on the left.

MS. HIPPSLEY: Right.

JUDGE CHAPPELL: By the time you read that entire ad, you might have forgotten that.

MS. HIPPSLEY: I don't think you're going to forget "backed by millions of dollars in science." They usually don't just say "backed by science." I can't think of one that just says "backed by science."

JUDGE CHAPPELL: I can, but that's not the point.

MS. HIPPSLEY: Oh, okay.

JUDGE CHAPPELL: But that alone could be a problem, but to you, that alone is a problem.

MS. HIPPSLEY: "Backed by science," then giving

an example of a clinical study on humans supposedly with a statistic on the benefit, that would be a problem.

JUDGE CHAPPELL: Well, you seem to have a problem especially with the dollar amount. What if it's backed by 45 cents or 800 million? Is there an amount that doesn't matter, or does any amount make it worse for you?

MS. HIPPSLEY: Well, I think we take the ads as they come, and here, they're quite dramatic in the amounts of money that are being touted to consumers. They're in the tens of millions of dollars.

JUDGE CHAPPELL: But you're not disputing they did spend money on research.

MS. HIPPSLEY: Oh, yes. It was a running expense tab when they said 25 million backed by medical research. But "backed by medical research," as Mr. Tupper said in the jury trial, in his mind and in the minds of consumers, that means -- and in the slogans they've used -- real science, real results.

They do not have $25 million in results that back up a claim that their product prevents, let's say, prostate cancer. They have only one human study, and that study cost only a couple hundred thousand dollars.

The final page of this magazine wrap basically

goes through what we were just talking about, highlighting the 25 million in medical research, 25 million in published medical research and proven health benefits.

Here we have the "off to save prostate" ad. I think we've basically covered these.

JUDGE CHAPPELL: And again, is it your position that "proven health benefits" means prevents disease?

MS. HIPPSLEY: I'm sorry. Say it again.

JUDGE CHAPPELL: Your position would be a statement that says "proven health benefits" is the same as prevents disease?

MS. HIPPSLEY: In the context of that ad, yes, 25 million in medical research was the last page after explaining all their prostate cancer research and the results that they got for men with prostate cancer.

Okay. And I'm sorry. I think I am going to need a little more time because of the questions.

JUDGE CHAPPELL: That's okay. You have time.

MS. HIPPSLEY: Okay. All right.

So here we basically discuss the topic of the target audience. And yes, under the law, if an ad targets a particular audience, the commission analyzes the ad from the perspective of that audience.

Statements susceptible to both a misleading and

truthful interpretation by the consumers, the target audience, will be construed against the advertiser.

And also, another important thing I think to keep in mind in this case is that if the ad is misleading if at least a significant minority of reasonable consumers take away the misleading claim, that is the responsibility of the advertiser, and they are liable.

We don't have to reach some kind of comfort level that all the consumers who see that prostate -- "off to save prostate" ad think and find that it communicates to them that prostate cancer prevents and treats -- that POM juice prevents and treats prostate cancer. By law, Your Honor, you just have to be comfortable that a reasonable consumer -- a significant minority of reasonable consumers seeing the "off to save prostate" ad would take away the message that it prevents prostate cancer, POM juice prevents prostate cancer.

JUDGE CHAPPELL: But again you're telling me that has to be a significant minority of reasonable consumers, and you're adding in "in the target audience."

MS. HIPPSLEY: Reasonable consumers and thinking about it from the perspective of who POM was targeting

for those ads, which in their creative briefs are men, 40-plus, high income, primarily -- primarily, not completely -- there's no bright line. I mean, marketers advertise -- they'll be happy if anyone believes their claims -- but basically primarily men who are scared to get prostate cancer seeing that "off to save prostate" ad, what is the takeaway for those consumers.

JUDGE CHAPPELL: Read that second one again. "Statements susceptible to both," read that one again.

MS. HIPPSLEY: "Statements susceptible to both a misleading and a truthful interpretation will be construed against the advertiser."

JUDGE CHAPPELL: I'm just wondering if you thought about how that factors into the burden of proof in a case.

MS. HIPPSLEY: Well, I think the burden of proof would be -- to me, it's similar to the next one about a significant minority having the takeaway.

JUDGE CHAPPELL: But isn't the point of that second statement you've got there --

MS. HIPPSLEY: Uh-huh.

JUDGE CHAPPELL: -- even though the government has got the burden of proof, an ad is to be construed against the respondent if it's susceptible to a couple of meanings?

MS. HIPPSLEY: Right. That's correct.

JUDGE CHAPPELL: How does that square with the burden of proof?

MS. HIPPSLEY: Well, our burden of proof is to establish that the ad does have a misleading aspect to it.

And even if there's a double meaning in that ad -- let's say -- I'm trying to think of one of their examples -- you know, some heart health ad is connoting that it maintains heart health. Let's say that could be one of the takeaways. But if you can also ascertain from analyzing the ad that a takeaway is that POM juice treats or prevents cardiovascular disease, so not only does it have a message that you can maintain your heart health by drinking POM juice, it also is susceptible to a misleading takeaway that it prevents cardiovascular disease, and we're able to establish that by showing that the facial analysis of various elements used has that misleading interpretation, that would be construed against the advertiser.

Just because there's a double meaning to the ad doesn't allow the advertiser to make a misleading statement along with a nonviolative statement.

JUDGE CHAPPELL: But if I follow your logic, you're saying that the finder of fact is at a point

where an ad can be construed for or against the respondent, and you're saying that -- is this not shifting the burden?

MS. HIPPSLEY: No.

JUDGE CHAPPELL: If I'm then supposed -- the finder of fact is then not supposed to construe it against respondent at that point, is that not a shifting burden of proof at least at that point in the analysis?

MS. HIPPSLEY: No. I don't think so.

I think what this statement means is if Mr. Fields gets up and says that ad says we maintain heart health, and I tell you that ad also says that it treats cardiovascular disease, if you as the fact-finder find that the ad has both meanings, the fact that one meaning is misleading is construed against the advertiser, and they're liable. They can't dodge liability by having ads have multiple meanings, both violative and nonviolative. They don't get off the hook if the ad has both a misleading message and a nonmisleading message.

JUDGE CHAPPELL: I'm not disagreeing with you, Counsel. I just like to see if people have pondered certain things in this case.

MS. HIPPSLEY: Right. And I think it's that if

respondents say there's a double meaning, that doesn't really shift the burden of proof or change the equation.

Okay. And then, just quickly, I wanted to touch on another issue that flows from the target audience. And that is, as you can see, their creative briefs spoke about consumers who are looking for a -- it's the second bullet -- a natural cure for current ailments or perhaps to maintain health and prevent future ailments.

Now, one thing that respondents have criticized is that in most of the ads at issue, let's say, for cardiovascular disease, we have charged that the ad makes both a prevent and a treatment claim, and the respondents think that there's something wrong with us not dissecting the ad further. And there is no need to dissect the ad further because consumers' takeaway is influenced by who they are coming to the ad.

A consumer who has heart disease and reads about a treatment study, reducing your plaque by 30 percent, will take away a treatment claim. A consumer who is concerned about preventing future heart disease will read the same ad and take away a prevent heart disease claim. The ad can have both meanings, using the net impression, of treatment, clinical studies, backed by

medical research, all of that.

In fact, respondents' experts said that a treatment study is likely to show a preventative effect, and consumers are sure to think the same thing. A treatment study can also establish for the consumer a takeaway that the POM juice is a preventative.

JUDGE CHAPPELL: Is it your position that the ad is sufficiently unlawful if it's either of the three, prevents, treats or reduces risk of?

MS. HIPPSLEY: Yes.

JUDGE CHAPPELL: Either one. Fill in the blank. You don't need one -- you don't need two. You don't need three. One out of three is all.

MS. HIPPSLEY: That's correct.

And that's because when we get to the other shoe that drops, none of the science backs up any of those three, you know, provides the proper substantiation.

JUDGE CHAPPELL: But my question was, as far as the net impression analysis goes --

MS. HIPPSLEY: That's right.

JUDGE CHAPPELL: -- your position is either of those three things makes it unlawful at that point.

MS. HIPPSLEY: Yes.

JUDGE CHAPPELL: At that phase or stage of the

analysis.

MS. HIPPSLEY: Correct.

All right. And in this matter we have just an incredible, overwhelming record of intent. And to move this along, I won't spend much time on this. But intent is very important because there is just an incredible record here of how these respondents intended to make the claims at issue, and that goes to both evidence of ad meaning and evidence of materiality.

Specific health benefits was respondents' marketing strategy. I won't dwell on this. We've written this up in much detail in our findings.

POM ads were designed to convey a serious health benefit message.

Now, one thing that respondents spend a lot of time on is trying to dismiss the ads, just because they're humorous, as somehow being puffery and not conveying a claim. But in the commission's deception statement, I really like the understanding there that exaggerated claims can be taken seriously by consumers. The deception statement says that the term "miracle" is commonly used in situations short of changing water into wine and that we will conclude that in the context of "electronic miracle," respondent's grossly exaggerated

claims would lead consumers to give added credence to the overall suggestion that the device is superior.

So here we have some of respondents' exaggerated claims.

Today, science confirms that pomegranate is truly a medical marvel.

This is on their Web site.

Mrs. Resnick: It's the magic elixir of our age, of all ages. And then she gives the objectives facts to back that up.

Mr. Tupper, on the Web site: As our scientists like to say, POM juice is truly health in a bottle. Our scientists are telling you this. This isn't my opinion. When you look at the medical research that's been conducted, he goes on to explain, in prostate cancer and heart health, heart disease benefits.

There's just boatloads of evidence that the respondents use science in the ads to validate the serious health benefit message. That is what an establishment claim is all about, giving consumers a reason to believe the benefit.

And this intent was understood and executed on by the marketing personnel. Perhaps the most compelling one is the press talking points: "Compared to other 'superfruits,' the pomegranate is the only one that has

medically proven health benefits in the human body. This is a key point." That's what the talking points for the press discuss.

I'll just touch briefly on materiality.

Under the law, here again with all the intent, these are deliberately made implied claims, and they are presumed to be material and are material. They involve significant health benefits. They pertain to central characteristics of the product, actual reliance by consumers. In the essence of time, I'll forgo reading some of the sad stories from their consumer logs, such as an 89-year-old man saying he has prostate cancer, he started taking the juice, and they tell him, "Great, send in your testimonial, let us know how it goes."

Respondents conduct consumer research over the years demonstrating the importance of the challenged claims. Their persistence in using these claims in the face of warnings -- and this is gone through in detail -- from the NAD, FDA, FTC, various ad screeners at NBC, Comcast, et cetera.

The fact that with that high risk and visibility they still made the claims of course is evidence of materiality.

Respondents will go through in great detail a survey that was done by Dr. Reibstein to try to rebut

this materiality, but it pales -- first of all, it was not done properly, but it pales in comparison to the overwhelming evidence of materiality.

Really, it's a practical decision. If the claims are that they can treat and prevent three serious diseases, how could that not be important to a consumer's purchase decision.

And Your Honor, if you don't have any further questions on the ad interpretation phase, I was going to switch over to substantiation.

JUDGE CHAPPELL: Go ahead.

MS. HIPPSLEY: Okay.

All right. So in this case, the advertisement claims break into two categories, establishment claims and nonestablishment. As we've said, 85 percent of the ads in the ad interpretation phase are making establishment claims.

Mrs. Resnick says that she communicates to consumers that she has rigorous scientific testing to back up the specific health benefits.

JUDGE CHAPPELL: Just so you know, you have one hour left in total.

MS. HIPPSLEY: This should take about a half hour. Well, it depends, but -- all right.

First, a very important point. None of the

scientific experts in this matter support the notion that respondents' scientific testing to date establishes that POM products treat, prevent or reduce the risk of the three diseases at issue. This is critical because, for establishment claims, when an ad expressly or implicitly represents that the claims are based on scientific evidence, the advertiser must have evidence sufficient to satisfy the relevant scientific community that the claims are true. They must possess competent scientific proof.

Because 85 percent of the ads make establishment claims, the analysis is do the respondents have substantiation that the scientific community would find establishes these benefits, and none of the experts here found that.

A Pfizer factor analysis is not needed, under Removatron and Thompson Medical, because the ads expressly or impliedly promised a certain scientific level of substantiation. Thus, the ads must be supported by the promised proof.

Now, Dr. Stampfer was complaint counsel's leading expert on nutrition and its relationship to the prevention and treatment of cardiovascular disease and prostate cancer. He testified that most scientists in the fields of clinical trials, epidemiology and disease

would agree that randomized, placebo-controlled human clinical trials are needed to support claims that a product like POM juice or pomegranate extract prevents or treats the diseases at issue.

Now, you'll hear respondents argue that Dr. Stampfer doesn't really hold this opinion or that they impeached him or something. This is based on their misreading of an article that he has written, entitled Evidence-Based Criteria in the Nutritional Context. This is in the record. It's RX 5007.

JUDGE CHAPPELL: Hold on a second.

MS. HIPPSLEY: Okay.

(Pause in the proceedings.)

JUDGE CHAPPELL: Go ahead.

MS. HIPPSLEY: So as I was saying, that the issue for establishment claims is whether the scientific evidence is enough to satisfy the relevant scientific community that the claim is true. And Dr. Stampfer testified to this specific point, testifying that most scientists would not find that their evidence was enough because scientists in the field would require randomized, placebo-controlled human clinical trials.

He has written an article called Evidence-Based Criteria in the Nutritional Context. This article, first of all, it relates to the level of evidence needed

to make public health recommendations, such as the 2010 Dietary Guidelines.

Respondents are not making health recommendations; they're trying to sell their juice.

Second, more importantly, what Dr. Stampfer said is, where no RCTs are available, the majority of the evidence will continue of necessity, for public health recommendations, to be derived from human observational studies.

All right. First of all, here, RCTs are available. They've been conducted. And I'll be going through those and showing why, because basically they all had negative results for heart disease, they don't provide substantiation for the claims.

Observational studies, human observational studies, are the other choice when making public health recommendations. But here Dr. Heber clearly stated and the record shows that there are no human observational studies on pomegranate juice or POMx diet supplements.

So really this article is not relevant.

And when Mr. Fields asked Dr. Stampfer about this article at trial, Dr. Stampfer said, "In this case the bottom line is the level of the claim has to match the level of the data." This was at transcript page 835 to 836.

Here, the establishment and nonestablishment claims do not match the level of science that respondents have. They far exceed the science.

And that's because respondents told the public that they had well-controlled human studies to back their claims. On the Web site, Matt Tupper said: Our research, it's almost more akin to research being done on pharmaceutical drugs.

Thus, respondents are required to have the level of science they told consumers they had.

And this is -- a very nice case that illustrates this point is Q-Ray, Inc. that the Federal Trade Commission brought a couple of years ago. It was affirmed by the Seventh Circuit.

Judge Denlow, in that matter, said: Look, defendants used medical health-related claims to sell this inert metal bracelet. Defendants would not be required to have a gold standard study to substantiate if the bracelet worked if they had not made such a strong medical claim. The choice was the respondents'.

And that's basically what you've been asking me about. If respondents made a "maintain health" claim, we would not be here. The claims they made were strong, specific medical-related claims.

Turning to one of the important pieces of

evidence in this case, it's the Medical Research Portfolio Review, CX 1029. This was done in January of 2009. It was created by Dr. Dreher, who was their scientific in-house adviser, and Mr. Tupper.

And here, I really want to highlight how respondents understood health claims and drug claims and what was required to make these claims.

So as late as 2009, they're going over their heart evidence, and they note "prevent heart disease." Well, that should be based on death or heart attack data, of which they have none. "Lower blood pressure" must be based on systolic blood pressure data. At this point in 2009, what is the required action to make these claims? More research. They don't have enough at this point to make those claims, and they know it.

"Reduce risk of heart disease," an unqualified health claim, it could be based on the IMT data or systolic blood pressure data. Their conclusion, Mr. Tupper's conclusion, is, again, they need two more studies for these options. They don't have enough research yet.

And skipping down to the last point, "publicize what we already have," even here, Mr. Tupper notes: It's a risk. Our research has holes. The current body of research in 2009 is only viewed as a 3 on a scale of

1 to 10 by medical doctors.

Going to prostate cancer, same overview, to make a prevent or treat prostate cancer claim, what is the required action by the company in 2009? More research. They don't have enough. PSA will not be accepted as an endpoint. They need endpoints that are more correlated to cancer progression.

What about a health claim, reduced risk of prostate cancer? Again, they still don't have enough science. They need at least one more study. And again, PSA alone is not sufficient as an endpoint in the clinical trials.

Finally with the -- even to make -- to have research for marketing or PR purposes, here what's interesting is, under the assessment, Mr. Tupper writes, "POM currently has a research gap: no data on prostate cancer prevention, prior to radiation or prostatectomy. In contrast, tomatoes and selenium are actively studying this approach."

One thing that respondents have argued is that foods don't need to meet this. This shows that, well, actually foods do need to have science. In fact, Mr. Tupper is noting that tomatoes and selenium, folks that are studying those foods, are actively studying whether or not those foods can prevent prostate cancer,

doing real science before the claim can be made.

In the area of erectile dysfunction in 2009, respondents note in required action, well, can they market this claim. They need to look for more science. They need a larger ED clinical study, and it needs to achieve statistical significance for stronger marketing value.

All right. So turning to the cardiovascular disease substantiation, our expert for heart disease is Dr. Sacks. He's a leading expert on nutrition and cardiovascular disease. He's an adviser to the U.S. government on the 2010 revisions to the U.S. Dietary Guidelines. He stated that the type of evidence needed to substantiate a claim that a product, including a conventional food or dietary supplement, to make a claim that those products treat, prevent or reduce the risk of heart disease, there needs to be appropriately analyzed results from well-designed double-blind, randomized controlled human clinical studies.

Respondents will attempt to argue that Dr. Sacks somehow doesn't really believe this, and they base this on discussing Dr. Sacks' renowned DASH diet, which are basically what the 2010 Dietary Guidelines are based on.

His DASH diet was published. It's very famous. He showed that the diet may help reduce the risk of cardiovascular disease. This DASH diet does not undercut his opinion here that pomegranate products -- respondents must have randomized controlled trial testing. This is really a silly argument.

The DASH diet is a complete diet. It contains a high intake of fruits and vegetables and a low intake of meat and fat.

Respondents are not advertising their product as being part of the DASH diet. They are advertising their products as taken by themselves, they have proven benefits for preventing and treating heart disease.

Again, Your Honor, with your hypotheticals, we probably would not be here if the ads stated that have pomegranate juice as one of your four helpings of fruit daily recommended by the U.S. government. It may help to reduce heart risk, as the entire diet has been shown, as part of reducing your meat, reducing your fat, having an intake of a myriad of vegetables and fruit.

That is not what's being advertised here. What's being advertised is POM juice and POMx supplements have a very special, magic elixir that is unique to POM juice to treat or prevent disease.

And Dr. Ornish, respondents' heart expert in

heart disease and nutrition, actually stated in his deposition, when you're trying to answer the question whether an intervention, not a diet but an intervention, if it's a drug, if it's a juice, if it's a lifestyle intervention, whatever it is, if you're trying to determine that that intervention is causing the effects and to determine -- or whether it's just a coincidence, the most rigorous design is a randomized, double-blind, placebo-controlled study. This is considered the most definitive of the scientific research constructs. And the reason is is that it controls to a large degree than any other design -- this is what Dr. Ornish said -- known or unknown, sources of bias that might give you incorrect information.

So, here, where Mrs. Resnick states that she put in "we have 25 million in medical research" to communicate to consumers in her ad that respondents have a rigorous level of scientific testing, the rigorous level is randomized controlled trials. And do those trials prove that POM juice or POMx treat, prevent or reduce the risk of cardiovascular disease? And the answer is no.

And the chart that we did at the opening in this case, Your Honor, hasn't changed at all. There were two initial studies by Dr. Aviram. These are the

two studies they tout in the advertising. They are not rigorous. They're not placebo-controlled. They're fine for what they were, preliminary, basic, mechanistic research, but they don't prove that the products treat, prevent or reduce the risk of cardiovascular disease.

In fact, these are very early studies, 2004, and Dr. Ornish was hired to try to replicate and show in randomized controlled trials that there was a benefit for heart disease, so his two studies are randomized controlled trials.

He tried to conduct a randomized controlled trial to show blood flow. It had a lot of flaws. It's really not very reliable. The peer reviewers that looked at it reinforced what Dr. Sacks said about the weaknesses of this study. He really was not an expert in doing a single intervention study with an agent like juice. His studies to date had all been on lifestyle -- holistic lifestyle changes.

He got negative results in his IMT study. Dr. Davidson got negative studies in his blood flow study, which was a randomized and controlled trial. Dr. Davidson did the definitive study on heart disease on POM juice in this case, and the definitive study of 289 people, well-conducted, well-controlled, is

negative.

This is basically what happened in the Q-Ray case. There was a large Mayo Clinic study of the Q-Ray bracelet. It came out negative. Judge Denlow could not possibly find that with the strong medical claims there was enough science to back those claims up when the best study in front of him, a large, randomized, double-blind, controlled study was negative, just as here the best study in evidence on cardiovascular disease is Dr. Davidson's IMT study and it's negative.

Now, Dr. Heber, interestingly, did three studies, one which is listed here, the overweight Accelovance study, and two diabetes studies. You'll hear that Dr. Heber has all this theory about, as you say, how antioxidants work and that that's shown through all these mechanistic in vitro studies about changes in inflammation and oxidative stress. Well, the problem is, when Dr. Heber tried to get those biomarkers to demonstrate in a randomized controlled trial in humans that he could prove that the POM juice and POMx actually did indeed change these biomarkers for heart disease, he didn't get it. And what did they do? They buried the studies. They weren't published.

What happens with the cardiovascular disease research is that the published results are positive

results, and except with the exception of Davidson, which took two and a half years for them to publish, the negative results are buried. And yet, the irony is that all of these studies are used to inflate that number that Mrs. Resnick uses to convince consumers she's got medical research backing the claims. The amount of money in the ads is in the tens of millions, and it includes all these studies, but when respondents go to analyze if they have enough science for their claims, these studies somehow disappear.

For prostate cancer, it's really pretty simple. Our expert, Dr. Eastham, reiterated what the researcher, Dr. Pantuck, stated in his study results and his deposition. His study is fine as an initial study. Dr. Eastham said it was. It's perfectly fine as a very initial, what they call phase II human trial on prostate cancer, but it was not a randomized controlled trial, and it did not use a validated endpoint for a clinical trial to show a benefit for prostate cancer. And Dr. Pantuck said, right in the study, the published study, that this study has to be replicated with a randomized controlled trial before the benefits can be established.

Respondents really have not gotten any further in their prostate cancer research than that Pantuck

study, particularly at the time the claims were made. The Carducci study was just recently completed. And I do want to note, because this happens a lot in respondents' findings and brief, they have said that the Carducci study has been published. It has not been published to date. The abstract was presented. The study is not published yet. But, again, it's similar to the Pantuck study. It really doesn't advance.

Erectile dysfunction, the same thing, there's just one negative study.

So basically respondents, they have cherry-picked their science, which they can't do. You need to look at the totality of the science. And when you look at the totality, the trending is that there is no rigorous testing to establish the claims as they told consumers they had.

Now, switching to the nonestablishment health-related efficacy claims, there are a few of those that are at issue in the case. And these claims that are just efficacy claims, not establishment claims, a multifactor analysis would --

JUDGE CHAPPELL: These charts you've been flashing up, are they exhibits in the record?

MS. HIPPSLEY: This is just a PowerPoint for the presentation. They're not in the record.

JUDGE CHAPPELL: Not the current one but the one before?

MS. HIPPSLEY: Oh, the charts? No. They were demonstratives. What's in the record is the respondents' research portfolio, which basically shows the same thing, CX 1029, as of 2009. That's as far as they had gotten. And they do honestly show that they got negative results, let's say, for all their blood pressure tests after Dr. Aviram's.

JUDGE CHAPPELL: Is respondent going to use demonstrative exhibits?

MR. FIELDS: Not nearly as much, Your Honor, as I'm technically impaired. I'll do my best without them.

JUDGE CHAPPELL: Join the crowd.

Could my office have copies of all the demonstratives just for our use?

MR. FIELDS: Yes, sir.

JUDGE CHAPPELL: Thank you.

And we understand they're not evidence.

MS. HIPPSLEY: Okay.

Now, quickly for the nonestablishment claims, here, there is a multifactor analysis. It really doesn't change the equation. Because of the types of claims, a higher level of substantiation is required.

Because of the type of product, a consumer health product, a high level of substantiation is required.

Now, respondents will make a lot out of the fact that their products are safe for human consumption and somehow this should create a lower standard of science or a pass on substantiation. But the Q-Ray case, that the Seventh Circuit again affirmed, shows that this just isn't the law. You can't get safer than an inert metal bracelet, and Judge Denlow again said, Look, the large study showed no scientific basis for the efficacy claims that that bracelet relieved pain. The Seventh Circuit agreed. They did not meet the level of science that was needed for the hard-hitting medical claims, and that's the same scenario here.

And this sort of illustrates what we're talking about. The pomegranate fruit, sure, it's a whole food. It's FDA healthy. It has dietary fiber, vitamin C. That is not what's at issue here. We're not talking about eating a pomegranate as part of the DASH diet with low-fat foods and meat and five fruits and vegetables a day. We're talking about whether POM juice, a processed food, with no dietary fiber or vitamin C, that does not meet the FDA standard of healthy, that's a reconstituted concentrate, that has 34 grams of sugar, whether that product treats or prevents cardiovascular disease and

prostate cancer.

Even further away from the whole food is the dietary supplement at issue, POMx. It does not meet FDA healthy, and it does not even contain all the magic antioxidants that are in the POM juice.

So the challenged claims, in our view, Your Honor, are deceptive. They have made false establishment claims and misleading and unsubstantiated efficacy claims.

Obviously we think that these factors for the remedy have been met, that the violations are serious and deliberate. They can easily be transferred among the various products that the company has, the food products.

There is no history of prior violations. We acknowledge that. But here we had an advertising campaign that was deceptive and endured for seven years using multimedia.

You had asked if I would outline the proposed order, and there are basically three injunctive provisions to the order.

The first part requires POM -- well, the respondents -- get FDA authorization for substantiation of a disease claim, a treat, prevent, reduce the risk of a POM product claim.

JUDGE CHAPPELL: Remind me what authority do you have to require FDA preapproval.

MS. HIPPSLEY: The commission is creating, like it did in Thompson Medical with the two RCTs, a construct that is clear and concise to meet the problem we have at issue here.

So Part I says FTC will look at whether or not the respondents have made a treat, prevent or reduce the risk ad claim. We're not giving the order to the FDA. What we're saying is that, if the FTC goes to court, it will show respondents are making a disease treatment claim, for example. They're saying, as they did here, that we can treat prostate cancer. And then we're saying, under the order, Your Honor, in a contempt proceeding, to make a disease treatment claim, we required, the commission required, the respondents to have already shown that the science is the correct level by going to get an FDA drug claim.

JUDGE CHAPPELL: That's your authority?

MS. HIPPSLEY: The authority is the same as it always is, that the FTC creates an order that's clear and precise, it's fencing in and it's reasonably related to the unlawful practices, and the FTC feels that it is necessary in this case -- they have a very bright-line standard --

JUDGE CHAPPELL: So you want to require the substantiation task to be performed by the FDA.

MS. HIPPSLEY: The substantiation that's required under the order, yes, would be availing ourselves of the scientific expertise of the FDA if they're going to make a disease claim for the POM products.

JUDGE CHAPPELL: Is the FDA on board with that?

MS. HIPPSLEY: All we have to know is whether the respondents availed themselves of the FDA process. The FDA is not going to determine a disease claim. The FDA is doing nothing here. It's the respondents. The respondents, if they want to make a disease claim, have gone to the FDA and gotten that drug approval, as they're trying to do now, for example, with their POMx product.

So right now they're trying to get an FDA -- an ED claim approved by the FDA. They're trying to get a drug claim approved by the FDA for their ED POMx products.

JUDGE CHAPPELL: So let me get this straight. You're wanting to require POM to do the same -- use the same procedure that Pfizer used for Lipitor.

MS. HIPPSLEY: Before they can advertise that this product works like Lipitor, yes.

Now, if the respondents do not make an unqualified health claim or disease claim, if they're making the kind of claim they say is the only kind of claim they want to make, a structure/function claim, a highly qualified health claim, that would fall under Part III of the order and require competent and reliable scientific evidence that would be judged by the court using experts and, you know, starting all over again basically. And the commission would interpret whether or not and then prosecute based on its interpretation whether the advertising claim was substantiated with the proper evidence.

So let's say they want to say POM juice maintains heart health. That claim is under Part III of the order, and the FTC would see whether or not they have competent scientific evidence for that kind of claim. As we've already said "maintain heart health" has a very low science standard, they probably would be fine under Part III of the order.

But if they want to continue to say, "We treat prostate cancer," yes, we want more precision. We want a bright line. We've already fought this battle, and in an order we want both of us not to be in court again.

If you want to say "treat prostate cancer," show us that you went to the FDA, used their scientific

expertise, got that claim approved, we're done.

JUDGE CHAPPELL: What about an FTC preapproval process? An advertiser -- a company says, "We want to run this ad. It's attached. Give us an answer."

MS. HIPPSLEY: Actually, that's a very good point. Under Part III with our orders, our enforcement division does have an open-door policy, and many of the companies, established food companies, of which there are many under Part III orders right now, they can come in and say to the enforcement division just that: Hey, we want to run a new ad for Kentucky Fried Chicken. We want to make a health claim. Here's what the ads are going to look like. Enforcement, are you going to come after us if we make these claims?

And enforcement gives them the -- the enforcement division gives them, you know, their informal opinion.

JUDGE CHAPPELL: What if someone -- what if it's a company not subject to a consent agreement? What if General Foods wants to run an ad for Cheerios and they send it to the FTC?

MS. HIPPSLEY: They don't send it to us formally, but we are commonly, in the advertising division, which I'm in, commonly ad asked about advertising by companies.

JUDGE CHAPPELL: And what's the turnaround?

MS. HIPPSLEY: Pardon?

JUDGE CHAPPELL: How much time does that take?

MS. HIPPSLEY: No time. They'll come in informally and meet with us. Hey, we've got this idea for our ad campaign. They show us the kind of science they have. They talk to us about the advertising. They just want an informal take. They know we're not in the business of preapproving ads. That's not what they're looking for.

JUDGE CHAPPELL: Do you want to be in that business? Do you want to be that committed to it so companies know what they can and cannot do?

MS. HIPPSLEY: Preconsent order we are not in that business. The FTC does not preapprove advertising. We look to see if advertising is deceptive that's in the marketplace. Informally, our door is always open.

Now, once a company is under order, there is a relatively formal compliance process. Under the order, the company submits a compliance report. Right there is the point where the company and the enforcement division lock opinions. If in that compliance report the advertising looks problematic, the enforcement division will advise them they'd better back down, change the

advertising. If the advertising looks good to go, they move forward.

So it actually is a better process once the company is in the -- under order to get advice. And again, the FTC would be advising and looking at the ad interpretation.

So POM wants to make just a structure/function claim. They can come in and see if enforcement thinks that's what they're doing or does enforcement tell them, hey, look, this is a treatment claim, and under the order, here's the bright line that we are working under, did you get FDA approval for substantiation for a treatment claim. POM says no. Enforcement says, well, you better back down that claim to a structure/function claim. That's how it would work.

All right. I just want to touch quickly on this one case, Matrixx.

JUDGE CHAPPELL: You have twenty minutes total remaining.

MS. HIPPSLEY: Oh, I'm finishing. I'm too tired to take twenty minutes.

JUDGE CHAPPELL: I mean including your rebuttal.

MS. HIPPSLEY: Okay. Then I'll have a seat. I'll re -- here.

There is this case, Matrixx, that respondents

have discussed in their briefings, and I just want to get the record straight on what this case is actually about.

Respondents, quite incredibly, stated on page 1 of their posttrial brief that the Supreme Court held in Matrixx that RCTs are -- this is a quote from their brief -- "RCTs are not required to show a causal relationship between a health benefit and a product." In this case I don't think the word "health" appears anywhere. It has nothing to do with health benefits in the product.

What the Matrixx Supreme Court decision is about is, under securities law, whether or not Matrixx was properly forthcoming with investors regarding material information.

In other words, there was a shareholder suit. Matrixx moved to dismiss. And the Supreme Court was determining whether or not that case could go forward because Matrixx had not been forthcoming with its investors regarding material information.

And the material information was adverse event reports for Zicam. Zicam is a product that you take for cold and flu. It was nose drops. And they were getting adverse event reports that it completely killed off the sense of smell for consumers that used it.

The Supreme Court said: You know what, that's pretty serious, and if that is what actually happens, this product is going down the tubes, and shareholders have a right to know that their investment is in jeopardy.

Matrixx argued that its failure to report the adverse event data was because it needed to confirm the validity of the data through RCTs. The Supreme Court said: No, these adverse event reports would be highly impactful on a shareholder's investment. You need to give the information now.

That's all that case is about.

So I just want to say in closing that at the beginning of this case, Your Honor, at my opening you asked is this a case of apples and oranges, and I said actually, it's apples and apple juice. Here, the analogy is pomegranates and POM juice. Whole fruit, pomegranates, whole fruit, apples, do not equate to health benefits, unless you have the science to prove it, for apple juice and POM juice.

In fact, the respondents have sued many of their competitors because they're worried that their specific health benefits provided a halo effect for their competitors' apple juice, which in their view is just sugar water.

This case is about respondents telling consumers that they have science to back up claims to the consumer that their POM juice can provide very specific health benefits, that it can reduce plaque by 30 percent, that it can lower PSA by 350 percent, which they erroneously claimed showed that it will stop prostate cancer. That's what the case is about.

Thank you.

JUDGE CHAPPELL: Thank you.

You'll have a total of 17 minutes left for rebuttal.

MS. HIPPSLEY: Okay.

JUDGE CHAPPELL: If you need it.

(Pause in the proceedings.)

MR. FIELDS: Shall I begin? Okay.

I'm going to begin with the issues in this case as I see them.

The first issue is what is the level of evidence required to substantiate the ads in question. And we contend of course that you don't close your eyes to everything but RCTs.

The second issue, what does the science show.

The third issue, did the ads go beyond the science. We say it's just the opposite. The science goes beyond the ads. And in addition, the information

out there with the public goes way beyond what we've advertised.

And lastly, if any ad did go beyond the science, was it material in the purchase decision.

So those are the four issues, and I'm going to take them in order.

Number one, what level of evidence is required to substantiate a medical claim --

JUDGE CHAPPELL: You're jumping to the assumption the claim has been made.

MR. FIELDS: Yes. A claim certainly has been made. We may have a big disagreement as to what is claimed, but certainly the advertisements claim to aid health. There's no question about it. We make health claims.

JUDGE CHAPPELL: I don't want to throw you completely off your agenda, but do you agree with complaint counsel's assertion that the net impression analysis is done only from the perspective of the target groups?

MR. FIELDS: No, I do not agree with this, nor do I agree about the target groups.

As a matter of fact, let me take things out of order and talk about that.

Counsel said portfolio reviews -- pardon me --

creative briefs -- I'll get to portfolio reviews later -- talked about the creative briefs showing the intent of the company. She said that a bunch of times.

But the evidence was uncontradicted, Your Honor, uncontradicted, that the creative briefs that they make so much of are done by a minor person in the marketing department -- that's number one -- number two, that they are almost never read by the owners or the officers of the company or even the guy who's in charge of marketing.

Number three, they are almost always revised before they get to the advertisement stage.

And number four, no one, including their expert, could tie any creative brief into any particular ad. They just couldn't do it. When Mr. Perdigao was asked, if you were looking for the intention of the company, would you look to the creative briefs, he gave us an unequivocal "absolutely not."

So you're talking about something that doesn't reflect the intention of the company at all.

Is intention relevant? Sure. I don't say intention is irrelevant, but that certainly doesn't show what their intention is, nor have they simply targeted one group.

Counsel talks about advertising in Health and

Fitness magazine. They did that, but they also advertised in Playboy and Fortune magazine and a broad, broad spectrum of magazines. They're reaching out to a broad audience, not just the people that counsel is talking about.

Of course, people who have a disease are going to be interested in anything that's going to make them healthy. I don't disagree with that. But to use a word like they targeted those people based on creative briefs, it really doesn't fly. It's much broader than that.

In addition, counsel didn't emphasize, although she showed up on the screen where it said they are particularly dealing with an audience of highly educated, affluent, professional people, who typically would have greater rather than lesser knowledge.

Indeed, their own -- one of their own experts, Dr. Stewart, testified that people who have a particular illness or are concerned about it typically would know a lot more and be a lot better able to deal with what's in an advertisement than people who don't. They typically have more information about their particular disease and condition.

JUDGE CHAPPELL: Do you plan to cover the net impression or facial analysis aspect?

MR. FIELDS: I certainly do, Your Honor.

JUDGE CHAPPELL: You kind of threw me off starting on the substantiation.

MR. FIELDS: Well, I can --

JUDGE CHAPPELL: I wasn't intentionally derailing the train.

MR. FIELDS: That's all right.

I totally disagree with counsel about the burden of proof.

Thompson Medical tells us that if we're going to rely on a facial analysis that it has to be a matter of clarity in the sense that we must be absolutely convinced of the implication that's in the ad; otherwise, we have to have evidence going beyond the facial analysis.

Now, we have presented evidence going beyond the facial analysis.

JUDGE CHAPPELL: You're referring to extrinsic evidence.

MR. FIELDS: That's exactly what I'm referring to, extrinsic evidence. You can't rely on facial analysis in the very situation counsel is talking about.

JUDGE CHAPPELL: But you don't disagree that's a first step.

MR. FIELDS: Well, I don't know that it's the first step.

JUDGE CHAPPELL: A first step.

MR. FIELDS: It is a step that one could take, but you can't rely on it when there are two possible constructions of an ad.

And that's exactly what Thompson Medical tells us. If the ad can be construed as X or Y, you don't just rely on facial analysis, you look to extrinsic evidence, and you must do that.

First of all -- and again, I'm out of order, but -- there is of course a presumption --

JUDGE CHAPPELL: I wouldn't say you're out of order.

MR. FIELDS: Okay. I'll probably get out of order before I finish.

The -- there is a presumption of materiality, no question about it, but the cases say that presumption -- this is the Novartis case holding from the Supreme Court -- that that presumption disappears when there is rebutting evidence, that it disappears, and now you're on an even playing field once there's rebutting evidence, and it's up to Your Honor to decide whose evidence on materiality is the more probative. And there --

JUDGE CHAPPELL: So then you're back to the scales we've all used in front of the jury to make our arguments.

MR. FIELDS: Right.

JUDGE CHAPPELL: 50/50.

MR. FIELDS: And at that point they have the burden of proof, so they have to tip the scale slightly in their favor, and they can't come near it on the issue of materiality. Now I'm way at the end of my outline.

We've got Dr. Reibstein. They didn't even ask their fellow, Dr. Mazis, to do a study. Presumably they knew how the study would come out. But let's get --

JUDGE CHAPPELL: Well, they may not agree with that.

MR. FIELDS: I'm sure they don't, but let me now get to the end.

JUDGE CHAPPELL: Is that FIJI Water there (indicating)?

(Laughter)

It looks like technology is forcing us to take a break here. The realtime has gone out again.

We will reconvene at 3:15.

(Recess)

JUDGE CHAPPELL: Back on the record Docket 9344. Continue.

MR. FIELDS: Thank you, Your Honor.

The first issue that I started to address was what level of evidence is required to substantiate the ads. And there are two sources of that. One source is case law. The other source is the expert testimony on the subject. We had a lot of that.

As to the case law -- and I'm not going to read a lot of different cases -- counsel just discussed the Matrixx case. I'm just going to read the brief quote: "Medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence." That's a Supreme Court case.

The QT case, which is the appellate court opinion, is 512 F.3d 858. And interestingly, counsel cites the district court opinion in that case talking about requiring RCTs. This is FTC versus QT, Inc. But here's what the appellate court said: "Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies." And they go on, "Placebo-controlled, double-blind testing is not a legal requirement for consumer products."

Now, that's the appellate court. Counsel cites the lower court.

Then of course we have Pfizer that tells us we should look at various factors, such as the degree of risk, the type of product, the cost involved, and many such things.

Then we have the whole line of Pearson cases and the Whitaker case that talk about credible evidence is what we need and that the government has a heavy burden -- that's a quote for both Whitaker and Pearson. We've cited these in our brief, so I'm not going to spend a lot of time on it -- the government has a heavy burden if it wishes to preclude a health statement, and that heavy burden can be met by credible evidence -- that's the phrase they use -- which doesn't have to be uncontroverted.

In other words, you can even have a situation where some experts say we don't agree with this evidence, but that evidence can still be sufficient to support an ad. Whitaker was that. Two-thirds of the experiments came down on the other side. You don't simply say you can't make a claim that has substantiation because some doctors don't agree with it.

Now, this is what the cases say. They haven't

cited a case yet except for the lower court in the QT case, and the upper court on that issue disagreed, said you don't need RCTs.

What do the experts say? Well, we called six experts, Your Honor, six, distinguished doctors every one of them, and they to a man testified that when you're talking about a harmless product like fruit juice -- and that's all we're talking about here, fruit juice -- you do not need RCTs. You need reliable science of course. Nobody says you don't need reliable science.

JUDGE CHAPPELL: Well, you're saying that when you're talking about it, but what if you go further and you suggest things, health-related claims?

MR. FIELDS: We're talking about what you need to support a claim. If I use language like "talking about," that's what I meant. I mean, I'm talking about advertising. You don't need -- when you are advertising the health benefits of a fruit or broccoli or blueberries, you don't need to have an RCT. Every one of these gentlemen said that.

Dr. Miller, who the court will remember --

JUDGE CHAPPELL: Well, again, now, there's that phraseology "health benefits."

What if you're talking about 50 percent of the

men in an ED study had improvement drinking POM juice? What if that's in the ad?

MR. FIELDS: You better be telling the truth when you say that. I don't deny that.

JUDGE CHAPPELL: But your position is that does not require the RCT?

MR. FIELDS: It does not require an RCT.

If you have said you have an RCT, you better have an RCT. If you said, as we said, that there is a pilot, preliminary study of 19 people and they got a 30 percent reduction in plaque, that is truthful. That is what we said. And we have to represent accurately what that study was, and we have done that.

Now, when you're talking about the kind of fruits that's -- I just dug out that "Decompress" ad. We're going to pull it up on the screen later. What it says is there are encouraging results in prostate and cardiovascular health. That's what it says, and I defy anybody to say there were not encouraging results in cardiovascular health.

JUDGE CHAPPELL: But you would agree that you must have results that are encouraging to say that.

MR. FIELDS: Yes, I do agree with that totally.

JUDGE CHAPPELL: And what about the fact that cardiovascular health is a disease claim?

MR. FIELDS: I don't think it is a disease claim, I don't think, not in the sense that they use "disease claim," that it means you're preventing a heart attack or you're curing a heart attack once it's occurred or you're treating a heart attack in the sense of medicinal treating. I don't think it's that kind of claim at all. To say we -- I mean --

JUDGE CHAPPELL: Well, we heard -- I think we heard argument that there's evidence in the record that absence of -- absence of disease or I guess -- no. Health is defined as absence of disease.

MR. FIELDS: Well --

JUDGE CHAPPELL: Now, is there evidence in the record contrary to that?

MR. FIELDS: That health is defined other than absence of disease? I don't think -- I can't point to evidence in the record, but I can tell you that health has a lot more to it than absence of disease. To be healthy means I feel fine. I don't have headaches. That's not a disease.

JUDGE CHAPPELL: So you think --

MR. FIELDS: Exercise --

JUDGE CHAPPELL: You would say being healthy means more than I don't have disease at this moment.

MR. FIELDS: That's correct. Of course it does,

Your Honor. I mean, that's just common sense.

I exercise in order to be more healthy. I'm not exercising just to prevent cardiovascular disease, although I'm sure it helps with cardiovascular disease. But health has a lot more to it than absence of disease. Health leads to happiness.

Anyway, I won't belabor that. Let me go back to where I was.

These doctors are talking about claims that can be made in advertising for the health benefits of fruit, and to a man they say you do not need RCTs.

Dr. Miller, who testified as the lead expert in Daniel Chapter One for the government, distinguished that case and said this is a case of a harmless product, which changes the equation considerably because he said in that case we were dealing with herbal products that were not necessarily harmless at all.

JUDGE CHAPPELL: In this statement you're making, are you including the supplement, the concentrated pill?

MR. FIELDS: Yes, sir. I'm making no difference between the two. It's -- what is in the supplement is comes purely from the pomegranate fruit. There's nothing added.

JUDGE CHAPPELL: What about that

super-concentrated extract juice? Is that still available?

MR. FIELDS: Same thing. I don't think that's on the market anymore, but it's the same thing. Every one of these products contains only what comes from a pomegranate, nothing else. There's no added herbs. There's no yohimbine or whatever that herb was. There's none of the things that were before the court in Daniel Chapter One at all.

And so Dr. Miller, who came here, by the way, at a --

JUDGE CHAPPELL: So I just want to be clear. When you refer to a harmless product, you mean all the products in question.

MR. FIELDS: All the products in question are harmless products. There's not even a hint of evidence that they've ever hurt anybody. Pomegranates have been eaten for centuries, and they're on the FDA list of things that are generally perceived to be safe.

And I think every expert, on our side at least -- and there were six of them -- testified that the product is safe and they had no indication of any lack of safety, so we start with that premise. And they all said, when you're dealing with a product like that, you don't necessarily need RCTs.

Now, I'm not attacking RCTs. RCTs are fine. We agree, RCTs are probably the gold standard of medicine, not disagreeing with that. That doesn't mean that you can't prove the things you have to prove, you can't show the things you have to show by other than RCTs.

And every one of those doctors said when you're dealing with a harmless product that you don't necessarily need RCTs, as you would for a dangerous drug. You don't want to put a dangerous drug out on the market unless you have the gold standard. But when you're talking about fruit juice, when you're saying fruit juice, as we say in the ad that they've used as their example, that there are encouraging results in prostate and cardiovascular health, you certainly don't need an RCT to demonstrate that.

Now, they had experts, too. Their experts, Your Honor may remember them because some of them were very dramatic. Well, their experts on direct examination tended to talk about RCTs, but let's take them one at a time and what happened on cross-examination.

Dr. Stampfer, you may remember, said that he felt that you should have RCTs and -- if you're going to make a public -- you know, tell the public about the health benefits of fruit. And then it turns out that he

was the guy who told the public that moderate alcohol use would prevent various diseases. I've forgotten what all of the diseases were. There were some pretty serious diseases. It turns out that Anheuser-Busch had a hand in their various presentations, gave money to their institution, and he was simply unable to reconcile that statement with his testimony that you should have RCTs before you do that kind of thing.

Your Honor asked the question is there a difference between his making a statement to a newspaper and a hang tag on a product. I don't know if Your Honor recalls that. It was a good question, but there is a -- there is a difference constitutionally. The interview with a newspaper is probably not advertising, and it probably isn't within the act, and it probably is protected by the First Amendment. But the standard that one uses in telling the public should be the same.

A man who gets up here and says you shouldn't tell the public in an advertisement that you can -- you have these health benefits for this fruit shouldn't be telling the public that moderate alcohol has these benefits, and he went way beyond what we did. He talked about preventing disease without applying the same standard.

And then we turn to his -- his article, and I

don't read his article the same way counsel does. I think in his article he very plainly says RCTs are often inefficient when you're dealing with nutrients and they should not be our standard at all.

Then we turn to Dr. Melman, and that was one of the most interesting moments in the trial. Your Honor probably recalls Dr. Melman. He's the guy who said not only do you need RCTs, you need two of them at two different institutions, and they have to be large. And since his field was erectile function, he said wives have to corroborate what the husbands say, and that they don't even reach orgasm, then it doesn't even count at all.

And then Your Honor may remember I said, "Well, Doctor, don't you have a product called hMaxi-K?" And he said, "It's not a product," because he hadn't yet put it on sale, but he intended it for sale. And he had said that it was "the fountain of youth." That's what he told the public, that he gave men new, young erections and went on and on about his product.

It is impossible to credit that man with any kind of testimony about whether you need RCTs. His own behavior was totally impossible with his standard being sincere, and I don't mean to be that pejorative about the man, but it was remarkable.

He also said, when I said isn't there a difference between fruit juice and a dangerous drug, and he said fruit juice is a drug. Water is a drug, he said.

JUDGE CHAPPELL: That's the -- that's the witness who said water is a drug?

MR. FIELDS: Yes, that's the guy. He's the "fountain of youth" guy, and he was telling you you need RCTs.

Dr. Eastham said you need RCTs. He did say that, but he's a surgeon. And Dr. Eastham cut out 200 prostate glands a year over many, many years and conceded that when he did that -- and by the way, they had the possibility of very serious side effects of incontinence, impotence, aneurysms. And he said, Oh, we had no RCTs that told us that was even effective at the time.

So these people didn't apply the same standard necessarily.

Now, Dr. Sacks -- counsel said that we talked about the DASH diet. We did more than talk about the DASH diet. I asked Dr. Sacks, isn't it true that you said that we don't need RCTs for fruit, that it can have a lower standard? Oh, yes, that's right, and pomegranates, too, because they've been tested, he said,

in the DASH diet, so we don't need that kind of standard. And finally, when I showed him the DASH diet that treated fruit juice the same as fruit, tested it the same way, he finally said yes, there's a different standard for fruit and fruit juice than the standard -- the heavier standard you apply for drugs, so he was wrong.

So the consensus of these people is, when you're talking about a harmless drug -- pardon me -- a harmless substance like fruit juice, you do not need RCTs.

Now, counsel has come up with a last-minute argument that hangs on their calling this an establishment claim and a nonspecific establishment claim. They argue that when we say in an ad that a pilot study shows a 30 percent drop in plaque that what we're really saying by implication is that we could prevent or cure heart disease and that we've proved it with our study. And they say because we said we've proved that we can cure or prevent heart disease, we're now a nonspecific establishment claim. Then they take that huge leap and they say, therefore, you can only look at RCTs because of a case called Removatron.

Well, first of all, our ads don't say what they said, and I'll get to that when we talk about ads. And

secondly, Removatron doesn't begin to say anything like that.

In the Removatron case, Removatron claimed that they -- their research proved that they would remove hair permanently, and there was no such research at all. There was no science whatsoever in Removatron. And far from ignoring expert opinion, which is what counsel is arguing, Removatron says you don't even have to look at expert opinion, you must have RCTs.

Removatron doesn't say that at all. They had one expert who testified, and he said, in that case, where they had no science at all, in order to prove their claim, what they would have to do is have a controlled study. Even he didn't say it had to be a placebo. He just said a controlled study. And that's what the court made Removatron do. The court made Removatron have in the future, before they made the kind of claims they made, would have to have a controlled study.

The circuit court set out for our guidance what might be applied in other cases; and that is, you've got to satisfy the relevant scientific community. And that's just what we've done. We've produced six experts who said what the standard was.

JUDGE CHAPPELL: Is that the same as saying the

experts in their fields?

MR. FIELDS: I think that's right, yes. That is what you're talking about.

And again, six got up there and said you don't need RCTs for a fruit product, a pure fruit product like this. Dr. Stampfer we believe in his article said it, and both Stampfer and Melman were out making public statements far beyond things that we've said, on behalf of their products, without RCTs. Sacks was cutting out 200 prostates a year for years without RCTs. And Dr. Sacks -- pardon me. Eastham was doing that. And Dr. Sacks conceded that when you're talking about fruit and fruit juice, you have a lower standard than a drug does.

So the consensus, whether you call it eight to two or nine to one, of the experts who testified here was you do not need RCTs, and that is what the cases say.

JUDGE CHAPPELL: So is it a numbers game? You go with the majority?

MR. FIELDS: No. I'm not saying that, Your Honor. I'm just saying was there a consensus here -- I think if we had some experts who said you don't need RCTs and they had some who said you do need RCTs, I think they have the burden, and you -- if it was

evenly matched, you go with us. But it didn't come anywhere close to being evenly matched. It was overwhelming on the side of, for a pure product like this, you don't need RCTs.

Now, what does the science show us? Well, we go back a little bit.

Mr. Resnick had some acreage. He ended up with some acres that had pomegranates on it. He's a cancer survivor, so he wanted to find out is it true that what these people have been saying for centuries that there's some health-giving qualities about the pomegranate, so he started out in what began as a small project, ended up with I think Dr. Liker told us a hundred studies in 44 different institutions and 70 peer-reviewed articles of those hundred studies, $35 million, to show what the pomegranate can and cannot do.

And by the way, what it can't do is just as important as what it can do when you're doing these scientific studies.

Now, the evidence was that Mr. Resnick didn't game the system. He followed the advice of his scientists. He had a regular group of scientist advisers, and he had specialized groups that came together: P.K. Shah, the world-renowned heart surgeon; Dr. Kessler, the former head of the FDA; Dr. Kantoff,

who came here briefly and testified. All of them, they debated and they advised him on what he should do and what he shouldn't do, and he went ahead and dealt with three main areas.

I'm going to try not to take too much time on this.

In heart, they began with a fellow named Aviram.

JUDGE CHAPPELL: Are you saying there's a due diligence defense, if you consulted with people and went with their advice, you're okay, regardless of what you say in the ad?

MR. FIELDS: I think that that -- no, I'm not saying that, Your Honor, no. If we said something that was false in an ad, it is not justified by the fact that we talked it through with a bunch of doctors. I'm not saying that.

What I am saying --

JUDGE CHAPPELL: How about a bunch of lawyers?

MR. FIELDS: Pardon me?

JUDGE CHAPPELL: A bunch of lawyers.

MR. FIELDS: Well, if it's a bunch of lawyers, then that's okay.

JUDGE CHAPPELL: Especially your firm?

MR. FIELDS: Yeah. Absolutely. If they pay

me.

(Laughter)

But if -- and by the way, as to your question, Your Honor, it would go to whether there was an intentional violation. It would go to whether it was a deliberate violation.

In other words, if a man was told by a team of doctors X and he says X in an ad, it's pretty hard to say he deliberately misled anyone, even if it turns out that the doctors were wrong.

Okay. So he goes to Dr. Aviram. Why us does he do that? Because Dr. Aviram was the guy who did the work on red wine and became kind of famous for doing that. Their experts conceded that Dr. Aviram was a fine researcher, that his institution -- I think even Dr. Melman said it was a fantastic institution, Technion.

Anyway, first they did in vitro and animal studies. And Dr. Sacks, their expert, told us that these in vitro and animal studies showed a decrease in LDL oxidation, a decrease in macrophage uptake of LDL, and reduction of atherosclerotic vessels, all from pomegranate juice.

Now, true, those were not yet clinical studies, but we don't just disregard them, and Dr. Sacks didn't

tell us we should disregard them.

The clinical studies confirmed the likely benefit from the lab studies, and that's where we got Dr. Aviram's 30 percent reduction in plaque. And actually it's a little better than that because the people with placebo -- they weren't a placebo group. They were an untreated group. The control group were people who just had to take the pomegranate juice, how did they do with a similar condition. They got 9 percent worse, so we have a 39 percent swing between the pomegranate juice people and the untreated people.

Now, true, that is small. In our ads you'll see that we mention that it's -- I think it was 19 people and that it was a pilot study. Nevertheless, that's not a good reason to ignore it, but it is certainly credible evidence that pomegranate juice has a likely benefit to people with plaque.

Then we come along with Dr. Ornish. He was also here in court. He was a pioneer and an iconic figure really. He appeared without pay you may recall. He made a fiery speech about how the government was overreaching and this was Big Brotherism.

He did a study called a myocardial perfusion study, which really means the flow of blood to the heart. And the flow of blood to the heart is the most

direct thing one could study in finding out what causes a heart attack.

Your Honor may remember we had a kind of a board up that showed how a heart attack happens. You begin with cholesterol, and then that cholesterol oxidizes, and then the oxidized cholesterol is eaten by something called macrophages, and that forms foam cells and that forms plaque, and that cuts off the flow to the heart. Well, the cutting off of the flow to the heart is right at the end of the process. It's much more direct than the two surrogates that the FDA recognizes, which are cholesterol and blood pressure.

Anyway, Ornish measured this and got a very positive result. I think it was 17 percent of the people had improved blood flow as opposed to the placebo group that did not and had some worsening of their condition.

Now, this was an RCT. Dr. Sacks criticized the methodology. He didn't -- and by the way, none of their doctors say that pomegranate juice does not work. Nobody says that. What they say is we criticize your studies, we say your studies are not good enough really, but no one says, well, we've done a study and it doesn't work at all.

So let's go on with Dr. Ornish. Dr. Sacks

criticizes his methodology. He says he would prefer to study what he calls SSS instead of SDS. But he conceded that Dr. Ornish is free to choose whatever he wants to study, that the principal text that he referred to -- I think it's Braunfeld -- listed both as valid surrogates, both SSS and SDS. One refers to the patient under stress, and what Dr. Ornish studied was the patient -- the difference between the patient's blood flow under stress and while he was seated.

Now, there were some -- one of the criticisms was that there were sicker people at the outset in the placebo group than in the pomegranate juice group, but the experts on both sides said that could have just as well have created a situation where they got more improvement rather than less improvement because they were sicker to begin with; therefore, the experiment would have looked even more successful rather than less successful in comparing the two groups.

The -- another criticism was that the experiment went on only for three months. Remember, Dr. Ornish testified his financing was dried up, so he ended it at three months, but that doesn't mean you throw it out for that.

There were some things that Dr. Sacks said were just demerits, and I won't even take the time to go into

that because he didn't say they would prove fatal to the study.

Counsel has pointed out that it was initially rejected by the AMA journal and I think one other journal. The AMA journal, the evidence was, accepts only 7 percent of papers that are submitted, and they sent him a letter saying we're sure it will be published in another journal, and it was.

Now, again, I'm not going to go into all the heart studies because there was a mountain of them, but the next one that we've talked about is the Davidson study.

And Davidson did twelve months. He got a difference in his overall group between the placebo group and the pomegranate juice group. The pomegranate juice group did significantly better. At 18 months, that was not there. And he speculated that everybody was interested in why there was that difference, and Dr. Davidson's view was that probably people after a year stopped drinking in the pomegranate juice group and probably people in the placebo group had read or heard about pomegranate juice and started drinking it, but we just don't know.

But the important thing about the Davidson study is that a subgroup of people who had greater at-risk

symptoms even over the 18 months had a very significant improvement in the pomegranate juice category over the non -- the placebo group, a 4 to 9 percent improvement in their condition, in the thickness of the artery. And there was testimony that there could be millions of people in the United States in that group. Dr. Heber said there could be tens of millions of people in that group who would be benefited by that.

And you may remember Dr. Sacks telling us that if a drug company found that even there was a 5 percent improvement factor for people, for millions of people in the United States, they would rush out and get a patent and make a lot of money from it. And here you had a 4 to 9 percent in just 18 months.

And then you had an attack on that because it was called post hoc, which means it wasn't the endpoint going in of the experiment. But even Dr. Sacks said that that doesn't disqualify it because he has done considerable post hoc work and published post hoc studies.

And Your Honor may remember my hypothetical to one of the other doctors who had talked about post hoc. And I said, Well, let's assume you're doing a study on blood pressure and you find out that the particular pill doesn't do anything for blood pressure, but it

cures cancer, and that wasn't the endpoint of your study at all. Would you just not tell anybody about that? Oh, no, of course you've got to tell everybody about that.

So it would be post hoc, but the fact that a benefit to millions of people in the United States demonstrated by an RCT in this instance happens to be post hoc does not at all disqualify it.

So you have a mountain really -- I don't know if we have a graphic that shows the number of heart studies that were done. There were just tons of them.

Now, it's true, some heart studies did not get a result with a significant -- statistically significant difference, but all of the experts testified, except Dr. Melman, that a null result is not a negative. It doesn't mean pomegranate juice doesn't work; it just means you haven't proved it in this study. Dr. Sacks said that. Dr. Meir Stampfer said it. That was -- there was no denial of that, other than Dr. Melman, the "fountain of youth" guy who said, if it doesn't have statistical significance, it doesn't exist.

Anyway, taken together, the heart studies certainly show a likely benefit from pomegranate juice. Taking just the subgroup of patients, taking Ornish, taking Aviram, it certainly shows a likelihood of

improvement from pomegranate juice. Dr. Ornish testified that if we show an improvement with people who already have cardiovascular problems, it is even more probable that there's a benefit to people who haven't yet developed cardiovascular problems.

Now, let me talk about the portfolio review a little bit because counsel spent a lot of time on that.

Again, it does say, oh, this only gets a 3 out of 10 and it isn't go to satisfy the FDA. The uncontradicted evidence, Your Honor, was that the portfolio review was designed to see if the studies would satisfy the FDA for a drug permit. That is what this was all about. Mr. Tupper testified to that. There was no contradictory evidence. And he said everything in that portfolio review was talking about can we satisfy the FDA.

And we felt we had a lot of problems because the FDA, for example, in heart recognizes only two surrogates, that is, cholesterol and blood pressure, and we've used other surrogates that are widely recognized, recognized by the Braunfeld's text, recognized by doctors in the field, like myocardial perfusion, like plaque in the arteries. Those things seem, to the doctors who testified here on our side, to be better surrogates, but they wouldn't be recognized

by the FDA.

In prostate -- and we're going to get to prostate in a minute -- the FDA doesn't recognize PSA or PSA doubling time as a surrogate.

So we knew we had a problem with the FDA. That's all the portfolio review does.

Now, moving on to prostate, we were -- it was not only reviewed by Dr. Heber but by Dr. deKernion, probably the dean of oncological urologists in the United States. Your Honor may remember a gray-haired, distinguished gentleman got up here from -- I think he had been acting dean at UCLA and a revered guy. And he described the various studies that had been done on the prostate.

And first he started with the in vitro studies, and he told us that in the vitro studies it inhibited and killed cancer cells.

Then he told us about the animal studies. And these were unusual animal studies, Your Honor, in that they were studies of human prostate cells injected into animals. It wasn't animal cells. It was human cells. And again, the pomegranate juice inhibited and killed cancer cells. Dr. deKernion told us about this. Dr. Heber told us about it.

Then we had the Pantuck study at UCLA and the

Carducci study at Johns Hopkins. They studied men who had had prostate cancer and had prostates removed, and they were studying the PSA doubling time. Now, why did they do that? Because if you studied healthy men to see whether or not they could be helped, whether they'd get longer lives, you'd have to follow them for 30 or 40 years. This allowed them to see how people were progressing in a very short period of time.

They had a dramatic result. The dramatic result was the -- as was predicted by the in vitro and animal studies, the people who got the pomegranate juice had a substantially lengthened doubling time for their PSA, which meant -- and here, even their own expert, Dr. Meir Stampfer, said, if they got that result, that means their lives were extended.

Now, there was a good bit of controversy as to whether the PSA doubling time is a valid surrogate. Your Honor may remember Dr. Eastham said that it was not, but then I confronted him with his own article in which -- I think we have a quote from the article. Yes. This is -- this is what he originally testified, his trial testimony. Could we see the reference to his article.

(Pause in the proceedings.)

Well, I'm not going to dwell on it if we can't

get it up there.

In his article, he flat-out said it was a valid surrogate, it was a predictor of a recurrence of a disease or death, totally contrary to what he said here in his testimony. The -- he was then confronted with his article that said doubling time of PSA was a valid surrogate, and what he said then was: Well, I meant in my article it was a valid surrogate only at the moment of intervention, and it stopped being predictive after that.

Well, that's impossible. I mean, as Dr. Sacks said, when I asked him, if something is a surrogate, that means changes in that surrogate indicate the likelihood or lack of likelihood of the disease that it's a surrogate for. Otherwise, it wouldn't be a surrogate.

So Dr. Eastham's criticism, which is contrary to his article, simply cannot stand. There were numerous articles written saying that PSA doubling time is a valid surrogate, and as I say, even Dr. Stampfer said it was a valid surrogate and that if indeed PSA doubling time was lengthened, then the lives of these men would be lengthened.

Now, the bottom line, Your Honor, was Dr. deKernion. You couldn't compare the credentials of

Dr. Eastham, a surgeon, with Dr. deKernion's background. And Dr. deKernion said two things. He said that, with a high degree of probability, people who have prostate cancer will benefit from pomegranate juice. But he said, even more importantly, with a high degree of probability, men who have not yet been diagnosed will find that pomegranate juice will inhibit the growth, the clinical growth of cancer cells. That is in men who have not yet been diagnosed.

And this is Dr. deKernion, Jean deKernion, who, as I say, is really the dean of oncological urology. And you couldn't ask for a more resounding statement of the potential benefits of pomegranate juice in the prostate area than what Dr. deKernion told us, in addition to what Dr. Heber told us and even what we heard from Dr. Miller, who is also an expert.

Now, erectile function, I'm not going to take a lot of time on it because I'm already using too much time.

Dr. Burnett, from Johns Hopkins, told us about the process by which blood flow is improved by nitric oxide, how nitric oxide inhibited a -- tremendously improves blood flow, and blood flow gives men normal erections. And he had -- it was thus his opinion, since -- based upon the various studies that he saw,

that pomegranate juice would aid, likely aid, in erectile function.

Dr. Goldstein, who specializes in that field also, testified to the same extent.

Now, we have, it's true, this study, the Padma-Nathan study that was a hair off of statistical significance. It was .058 instead of .050. That means it was 95 -- 94 percent accurate as opposed to 95 percent accurate. We don't -- as the Supreme Court says in Matrixx, we don't discount or throw out a study because it missed by a hair statistical significance. That would be a very, very arbitrary way of looking at things.

But, again, what we have on the other side here is merely Dr. Melman, who says, if it doesn't have significant -- statistical significance, it doesn't exist and who said a lot of things, like rather than tell people to drink pomegranate juice he would suggest they stop having intercourse. And you may remember Dr. Goldstein's response to that was something like no ethical, competent doctor in the field would make a statement like that.

Now, Melman's testimony on erectile dysfunction is tremendously outweighed by Dr. Burnett from Johns Hopkins and Dr. Goldstein. And then we have

Dr. Ignarro, who is the Nobel Prize winner, and Dr. Ignarro was doing the studies and did the studies on nitric oxide production caused by pomegranate juice.

Let's see if we can get up Dr. Ignarro's statement.

(Pause in the proceedings.)

Okay. Well, it worked this time.

"Based on the studies conducted in my laboratory, pomegranate juice was twenty times better than any other fruit juice at increasing nitric oxide. It's astonishing. I've been working in this field for twenty years, and I have never seen anything like it. I drink it three times a day without fail."

And this is the guy who won the Nobel Prize for his work.

Now -- so in all three fields you have substantial evidence by very distinguished doctors who were not going to come down here and lie about the story about the fact, men like deKernion, men like Ornish, and men like Burnett from Johns Hopkins. They're just simply not going to do it, and they told Your Honor that there is a very significant benefit and, in Dr. deKernion's words, highly probable that even men who have not yet been diagnosed will find their prostate cancer will be inhibited, not necessarily killed,

because it's not a hundred percent, but it will be inhibited by pomegranate juice. And the government is saying they don't want to tell people about that, even though there's no harm from the product, and there might be a very significant benefit. If you believe these doctors, it is highly probable.

Now, let's talk about what the ads said.

First of all, we've got to talk about which ads because, from the beginning of this case, unlike any other case I think I've ever been in, we didn't get any reasonable notice of what the claim was, that nobody would tell us the particular ads they were attacking or why that particular ad was being attacked, as you would normally get in this kind of litigation. We went on, and it was only after the evidence was closed that we were able to find out the 43 claims that counsel is attacking. I don't mean to be a whiner about it, but that really doesn't comport with due process.

So let's turn to the 43 ads.

We ought to start with the fact that some of the ads really shouldn't even be in consideration

JUDGE CHAPPELL: Let's go back to what you said. You may not have had the actual ads, but you had the gist of the ads from the complaint.

MR. FIELDS: We had the gist, but there are

600 ads, Your Honor, and we weren't told which ones -- they refused to limit it until at the very end, after the evidence was closed. That's when they limited it.

And they never got to the point, before the evidence closed, of telling us which ads. They just said, well, the ads -- your ads in general are statements that you prevent, treat or cure cancer. It was all lumped, those three things, not this particular ad says you prevent or this particular ad says you treat. All 600 of your ads, so far as we're concerned, do all these things. And we'd say, Which ones do you mean?

But, again, I want to move beyond that because we now have 43 ads they're talking about. But we've got to eliminate some.

There were very definite changes in the nature of the ads in or about 2008, started in 2007 -- and we can show that to Your Honor -- so that the early ads, although we believe they are truthful and we're prepared to talk about them, really shouldn't be the basis of seeking an injunction. We're not seeking -- this is not a damage case. This is not a criminal case. We don't punish for old acts. And when you talk about things that happened seven, eight years ago, that's not the proper basis for an injunction. We cited cases to that

effect. And that's particularly true, Your Honor, where you can show that the type of advertising changed, and indeed it did.

JUDGE CHAPPELL: I think their position would be you ran them once, you may run them again.

MR. FIELDS: Well, that's correct, but the issue is are we likely to. And when we haven't run something for seven or eight years and we've done a different type of advertising since then, although I'm going to get to a specific example, the "Cheat death" ad that they have talked a great deal about --

JUDGE CHAPPELL: The bottle with the noose around the neck.

MR. FIELDS: Pardon me?

JUDGE CHAPPELL: The bottle with the noose around the neck?

MR. FIELDS: Yes, the bottle with the noose around the neck.

In -- I think it was 2004 that ad ran, and it ran -- and it was really a mistake, because when it was supposed to say that antioxidants would have an effect on disease, it said pomegranate juice -- this is the early ad in 2004 -- pomegranate juice has antioxidants and can help prevent various diseases. And that mistake was caught. It was stopped in 2005, has never run

again.

I'd like Your Honor to look at the present "Cheat death" ad. I shouldn't say present. It ran in I think 2008 or 2009. Totally different. Totally different. It -- now it talks about hopeful results and promising results from the ads. It doesn't say anything at all about helping -- even helping to prevent any disease. We'll be putting it up on the screen I hope in a moment.

The other thing that should be excluded is that Mr. Mazis told us that ads later than 22 months before the Reibstein survey -- and that would be after November 30, 2008 -- should be excluded, that they were not attacking them. And counsel has not denied that they were eliminating certain periods, but they just said it's 22 months before Dr. Mazis' report, not 22 months after the Reibstein, and that would make it June of 2009.

JUDGE CHAPPELL: I just want to let you know that you're under 60 minutes now.

MR. FIELDS: I'm under 16 minutes?

JUDGE CHAPPELL: 60.

MR. FIELDS: 60. Oh, okay. 16 was scary.

But thank you, Your Honor. I see 59:09 on this handsome thing in front of me. Okay.

So whether we follow their interpretation of what's excluded or our interpretation, whether it's June '09 or November '08, that excludes a number of other ads. When you take out the old ads -- they say there are nine of them that go on back seven or eight years -- and you take out the ads here after November 30, 2008 or June 2009, you're talking about on the one hand like ten ads and on the other probably 20-25 ads.

Now, that's a relatively small part of 600 ads, but we can focus on them because I think Your Honor will see that the ads in the period that is not excluded, that shouldn't be excluded, are highly qualified ads. They are ads like -- can we see Exhibit 0092, What Gets Your Heart Pumping?

(Pause in the proceedings.)

I don't have it on my screen, so -- I don't know if Your Honor can read it. It is kind of fuzzy.

But it talks about emerging science telling us that free radicals can be damaging to healthy cells that emerging science suggests it even says -- it doesn't even say emerging science shows, it suggests -- and then it goes on to talk about the experiments, and then it says what do they do, they provide encouraging results for prostate and cardiovascular health.

So that's typical of the ads that followed, starting in late '07 and coming forward, very different from the ads that appeared before that. And that's another reason, Your Honor, why, in looking at whether you should issue an injunction, you'd want to even consider those older ads, because it's not just that they were older, it's just that they changed the entire approach of their ads to this much more qualified kind of statement.

There are a number of ads that fall into that category, but let's assume that for the moment that all 43 ads are in play and we have to deal with all of them. Let's assume that for a moment.

JUDGE CHAPPELL: You should be able to pull that microphone toward you if you don't want to lean over.

MR. FIELDS: But it slides downhill, Your Honor. I'm hoarse today, so I'll try to do better. Okay.

Now, assuming they're all in play, they still are -- and I'm going to get to this -- much more conservative in their approach than the science and much more conservative in their approach than other information that's out there in the public. And I'm going to get to that because there's a way lot of information about pomegranate juice that's out --

JUDGE CHAPPELL: But the government's position is all 43 at issue are unlawful, not just the old ones, not just the semi-old ones but all 43.

MR. FIELDS: Well, they say that, but the ones after the cutoff period that they themselves have said we're not attacking the ads, 22 months -- later than 22 months after the Mazis report, and Mazis' testimony was it was 22 months after the Reibstein survey, which would be November 30, 2008, they can't back away from that.

But I'm assuming for the moment that all 43 are in play and that -- and I'm going to deal with all 43. I'm not going to -- not one at a time.

JUDGE CHAPPELL: So how many do you say were after the Mazis report?

MR. FIELDS: Well, if you take our view on what Mazis said, which would make it November 30, 2008, and you leave off the older ads, the ads prior to '08, which is more than four years ago, you will get about ten ads. And in their view, if you use June '09, you'll get -- I haven't counted them -- probably 25 ads, excluding the old ads, they say nine of those, and the ads after June of '09.

So on our view you're talking about 10, on their view probably 25 or so. But I'm going to deal with them

as if they're all --

JUDGE CHAPPELL: So if that's their position, can we agree to eliminate some of the 43?

MR. FIELDS: I don't think they're going to agree with me, Your Honor. I'd be very surprised if they did.

But they did say this. Counsel apparently told Dr. Mazis that they were not attacking any ad that was later than 22 months after the Reibstein survey. In their response, as I've read it, they don't deny there was a cutoff, but they say it's 22 months before Dr. Mazis' report, which would be June of '09 instead of December of '08. But there has to be a cutoff.

In any event, let's talk about it as if all 43 were in issue here.

JUDGE CHAPPELL: That's probably a good idea.

MR. FIELDS: Thank you, Your Honor. Once in a while I have them.

We can look at two sources really. One source Your Honor has already talked about with opposing counsel, and that is a facial analysis. The other source would be the extrinsic evidence, the evidence of the experts as to what they mean.

Well, we called an expert, Dr. Butters. Dr. Butters looked at all of the ads. He didn't even

limit it to the 43. And he said that there is not an ad that says or implies that pomegranate juice or pills or any of the respondents' products prevents or cures anything. He said there's not an ad that says or implies that.

He said that as to treat, if you mean a medical-type treatment or a substitute for a medical-type treatment, there is not an ad that says they do that. He said if by "treat" you mean can they help with a condition in some way, in some way make it better, yes, but he wouldn't call that a treatment.

As to whether it could reduce the risk of some disease, he said some people might construe it as reducing a risk or possibly reducing a risk, but he doubts very seriously that that would occur, given that it was just talking about fruit juice, a healthy product, and he doubted that that would occur. He said flat out that it does not say prevent, cure or treat in the sense of a medical treatment.

And he went on to talk about the effect of puffery and humor, that these catch phrases at the beginning of an ad are not something that anyone would take literally, that you're going to outlive your 401(k) or amaze your urologist, things like that. The pictures of the bottle lying on a therapist's couch are obviously

humor and puffery, and so taking the whole of the ads, he came to the conclusion that they did not do the things that counsel has argued they do.

Now, that was extrinsic evidence, and it was expert evidence. They did not call an expert on what the ads meant. They did not present a survey of what the ads meant. They presented Dr. Stewart.

You remember Dr. Stewart was the fellow who got up here and said that he hadn't been reduced from dean, it was a voluntary thing, and then it turns out, he had to admit, yes, he had been asked to step down, it wasn't voluntary at all, and he wasn't even allowed to stay in office until the interim could be appointed. Now, that in itself is not a terrible thing, of being demoted from dean to whatever position he had, but the fact that he didn't tell us the truth kind of affects our thinking about him.

In any event, he criticized the methodology of Dr. Butters, and Your Honor may remember his criticisms. He said Dr. Butters did not consider the gestalt of the ads or the holistic implications of the ads. And he went on to say --

JUDGE CHAPPELL: Would that be the entire mosaic?

MR. FIELDS: Yes. His testimony was a mosaic in

itself.

He told us that the pragmatic implications of the ads had their holistic implications and their total gestalt went beyond -- and this is critical I think -- went beyond what is expressed or implied.

Now, that just isn't the law. It's true that counsel can show something is implied that isn't expressed in an ad, but I think that counsel can't go beyond what's expressed or implied to talk about the holistic interpretation of the ad or its gestalt, so I think we can put aside Professor Stewart's testimony. Besides, he very clearly said that he had not formed an opinion as to what the ads said or meant. He simply was criticizing the methodology of Dr. Butters.

You remember he also relied on a report by two low-level English academics, but then he conceded on cross-examination that they exaggerated their paper in order to get it published. They were -- I won't even take the time to go over it or talk about it.

In any event, the extrinsic evidence was one-sided, it was Dr. Butters, not rebutted at all.

What about the face of the ads? Well, we talked about this earlier when I first got started. That is, if you are relying on facial analysis, there cannot be two conflicting versions of the ad. That's

what the Thompson Medical case tells us. If there are two conflicting versions, you better have extrinsic evidence that shows you what the ads mean.

And again, counsel, complaint counsel, would have the burden to prove which of those two was in fact the case, but they didn't call any expert, and they didn't provide a survey of what the ads meant at all.

JUDGE CHAPPELL: You don't think attacking your extrinsic evidence is itself extrinsic evidence.

MR. FIELDS: I do not.

They attacked his methodology. If they had attacked the substance of what he said, that would be different, Your Honor. If they had said, well, you took ad X and you said it meant this and in fact it means that, that would be a substantive attack and that in itself would be substantive extrinsic evidence.

He didn't do that. He said, Your methodology is wrong, Professor Butters. Why is it wrong? You didn't consider the gestalt. You didn't go beyond what was implied to consider the holistic implications, which is not the law. Dr. Butters didn't have to do that, so --

JUDGE CHAPPELL: And your position is the government, to offer extrinsic evidence that would be considered, would have to go further and have the actual

ads reviewed by the expert.

MR. FIELDS: That's correct. They would have to call an expert who would say, I've reviewed these ads, and I find that this ad that you say is only a statement about reduction of plaque really implies that you cure cardiovascular disease. That's what counsel argues, but they haven't produced a witness who says that and nor have they produced a survey which says that.

Now, they talk about the Bovitz survey. The Bovitz survey --

JUDGE CHAPPELL: I was just thinking about Bovitz. Bovitz is the billboard.

MR. FIELDS: That's correct. And it doesn't have the text of the ad, so you can't be fulfilling your obligation when you're just talking about a billboard, just the caption, to look at the entire ad.

So there is no evidence they've provided on the meaning of the ads at all.

Now, they -- they do have two other surveys, the A&U survey and the Zoomerang survey, but those are not about the meaning of the ads. They're about what's important to you about pomegranate juice. Now, we'll be talking about those surveys, but they're not -- they don't talk about what the ads mean at all.

So they have no evidence on that subject, and they can't rely, under Thompson Medical, on a facial analysis because they can't say, in looking at these ads, there's just one possible meaning, that -- I don't think anybody can say that.

JUDGE CHAPPELL: Didn't -- but didn't Stewart attack substance in some areas --

MR. FIELDS: I --

JUDGE CHAPPELL: -- what words meant, what the phrase meant?

MR. FIELDS: I don't think so, Your Honor. I think all he did was to say your methodology isn't good enough. On the contrary, I think he said, "I am not forming an opinion as to what the ads said."

JUDGE CHAPPELL: But if he did generalize as to any ad that used a certain phrase, would it be your position that's not enough without talking about a specific ad?

MR. FIELDS: I would have said that, although I couldn't then say there was no evidence. I would have to say that the evidence was really slim. If he had simply said there are ads out there, without identifying them, that do -- that make these claims, I suppose that's evidence if I didn't object to it, but whether it's evidence that stands up to the evidence

presented by Butters, certainly not. It doesn't begin to.

But I don't think he even did that, Your Honor. I think he did the opposite. I think he said, "I have no opinion on the meaning of these ads. I am simply criticizing Dr. Butters' methodology."

So they can't just rely upon a facial analysis because they can't really say, Your Honor, the meaning is very clear and convincing to us and we are convinced that these can only mean that the -- that you have proven that you cure or prevent or treat, whatever that litany of words is.

JUDGE CHAPPELL: You mean they can't rely just on that if they're incorrect.

MR. FIELDS: That's correct. That's correct. They've got to produce extrinsic evidence because it's very obvious that there is a potential innocent reading of those ads because the face of the ads simply say we have promising results, we have encouraging results, we have hopeful results for prostate health or -- and we can look at -- I mean, let's look at the one they put up on the board, the "Decompress" ad, what's their example of a really bad ad.

Could you put that back up on the screen for us.

There it is. It's on there. Okay. I have it. I have to put my glasses on to see it. All right.

Now, first of all, the testimony was that the ad may talk about potentially -- was not intended to be about blood pressure at all, the picture, but to be -- it is a blood pressure cuff, but it meant decompress in the sense of relax, ease up. But putting that aside, there's not a word about blood pressure in the rest of the ad.

And what does the ad say? It says that pomegranate juice helps guard your body against free radicals and that emerging science suggests -- again, it doesn't say emerging science proves -- emerging science suggests that free radicals destroy and weaken healthy cells. Then it goes on to talk about the 20 million of initial scientific research, which is true, and then it says what do we have, we have encouraging results in prostate and cardiovascular health.

Now, there's no way you can say that the words "encouraging results in cardiovascular health and prostate health" has to mean -- and that's what they have to do based on a facial analysis -- has to mean, it can only mean that we have proven that we prevent or cure or treat prostate cancer or we prevent or treat or cure cardiovascular disease. You can't make that leap

at all.

So -- and this is their example of a really bad one. And Your Honor, between '07 and on, that's what these ads do. Virtually every ad you will find in that period is highly qualified in the same way. It talks about hopeful results, promising results, encouraging results for health, for prostate health or cardiovascular health, and that is more than substantiated by the scientific evidence. The results are promising and encouraging and hopeful beyond that.

But let's talk about some of the ads that they criticized at the hearing while we were here. They called them outliers. They're not all outliers. Some of them were just things they criticized.

The "Cheat death" ad, we talked about that. The original "Cheat death" ad, as I said, ran in '04, eight years ago, and was stopped. The new "Cheat death" ad, like the ad you just saw for the "Decompress" ad, the same kind of thing, it says that emerging science suggests that free radicals have this bad effect and that we have generated encouraging, hopeful and promising results, the same kind of thing.

There is an ad, the next ad -- I was waiting -- there is an ad that was a mistake that says the money spent was spent on published ads. That was just a

flat-out mistake. Somebody put the word "published" in there. That was stopped as soon as it was found, and Mr. Tupper testified about that, because not all of the money resulted in published reviews, published articles in peer reviews. Some did. Seventy of them did.

JUDGE CHAPPELL: So are you saying intent matters?

MR. FIELDS: I'm saying the issue before the court is are we likely to be making false and misleading statements in the future, and the fact that -- I think this was back five years ago -- somebody blew it by saying "published studies" and when they found out they knocked it out makes it very unlikely that they're going to be doing that in 2013. That's what I mean.

It is correct that very early on there were some blood pressure ads that were based on Dr. Aviram's study, and Mr. Resnick determined that until they could do the very specialized blood pressure tests that require very specialized equipment, they should stop advertising that, and they did stop advertising. They -- again, they were ordered to scrub that out of the online material and they didn't scrub it all. There were some in there even after the cutoff date that counsel has assigned.

But they're not advertising blood pressure. They don't intend to advertise blood pressure. They haven't actually had an ad for blood pressure, as opposed to a figurative, scrubbed it out of the online, which was just a mistake, for years.

The money spent -- the complaint is that all of the money wasn't spent on studies that were successful. Some of the studies in some of the fields like the common cold and other things were not necessarily successful, but that's still a part of the experimentation. You spend money, and all of these studies don't work, but what you find that you can't do and you can't advertise is just as important as what you can do and you can advertise.

They talk about the fact that -- and by the way, the surveys show -- and no survey shows to the contrary, that anyone ever bought a jug of pomegranate juice in the belief that $20 million was spent. That is not one of the factors that's listed in the Reibstein survey or any survey as something that motivated somebody to buy, so that statement, even if you accepted counsel's argument, is not material.

In addition, they argue that we continue to advertise Dr. Aviram's 30 percent plaque reduction when Dr. Davidson's subgroup got a lower number. True. But

there's no inconsistency, as Dr. Davidson testified in his deposition. There's nothing inconsistent. They were studying different things. Dr. Aviram had people with heavy plaque to the point where they had stenosis. Dr. Davidson was studying the thickness of the artery and excluded from his study people who had substantial plaque.

So it's totally different things they're studying. Naturally, if you're talking about people who don't have plaque, you're going to get a lower percentage than the people who are full of plaque in their arteries and are going to get more of an impact.

We've talked about the creative briefs. I'm not going to go back into it again. Again, the overwhelming evidence is that they are no way an indication of the intention of the company.

Counsel has talked about in the brief on supposed warnings by the NAD. The NAD did give warnings in '05 and '06. We disagreed with the points they made but changed the advertising anyway, so it was beginning in '07 and then into '08 that you found this highly qualified kind of ad instead of a more open sort of statement, and that was in part in response to the NAD warnings back in '05 and '06.

I'm not going to go into the other so-called

warnings like NBC with regard to a television commercial, which is not before the court, and we don't know what their standards are.

The IRB -- Johns Hopkins wanted an IND filed. It had nothing to do with advertising. These are not warnings. The NAD could be considered a warning, but, again, we modified our behavior after we got it, even though we disagreed with it.

Now, let me turn to materiality because this case should not result in an order against respondents if only based on no showing of materiality.

Materiality means the ad must be material to the purchase decision. Now, again, there is a presumption of materiality, but under Novartis, citing the St. Mary's case from the Supreme Court, that presumption disappears if there is rebutting evidence. And in the Novartis case, that is not a high hurdle. And certainly the Reibstein survey was rebutting evidence and the presumption, as Novartis puts it, drops out, at which point, as we discussed earlier, Your Honor decides which side presented the more believable evidence on materiality, and they would have the burden of proof.

Now, Dr. Reibstein is a fairly distinguished guy. He was the dean of the Graduate Division -- he is

the dean of the Graduate Division of The Wharton School of Finance, which is a very prestigious school, probably one of the most in the country. He took 406 people through an initial question and two follow-up questions. And they were open-ended questions. And he asked them, "Why do you buy this product?" Nothing could be more directly related to a purchase decision than why do you buy this product.

One percent, approximately, mentioned they bought it because of a disease. A lot of people -- and we could put up a little chart that shows this, and I won't stop to wait for it.

Oh, it's up. Okay.

A lot of people bought it for taste, a lot of people for general health -- no question that we say it's healthy, it's good for you -- less than 1 percent for disease.

And then he asked two follow-up questions, again giving them a chance, and again they came up with approximately the same percentages. Approximately 1 percent talked about disease. And he even included in the disease category, as I recall it, a lady who said she had a better bowel movement, another lady who said a urinary tract infection, which was something we never advertised, so if anything, the 1 percent is

expanded.

And he had -- Dr. Reibstein had two types of control. One control group were people who did not drink POM, they drank other products, and they came out with very similar results as to why they bought pomegranate juice. Again, probably they're not being influenced by POM ads because they're not even buying POM.

But the real control that I think is very important to us is he also had a control of people who had never seen a POM ad. And they -- this is kind of extraordinary and I think very important. The people who had never seen a POM ad had a higher percentage of referring to disease as the reason they bought than the people who had seen POM ads.

Now, why is that, Your Honor? Here's what that tells us. It tells us there is a great deal of information out there about the value of POM, the health value of POM, that is not coming from POM ads, because the people who never saw a POM ad registered higher on the disease scale than the people who had seen a POM ad.

We have evidence in this case that our competitor -- remember, there was a long list of health benefits that -- I've forgotten the name of the company

who listed it, but there's an exhibit in evidence that shows that. It went way beyond anything POM claimed, publicly claiming all kinds of health benefits for POM, pomegranate juice.

The NIH, the National Institutes of Health, actually has stated publicly that POM will help to prevent rheumatoid arthritis. We don't even advertise that, but that's the NIH said that.

So the world is full of this noise, and why are people who have seen the POM ads less inclined to say it's disease than the people who haven't seen the POM ads? Because they are looking at ads that say all we have are hopeful results, promising results, encouraging results, but the stuff that's in the newspapers, the stuff the NIH is coming out with, the stuff our competitors are coming out with goes way beyond that. And that's why people who haven't seen the POM ads say more often than people who have seen the POM ads we think it's about disease. That's a really important thing.

But in any event, we've got the Reibstein survey, and it is right there and it's rock solid. The criticisms -- well, their expert, Dr. Mazis, specifically says that -- and this is at page 2703 to '4 of the transcript -- he specifically says you cannot

rule out Dr. Reibstein's survey as probative evidence of nonmateriality. Now, that in itself knocks out the presumption and in itself because there is no rebutting evidence.

Professor Mazis did not provide evidence of what -- why people bought. In fact, he says specifically -- he says he knows of no evidence that POM ads affected the purchase decision. That's at 2753 of the transcript. He knows of no evidence -- this is their expert -- that POM ads affected the purchase decision. And he didn't.

Now, Mazis is a professional witness. He's the guy who testified in 24 cases in the last four years. That's a case every other month. He worked for the FTC. He takes surveys. That's what he does. Did they ask him to do a survey on why people buy this product? No. And he didn't do one. And he has no knowledge of any evidence that these ads resulted in any impact on a purchase decision. And that's their expert.

Now, sure, they criticize -- they criticize Reibstein's survey. Why? Criticize Reibstein's survey by saying, well, he asked open-ended questions and he should have followed it up with closed-ended questions after that and -- but if you look at the article, which we've cited, Dr. Mazis -- I say "Dr." I don't know that

he has a doctorate. But in Mazis' own article on how to prove nonmateriality, he asks almost identical open-ended questions, the same three questions that Dr. Reibstein did. And Mazis doesn't even have a control like Reibstein did, and Mazis doesn't say supply all of the details the way Reibstein did. Mazis simply says in his article here's how you prove nonmateriality, you ask these three kinds of questions, which is what Reibstein did.

So his criticism of the methodology goes nowhere, but again -- again, Your Honor, you're talking about their having to come up and meet the burden of proving materiality because very clearly the presumption is gone and because we've provided rebutting evidence, and they haven't provided any evidence of materiality.

Now, I'm going to turn to these other two surveys, the A&U survey and the Zoomerang survey. Neither of those surveys is about why you buy the product. And their expert testified that they -- neither of them was a causal survey; that is, it didn't show that these ads caused anything at all. They are not causal surveys. They did ask is a particular thing important to you.

For example, Zoomerang listed a bunch of

diseases and said which of these diseases is more important to you when you think about this juice.

And none of those are surveys about the materiality of the -- to the purchase decision. Only Reibstein deals with that, and that is the only evidence before the court.

Now, counsel argued in the brief, well, they kept putting out these ads after they were warned -- I've already talked about these so-called warnings -- that that shows us they must be material. Well, that's not evidence of materiality. That's just argument.

They cite the Kraft case. The Kraft case was very different. In the Kraft case, the executive said, I'm not going to give up this ad. This ad is what's getting people to buy the Kraft cheese.

That's very different. There's no evidence like that here at all, anything like that at all.

So they have no evidence of materiality.

Now let me move on to another reason, just independent reason, why there can be no finding of materiality in this case, because both Mr. Stewart and Mr. Mazis testified that you would ordinarily need three good exposures to an ad in order to have any impact on the purchase decision of a consumer. And both of them testified that there was no indication anywhere in the

evidence that they could see that any of these ads had three exposures or even two exposures. And that means that on that basis as well.

Now, counsel has argued that that was only optimum, that it wasn't a requirement. But we've got up on the screen here that three good exposures is the general rule of thumb, that it takes many more than three actual exposures to constitute three good exposures, that it is true that a couple of exposures to an ad are probably not going to affect people's belief about a product. And he goes on to say he doesn't know how many times any of these ads were put out there, so -- but even putting aside the other evidence of materiality that -- of nonmateriality we presented and no evidence of materiality that they presented, you've got this three exposures problem that they have to deal with.

So even aside from what we've said about the ads and what we've said about the science, even aside from that, there simply is no case on materiality.

Now, I'm going to spend just a moment on -- or two on the interviews because counsel keeps talking about which -- what Mrs. Resnick said in interviews in Newsweek and on The Martha Stewart Show. We submitted a brief on this, Your Honor. They are not advertising for

a number of reasons. They're not advertising. We cited a case that says that.

Actually, it's the Reynolds case that says that advertising is paid for. This was not paid for. It talks about the main purpose. This lady was out trying to sell her book. She wasn't out giving these interviews in order to sell pomegranate juice. And we cited a case that says selling a book and going around trying to sell your book is not advertising within the meaning of the statute.

The reference to pomegranate juice in the Newsweek interview, for example, is a small part of a very, very long interview. We cited the Boulé case that talks about was it reactive or proactive. And of course, these were reactive answers to questions asked by somebody else. It wasn't like an infomercial where she got on television and just ranted about pomegranate juice. She was being interviewed.

And finally, it is -- these were her opinions. There is no evidence she didn't really believe these opinions, and they are protected by the First Amendment, and we cited cases on that as well.

In addition, I forgot that one of the indicia in the cases is does the -- in order to be even classified as advertising, does it promote -- propose a

commercial transaction, and of course in this instance it did not propose a commercial transaction.

So really we should put aside those interviews and focus on the ads that really are advertising and are a very different kind of thing.

Now, I'm going to talk very briefly about the order. I don't think there should be any order against respondents, and I think I've been very clear about that.

But this business about having to submit any proposed ad that might even be considered to be a -- what counsel calls a disease claim to the FDA is, in our view, not appropriate and not proper under the Federal Trade Commission Act. It is really just abstaining from something the FTC should be determining itself rather than the -- having the FDA determine it, and it puts -- in addition, in order to have the FDA make that determination, the FTC is in effect saying these are drug claims within the FDA jurisdiction and the FTC shouldn't be making that determination, that's for the FDA to determine.

So first, the -- by sending these things to the FDA, the FTC is making a determination that it's a drug claim. And then secondly, it is abdicating its own function.

I could understand if the FTC said from now on you've got to come to us, the FTC, and get our approval. I would object to that. I think it would be a prior restraint, but I could understand that at least the FTC would be dealing with what the FTC should be dealing with.

In this instance, the FTC is saying, if you think you may be making this kind of a claim, you'd better go to the FDA. And Your Honor, we don't even know that the FDA is issuing these kinds of permits in this kind of situation. We don't -- we -- nobody has gone to the FDA to say, Hey, if we send you all these people who we find that engage in this kind of conduct, are you going to pass upon their claims in the future?

I don't find any evidence that the FDA is about to do that.

JUDGE CHAPPELL: You don't know if they'll let you in the gate.

MR. FIELDS: I -- I -- I think not. I think that what you're really saying here is you're being barred from having this kind of claim in the future because you're probably not going to be able to get a ruling from the FDA, and certainly we don't know that you're going to get a ruling.

And it puts everyone in a terrible position. It

puts the respondent in a terrible position. They're told, well, you're violating the order if you're making a particular type of claim, and you won't know whether you're making a particular type of claim until you come back to us. In the meantime, you've got to go to the FDA and get their approval if you think you may be having this kind of claim. Well, that just doesn't make any sense, and it's not appropriate.

As I say, if the FTC wants to say you've got to come to us, the FTC, and we'll decide whether your claim is a good one or a bad one and whether you can go forward with it, that at least would make sense. It might have constitutional problems. But to impose that on the FDA and to impose it upon respondents and any other companies to go to the FDA to do that because they might ultimately be held to have made this kind of claim is just wrong. It doesn't pass statutory muster. It goes beyond what the FTC is supposed to do, and it's unconstitutional.

JUDGE CHAPPELL: You're suggesting that someone should have introduced evidence from someone at the FDA?

MR. FIELDS: I would think before they were going to order people to go to the FDA and get approval, the FDA should at the very least indicate yes,

we will set up a structure by which we will give these approvals to your people that you send over to us because you have found they're likely to make these statements. I think at the very least we should do that. I don't think that would solve all the problems, but I think at the very least you'd want to know the FDA is going to do this.

We have no knowledge that the FDA is willing to do this at all. They just -- I mean, they might as well have said why don't you go over to the FBI and see if they'll approve your ads and then come back if the FBI approves them and we'll decide whether that's -- you're okay or not. We don't know anything about the FDA and how it would treat these things.

But moving on to the next step, because I'm running out of time, we have the fact that they are asking for a finding that the respondents here did bad things deliberately.

Now, I don't think that they have made the statements that they are claimed to have made. I think the science supports the statements that they made. The science goes way beyond what they have claimed. The science goes way beyond saying we have promising results for prostate health. It goes way beyond saying we have hopeful results for heart health.

But if they've gone beyond it, they certainly haven't deliberately intended to mislead the public. Mr. Resnick didn't get into this to mislead the public. He got into it because he wanted to find out what pomegranate juice could do. And he spent a heckuva lot of money trying to find that out and still is.

This is not -- from the very first day I said this is not a case of a snake oil salesman. This is not Daniel Chapter One or Removatron. This is a fellow who really is trying to and at this point his conferring with doctors does carry weight. He is not a man who should be tarred with the idea of a deliberate violator, one who deliberately misleads the public, nor is there really any -- and by the way, counsel concedes he's never done anything like this before. He's not a repeat violator, a serial misstater of the facts.

The next is, if you were to enter an order, should it cover all of the other businesses. There's no indication that his citrus fruit or his nut business has ever made any kind of misleading statement to anyone, or his water business, to do that.

And finally, there's Mr. Tupper. Mr. Tupper is retired now. He was the president, but he very clearly said that he was not setting policy other than policy approved by Mr. Resnick or in some instances

Mrs. Resnick. He was really in a position of participation but not control. He did participate. He didn't control. Mr. Resnick controlled. He's the head of the company, not Mr. Tupper.

But I very strongly urge Your Honor not to impose any order on these people. Again, coming back to the beginning, we're talking about fruit juice. We're talking about the fact that it's healthy. You could say the same thing about exercise, broccoli, blueberries. You could have the very same ads about all of those things. Science I'm sure has shown that blueberries probably do help you in many ways, probably or perhaps we should use them as well, and to say that that's not supported by science is just -- they haven't made that case because it is supported by the science. The science goes well beyond it.

And aside from all this, materiality, there simply is no basis, nothing in the evidence from which Your Honor could find materiality. They've presented no evidence on that subject at all, and we have very, very reliable evidence, so I ask Your Honor not to tar these people with an order that they have misstated the facts to the public, because they really haven't.

JUDGE CHAPPELL: Thank you.

Rebuttal?

MS. HIPPSLEY: I guess I'll start with what Mr. Fields just finished off with, what he left us with, because I can't resist. He says there's no evidence of materiality, but at the very beginning, when we go back in this transcript, he said, Gee, if we are making these kind of serious disease claims, I wouldn't deny that they were important to consumers. I mean, it's that practical on materiality.

Now, in terms of healthy, we wouldn't be here if that's all the ads said. That's not our position. This isn't about pomegranates, which the FDA recognizes can make a health claim. It's not about broccoli being healthy. It's not even about POM juice being healthy. It's about ads for POM products saying that they treat and prevent serious diseases and that these benefits they've told consumers they established through science.

Backing up a little bit, Mr. Fields -- he first launched into the science, but his whole science discussion was in a vacuum. We need to know what the claims said. Then we can figure out whether the science backed them up.

At page 28 of respondents' posttrial brief, respondents even say that Mr. Resnick would not advertise the health benefits unless he had human

studies that established those results.

I find it interesting that all these famous doctors that supposedly helped him are referred to: Mr. P.K. Shah, Mr. Ignarro -- I'm sorry -- Dr. P.K. Shah, Dr. Ignarro, Dr. Kessler. Where are they? They did not testify. We don't know what those men said in these review meetings of the science. Dr. Heber attempted to tell us what they said. Dr. Kantoff rebutted and showed that what Heber was trying to say was wrong.

And they were so worried about Dr. Kantoff, who is the renown prostate cancer gentleman in this country, they were scared to death that he would tell you what actually went on in these meetings. That's why they tried to block him and limited his testimony to exactly his statement where he said, well, there's potential benefit here, that's what I told them, but not benefit yet.

Mr. Fields even said the experts -- he used words like "likely, potential benefit." This is not what the ads are saying. They're not talking about a likely benefit, a potential benefit. They're saying we have 25 million in medical research that shows you, Mr. Consumer or Ms. Consumer, we have benefits right now.

You asked about Dr. Stewart. He was a rebuttal expert on ad meaning. It would be out of bounds for the FTC to have had him do a holistic review of all the ads. He was not called as an affirmative witness.

You're correct that he did attack the substance on many lines of Dr. Butters' testimony, the most significant being a substantive discussion about the disclaimers that were used in the ads and the fact that they did not change a net impression. They were just too minor. There's literature about the use of the word "can" versus "may," and Dr. Stewart ably went through that.

JUDGE CHAPPELL: I think his point was not that Dr. Stewart didn't review the ads but that no one else reviewed the ads that was put forth by complaint counsel.

MS. HIPPSLEY: We did not introduce a copy test, that is correct, and neither did respondents.

If they were worried about the facial analysis, they, too, had the ability to provide a rebuttal copy test, but they chose not to.

The commission has met its burden of proof through the facial analysis and the additional extrinsic evidence of intent and, again, reviewing from the target audience the creative briefs, all that information. A

facial analysis here is adequate to determine the challenged claims.

Now, let's see. Okay. I think I'll switch up to the law.

In terms of all the other facts that Mr. Fields discussed and who said what during the trial -- of course, Your Honor was here -- he's taken great liberties with the record and the testimony, and I would just say that we have covered all of these points in the findings. They clearly -- our findings, our reply findings, they clearly go through the factual record with appropriate citation and deal with all of these issues about the experts and who said what and what they stand for.

And the actual record establishes that these claims were the intent of the respondents to make, that the substantiation does not meet the claims, and that there's a need for a remedy here.

And in terms of the law, I have to take exception with the description of the Seventh Circuit in the Q-Ray case. I actually did that case. And Judge Easterbrook of the Seventh Circuit affirmed Judge Denlow's decision. All he said in dicta, which is perfectly accurate, is that there's not words written into the FTC statute into section 5 that describes the

exact level of science for all cases. It's a sliding scale. You look at the claims. You determine what the level of substantiation is that is needed.

Judge Easterbrook gave an example: If I have a Band-Aid with iodine and I say it kills bacteria, of course it does. You don't need any more science than that. He went on to say: If I have an inert metal bracelet totally safe, but I'm telling the public to buy it for pain relief claims, Judge Easterbrook said, of course they need science.

Judge Denlow reviewed all the science. He reviewed a 670-person Mayo Clinic study. And he found that the science did not back up those establishment claims or the nonestablishment claims in that case.

The respondents have also misused the Pantron case in their findings. This was quite remarkable. They wrongly cited the Ninth Circuit decision at their reply finding 536.

And Mr. Fields has alluded to this, somehow implying that the FTC has to prove that the products do not work. This is absolutely not part of the legal analysis.

And what Pantron stands for is the Ninth Circuit said, Look, the district court held that the FTC must prove that the product is wholly ineffective. That is

the part of the Ninth Circuit decision that respondents cited wrongly in their findings. If they had read two pages further, they would have seen that what the Ninth Circuit actually held is: We hold the FTC is not required to prove that a product is wholly ineffective in order to carry its burden of proof that the sellers' representations of product efficacy are false.

Q-Ray also said this as well. We -- it's not our burden to conduct clinical studies. We have to prove to the court that respondents' studies for cardiovascular disease, prostate cancer, et cetera, don't measure up to the establishment claims they've made to consumers. I just want to make sure that's clear.

Your Honor, I think I want to circle back and just make sure we're clear on what the order requires in Part I because there seems to be a lot of confusion the way Mr. Fields discussed it.

Part I does not set up the FDA as an ad reviewer for respondents' ads. That's not at all what's going on.

Part I says, if respondents choose to make disease benefit claims that are covered under section 15 of the FTC Act, if they choose to make a claim that POM juice -- just the POM products. It's limited to the POM

products -- that POM juice treats prostate cancer, if they choose to make that claim, the level of substantiation they must have to make that claim is FDA approval for a drug claim.

There's nothing here sending them off to the FDA for prescreening of their ads. It's their --

JUDGE CHAPPELL: Unless they want to make that claim.

MS. HIPPSLEY: If they want to make that claim, it's not the ad that is reviewed by the FDA. They have to show the FTC and ultimately a court for a civil penalty action, they have to show a court that, yes, we're making a prostate treatment claim because we did what the order required us to do, we submitted a new drug application to the FDA, and it was approved. Our POMx pills are approved as a drug to treat prostate cancer. We can put that on the label, and under the FTC's order, we can tell the public in an ad that we treat prostate cancer. That's how it would work.

And I think that one explanation of the science that Mr. Fields went through really explains why we feel this is necessary. Oh, but first -- I'm sorry -- to completely change track for a second, when Mr. Fields was going through the "Decompress" ad, he conveniently, continually left off the sentence about how the POM

juice guards your body against free radicals, unstable molecules, that emerging science suggests destroy and weaken healthy cells in your body, and he left off the most important part of that sentence, "and contribute to disease." All right.

So the ad is setting up the mechanism of action by which POM juice provides the benefit. It's going to stop those radicals that contribute to disease. Okay. Setup. They have 20 million in research telling you that they can prevent disease.

Okay. Now, switching back to the remedy briefly, this is why we need this kind of fencing in in Part I, limited to the POM products only and limited to claims when they want to make disease treatment or prevention claims.

The discussion of the Davidson study is really quite unbelievable. Davidson is the most important cardiovascular study. It is a cut above all the rest of the studies. It's a 289-person randomized, double-blind, controlled study. Dr. Davidson is an eminent researcher. It was a very, very well-conducted study. And Mr. Fields said, well, the important part of that study is the subgroup.

I just want to read to you what shows what the community of scientists think about this study. It's

from our findings, finding 891. This is one of the peer reviewers who looked at the study and requested that changes be made before the study can be published. And the reviewer advised, "The study needs to be reported as a negative study as it is." In his response, Dr. Davidson affirmed that it was a negative study, and he committed to revise the manuscript to emphasize that caution is warranted with regard to the subgroup finding. These findings, quote, should be considered hypotheses that will need to be replicated in future trials designed to assess the efficacy of pomegranate juice consumption in these subgroups.

The Davidson study does not stand for the subgroups showing anything. The Davidson study is negative. It's the largest study. It's the most recent study. It trends against cardiovascular disease benefit. If they can replicate the subgroups someday, if they can convince the FDA that that's enough for a drug claim, perfect. Then they can make an ad that says they treat cardiovascular disease.

Thank you.

JUDGE CHAPPELL: Thank you.

Anything further?

MS. HIPPSLEY: No, Your Honor.

MR. FIELDS: Nothing further, Your Honor.

JUDGE CHAPPELL: Hearing nothing further, thanks to everyone for your efforts.

We are adjourned.

(Whereupon, the foregoing hearing was adjourned at 5:24 p.m.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9344

CASE TITLE: In Re POM Wonderful LLC, et al.

HEARING DATE: March 6, 2012

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

DATED: MARCH 12, 2012

JOSETT F. WHALEN, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

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

ELIZABETH M. FARRELL