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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
WESTERN DIVISION

THE HON. JUDGE DOLLY M. GEE, JUDGE PRESIDING

KIM ALLEN, et al., on behalf of )  
themselves, all others similarly )  
situated and the general public, )  
 )  
Plaintiffs, )  
 )  
vs. )  
 )  
HYLAND'S, INC., a California )  
corporation; and STANDARD )  
HOMEOPATHIC COMPANY, )  
 )  
Defendants. )  
 )

NO. 13-CV-5102-DMG

JURY TRIAL - DAY 7 (P.M. Session)  
Los Angeles, California  
Thursday, September 10, 2015

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U.S. District Courthouse  
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**I N D E X**

**CHRONOLOGICAL INDEX OF WITNESSES**

<b>PLAINTIFFS'</b>				<b>VOIR</b>
<b>WITNESS</b>	<b>DIRECT</b>	<b>CROSS</b>	<b>REDIRECT</b>	<b>RECROSS DIRE VOL</b>
<b>Dr. Iris Bell, Ph.D.</b>	<b>4</b>	<b>59</b>	<b>109</b>	
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1 LOS ANGELES, CALIFORNIA; THURSDAY, SEPTEMBER 10, 2015;

2 1:15 P.M.

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4

5 THE COURT: All right. Mr. Margulies, are you  
6 ready to proceed?

7 MR. MARGULIES: I am. Thank you, Your Honor.

8 DIRECT EXAMINATION

9 BY MR. MARGULIES:

10 Q Dr. Bell, welcome back.

11 A Thank you.

12 Q Just before the break we started to talk about the  
13 issues of nanoparticles. And just so we can kind of  
14 reorient ourselves, I had asked you about what was it about  
15 nanoparticles interested you as a research field, and you  
16 said that you were familiar with the debate that there was  
17 nothing there.

18 So with that in mind, my follow-up question to you  
19 is: What was it about nanoparticles that you thought was  
20 relevant to the controversy about nothing being in  
21 homeopathic medicine?

22 A Well, first, the issue is that there were nanoparticles  
23 of source material in the original published paper. They  
24 confirmed that when they said there was silver or gold or  
25 tin or copper in a particular product from actually one of

1 two different homeopathic manufacturers, that they were able  
2 to identify that with their techniques.

3           And so it fit with some of the earlier research I  
4 was aware of that had already demonstrated optical signals,  
5 things related to light emission and reflection and  
6 absorption, somewhat of what I talked about earlier where  
7 they were able to show that compared with a control or  
8 placebo, there was a unique signal that appeared to be very  
9 similar to the signal that they obtained when they used the  
10 ordinary material.

11 Q    You read Dr. Lee's reports in this case; right?

12 A    Yes.

13 Q    And you understand that he referred to those studies as  
14 violating the laws of physics?

15 A    Yes.

16 Q    Did you agree with that?

17 A    No.

18 Q    Why not?

19 A    Because the materials were there. Unless he was  
20 accusing them of some particular methodologic problem, I  
21 accepted that they were there and they needed more further  
22 research to confirm or evaluate what was reported.

23 Q    And what did you think -- so you see this research that  
24 shows the presence of nanoparticles, or was it gold and  
25 silver?

1 A There were actually six different metals, among them  
2 gold and silver.

3 Q And it was present at these very, very low dilutions,  
4 and I think you said you tied that in your mind to some of  
5 the other research. Did you start to form a hypothesis at  
6 that point about what the presence of nanoparticles could  
7 mean with regard to the homeopathic medication?

8 A Yes. Again, there was other work that had shown that  
9 there were changes in solutions of the, quote, true  
10 medicines that were prepared homeopathically experimentally  
11 where they were able to demonstrate not only the optical  
12 signals but also just straightforward electromagnetic  
13 signals and changes in other properties of the solution when  
14 they manipulated the solution. So there was work to be  
15 understood to put together with all of that.

16 Q Did you consider doing further research in order to try  
17 to figure out whether nanoparticles were -- actually, strike  
18 that. Let me ask you a different question.

19 Did you monitor or do any literature research to  
20 look into whether there was other information about  
21 nanoparticles in homeopathically prepared materials?

22 A Yes, I did. I was actually at the time asked to invite  
23 various speakers by the National Center for Homeopathy to  
24 update the membership on the state of the science and  
25 research. And during that time was when I realized that the

1 nanoparticle paper had been published, and I was able to  
2 contact the authors in India and they gave a webinar to the  
3 larger group on the topic.

4           So my first contact with all of that information  
5 was to actually be able to ask some questions of the  
6 investigators, and I learned that -- one of the questions I  
7 asked was how do you make them in modern nanotechnology,  
8 because you obviously had never heard of homeopathy in this  
9 field before.

10           And I was told that one of the two main ways they  
11 make them was to grind them up or mill them very extensively  
12 in order to take, for example, a new drug or an old drug  
13 that was not very soluble to make it more available to the  
14 body. If you just grind it up and make it smaller, it  
15 improves its accessibility to the body.

16 Q     I'm sorry. Were you saying that they were grinding  
17 products to make nanoparticles?

18 A     Yes.

19 Q     And did that have in your mind any application in the  
20 field of homeopathy?

21 A     Well, yes. That sounded to me like a much more modern  
22 form of what had been originally discovered by the founder  
23 of homeopathy as a manufacturing method, which is called  
24 trituration. It's done often by many manufacturers in  
25 modern day by using mills that are also available for that

1 purpose and other forms of technology.

2 Q When you say mill, are you talking, like, the old wheel  
3 mill, water wheel and grinding? Is it the same principle?

4 A Originally I believe they used, as you might have seen  
5 in old pharmacy movies or pictures, a mortar and a pencil  
6 where they were doing mechanical grinding of things. They  
7 had then moved on in various ways to have more mechanized  
8 ways of doing that particular step.

9 That fascinated me because of that potential link  
10 of that one piece of the manufacturing, and so I then went  
11 into the nanoparticle literature in as much depth as I could  
12 searching in the available databases for research in modern  
13 nanotechnology that might provide me some clues about the  
14 nature of what was being used in homeopathic manufacturing.

15 Q Let me ask you for a moment -- well, when you do the  
16 research in the literature, can you describe what it is  
17 you're doing. How are you reviewing the literature? What  
18 does that consist of? Are you sitting there and typing a  
19 search into Google, or are you doing something different?

20 A I occasionally had to look words up and Google, but  
21 most of my work was on what is called PubMed.gov, and it's  
22 one of the publicly available databases for consumers as  
23 well as professionals. But it is in the National Library of  
24 Medicine, so it's a governmental function and it provides an  
25 online resource.



1           It's one of several or many that are available to  
2 researchers where you can search by particular terms and  
3 then see the article name, the authors, and the abstract.  
4 And you can discover quite a few articles at once.

5 Q       So what are you searching in PubMed? What's actually  
6 in there?

7 A       The articles are all indexed often by what date they  
8 were published. So you might find 20 to 50 or 100 pages of  
9 references relating to the research on a particular topic,  
10 and on each page there might be 20 or more references.

11 Q       And where are these articles located that you're  
12 finding in the database?

13 A       They're typically in various professional journals,  
14 peer-review journals.

15 Q       So, for example, we looked at some of the references in  
16 the articles that you wrote out of your studies.

17 A       Yes.

18 Q       Would those articles then get indexed into this PubMed  
19 so that other people who wanted to research EEG and  
20 homeopathic medicines, they would find them?

21 A       Yes. Ideally that should occur when research is done.

22 Q       And is that fairly standard type of research that an  
23 academic would do, to look to see what's been published on a  
24 particular topic by scientists around the world?

25 A       Oh, yes.

1 Q Okay. And you mentioned trituration and its similarity  
2 to manufacture of nanoparticles. Did you run across any  
3 literature or any other information that related to whether  
4 the succussion process would also have the potential to  
5 create nanoparticles when a homeopathic drug is made?

6 A Yes, I did. It was a little bit harder to search, but  
7 I was just doing -- there are different ways to do the  
8 search, so I started with the word nanoparticles, but then I  
9 put in other things like nanoparticle and ethanol because I  
10 know ethanol was used. And I discovered that again there  
11 are a number of modern mechanical methods by which solutions  
12 are agitated, and some of those enable modern  
13 nanotechnologists to make nanoparticles.

14 Q I think you mentioned that you'd started -- let me ask  
15 you, because maybe you didn't. What year was it when you  
16 ran across this article about the group out of India that  
17 had done the work on the nanoparticles in the  
18 homeopathically prepared materials?

19 A I know that the paper was published in 2010, and I have  
20 Googled words on my computer about the topic of homeopathy,  
21 so I'm not sure but I probably read it originally in 2010.

22 Q And has the literature on nanoparticles and homeopathy  
23 expanded since 2010? Have there been additional studies  
24 done? additional papers written?

25 A Yes.

1 Q Can you describe how that literature has grown over the  
2 last five years.

3 A To my knowledge there are at least ten published papers  
4 from researchers in various countries, all of whom have  
5 reported some type of nanostructure that they discovered in  
6 homeopathically prepared materials. In addition to that,  
7 based on a grant that I had received a few years ago, I've  
8 now added to that literature separately on my own.

9 Q Great. Let's talk a little bit about what work you've  
10 done. Is this laboratory work that you've done or you've  
11 participated in?

12 A It's laboratory work I've collaborated on with people  
13 who are expert in nanotechnology assessment methods.

14 Q Can you describe that work for us, please.

15 A I received a grant from a private research foundation  
16 that was intended to characterize the nanoparticles that  
17 were present in some of the more widely used homeopathic  
18 medicine.

19 My rationale for the selection was partly related  
20 to the existing modern nanotechnology literature where  
21 things like silver are made into nanoparticles, and I knew  
22 that there was a literature in homeopathy showing  
23 nanoparticles. That seemed like a logical remedy or  
24 homeopathic medicine to look at as one of the first.

25 And then separate from that, I was collaborating

1 with two other again modern nanotechnology experts in a  
2 private grant from a different foundation where we knew that  
3 in India there are many clinicians who use certain  
4 homeopathic medicines to treat people with cancer. And at  
5 that point I wanted to take a look at what was the one that  
6 had the strongest research on the biology of the medicine so  
7 that I could take a look and see if there were nanoparticles  
8 there. So I chose a remedy called Gelsemium.

9 Q And has the work that you've done in these  
10 collaborative efforts been published in the scientific  
11 literature?

12 A Yes.

13 Q I'm going to show you Exhibit 1033, page 23. And I've  
14 circled references 145 and 146. Do those reflect the work  
15 that you've just been describing for us?

16 A Yes.

17 Q What else have you done with regard to the issue of  
18 nanoparticles in homeopathic medication?

19 A Well, I've continued to be monitoring the literature in  
20 nanomedicine and nanotechnology. I periodically do searches  
21 on things that have been used historically for over 200  
22 years in making homeopathic medicines looking for papers  
23 where there might be a parallel between homeopathic  
24 manufacturing and the modern kinds of manufacturing methods.

25 Q Can you describe for the jury what you understand to be

1 the state of the art right now with regard to the presence  
2 of nanoparticles in homeopathically prepared materials with  
3 regard to the issue of a potential mechanism of action.

4 A Well, the presence of nanoparticles answers one of  
5 those primary objections that historically has always been  
6 present with homeopathy, and that is that there's so-called  
7 nothing there; therefore, there couldn't be anything doing  
8 anything if a patient were to respond.

9 That answer, I believe, is partly addressed by the  
10 presence of the nanoparticles, but it provides us with an  
11 actual physical measurement that suggests a source material  
12 in some form, and this is a matter of form. It's nano-sized  
13 rather than bulk size or larger size. It is present.

14 And that again, the literature suggests that many  
15 nanoparticles are capable of having some very interesting  
16 properties that could overlap with some of the findings that  
17 have been reported in homeopathic literature on the  
18 electromagnetic signals and the optical signals.

19 Q Are you familiar with a concept called hormesis?

20 A Yes.

21 Q What's your understanding of what hormesis is?

22 A Hormesis has a variety of descriptions, but it is a  
23 phenomenon that was described in both pharmacology and in  
24 physiology where low doses of something produce effects in  
25 the direction opposite to the direction that higher doses of

1 the same substance can do. And it's been studied both in  
2 conventional drugs, in toxicology with toxic materials.  
3 It's been studied with radiation. It's been studied also  
4 just with stress.

5 Q And we'll hear more from Dr. Calabrese about hormesis  
6 next week, but the question I have for you is: Are you  
7 aware of any relationship between hormesis and  
8 nanoparticles?

9 A Yes.

10 Q What is it you're aware of?

11 A There are a series of original research studies which  
12 have been summarized in several review papers on that  
13 particular topic, and it's very clear that nanoparticles in  
14 low dose are capable of causing hormetic effects. So it  
15 would be that low doses do one thing in one direction and  
16 high doses in the opposite.

17 Q Is that consistent with your understanding of how  
18 homeopathy is intended to work?

19 A It is in general, yes.

20 Q Okay. Now, you understand that Dr. Lee thinks there's  
21 not enough nanoparticles present to make a homeopathic  
22 medication be effective; right?

23 A I understand that he said that, yes.

24 Q Do you agree with him?

25 A No.

1 Q Why not?

2 A Because he really didn't address the issue of hormesis,  
3 and he didn't address the very significant literature on the  
4 actual documented effects in cells and animals separate from  
5 the clinical research literature in homeopathy showing there  
6 are effects.

7 So if he's saying that they're not there, even  
8 genes are affected by homeopathically prepared materials,  
9 and there's an ample body of research in the nano literature  
10 suggesting that that can occur.

11 Q Are you aware of any studies that would allow you to  
12 determine the number of nanoparticles that might be present  
13 in a homeopathically prepared material?

14 A I believe there was an initial attempt in that first  
15 report from the group at the Indian Institute of Technology.  
16 I was aware at the time I did my research that there was  
17 another technique that involved even less requirement for  
18 manipulating the sample. You could literally put a drop of  
19 it essentially on the slide.

20 The technique is called nanoparticle tracking  
21 analysis, and it's another more light-based or  
22 optically-based laser base kind of system where you can  
23 watch the nanoparticles moving around. And their movement  
24 in a liquid is quantified, and it gives you information on  
25 concentration of nanoparticles as well as the size of those

1 nanoparticles.

2 Q And do you have any estimate as to how many  
3 nanoparticles might be present in typical homeopathically  
4 prepared material?

5 MR. GOMEZ: Object. Foundation as to this  
6 witness, Your Honor.

7 THE COURT: Sustained.

8 BY MR. MARGULIES:

9 Q Based on your review of the literature, Dr. Bell, do  
10 you have an opinion as to whether the amount, the number of  
11 nanoparticles in homeopathic material is quantifiable?

12 A Yes.

13 Q And what is that opinion?

14 A Well, based on my own studies that I've just recently  
15 described as well as others, I identified in the types of  
16 samples that we did compared with placebo that there were  
17 approximately almost a billion nanoparticles per milliliter.  
18 So compared with this bottle of water which is  
19 591 milliliters, there would be presumably quite a few  
20 nanoparticles in there.

21 Q 591 million?

22 A Could be.

23 Q Okay. Do you have an opinion as to how a nanoparticle  
24 could cause the response to a homeopathic medication along  
25 the lines that it is intended, which is the like cures like



1 principle?

2 MR. GOMEZ: Objection. Foundation.

3 THE COURT: Overruled.

4 THE WITNESS: In homeopathy, as I mentioned, with  
5 hormesis you have the notion that a low dose will produce an  
6 effect in direction opposite from a higher dose. And since  
7 nanoparticles can cause that, you have to look at the  
8 research literature in hormesis.

9 When I did that, I discovered that the modern  
10 thinking about hormesis included the notion that it was  
11 causing the recipient at a low dose to do at a patient to  
12 what it anticipated might be the onslaught of something more  
13 toxic or dangerous or stressful for it in the future.

14 Q Can you explain what you meant by that. How is the  
15 organism adapting to something?

16 A The mechanisms are something that I'm sure  
17 Dr. Calabrese can speak to because he's done more work in  
18 the literature, specifically on the biology of hormesis.  
19 But it shows what is referred to in a general sense as  
20 biological plasticity, which means you can shape the  
21 response of the organism by changes in the biology when the  
22 organism receives a signal, if you will, that is salient or  
23 relevant to that organism.

24 Q Is a vaccine like a flu shot a similar principle?

25 MR. GOMEZ: Objection. Foundation.

1 THE COURT: Overruled.

2 MR. GOMEZ: It's also vague.

3 THE COURT: Overruled.

4 THE WITNESS: It is somewhat similar to a vaccine,  
5 yes.

6 BY MR. MARGULIES:

7 Q Do you believe that there are legitimate needs or bases  
8 to research the biological mechanisms underlying homeopathic  
9 drugs?

10 A Yes.

11 Q Do you understand that Dr. Lee in his report asserted  
12 that anyone who's doing --

13 MR. GOMEZ: Object as to what's in the report and  
14 what's been testified to, Your Honor.

15 THE COURT: Sustained.

16 BY MR. MARGULIES:

17 Q Do you understand that Dr. Lee testified that anyone  
18 who's doing research in homeopathy is biased?

19 A I was told that that was his testimony.

20 Q What's your response to that?

21 A A scientist follows the data. And if you have an area  
22 of research that you're doing and you're a researcher, you  
23 should follow the information that you obtain in your own  
24 work as well as what you learn about in the research  
25 literature.

1 Q Do you believe that it is proven at this point that  
2 nanoparticles are the reason why homeopathic drugs are  
3 effective?

4 A Not directly, no.

5 Q And what more work do you think needs to be done before  
6 you would be able to reach a conclusion about something like  
7 that?

8 A Well, there are several studies suggesting certainly  
9 that hormesis occurs with homeopathically prepared materials  
10 in animals and to some extent cells. I've actually recently  
11 reviewed a paper that demonstrated that as well that I  
12 presume will be forthcoming in the literature at some point.

13 So the work that has to be done is to show the  
14 hormetic effects of the particular remedy that's been  
15 characterized from the standpoint of a nanoparticle  
16 hypothesis, if you will, or nanoparticle finding, and then  
17 take a look at the correlations or the association between  
18 the findings of the particles and their properties, which  
19 turn out to be much more important than just are they there  
20 or not, and the biology.

21 Q Dr. Bell, as a researcher, is it important -- do you  
22 need to know how a drug works to reach a conclusion about  
23 whether it works?

24 A No.

25 Q So why are you doing this research?

1 A Because of the debates in the field, my own curiosity  
2 about what the answer is to that type of question.

3 Q Can you characterize for us -- you said you published  
4 some of the studies you've done. Have you published other  
5 articles in the scientific literature regarding  
6 nanoparticles?

7 A I've published a number of papers on nanoparticles.

8 Q Do you recall approximately how many?

9 A I think there are at least ten of them perhaps. I'd  
10 have to count what's in the CV.

11 Q They're all in your CV?

12 A Yes.

13 Q Okay. And other than the original research that you  
14 participated in, what other types of papers have you  
15 written?

16 A I'm sorry. In the nanoparticle area or --

17 Q In the nanoparticle area; correct.

18 A I've reviewed literature in infectious disease and in  
19 cancer with colleagues who had particular interest in that  
20 and how it might relate to the nanoparticle literature. And  
21 I've also reviewed -- again I've gone as far as I could at  
22 the time. I keep learning new information. But I have  
23 written several papers about the way homeopathic medicines  
24 are made and how that might relate to modern nanotechnology  
25 methods.

1 Q Thank you. I'm going to shift gears and talk about a  
2 different topic now if that's okay.

3 I want to talk about your work with Standard  
4 Homeopathic Company.

5 A Okay.

6 Q You said you were approached by Dr. Borneman maybe  
7 about ten years; is that correct?

8 A Probably.

9 Q And it was at a conference?

10 A That's what I recall.

11 Q And what did he ask you to do?

12 A I believe he asked me if I would be interested in  
13 consulting for his company to advise him about trends in the  
14 medical literature that related both to research and  
15 homeopathy and also to the kinds of symptom problems that  
16 his products addressed.

17 Q Had you known him before this time?

18 A I knew of him because I had heard his name, but I had  
19 not met him.

20 Q Did you agree to take that consulting job on?

21 A Yes.

22 Q What type of time commitment were you asked to give?

23 A I don't recall. It was a very limited part-time  
24 responsibility. I was still finishing some of my grant  
25 research, and I was still not emeritus or retired from the

1 university, per se.

2 Q Has your time commitments to the company changed over  
3 the last ten years?

4 A Yes.

5 Q What currently is your time commitment to the company?

6 A Approximately 20 hours a week.

7 Q So about half time if 40 hours is a full-time week?

8 A Yes.

9 Q So you were asked to consult on literature and you  
10 accepted?

11 A Yes.

12 Q So what did you start doing for Standard and for  
13 Dr. Borneman?

14 A Literally doing the kinds of searches setting up Google  
15 alerts to tell me what was coming through in the current  
16 findings, looking for new information in the field that  
17 might present perspective on the medicines that he made.

18 Q Did you understand that Dr. Borneman or Standard didn't  
19 have a good understanding of the medicines that they made at  
20 the time he retained you?

21 A No.

22 Q Okay. Did your job change over any period of time?

23 A The job has changed in a variety of ways. One of the  
24 first things that he wanted me to address was finding  
25 external researchers who would be able to serve as principal

1 investigators on research projects studying his products.

2 That was the first aspect of that that was added.

3 Q And did you do so for him?

4 A Yes.

5 Q Who did you identify as potential external  
6 investigators?

7 A Well, there were various people and there have been  
8 over the years. The first person I identified because of  
9 the company's prior work with her was Dr. Jennifer Jacobs.

10 Q Did you identify James Taylor, Dr. James Taylor, as a  
11 potential investigator?

12 A No, not at that time.

13 Q Do you know if he ever became an investigator for  
14 Standard?

15 A He became an independent investigator later on, yes.

16 Q And was that through you or somebody else?

17 A It was through Dr. Jacobs because they had -- as I  
18 understand it, they had worked at the same university, the  
19 University of Washington.

20 Q What other things were you asked by Standard to do over  
21 the years?

22 A As the work with them evolved, they wanted me to assist  
23 them in identifying ways of evaluating adverse event reports  
24 that came in from consumers.

25 Q What's an adverse event report from a consumer?

1 A The FDA, the Federal Drug Administration, basically  
2 requires any manufacturer of products to report to them  
3 particularly if there is serious adverse events, so some  
4 untoward medical outcome that could be at the serious level,  
5 so serious that it was life-threatening and the person  
6 needed emergency medical intervention, or so minor that they  
7 developed a rash. And we don't report the rashes, but the  
8 FDA does regulate that type of information.

9 Q And how were you determining what events needed to be  
10 reported to FDA? Are there some rules about --

11 A Yes. The FDA provides anyone doing both research on  
12 medication or someone who's manufacturing medication to  
13 follow certain guidelines.

14 Q Do the reports -- if somebody calls and says I have a  
15 rash, does it need to be determined that it's related  
16 causally to the use of the medicine in order to determine  
17 that it's an adverse event?

18 A No.

19 Q What other things have you done for Standard beyond  
20 what you've discussed for us already, or have we hit it all?

21 A We may have hit the basic description.

22 Q And you're compensated by Standard for the number of  
23 hours you work for them; is that correct?

24 A That's correct.

25 Q And the work that you've done for us in this case --



1 preparing a report, giving a deposition, and coming to  
2 trial -- do you get paid extra for that?

3 A No.

4 Q Have you had an opportunity to be involved in any  
5 clinical research that was done by Standard Homeopathic  
6 Company?

7 A Yes. When I was first asked to take over identifying  
8 investigators, Dr. Jacobs I was told had just finished a  
9 study on teething tablets, and I reviewed the findings with  
10 her. So that was the beginning.

11 Q What was the study that she'd done just before you  
12 arrived?

13 A As I understood it, it was a pilot study to identify  
14 the feasibility of doing further work with the product to  
15 determine its effects on children who were judged by their  
16 parents to be teething.

17 Q Can you describe what you meant by a pilot study, maybe  
18 give us a little bit of detail about how the study was done.

19 A In research there's usually multiple phases of doing  
20 research, and you have to often do preliminary work of some  
21 type in order to identify what could be done in a larger  
22 scale study with a larger number of people and with certain  
23 methodologies.

24 So you have to determine that -- one of the most  
25 fundamental things that they ask at NIH or any other grant

1 agency, including at Hyland's, is can you get subjects; do  
2 you have a method of recruitment where you can actually  
3 identify people who might be able and willing to enroll in a  
4 study.

5 Q Did the study, the pilot study that Dr. Jacobs had  
6 done, was it a placebo-controlled trial?

7 A I don't believe it was.

8 Q And I think you said you were evaluating whether to do  
9 a follow-up study to that when you came on?

10 A Yes.

11 Q I'd like you to turn, if you wouldn't mind, to the book  
12 that's in front of you to Exhibit 41, page 1. Sorry --  
13 Exhibit 74-1.

14 A (Witness complies.)

15 Q Do you have that, Dr. Bell?

16 A Yes, I do.

17 Q Do you recognize that exhibit?

18 A Yes.

19 Q What is it?

20 A It is an --

21 Q I think you need to speak into the microphone.

22 A I'm sorry. It's an email that I sent to Mr. Borneman  
23 talking about what Dr. Jacobs was hoping to accomplish in a  
24 follow-up study to her pilot study.

25 Q So was this email discussing -- so we've heard some

1 testimony from some other folks about a randomized control  
2 trial done by Dr. Jacobs. You and I haven't discussed it  
3 yet, but was this email talking about, when it says key  
4 differences from the last project, was the last project a  
5 randomized control trial or the pilot study that you were  
6 just discussing?

7 A To my understanding it was the pilot study.

8 Q Okay. And you were recommending in this email that  
9 Dr. Borneman approve a new study; correct?

10 A Yes.

11 Q In the first paragraph it says parents would receive a  
12 randomly assigned packet of either active Hyland's teething  
13 tablets or indistinguishable placebo tablets. Do you see  
14 that?

15 A Yes.

16 Q Was that study conducted?

17 A Yes.

18 Q And did you -- were you ever informed of the results of  
19 that study?

20 A I was, yes.

21 Q And what were you informed -- by whom were you informed  
22 of the results of that study?

23 A I believe by Dr. Jacobs.

24 Q Do you recall what she told you were the results of the  
25 study?

1 MR. GOMEZ: Objection. Hearsay.

2 THE COURT: Sustained.

3 MR. MARGULIES: Your Honor, I believe this goes to  
4 effect on a listener, non-hearsay purpose.

5 THE COURT: All right. It is admitted solely for  
6 the purpose of showing the effect on the listener.

7 You may answer.

8 THE WITNESS: She indicated to me that there  
9 appeared to be a small difference that was statistically  
10 significant, wasn't clear about clinical significance  
11 between the two groups, the placebo and the tablet.

12 Q In favor of the placebo or in favor of the teething  
13 tablet?

14 A In favor of the group that we were told had received  
15 the placebo.

16 Q And did this result make sense to you as a researcher?

17 A No.

18 Q All right. What did you do to try to respond to --  
19 what did you do to evaluate the report or the information  
20 that you received from Dr. Jacobs with regard to the result  
21 of this teething tablet study?

22 A We reconfirmed that the tablets had been correctly  
23 labeled as best we could -- this was an after-the-fact  
24 question -- and that those had been what had been provided  
25 by the research staff to the parents.

1 Q Were you able to draw any conclusions from this study  
2 about the meaning of its results?

3 A No.

4 Q Why not?

5 A There were many difficulties that revealed that while  
6 the investigator had a design that had sounded reasonable to  
7 start with, that there were a number of questions that came  
8 up again in the way the study was conducted.

9 Q Can you give us some examples of the issues that you  
10 identified and discussed with regard to how the study was  
11 designed and conducted.

12 A One of the biggest issues in teething, it turned out,  
13 is that children may or may not be teething, first of all,  
14 when a parent thinks they are. They usually are but not  
15 always. And the duration of the time between the parent  
16 believing the symptoms of teething have started and when the  
17 tooth shows up is extremely variable.

18 Q And what is that variability? What concern did that  
19 cause you in interpreting the results of this study?

20 A This study went on for quite a few doses and quite a  
21 bit of time compared with the acute use that the company and  
22 the FDA expect an acute use to be used for.

23 Q Can you explain? What do you mean by the acute use  
24 that the company expected?

25 A Well, an acute problem lasts in theory about seven

1 days. And if a condition goes past that, you are usually  
2 encouraged to consult your physician to see if there's  
3 anything more about a diagnosis or treatment plan that might  
4 be done. And this study, I believe, went on for over a  
5 month on average with the children.

6 Q What conclusions were you able to draw in this study at  
7 the end of it?

8 A That it was not definitive in giving us an answer.

9 Q Have you considered doing any follow-up studies on  
10 teething tablets to try to get a more definitive answer?

11 A Yes.

12 Q What has that follow-up consisted of?

13 A We have contacted an investigator --

14 MR. GOMEZ: I've got to object, Your Honor, based  
15 on the prior discussion.

16 MR. MARGULIES: I think we're being consistent  
17 with the prior discussion at this point.

18 THE COURT: Well, at this point I don't know what  
19 the answer is going to be, so let me --

20 MR. GOMEZ: I'll object to the question what have  
21 you considered doing as follow-up to that study, Your Honor.

22 THE COURT: To the extent that the question is  
23 potentially broad, perhaps you can rephrase your question.

24 MR. MARGULIES: I'll be happy to, Your Honor.

25 BY MR. MARGULIES:

1 Q Have you discussed potentially hiring other  
2 investigators to do an additional study?

3 A Yes.

4 Q At this time what is the status of those discussions?

5 A We have not moved forward. We have not identified a  
6 specific investigator at this point.

7 Q Have you discussed potential different methodologies to  
8 do a study that would avoid some of the issues you raised in  
9 your testimony today?

10 A Yes.

11 Q Are you familiar with a study on the Hyland's 4 Kids  
12 Cold 'n Cough product by Dr. James Taylor at the University  
13 of Washington?

14 A Yes.

15 Q Were you involved at all in the development of that  
16 study?

17 A Well, as my position evolved, I was involved with  
18 discussions with Dr. Taylor and Dr. Jacobs who was his  
19 co-investigator in this study where they were developing the  
20 protocol and I was trying to advise them on methodologic  
21 concerns or questions. I wasn't even advising them. I was  
22 asking them questions about their protocol plan.

23 Q So we've heard that there was a pilot study first and  
24 then a randomized control trial. Is that your  
25 understanding?

1 A Yes.

2 Q Were you involved in the development of the pilot  
3 study?

4 A I believe I was.

5 Q Okay. And do you recall what the results of the pilot  
6 study were?

7 A As I recall, they were that the Cough 'n Cold 4 Kids  
8 product was effective in improving the symptoms that the  
9 children had had. And Dr. Taylor at that point had a  
10 comparison study that he had previously done where he put  
11 the data he had in context of that previous study.

12 Q So let's see if we can break that down. You said the  
13 study showed that the product was effective. What did you  
14 mean by that?

15 A That it appeared that when children received that  
16 product, that their cold and cough symptoms improved.

17 Q Was this placebo controlled?

18 A I don't believe it was.

19 Q And then you said he compared that to another study.  
20 Do you recall what that other study was?

21 A As I understand it, it was a study he had done using  
22 Dimetapp, which was a commercial over-the-counter product  
23 which at the time was available for children, and placebo.

24 Q Was Standard involved in the Dimetapp study?

25 A No.



1 Q Do you know whether the method in the Dimetapp study  
2 was similar to the method that he was using in the pilot  
3 study?

4 A It was my understanding that it was similar in some  
5 senses.

6 Q And did I understand you right that he compared the  
7 results of the pilot study to the results of the Dimetapp  
8 study and found that they were similar in terms of  
9 effectiveness?

10 A He found that the product I believe was somewhat more  
11 effective than the Dimetapp.

12 Q And he made a proposal to Standard to do a randomized  
13 control trial based on the conclusion of that pilot study?

14 A Yes.

15 Q And did you evaluate the study proposal that he made?

16 A I believe I did.

17 Q Did Standard approve the proposal that Dr. Taylor made  
18 to do the study on Cough 'n Cold?

19 A Yes.

20 Q Did you have input into the design of the study?

21 A Again, I was involved in conference call discussions  
22 with Dr. Taylor and Dr. Jacobs periodically about their  
23 design.

24 Q Was Dr. Jacobs a participant in these discussions in  
25 terms of the design of the study?

1 A Yes.

2 Q What were the end points that were being discussed to  
3 be evaluated in this study? What were the measurements that  
4 they were looking at doing?

5 A Well, as I understood it, based on Dr. Taylor's  
6 previous study with Dimetapp, he was looking -- wanting to  
7 look at one-hour post-dose changes in the symptoms of the  
8 cold and cough.

9 Q And did Dr. Jacobs have any viewpoints on what end  
10 points ought to be studied?

11 A Yeah. She was not --

12 MR. GOMEZ: Hearsay objection.

13 MR. MARGULIES: Non-hearsay purpose, Your Honor.

14 THE COURT: The objection is overruled.

15 THE WITNESS: Dr. Jacobs from her experience in  
16 doing both clinical care of patients with homeopathy and her  
17 experience as an investigator, the various other studies,  
18 felt that a more appropriate set of outcomes would be  
19 measured twice a day where the parent would basically in  
20 their mind think back over half a day's period of time and  
21 say this is how my child's doing now.

22 Q Were Dr. Taylor's objectives included in the study?

23 A Yes.

24 Q And were Dr. Jacobs' objectives included in the study?

25 A Yes.

1 Q Did you have an opinion when you were party to these  
2 discussions as to what were the right objectives to be  
3 measured?

4 A Not specifically, no.

5 Q Okay. And you understand that Dr. Taylor's objectives  
6 became the primary objectives?

7 A Yes.

8 Q And what does it mean in a study to have primary  
9 objectives versus secondary objectives?

10 A Well, the study design requires more considerations  
11 than just what you're going to test. It also requires an  
12 understanding of how many subjects or some sense of how you  
13 get to the plan, about how many subjects you're going to  
14 recruit and run through the study. That's what's called  
15 statistical power.

16 Q And how does primary versus secondary objectives play  
17 into statistical power?

18 A At some level the statistical power is calculated based  
19 on the outcome measure that you plan to use, so you have to  
20 be sure it's the outcome measure you want to use.

21 Q And the one hour post dose was chosen to be the primary  
22 objective; is that correct?

23 A That's my understanding.

24 Q All right. And were you aware whether Dr. Taylor did a  
25 power calculation based on that primary end point?

1 A That was my understanding, yes.

2 Q If you wouldn't mind turning to Exhibit 181, please.

3 A (Witness complies.)

4 Q Do you have that in front of you?

5 A Yes.

6 Q Do you recognize that?

7 A Yes.

8 Q What is it?

9 A It is a proposal for randomized control trial of  
10 Hyland's Cold 'n Cough 4 Kids in children two to five years  
11 old.

12 Q Is this the proposal Dr. Taylor provided to Standard  
13 that you reviewed?

14 A Yes.

15 Q Let's turn to page 7 if you wouldn't mind.

16 MR. MARGULIES: Tom, if we could have the first  
17 full paragraph enlarged, that would be great. Thank you.

18 BY MR. MARGULIES:

19 Q On page 7 under the heading Sample Size and Power  
20 Calculation, is this something you read at the time -- well,  
21 let me back up. Who approved the Taylor study at Standard?  
22 Who approved the funding of it?

23 A In the end I was asked to give an opinion, but the  
24 ultimate decision about whether to fund it as far as I  
25 understood came from Dr. Borneman.

1 Q And you would have reviewed this entire protocol in  
2 order to recommend whether to proceed; correct?

3 A Yes, I would have.

4 Q And did you read this sample size and power calculation  
5 at the time you read the proposal?

6 A Yes.

7 Q What did you understand this particular paragraph to be  
8 discussing? What was Dr. Taylor doing here?

9 MR. GOMEZ: Object. Calls for speculation. Lack  
10 of foundation.

11 THE COURT: Sustained.

12 BY MR. MARGULIES:

13 Q Dr. Bell, you're familiar, having done clinical trials,  
14 with power calculations?

15 A Yes.

16 Q You've done them yourself?

17 A My statisticians have done them, yes.

18 Q You understand the words in this paragraph and what  
19 they mean?

20 A Yes.

21 Q And you understood it at the time you approved --

22 MR. GOMEZ: Object to leading, Your Honor. The  
23 questions are leading.

24 THE COURT: Sustained.

25 BY MR. MARGULIES:

1 Q Did you understand the words in this paragraph at the  
2 time you read the proposal from Dr. Taylor?

3 A Yes. Some of them were statistical terms which I had  
4 some familiarity with.

5 Q All right. The first sentence says that: In a  
6 previous study of an OTC cold medication using a similar  
7 design as we used in the pilot study, we found that parents  
8 reported improvement in runny nose, nasal congestion, and  
9 cough after 57.5, 50.6, and 43.1 percent, respectively,  
10 doses of placebo.

11 Do you recall, was this the Dimetapp study that  
12 you were referring to earlier?

13 A That would be my understanding, yes.

14 Q And then: After averaging these rates of improvement,  
15 we estimate that parents will report improvement in each  
16 specific symptom of URI after approximately 50.4 doses of  
17 placebo. URI is what?

18 A Upper respiratory infection. Basically a cold.

19 Q And then it states: By contrast, in the pilot study of  
20 the homeopathic remedy, improvement in these same symptoms  
21 was noted after an average of 62.7 percent of doses.

22 Where did you understand that this -- well, strike  
23 that. Based on this difference we would need data on 512  
24 doses of study medication. Is this a power calculation of a  
25 type that you are familiar with?

1 A It is a type of power calculation.

2 Q Is it common for power calculations to determine what  
3 you estimate the response to be in the placebo group and in  
4 the treatment group?

5 A You have to take into account what you estimate those  
6 on both sides.

7 Q And what, then, if you run it through a statistical  
8 calculation of the estimated effect of the placebo in the  
9 control group, what answer do you get out of the power  
10 calculation?

11 A It helps you identify the total number of subjects that  
12 you would actually have to recruit and enroll in the study  
13 on the assumption of certain levels of dropout, which are  
14 typically -- you know, many studies are 10 to 15 percent.

15 Q And did Dr. Taylor actually calculate the number of  
16 participants he needed to get, assuming a dropout rate in  
17 this proposal?

18 A Yes.

19 Q What number did he tell you he needed to get?

20 A In this proposal it says that they plan for a total  
21 sample of 400 study participants.

22 Q And how many did he believe he needed to get data from  
23 after dropouts?

24 A I believe he said he needed data from 356 patients,  
25 each taking four doses.

1 Q So if one doesn't meet -- if you're doing a study and  
2 you do a predefined power calculation and you don't meet it  
3 and the results are not statistically significantly  
4 different between one group and the other, what conclusions  
5 can you draw from those results?

6 A That the investigators needed to have run more  
7 subjects. You can't draw conclusions.

8 Q Can you say that the product's not more effective than  
9 a placebo if you haven't collected enough subjects and the  
10 results are not statistically significant?

11 A No. That's called a type 2 error.

12 Q What's type 2 error?

13 A In statistics as I understand it, it is that there is a  
14 true effect there but it was missed by the way the study  
15 actually was done.

16 Q So a false negative?

17 A A false negative.

18 Q Okay. Thank you.

19 Can you turn to Exhibit 191, please.

20 A (Witness complies.)

21 Q Do you recognize that document?

22 A Yes.

23 Q What is it?

24 A I believe it's a summary of findings that Dr. Taylor  
25 provided us with his calculations of the statistics from the



1 study.

2 Q It's dated June 1, 2014. Did you receive it on or  
3 around that day?

4 A I believe I did.

5 Q Okay. Do you know if there have been -- well, strike  
6 that. Was this a complete statistical analysis in your mind  
7 of this study?

8 A No.

9 Q What was missing?

10 A Well, he didn't even actually provide us with the  
11 information about how he approached doing the statistics and  
12 really wasn't very clear about the baseline status of the  
13 children and a variety of other descriptive things that one  
14 would want to know, including concomitant medication use and  
15 controlling for that type of thing.

16 Q What's important about baseline? Why was that an issue  
17 for you?

18 A In any study if people are already better, they are at  
19 what might be called a ceiling effect. They can't get any  
20 further better. If they are very close to bottom, they have  
21 a much larger room within which they could improve.

22 Q So what is the issue, then, with regard to baseline?

23 A The baseline is something you often have to control  
24 for. You randomize the subjects to the two different  
25 groups, but randomization sometimes fails to put people who

1 are completely comparable into the two groups. At that  
2 points it's especially important to actually include a  
3 control for the baseline status where everybody started in  
4 order to make sure that you weren't missing an effect or  
5 finding an effect that wasn't really there.

6 Q Is that a statistical analysis that's done after you've  
7 collected the data?

8 A It's part of the -- yes, after you collect the data.

9 Q And you said concomitant medications. What do you mean  
10 by that?

11 A Medications that the children might have received  
12 during the course of participation in the study.

13 Q Did this report contain any analysis of the data?

14 A It did in terms of having an analysis, yes.

15 Q Did it have any discussion by Dr. Taylor about what the  
16 results meant?

17 A Not much to my recollection.

18 Q Did you have any discussions with Dr. Taylor at this  
19 time about this study and what the results meant?

20 A I believe part of what I may have discussed with him  
21 was around the statistical analysis and asking for him to be  
22 considering some other factors in his analysis.

23 Q Did he give you an oral report on this study beyond the  
24 written report?

25 A He probably did. I don't recall.

1 Q Did you have an understanding from reading this report  
2 that he sent you what the results of the study were?

3 A No.

4 Q Did you have -- did you ask anyone with expertise in  
5 biostatistics to take a look at the data to help you analyze  
6 it?

7 A Yes.

8 Q Who did you ask to do that?

9 A Initially I asked a consultant to the company Hyland's  
10 whose name is Audrey Brooks. She's a Ph.D. And ultimately  
11 for purposes of publication I asked Dr. Brooks to identify  
12 an independent statistician who might give us further  
13 insight.

14 Q When you say for the purposes of publication, what did  
15 you mean?

16 A The agreement between Hyland's and Dr. Taylor at the  
17 University of Washington was that he would publish his paper  
18 regardless of findings, and I was concerned after I reviewed  
19 his report and discussed it with our statistical consultant  
20 that his analysis was not sufficiently sophisticated  
21 compared with what I knew usually was done in grants and  
22 projects that I have done. And so I wanted more input  
23 before he moved ahead with publishing.

24 Q Did you discuss this with Dr. Brooks?

25 A Yes.

1 Q Is Dr. Brooks a biostatistician?

2 A Yes.

3 Q Did you ask her to do the work?

4 A I asked her to do some of it, yes.

5 Q Did you ask her to do the work to assist Dr. Taylor  
6 with the publication?

7 A I recall that Dr. Taylor really hadn't -- he hadn't  
8 identified a statistician, and I felt that someone working  
9 who was a consultant for the company would not be the best  
10 person to do that analysis for a published paper.

11 Q And I think you said you asked Dr. Brooks to identify a  
12 biostatistician. Was she able to do so?

13 A Yes.

14 Q Do you know who that biostatistician was?

15 MR. GOMEZ: I object at this point, citing to  
16 Volume II of Dr. Bell's deposition at page 186, 16 to 25,  
17 and the representations by counsel therein about this  
18 subject matter.

19 MR. MARGULIES: I'm sorry. May I have the page  
20 reference again, please.

21 MR. GOMEZ: Volume II, 186, 16 to 25.

22 Does the clerk care to look at my copy?

23 THE COURT: What page again?

24 MR. GOMEZ: 186, lines 16 to 25.

25 MR. MARGULIES: Oh, I'm not going to go into

1 anything that --

2 MR. GOMEZ: -- we're not going to offer her to  
3 testify about.

4 MR. MARGULIES: Correct.

5 THE COURT: All right. Based upon Mr. Margulies'  
6 response, you can proceed.

7 MR. MARGULIES: Thank you.

8 BY MR. MARGULIES:

9 Q Do you know who Dr. Brooks was able to identify?

10 A Yes.

11 Q Who was that?

12 A I believe her name is Dr. Susanne Doyle.

13 Q Where was Dr. Doyle employed?

14 A At the University of Washington.

15 Q Is she also a biostatistician?

16 A Yes.

17 Q Did she have any prior affiliation with Standard  
18 Homeopathic Company or Hyland's?

19 A No.

20 Q Did she have any prior affiliation with you?

21 A No.

22 Q Did you know her?

23 A No.

24 Q Did you know what she was going to say before she was  
25 contacted?

1 A No.

2 Q Was she told to your knowledge anything about what to  
3 do with Dr. Taylor?

4 A It was to my knowledge she was asked to work with him  
5 as he wrote his paper up on the statistical aspects of his  
6 paper.

7 Q And was she to your knowledge given any directions  
8 about how to work with Dr. Taylor?

9 A No.

10 Q Thank you, Dr. Bell.

11 Do you believe that the Taylor clinical trial is  
12 conclusive on the question of whether Cold 'n Cough 4 Kids  
13 is effective for treating cold and cough in kids?

14 A I do not believe it's conclusive.

15 Q Why not?

16 A The data that we have available at this point and in  
17 the past suggests that there was -- that not enough subjects  
18 were run to meet Dr. Taylor's own statistical power  
19 calculations which basically said he didn't run enough  
20 subjects to come up with an answer; and if there was an  
21 effect there, it would be missed.

22 Q Have you seen any reports of any abstracts on this  
23 study?

24 A Yes.

25 Q What did you see?

1 A I saw an abstract that was presented at a conference in  
2 Rome that was sponsored by the Homeopathic Research  
3 Institute sometime I believe in June of this year.

4 Q Did you know that this was going to be presented before  
5 you saw the abstract?

6 A I don't recall knowing that.

7 Q How did you find out about the abstract?

8 A Dr. Jacobs called me after she had gone to the  
9 conference and said she wanted to share what she had learned  
10 at the conference with me.

11 Q Based on your understanding of the agreement between  
12 Standard and the University of Washington, whose decision is  
13 it to present this paper at a conference or publish it in  
14 the scientific literature?

15 A That's entirely in the hands of the investigators.

16 Q And who are the investigators?

17 A Dr. Taylor and Dr. Jacobs.

18 Q Okay. Thank you. Do you have any control over what  
19 they say in terms of the reports of that study?

20 A I do not have control, no.

21 Q So if they want to report that the study conclusively  
22 shows that Cold 'n Cough 4 Kids isn't effective, you have no  
23 ability to stop that?

24 A That's correct.

25 Q And if they want to report that it is conclusively

1 effective, do you have an ability to stop that?

2 A No.

3 Q Thank you.

4 I'd like to switch gears yet once more and promise  
5 this will be the last time and talk a little bit about some  
6 of the products that are involved in this case. Are you  
7 familiar with the products that are involved in this case?

8 A Yes.

9 Q And have you reviewed the ingredients of them over the  
10 course of this case or otherwise in your consulting with  
11 Standard?

12 A Yes, both.

13 Q Have you reviewed the ingredients of the products in  
14 this case in the homeopathic literature to assess whether  
15 they are in fact effective for the uses for which they're  
16 indicated?

17 A Yes.

18 Q When I say the word homeopathic literature, what does  
19 that mean to you?

20 A Well, it would be two levels. One would certainly be  
21 the research literature we've been discussing in part, but  
22 the other part is there is a very extensive clinical  
23 literature that's been developed within the field to assist  
24 clinicians who treat patients for either acute self-limited  
25 problems or chronic illness to understand more about the



1 range of options they have for treating individual patients.

2 Q Does that clinical literature have a name?

3 A It's called Materia Medica.

4 Q And is there more than one Materia Medica?

5 A Yes, there are.

6 Q Okay. Can you recall the names of any of the more  
7 prominent authors of Materia Medica?

8 A In medical considerations one of the most commonly used  
9 is Materia Medica by William Borkey, an M.D. who I believe  
10 was writing his book in the late -- in the early 1900s.

11 Q Any other prominent authors of Materia Medica that you  
12 consider prominent?

13 A These are all compendia. Constantine Herring, James  
14 Tyler Kent, and I believe Clark. I can't remember his first  
15 name.

16 Q John Henry?

17 A John Henry sounds correct.

18 Q When you say these are all compendia, what do you mean  
19 by that?

20 A Whoever the author is was collecting the clinical  
21 experience that was documented at the time they wrote that  
22 material, organized by the specific individual homeopathic  
23 medicine and organized typically in Materia Medica with what  
24 would be called the medicine or review of systems. So it  
25 starts with symptoms that might affect the mind and

1 behavior, and it goes all the way through head, ears, eyes,  
2 nose, throat, back, limbs.

3 Q Sexual organs?

4 A Sexual organs, all body parts.

5 Q Okay. Did you consult any other literature -- I think  
6 you mentioned the clinical research. Was there other  
7 literature you consulted in looking at the ingredients of  
8 these products to determine their effectiveness?

9 A Not directly that I recall, no.

10 Q Did you consult any herbal literature?

11 A Yes.

12 Q What is the herbal literature?

13 A There is research -- again, many of the traditional  
14 forms of medicine in the world, not just in the  
15 United States but in the world, often involve the use of  
16 plant-based material to help with various conditions. And  
17 these are sometimes referred to as herbs, and they are not  
18 necessarily diluted at all. They are simply often an  
19 alcohol-based extract of whatever that plant material is.  
20 And in homeopathy that would be called a mother tincture  
21 sometimes. But in the herbal literature the focus is the  
22 plant and its actual effects on living beings.

23 Q Can you give us some examples of any herbs that you  
24 understand are in the products that are in this case.

25 A An example might be chamomile, which is something that

1 many of us would get in a chamomile tea bag and use if we  
2 had an upset stomach or we were anxious, having trouble  
3 sleeping, that kind of thing.

4 Q Thank you.

5 Please turn to Exhibit 203-1 if you wouldn't mind.

6 MR. MARGULIES: Would you zoom in on the active  
7 ingredients.

8 BY MR. MARGULIES:

9 Q Do you recognize this, Dr. Bell?

10 A Yes.

11 Q And it's the labeling for the Calms Forté. If you look  
12 at the active ingredients on the back, do you see that?

13 A Yes, I do.

14 Q Are you familiar with these active ingredients?

15 A Yes.

16 Q Have you reviewed the homeopathic or herbal literature  
17 to determine whether they're appropriate and effective for  
18 the uses that are indicated on the purpose and uses on that  
19 label?

20 A Yes.

21 Q And are they in fact appropriate and effective for  
22 those purpose and uses?

23 A Yes.

24 Q Thank you.

25 Let's turn next to Exhibit 1011 and let's look at

1 the drug facts back panel, please. Do you recognize this?

2 A Yes.

3 Q It's the labeling for teething tablets. On the back  
4 drug facts we see some active ingredients and purpose. Have  
5 you reviewed the homeopathic and herbal literature to  
6 address whether these ingredients are appropriate and  
7 effective for the purposes and uses listed on the label for  
8 this product?

9 A Yes.

10 Q And are those ingredients appropriate and effective for  
11 those uses according to that literature?

12 A Yes.

13 Q Okay. Thank you.

14 Turn to the next one, 1012. And this is a  
15 two-pager. It's 1012-1 and 1012-2. We'll take a quick look  
16 at the front of the box, and then we'll turn to page 2,  
17 which is the back.

18 A Okay.

19 Q Do you recognize this product?

20 A Yes.

21 Q This is the migraine, Hyland's migraine headache  
22 relief?

23 A I'm sorry. I may have baby teething tablets -- oh, I  
24 see it.

25 Q You have it?

1 A Yes.

2 Q Page 2.

3 A Yes.

4 Q Under drug facts you see the active ingredients there?

5 A Yes.

6 Q Have you reviewed the homeopathic and herbal literature  
7 to determine whether these ingredients are appropriate and  
8 effective for the purposes and uses listed on the labeling?

9 A Yes.

10 Q And are the ingredients that are listed on page 1012-12  
11 appropriate and effective for the uses and purposes listed  
12 on the labeling pursuant to that literature?

13 A Yes.

14 Q Thank you.

15 Turn to Exhibit 1013. I'm sorry. We have a  
16 little bit of a technical difficulty. We're going to turn  
17 to 42-29.

18 A I'm sorry. What number?

19 Q 42-29.

20 A Okay.

21 Q And do you recognize this labeling?

22 A Yes.

23 Q That's the leg cramps with quinine labeling?

24 A Yes, it is.

25 Q If you turn to the next page, 42-30, please. If you

1 look at the back panel there, are you familiar with those  
2 ingredients?

3 A Yes.

4 Q Have you reviewed the homeopathic and herbal literature  
5 to determine whether those ingredients are appropriate and  
6 effective for the purposes and uses listed on the labeling  
7 of the leg cramps on Exhibit 42-30?

8 A Yes.

9 Q And are those ingredients appropriate and effective for  
10 the purposes and uses listed on the labeling?

11 A Yes.

12 Q Thank you.

13 Let's turn to Exhibit 6-1. Do you see that one?

14 A Yes.

15 Q This is leg cramps but without the quinine?

16 A Yes.

17 Q All right. And if we turn to Exhibit 6-2, do you see  
18 on the drug facts -- have you reviewed the homeopathic  
19 literature and herbal literature to determine whether the  
20 active ingredients are appropriate and effective for the  
21 purposes and uses listed on the labeling of this product?

22 A Yes.

23 Q And according to that literature, are these active  
24 ingredients appropriate and effective for those uses as  
25 indicated on the labeling?

1 A Yes.

2 MR. MARGULIES: Pardon me one moment, Your Honor,  
3 please.

4 *(Defense counsel conferring)*

5 BY MR. MARGULIES:

6 Q Dr. Bell, let's turn back to 1013-1 if you wouldn't  
7 mind. We had a little glitch and I was using one that  
8 wasn't in evidence.

9 Do you recognize the labeling on page 1013-1 and  
10 1013-2?

11 A Yes.

12 Q What is it?

13 A In the book that I'm looking at, it's colic tablets.

14 Q This is a Hyland's colic tablets?

15 A Yes.

16 MR. MARGULIES: Your Honor, we would move 1013-1  
17 and 1013-2 into evidence.

18 MR. GOMEZ: No objection, Your Honor.

19 THE COURT: All right. They are admitted.

20 MR. MARGULIES: Thank you.

21 *(Exhibits Nos. 1013-1 and 1013-2 received)*

22 BY MR. MARGULIES:

23 Q And if you'd turn to page 2, please. Looking at the  
24 drug facts on the back panel, have you reviewed the  
25 homeopathic and herbal literature to determine whether the

1 active ingredients listed on the label are appropriate and  
2 effective for the purposes and uses listed?

3 A Yes.

4 Q And are those active ingredients appropriate for the  
5 purposes and uses listed?

6 A Yes.

7 Q Thank you.

8 Let's turn to 1016-1 and 1016-2, please. Do you  
9 recognize this?

10 A Yes.

11 Q What is it?

12 A It is the Hyland's Defend Cold 'n Cough product.

13 Q Turn to page 2, 1016-2. In the drug facts have you  
14 reviewed the homeopathic and herbal literature to determine  
15 whether these active ingredients are appropriate and  
16 effective for the uses and purposes listed on the labeling?

17 A Yes.

18 Q And are the active ingredients appropriate for the  
19 purposes and uses listed?

20 A Yes.

21 Q Turning to page 1017-1 and 1017-2, please, the labeling  
22 for the Hyland's Defend Cold 'n Cough Night.

23 A Yes.

24 Q Are you familiar with this?

25 A Yes, I am.



1 Q And on page 2 under the drug facts, have you reviewed  
2 the homeopathic and herbal literature to determine whether  
3 the active ingredients are appropriate and effective for the  
4 purposes and uses listed on the labeling?

5 A Yes.

6 Q And are the active ingredients appropriate and  
7 effective for the purposes and uses listed on the labeling?

8 A Yes.

9 Q Turn to Exhibit 1019, please.

10 A (Witness complies.)

11 Q Do you see that?

12 A Yes, I do.

13 Q This is the Seasonal Allergy Relief labeling?

14 A Yes.

15 Q And if you turn to 1019-2 under the drug facts, have  
16 you reviewed the homeopathic and herbal literature to  
17 determine whether these active ingredients are appropriate  
18 and effective for the purposes and uses listed on the  
19 labeling?

20 A Yes.

21 Q And are the active ingredients appropriate and  
22 effective for the purposes and uses listed on the labeling?

23 A Yes.

24 Q Finally I would ask you to turn to Exhibit 1018. Do  
25 you recognize this 1018-1 and 2? Do you recognize this?

1 A 1018-1 and 2 appear to be Hyland's Defend Cough.

2 Q Is this the same product you know as Hyland's Cough?

3 A I do not know with certainty.

4 Q Okay. Well, we'll drop that one.

5 MR. MARGULIES: Your Honor, this would be a good  
6 time to take a break if it's good with the Court.

7 THE COURT: All right. I just wanted to make  
8 clear for the record that Exhibit 1018 has not been  
9 admitted.

10 MR. MARGULIES: Correct.

11 THE COURT: All right. We'll take our afternoon  
12 break and return at 2:45.

13 *(Recess taken at 2:29 p.m.;*

14 *proceedings resumed at 2:46 p.m.)*

15 THE COURT: All right. Mr. Margulies.

16 MR. MARGULIES: Thank you, Your Honor. I think we  
17 got our exhibit confusion straightened out. I apologize  
18 it's not in the notebook, but we'll put it up on the screen,  
19 Exhibit 2010, if we could have that displayed.

20 BY MR. MARGULIES:

21 Q Do you recognize that, Dr. Bell?

22 A Yes, I do.

23 Q The Hyland's cough labeling?

24 A Yes, I do.

25 MR. MARGULIES: If you could blow up the third

1 panel on the right side, indications and formula.

2 BY MR. MARGULIES:

3 Q Did you review the homeopathic and herbal literature to  
4 determine whether the ingredients listed in this product  
5 were effective and appropriate for the indications listed on  
6 the labeling for this product?

7 A Yes.

8 Q And are the ingredients listed for this product  
9 appropriate and effective for the indications on this  
10 labeling?

11 A Yes.

12 Q Dr. Bell, thank you very much.

13 MR. MARGULIES: Your Honor, I don't have anything  
14 further with this witness.

15 THE COURT: All right. Cross-examination.

16 MR. GOMEZ: Thank you.

17

18 CROSS-EXAMINATION

19 BY MR. GOMEZ:

20 Q Good afternoon, Dr. Bell.

21 A Hello.

22 Q And you've been affiliated with Standard since 2006; is  
23 that right?

24 A Yes.

25 Q And 2006 was the date of the teething tablet study that

1 we just got done talking about. Do you remember that email?

2 A I don't believe that was the date. It might have been  
3 in that vicinity, but I don't know if it started exactly in  
4 2006.

5 Q Does that sound about right? Do you recall that being  
6 one of your first projects once you came on board?

7 A Yes.

8 Q And you've actually been the medical director since  
9 2011; is that right?

10 A Yes.

11 Q So you've been with the company now or affiliated in  
12 some capacity for nine years?

13 A Yes.

14 Q And a good part of that, at least in the beginning one  
15 of your first assignments was dealing with this clinical  
16 trial involving teething tablets?

17 A Yes.

18 MR. GOMEZ: And so could you put that up, August,  
19 22. Thank you.

20 BY MR. GOMEZ:

21 Q And so, Doctor, you understand that this case involves  
22 the products that are on the screen now; namely, teething  
23 tablets, Defend Cold 'n Cough Night, Defend Cold 'n Cough,  
24 Leg Cramps, Leg Cramps with Quinine, Migraine Headache  
25 Relief, Colic Tablets, Hyland's Cough, Seasonal Allergy

1 Relief, and Calms Forté?

2 A Yes.

3 Q And so we heard a little bit about the study that was  
4 conducted in 2006 involving teething tablets whereby the  
5 placebo participants reported better outcomes than those  
6 persons that received the actual product. Do you recall  
7 that discussion?

8 A I recall that, yes.

9 Q And you had determined that that was not a  
10 scientifically reliable study; correct?

11 A That is correct.

12 Q Likewise with the study that we discussed involving  
13 Defend Cold 'n Cough 4 Kids, do you recall that discussion?

14 A Yes.

15 Q And you determined that that study did not provide  
16 scientifically reliable data as well; correct?

17 A Yes.

18 Q Now, you recognize, Doctor, that your company -- that  
19 is, Standard -- through its Hyland's products realized  
20 \$96 million in sales of these and other products?

21 MR. MARGULIES: Objection. Beyond the scope.

22 THE COURT: Overruled.

23 THE WITNESS: I was not familiar with that.

24 BY MR. GOMEZ:

25 Q Does that sound about right to you?

1 A I have no information.

2 Q Let me ask you this, then. It's true in the nine years  
3 that you've been affiliated with the company, you're aware  
4 of no clinical trial of any of these products that provides  
5 reliable scientific data to consumers that they actually  
6 work. Is that a fair statement?

7 A Can you rephrase that question.

8 Q Sure. We've talked about the two trials, right, one  
9 teething tablets, one Cold 'n Cough 4 Kids; right?

10 A Yes.

11 Q Looking at the products up here on the screen, you can  
12 point to no clinical study that your company has funded or  
13 allowed you to do that would help you provide reliable  
14 scientific data that any of these products actually help  
15 consumers; correct?

16 A Well, as I said, in the sense that the homeopathic  
17 literature supports the choice of the ingredients in those  
18 products, there is an extensive historical literature on  
19 that point.

20 Q Sure. Thank you, Doctor. I appreciate that, and we're  
21 quite familiar with the Materia Medica, and I guess there's  
22 some herbal literature, and there's the studies that you've  
23 read about. What I'm talking about is any clinical trial  
24 involving human beings with these combination products that  
25 are sold to consumers that demonstrate they actually work on

1 human beings. Can you cite one?

2 A In those specific products that was part of our  
3 portfolio that we've already discussed. There actually have  
4 been other studies that the company has funded.

5 Q None that we can present here today or that you can  
6 point to that demonstrate that any of these products  
7 actually relieve the symptoms that Hyland's promises to  
8 consumers; correct?

9 A There are no definitive studies on that topic at this  
10 point.

11 Q Now, let me ask you this, Doctor. Do you believe that  
12 your employer values medicine more or marketing more?

13 MR. MARGULIES: Objection. Lacks foundation.  
14 Vague and ambiguous.

15 THE COURT: Overruled.

16 THE WITNESS: I believe the company values  
17 homeopathy more.

18 BY MR. GOMEZ:

19 Q Would that fall within medicine?

20 A Yes.

21 Q So what was your budget last year to conduct clinical  
22 trials and testing on the products that your company sells  
23 to consumers?

24 A Well, as I said, I'm a consultant to the company, so I  
25 do not ask for a specific budget. That is managed

1 internally. And when a promising study is brought to my  
2 attention, I bring it to the attention of the company or  
3 vice versa for review.

4 Q Despite your ability to bring it to the attention of  
5 the company, there's not one actual test or clinical trial  
6 that you can point to that the company has conducted in the  
7 last nine years to support the conclusion that any of these  
8 products here actually help people; true?

9 A As I stated, there have been other studies that do  
10 indicate some of their other products do help people in the  
11 sense of an experimental trial.

12 Q Experimental trial. And so do you have a budget in  
13 mind? Do you believe you have unlimited funds to conduct  
14 clinical testing?

15 A No.

16 Q Do you believe you have \$7.5 million a year to conduct  
17 clinical testing?

18 A No.

19 Q So what would be your best estimate? Do you believe  
20 you have \$1 million a year to conduct clinical testing?

21 MR. MARGULIES: Objection. Lacks foundation.

22 THE COURT: Sustained.

23 BY MR. GOMEZ:

24 Q You had told us that you believe and it was your  
25 testimony you did not have \$7.5 million a year; true?



1 A It is true. I don't have any information on what  
2 budget I might be able to employ to do these studies.

3 Q Have you had that -- I get the feeling that it would be  
4 important to you to demonstrate to this jury that those  
5 products actually work; is that fair?

6 MR. MARGULIES: Objection. Argumentative. Lacks  
7 foundation.

8 THE COURT: Overruled.

9 THE WITNESS: It would be desirable, but as I  
10 indicated, the field of research in homeopathy requires a  
11 lot of additional research to be done to really determine  
12 the proper methodology for designing studies on each product  
13 for each indication. And that type of work is available to  
14 a limited extent in the literature at this point, but it is  
15 not specifically available to us. So there would probably  
16 be a multi-year program of effort to get to the point of  
17 doing the trials you're discussing.

18 BY MR. GOMEZ:

19 Q Sure. And in terms of multi-year, this was something  
20 that your company first embarked upon with these products in  
21 2006 or nine years ago; true?

22 A It is my understanding that the company funded other  
23 studies before I became affiliated with them.

24 Q Sure. So going back even further than nine years;  
25 true?

1 A As far as I understand, yes.

2 Q You certainly have -- you I think told us that you are  
3 at least tangentially involved in some studies involving  
4 nanostructures or the presence of nanostructures in  
5 homeopathic solutions; is that true?

6 A Yes. I have external grants, as I said, and the  
7 company itself has looked into setting up the capacity to  
8 look at that question.

9 Q Are you suggesting to the jury that you as the medical  
10 director of this company and Standard with revenue  
11 approaching \$100 million a year lack the technical ability  
12 to actually conduct clinical trials on these products?

13 MR. MARGULIES: Objection. Lacks foundation.  
14 Argumentative.

15 THE COURT: Overruled.

16 THE WITNESS: I'm suggesting that it is well known  
17 in the homeopathic research literature that there are  
18 methodologic problems with applying -- again I'm assuming  
19 what you mean by a clinical trial -- that applying the  
20 methodology that most is useful for studying conventional  
21 drugs is not always completely appropriate for studying  
22 homeopathic medicines. And that is a generality in the  
23 field of complementary medicine as well.

24 BY MR. GOMEZ:

25 Q Okay. And what I'm getting at, Doctor, is taking

1 something like teething tablets -- or maybe that's not the  
2 best example. Maybe Defend Cold 'n Cough, one of your  
3 products, giving this product in its completed form to a  
4 number of participants in a study and tracking to see if  
5 they get better and comparing it with a placebo group and  
6 not telling the two groups which got which. Is that  
7 possible?

8 A It is theoretically possible.

9 Q But it's not happened that you know of in the nine  
10 years since you became affiliated with the company as to any  
11 of these products; true?

12 A Well, we've discussed some other studies, so we have  
13 done it on some of those. And we have had discussions about  
14 research with the leg cramps product.

15 Q Discussions are different than clinical trials; right?

16 A Yes.

17 Q Have you heard saying something like the road to  
18 somewhere, I can't recall, is laid with the best intentions?  
19 An intention is different than a clinical trial; right?

20 A Well, it's not a question of intention. There are many  
21 other factors that go into designing an appropriate study on  
22 any product for any particular indication.

23 Q Thank you, Doctor.

24 And so what I'd like to do next if I can, we just  
25 heard you go through a number of the ingredients and a

1 number of the products at issue. Do you recall that?

2 A Yes.

3 Q And we certainly appreciate you as a medical doctor  
4 using your expertise and background to look at each of those  
5 ingredients to ensure that they actually provide meaningful  
6 medical benefits to consumers, and so I'd like to talk to  
7 you a little bit about that. Okay?

8 A Okay.

9 MR. GOMEZ: So can you pull up 25 on the  
10 PowerPoint, please.

11 BY MR. GOMEZ:

12 Q So this will be an example, Doctor, and this can be up  
13 on the screen for you. Do you see this Defend Cold 'n Cough  
14 product?

15 A Yes. Yes, I do.

16 Q So did the company -- that is, Standard -- consult with  
17 you prior to --

18 MR. MARGULIES: I'm sorry. Excuse me, Your Honor.  
19 I don't believe this is an exhibit. It looks like a  
20 demonstrative from opening statement.

21 MR. GOMEZ: That's what it is.

22 MR. MARGULIES: Well, I would object to it being  
23 shown.

24 THE COURT: It's a demonstrative.

25 MR. GOMEZ: Thank you.

1 BY MR. GOMEZ:

2 Q Doctor, do you have this product in mind here, Defend  
3 Cold 'n Cough?

4 A I know the name of the product, yes.

5 Q Okay. So my question to you is: Certainly you as a  
6 medical doctor affiliated with the company, you of course  
7 provided input as to this formulation including the  
8 ingredients and dosages before this product was released to  
9 the public; true?

10 A Yes. To a certain extent, yes.

11 Q Okay. And so is it your testimony here to this jury  
12 that you actually were consulted prior to the release of the  
13 products at issue in this case?

14 A In the case of the Defend Cold 'n Cough product, I  
15 believe I was. I'm often sent proposed formulas that the  
16 pharmacists have developed, and I'm asked to review it as a  
17 homeopath in terms of the symptom indication.

18 Q So is it your testimony that you actually came up with  
19 the ingredients that are included in the Defend Cold 'n  
20 Cough?

21 A No.

22 Q In fact, can you tell me whether the Defend Cold 'n  
23 Cough contains the exact same ingredients as Hyland's Cough  
24 'n Cold 4 Kids?

25 A I can't specifically say that without comparing the

1 labels head to head, not ingredient wise but potency wise.

2 Q And do you understand that Hyland's -- when was  
3 Hyland's Cough 'n Cold 4 Kids first sold to the American  
4 public?

5 A I do not know.

6 Q Was that before you?

7 A I do not know.

8 Q Would it surprise you to learn that there's been  
9 testimony in this case that this product that you claim you  
10 had input regarding is the exact same formulation as was  
11 sold to kids as Hyland's Cough 'n Cold 4 Kids?

12 MR. MARGULIES: Objection. Beyond the scope.

13 THE COURT: Overruled.

14 THE WITNESS: In the world of homeopathy, a remedy  
15 or medicine, a specific medicine, is indicated for symptom  
16 pattern or a particular picture of symptoms an individual  
17 might have. The age of the individual is not typically  
18 considered in the selection of the name of the ingredient.  
19 The type of symptoms the individual might have and the way  
20 they experience them is considered.

21 BY MR. GOMEZ:

22 Q Sure. So just my simple question to you is: It's  
23 true, is it not, that this product that we're looking at,  
24 Defend Cold 'n Cough, was simply a marketing decision to  
25 sell the exact same product that had been sold as Defend

1 Cough 'n Cold 4 Kids to grownups?

2 MR. MARGULIES: Objection. Lacks foundation.

3 THE COURT: She can answer if she knows.

4 THE WITNESSS: I do not know.

5 BY MR. GOMEZ:

6 Q Have you met Thao Le?

7 A Yes.

8 Q Have you spoken to her about that subject?

9 A I don't recall that I did.

10 Q Have you met certainly Mr. Phillips back here?

11 A Yes.

12 Q And you claim that you had conversations with him about  
13 the ingredients contained in Defend Cold 'n Cough before it  
14 was released to the American public?

15 A I don't recall that I had specific conversations with  
16 any specific person. I recall that I was asked, and I don't  
17 remember who made those inquiries.

18 Q Now, you are a trained psychiatrist; is that right?

19 A Yes.

20 Q You are board certified in psychiatry?

21 A Yes.

22 Q And who provides that certification?

23 A The American Board of Neurology and Psychiatry.

24 Q And in that capacity as I understand it, you have  
25 prescribed medications to patients over the years?

1 A Yes.

2 Q You've also treated people with psychiatric conditions?

3 A Yes.

4 Q And so do you continue to treat patients in a  
5 psychiatric setting today?

6 A Not at this time.

7 Q When was the last time that you actually prescribed  
8 psychiatric medication or conventional medication to a human  
9 being?

10 A It would have -- well, again, I was teaching trainees,  
11 so I would have potentially done that up through  
12 approximately the year 2000.

13 Q You say potentially. Was that something you were  
14 commonly doing in 2000; that is, prescribing medication to  
15 human beings?

16 A Yes.

17 Q And when you did that, did you tell them that they  
18 could take as much or as little of the medication as they  
19 wanted?

20 A Typically not, no.

21 Q In fact, what kinds of medications were you dealing  
22 with in a psychiatric setting?

23 A In a psychiatric setting it depended on the problem the  
24 individual had. It could be drugs that were to treat  
25 psychotic symptoms or just agitation, anxiety, and



1 depression.

2           In the context of my taking care of elderly  
3 patients in inpatient settings, I worked with a geriatrician  
4 who is an internal medicine doctor certified in taking care  
5 of older patients, and as the physician of record I would  
6 commonly order things that my consultant experts in  
7 geriatric medicine would suggest.

8 Q     Thank you for that explanation. And certainly would  
9 you actually write out a prescription for these medications?

10 A     It depends.

11 Q     How else -- how would the medications get into the  
12 system of the people that you were treating?

13 A     Well, I would write orders if I was in an inpatient  
14 setting.

15 Q     Thank you so much. And would those orders I imagine  
16 set forth the dosage and the frequency of the medication at  
17 issue?

18 A     Typically in conventional medicine that's what's done.

19 Q     And when you say typically with regard to something  
20 like an antipsychotic medication, it's pretty much always  
21 done; true?

22 A     Well, there are standard doses that are given on a  
23 regular basis. But in the case of a patient who might  
24 become agitated, there might be medication that would be  
25 recommended on an as-needed basis. It's sometimes referred

1 to in medicine as PRN.

2 Q Sure. I appreciate that. And so what about this  
3 concept of placebos? Have you ever prescribed a placebo?

4 A Not specifically, no.

5 Q When you say not specifically, what does that mean?

6 A Well, in my research projects I sometimes included  
7 placebo conditions in my study.

8 Q What about as a treating psychiatrist? Did you ever  
9 provide placebos to your patients?

10 A I don't recall doing that, no.

11 Q Do you believe that would be ethical for you to do as a  
12 psychiatrist, provide a placebo to one of your patients  
13 without telling them?

14 A Without telling a patient, no. A person has to be  
15 informed.

16 Q Why is that important?

17 A The risks of conventional medications are very  
18 significant. Many of them have side effects that could even  
19 be life-threatening if they're not taken appropriately, and  
20 it would just be inappropriate to slip someone a medication.  
21 In the world of psychiatry, we often have to go to court if  
22 someone is refusing treatment in order to get a third-party  
23 evaluation of whether it's appropriate to proceed.

24 Q What about in the field of homeopathy, as you've said,  
25 a form of medicine, would it be ethical to provide placebos

1 to consumers without telling them that's what you were  
2 providing them?

3 A I don't think the question of ethical is in the realm  
4 of what I do. I treat people with homeopathic medicine.

5 Q What about as the medical director of a company that  
6 sells close to \$100 million of product a year? Do you  
7 believe as the medical director it would be ethical for your  
8 company to sell placebos to consumers without telling them?

9 MR. MARGULIES: Objection. Lacks foundation.  
10 Argumentative.

11 THE COURT: Sustained as to argumentative.

12 BY MR. GOMEZ:

13 Q Now, Doctor, you are not an expert in the general  
14 concept of nanoparticle research and conventional medicine;  
15 are you?

16 A Not in conventional medicine, no.

17 Q And I appreciate that. It appears you do a lot of  
18 reading. Is that fair to say?

19 A Yes. That's one part of what I do.

20 Q And where do you read all these articles? Where are  
21 you physically when you're doing all the reading that you've  
22 described?

23 A Most of the time I have a home office, and I have a  
24 specific room in my house that's set aside for my work.

25 Q Okay. And where is your home office? Tucson?

1 A Yes.

2 Q Now, you've never designed a nanoparticle as part of a  
3 drug delivery system; have you?

4 A Not specifically, no.

5 Q And you certainly did not design the products at issue  
6 in this case to generate nanoparticles of any particular  
7 specification or design; did you?

8 A No.

9 Q In terms of your day-to-day work, it sounds like most  
10 of the time is at your home in Tucson; is that true?

11 A Yes.

12 Q And so you don't work in a lab in which you have the  
13 ability to generate and produce nanoparticles for drug  
14 delivery; do you?

15 A I don't personally. Some of my collaborators in my  
16 current grant do.

17 Q Okay. You don't run a lab today?

18 A No.

19 Q Do you have Ph.D.'s and post-doctorate fellows working  
20 for you today that work specifically on generating  
21 nanoparticles for drug delivery?

22 A No.

23 Q Let me ask you this: Do you recall the testimony to  
24 the jury where you said you had heard this term nano and you  
25 began to do the research that you've described?

1 A Yes.

2 Q When was that about? What year?

3 A It would have been probably around 2006.

4 Q 2006. Does that sound -- I had heard that the article  
5 from India was 2010.

6 A Yes.

7 Q Does that sound better than 2006 or more accurate or --

8 A No. The nano bubble issue came up in the course of the  
9 work I was doing with Dr. Malloy at Penn State, and I  
10 believe there were several of us who were co-authors on a  
11 paper probably around 2006. I'd have to look at my CV to be  
12 sure.

13 Q That's okay. No problem. Is it true that the  
14 overwhelming majority of the research that you've done has  
15 been while you have been an employee of Standard?

16 MR. MARGULIES: Objection. Lacks foundation.  
17 Mischaracterizes testimony.

18 THE COURT: Overruled.

19 THE WITNESS: No.

20 BY MR. GOMEZ:

21 Q Not an employee. I'm sorry. As a consultant?

22 A As a consultant, no. I had grants for many years  
23 before I became a consultant for Hyland's.

24 Q What I'm getting at is nano and your interest in  
25 nanotechnology as it relates to homeopathics, and I believe

1 you said that you had first heard that term and become  
2 interested in or around 2006; is that right?

3 A Yes.

4 Q And it's true that since that time you have  
5 continuously been employed as a consultant with Hyland's or  
6 as its medical director; true?

7 MR. MARGULIES: No objection.

8 THE WITNESSS: I've been employed as a consultant  
9 in both those capacities.

10 BY MR. GOMEZ:

11 Q Now, one of the things that you do for Hyland's, fair  
12 to say, is to provide it litigation support; that is, to  
13 lend your work as a researcher and doctor to its efforts in  
14 defending itself in court cases like this?

15 A In one sense, yes.

16 Q And so in the sense of you sitting here testifying and  
17 providing your opinions, you are being paid by Standard;  
18 correct?

19 A Yes, that would be true.

20 Q And you have written a number of very lengthy reports,  
21 and we appreciate the amount of work that you've done. But  
22 in terms of doing all the research and writing these  
23 reports, you were paid by the defendant in this case to do  
24 so; true?

25 A No.

1 Q I'm sorry?

2 A I was on my time associated with the company, but the  
3 work I did with nanoparticles was not all supported by the  
4 consulting fees that I received from Hyland's.

5 Q Setting aside the research that you've done under a  
6 grant from a private foundation, what I'm getting at is the  
7 actual court reports that were filed in this case.

8 A Yes.

9 Q That was on Standard's time; correct?

10 A Yes.

11 Q Now, it's true, Doctor, that many of the changes in  
12 your career were forced by financial changes; true?

13 MR. MARGULIES: Objection. Vague.

14 THE COURT: Sustained.

15 BY MR. GOMEZ:

16 Q Was that your testimony in this case, Doctor, that many  
17 of the changes in your career were forced by financial  
18 changes?

19 A No.

20 MR. GOMEZ: Direct the Court and counsel to  
21 Volume I, page 11, line 25, through page 12, line 1.

22 I think the question actually begins on the very  
23 lengthy discussion.

24 MR. MARGULIES: I think taking it out of context  
25 would be inappropriate, Your Honor. No objection to reading

1 the entire question.

2 THE COURT: I don't even know where we are because  
3 I don't see what you're talking about.

4 MR. GOMEZ: We need to provide the first volume, I  
5 think, which is dated August 2nd, 2012.

6 THE COURT: Okay. I don't have the right volume.  
7 I have July 14<sup>th</sup>.

8 MR. MARGULIES: Oh, I'm sorry. I had the  
9 original.

10 MR. GOMEZ: So what I'm referencing is 11, 25, to  
11 12, 1.

12 THE COURT: I'm sorry. What was your objection,  
13 Mr. Margulies?

14 MR. MARGULIES: I think it's taken out of context.  
15 I have no objection to the entire question and answer being  
16 read.

17 THE COURT: And, Mr. Gomez, you want to start at  
18 line 25 without a question?

19 MR. GOMEZ: Yes. I think the statement's  
20 freestanding, Your Honor. It's admittedly a narrative, but  
21 it's her narrative.

22 THE COURT: Well, I'll allow Mr. Margulies to  
23 redirect as to that question, but you may proceed.

24 MR. GOMEZ: Sure.

25 At 11, 25, under oath your testimony was:



1           "A     Many of the changes in my career were forced  
2           by financial changes."

3 BY MR. GOMEZ:

4 Q     Does that refresh your memory?

5 A     I remember that there was such a statement. That is  
6 partly true.

7 Q     Yes. And it's true that at a certain point there was a  
8 loss of funding in your grant support and you moved on to  
9 other funding; correct?

10 A    Yes.

11 Q    And it's true we heard earlier that you had at least  
12 three grants, maybe four on homeopathy funded by the  
13 National Center for Complementary and Alternative Medicine;  
14 true?

15 A    Yes.

16 Q    And that is the funding that you described to the jury;  
17 true?

18 A    That was one part of it. There were two other grants  
19 that were providing me with support.

20 Q    Are those both the private foundation grants?

21 A    No. No. The grants -- one of them was a career  
22 development grant that covered a ten-year period for upwards  
23 of 50 percent of my salary, and the other was a T32 which is  
24 a research training grant where I was the director of that.  
25 So those were additional grants and activities and

1 responsibilities I had.

2 Q That's fine. Thank you, Doctor. And so when you  
3 received this money from the National Institute of Health,  
4 that is the national government; right?

5 A Yes.

6 Q And they have an actual center designed to look at  
7 complementary and integrative medicine; is that right?

8 A Yes.

9 Q And so they provided you funding to look at these  
10 issues that you're involved with; correct?

11 A Yes.

12 Q And you reported back to them on the results that you  
13 reached based on the money that they gave you; true?

14 A Yes.

15 Q And we'll talk about that in a little bit. You  
16 understand at this point the National Institute of Health  
17 after having considered all of the evidence, including the  
18 research that you've done, has come to certain conclusions  
19 about homeopathy?

20 A It is my understanding that they have not -- they have  
21 expressed to the public that there's no evidence related to  
22 the topic of homeopathy, which I've always found peculiar.

23 Q That must be disappointing to you after having provided  
24 your own research to the government.

25 A It's not unusual for parts of the government to not

1 know what other parts might be doing.

2 Q Sure. Now, when you first began association with  
3 Standard, your job at the time was to give them advice on  
4 trends in the homeopathic research literature and the  
5 mainstream medical literature that might relate to market  
6 opportunities for their products or new products that they  
7 might actually develop in the future; true?

8 A That was -- yes.

9 Q And that was with Mr. Borneman; is that right?

10 A Primarily with Mr. Borneman, yes.

11 Q Now, in 2011 you became the medical director; true?

12 A Yes.

13 Q And did your job duties change once that happened?

14 A Yes.

15 Q Did your compensation change?

16 A Yes.

17 Q And it's true that when we spoke with you in 2012, you  
18 estimated that somewhere between 90 and 98 percent of your  
19 compensation was paid by Standard; true?

20 A I believe I did.

21 Q And it's true that you are a paid consultant to  
22 Standard and Hyland's on scientific and medical issues and  
23 that you are compensated as an independent contractor  
24 through your own LLC; is that right?

25 A Yes.

1 Q Now, how much money did Standard pay you last year?

2 MR. MARGULIES: Objection. Relevance. Privacy.

3 THE COURT: Sustained.

4 MR. GOMEZ: All right.

5 BY MR. GOMEZ:

6 Q You understand that you are a witness in this case;  
7 true?

8 A Yes.

9 Q And you understand that one of the things that the jury  
10 might be interested in is whether you may have biases or  
11 some interest in the outcome of this litigation; right?

12 MR. MARGULIES: Objection. Argumentative.

13 THE COURT: Overruled.

14 THE WITNESS: Yes.

15 BY MR. GOMEZ:

16 Q And so you have a financial interest in the well-being  
17 of this company and its continued business model; true?

18 A In one sense, yes. In another sense I'm approaching  
19 retirement age for real at this point, and I'm more  
20 concerned as a consumer of homeopathy that it be available  
21 to myself and other people.

22 Q Sure. And you understand that us over here, we're not  
23 trying to take away homeopathy. We're just trying to put  
24 the words on the label so that people know what they're  
25 buying. Do you understand that?

1 MR. MARGULIES: Objection. Lacks foundation.

2 THE COURT: Overruled.

3 THE WITNESS: I understand that's what you said,  
4 yes.

5 BY MR. GOMEZ:

6 Q Okay. And so I'll ask the question again just for the  
7 record: How much money did Hyland's pay you last year?

8 MR. MARGULIES: Same objections, Your Honor.

9 THE COURT: Overruled.

10 THE WITNESS: I don't recall specific amounts, but  
11 I believe the amount was probably around \$125,000. There  
12 were no bonuses related to any legal work.

13 BY MR. GOMEZ:

14 Q Now, today do you receive any funding from the national  
15 government?

16 A Not specifically, no.

17 Q And so no NIH grants through the Department of Health  
18 and Human Services?

19 A Not at this point. I'm building up to it with my pilot  
20 data.

21 Q You had told us that right now you have a grant from a  
22 private foundation; is that right?

23 A Yes.

24 Q What foundation is that?

25 A Well, there were two. The one that I published those

1 papers on is now over. It was a one-year grant basically by  
2 the AlterMed Research Foundation. I believe they're based  
3 in Colorado.

4 The other grant is -- I'm not the PI. I'm a  
5 consultant to the grant, and it's specifically related to  
6 nanoparticles because there have been other grants. And  
7 there is another grant I also consult on on another topic,  
8 but the other one is funded by the Hecht Memorial  
9 Foundation. It's based I believe in Vancouver in Canada,  
10 and it is two different nanotechnology researchers who study  
11 in part cancer biology.

12 Q Who funds those foundations?

13 A They were privately endowed to my knowledge.

14 Q By whom?

15 A In the case of the Hecht Foundation, the best I know is  
16 that it was funded by a couple named John and Lotte Hecht.

17 Q They were persons interested in homeopathy?

18 A No. As far as I know, the mission of that organization  
19 is very broad and I'm not part of it, so I can't speak to  
20 them.

21 Q Okay. We should ask them, I guess.

22 A Yes.

23 Q All right. Thank you.

24 Now, you would agree that bias has no place in  
25 science?

1 A Bias -- you do the best you can to control for bias.  
2 Bias is frequently found in people who do science.

3 Q Do you recall there was a brief discussion of you  
4 hiring an outside statistician to look at some items because  
5 you felt it would be better to have someone from outside of  
6 the company do the analysis? Do you recall that?

7 A Yes.

8 Q And that was because of bias; true?

9 A No.

10 Q You would agree that the bias of a researcher can  
11 undermine results?

12 A It could.

13 Q You certainly would not be an investigator or a  
14 researcher that had a financial interest in the outcome of  
15 the science that you were considering; would you?

16 A Right. And generally speaking the current  
17 conflict-of-interest rules prevent me right now from being a  
18 principal investigator on a federal grant.

19 Q Because you are affiliated with this company?

20 A Yes. They've asked me to quit that position  
21 completely.

22 Q Yes. And it's true that on at least one occasion the  
23 University of Arizona has determined that your relationship  
24 with Hyland's represents a conflict of interest which would  
25 preclude you from receiving funds to study homeopathy; true?

1 A Not completely. It would preclude me from serving as a  
2 principal investigator. I was informed at this point as are  
3 all investigators at the University of Arizona that it is  
4 not permissible to have a vendor who makes a product that  
5 you're studying even if it's not their product, for you to  
6 be the principal investigator.

7 So I was instructed that I could do so if I could  
8 find another member of the faculty who would be considered  
9 qualified to do homeopathy research as a principal  
10 investigator and who had no such relationships with any  
11 homeopathic companies.

12 Q Do you recall that you received a grant through Indian  
13 Health Services to look at the use of complementary medicine  
14 on Native American tribe reservations and you were  
15 specifically asked by the University of Arizona to exclude  
16 homeopathy?

17 A Yes.

18 Q And you told us that the university has very strong  
19 conflict-of-interest rules whereby an investigator who wants  
20 to be a principal investigator in an area in which he or she  
21 has a specific financial interest cannot be a principal  
22 investigator, and your relationship with Hyland's precluded  
23 that. Is that what we're talking about?

24 A It is in part connected with that. I was a  
25 co-principal investigator with a colleague, and actually we



1 were site principal investigators for a larger grant that  
2 was granted to a Native American researcher affiliated with  
3 the University of Arizona and another -- it was from, I  
4 believe, the National Health Service, the broad category.  
5 And that was when the University of Arizona was just  
6 beginning to implement their rules about conflict of  
7 interest.

8 Q Sure. And it was determined that you had a specific  
9 financial interest that precluded you from being a principal  
10 investigator associated with a grant studying homeopathy;  
11 true?

12 A Yes.

13 Q And did you appeal that decision?

14 A I asked for a meeting with the leaders of the  
15 conflict-of-interest office in order to understand more  
16 about what the rules were and how I could comply with them.

17 Q Did you disagree that you had a specific financial  
18 interest in homeopathy?

19 A No.

20 Q So you do agree that you have a specific financial  
21 interest in homeopathy and the industry associated with it?

22 A Well, as I indicated, I have that and I have a personal  
23 interest as a patient.

24 Q Sure. Now, you have some theories as a scientist about  
25 how homeopathy may work; is that right?

1 A Yes.

2 Q And it's true that your theories are applicable to  
3 homeopathy as a whole, not just the products at issue in  
4 this case; true?

5 A Yes.

6 Q And so what I'd like to do if I may, Doctor, is just  
7 discuss some basic homeopathy principles. And I'll begin  
8 with the principle of like cures like. Do you have that in  
9 mind?

10 A I'm aware of that principle, yes.

11 Q Right. And you have testified, have you not, that the  
12 data does not confirm definitely that this core principle  
13 works in the entire field of homeopathy? That has not been  
14 tested at this point? Was that your testimony?

15 MR. MARGULIES: Objection. Beyond the scope of  
16 direct exam.

17 THE COURT: Overruled.

18 THE WITNESS: It -- maybe.

19 BY MR. GOMEZ:

20 Q Maybe?

21 A Could you repeat the question.

22 Q Sure. I'm just getting to the very basic principle of  
23 like cures like. And it's your testimony in this case that  
24 the data does not confirm definitely that this core  
25 principle works in the entire field of homeopathy. That has

1 not been tested at this point; true?

2 MR. MARGULIES: Your Honor, I would repeat my  
3 objection, and it is grounded in the Court's motion in  
4 limine regarding the scope of expert testimony. I didn't go  
5 into topics like this with Dr. Bell, given the ruling, and I  
6 don't think it's appropriate on cross to allow that to occur  
7 as well.

8 THE COURT: I believe that during the direct you  
9 asked her whether it was in some ways similar to a vaccine.  
10 Is that not questioning about like?

11 MR. MARGULIES: In the context of -- correct, but  
12 I believe that the questioning here goes to data beyond  
13 which we discussed on direct on topics that the Court  
14 excluded.

15 THE COURT: Well, I'm going to allow some cross on  
16 it. We're not going to go into it in great depth.

17 MR. GOMEZ: Thank you, Your Honor. And I'll  
18 suggest that the only questioning about the particular  
19 products was in the last ten minutes.

20 BY MR. GOMEZ:

21 Q So, Doctor, is it true that the data does not confirm  
22 definitely that this core principle works in the entire  
23 field of homeopathy? That has not been tested at this  
24 point?

25 A It has not been tested other than through the evidence

1 which is in the literature, in the research literature, that  
2 homeopathically prepared material can trigger hermetic-type  
3 reactions, which go in opposite directions, low doses versus  
4 high doses.

5 Q Okay. And we learned, I think, through Dr. Borneman  
6 and Dr. Phillips that age doesn't matter, and I think we  
7 heard that from you. Do you agree with that?

8 A In what context?

9 Q In the context of providing medication to a Hyland's  
10 consumer, a homeopathic medication.

11 A Well, as a geriatric psychiatrist, I would say that  
12 there are certain clinical guidelines that one tries to  
13 avoid if you have a very vulnerable patient who's at risk  
14 from a very serious medical condition that would guide your  
15 decision about what to use.

16 Q To be sure. And what I'm limiting my question to,  
17 Doctor, is the issue of homeopathic products like those at  
18 issue in this case. It doesn't matter how old or young the  
19 person is, the homeopathic product will have the same effect  
20 on the person; true?

21 A Homeopathy rarely has the exact same effect on two  
22 different people.

23 Q And so is it your testimony that -- and I think there  
24 was some testimony by you that I found interesting about --  
25 let me find it -- homeopathic constitutional types. Do you

1 recall that?

2 A Yes.

3 Q And so is there a particular type of person that a  
4 homeopathic product is better suited for?

5 A That concept comes mainly from the treatment of  
6 chronically ill people, and it's based on, as I mentioned,  
7 the entire clinical pattern of the individual; so mental,  
8 emotional, physical symptoms and where they are, what the  
9 qualities of those symptoms are. So it's a very complex  
10 matter of matching the type.

11 However, there is a type in the acute world,  
12 certain remedies that certain types might be more likely to  
13 need for treatment of acute illnesses they might develop.

14 Q Okay. Thank you for that explanation. And so within  
15 that context there is a type of person and a type of  
16 homeopathic solution or product that might be appropriate  
17 for them. Does that sound right?

18 A To some extent, yes.

19 Q Otherwise what I'm talking about is I think you told us  
20 that homeopathic products rarely work the same way on two  
21 different people; is that right?

22 A They are not expected to work directly with regard to a  
23 specific mechanism as is understood in conventional drugs  
24 and pharmaceuticals.

25 Q Sure. So does age matter? That is, if I take this

1 bottle of Calms Forté and I feed it to my six-year-old, is  
2 it going to affect my six-year-old differently than if I eat  
3 this whole bottle of Calms Forté?

4 A I don't know.

5 Q You can't tell us the answer to that question as the  
6 medical director of this company?

7 A One has to evaluate the patient. What I can tell you  
8 is that there's a list of ingredients in there and that each  
9 of those ingredients is indicated for different individuals.  
10 So the concept behind that is that any given person might  
11 benefit from a particular ingredient or the product may not  
12 contain any ingredient that might be beneficial to every  
13 single person who consumes it.

14 Q Okay. Thank you for that explanation. So you  
15 understand that these products that your company sells to  
16 American consumers are at least advertised or represented to  
17 be appropriate for everyone that suffers from the conditions  
18 that are on the front of the box of the products?

19 A With the exclusions of what is on the labeling about  
20 what ages a particular product should be used in?

21 Q Yes.

22 A Yes.

23 Q All right. And you understand that the products at  
24 issue in this case contain a combination of a whole bunch of  
25 active ingredients that you went through for us; do you

1 recall that?

2 A Yes.

3 Q And so it's true, you've told us, that each of these  
4 different active ingredients by themselves can have a  
5 different effect on different people; is that true?

6 A Yes.

7 Q So you would probably question whether or not taking a  
8 whole bunch of different so-called active ingredients and  
9 combining them would be appropriate to sell to everyone in  
10 the American public; true?

11 A I would not question that, no. It's a different  
12 approach to using homeopathic information.

13 Q And is it true that size -- that is, the weight or mass  
14 of the human being -- does not matter in terms of the effect  
15 that these products will have on human beings?

16 A Probably does not.

17 Q Probably or does not as a medical director and a person  
18 who appears to have a great deal of interest in this topic,  
19 that is, the literature and understanding of homeopathy?

20 A I've given those types of ingredients to my dog, who's  
21 much smaller than myself and different from other people. I  
22 haven't given that exact product, but I've given  
23 ingredients.

24 Q So we heard from Dr. Borneman that he feeds these to  
25 his dog. You provide these to your dog as well?

1 A Not those specific ingredients, but I've certainly had  
2 my dogs treated by homeopathy, yes.

3 Q Okay. And so are they combination, diluted products  
4 that are found in places like CVS? Do you give that to your  
5 dog?

6 A Not myself because as someone trained in homeopathy and  
7 someone who also consults with a homeopathic veterinarian  
8 with specific background, I typically use one remedy at a  
9 time to treat my dog.

10 Q Before I get on to something else and we're talking  
11 about animals, what was the outcome of the study that you  
12 conducted about whether loud noises cause anxiety in  
13 animals?

14 A As I recall, it was a study again where I was  
15 collaborating with a senior investigator whose special area  
16 of investigation at the time was the stressful -- the  
17 biological effects of stress from noise on animals.

18 Q And so you don't, I think, suggest to the jury that  
19 that study -- that is, the study of whether noises would  
20 cause stress in animals -- pertains to the products at issue  
21 here?

22 A Well, that particular study was the study of another  
23 company's combination product. It was called Traumeel, and  
24 it was put in the animal's drinking water.

25 Q Okay. Now, is it true that a basic principle of



1 homeopathy is that dose does not matter? It doesn't matter  
2 if you take one or two or three; it's just frequency?

3 A That's a difficult question to answer.

4 Q Well, do you have an answer for us?

5 A My answer is that if the individual is sensitive to an  
6 individual ingredient in that product, the number of pellets  
7 should not matter.

8 Q I'm sorry. If an individual is sensitive to an  
9 ingredient in the product, the number of pellets should not  
10 matter?

11 A And by sensitive, I mean if they are capable of  
12 responding therapeutically to that particular ingredient,  
13 the number of pellets you might take, assuming the medicine  
14 is on that pellet, is not as important within a certain  
15 range. There is a point at which you could give medicine  
16 and it's more by frequency of dosing than it is by amount.

17 Q Now, have you consulted with pharmacists, formulating  
18 pharmacists like Mr. Phillips or Dr. Phillips about the  
19 directions that go on the labels for consumers to whom your  
20 company sells these products?

21 A I don't recall specifically discussing it with him, but  
22 I at times have had conversations with members of the  
23 company.

24 Q Members of the marketing company or other members of  
25 the company?

1 A Both.

2 Q And so what would marketing have to do with directions  
3 for use of a drug?

4 A They would be consulting with our pharmacists and with  
5 me to ask whether the instructions for using the drug were  
6 appropriate to put on the box.

7 Q Dr. Phillips told us that he came to an understanding  
8 of the proper dosages or number of pills to direct consumers  
9 to use in the following way, and I want to see if you agree  
10 with that approach as the medical director of this company.  
11 Okay?

12 A Okay.

13 Q He told us that after completing his training in  
14 homeopathy and upon beginning his work with the company, he  
15 went to a conference where he ran into a medical  
16 practitioner of homeopathy who said that they typically used  
17 one or two tablets. And so he came back and determined that  
18 since the tablets were smaller, then he could put on the  
19 direction use two or four or six pills, and he told us  
20 there's no difference in those numbers. Do you agree with  
21 all of that?

22 MR. MARGULIES: Objection. Mischaracterizes  
23 testimony.

24 THE COURT: Overruled.

25 THE WITNESS: I agree that in general the number

1 of pellets does not matter. It is usually -- within the  
2 range of dose you're talking about, it usually depends more  
3 again on whether the individual is encountering an  
4 ingredient in homeopathic potency that speaks to their  
5 particular situation.

6 From a practical point of view, when I've spoken  
7 with clinicians, I've been told that if they were making  
8 something like that themselves from an existing product,  
9 they would want more than one pellet because it may not have  
10 been evenly distributed across all the pellets that were in  
11 the bottle. And so it would be very important to ensure  
12 that the individual actually received the dose.

13 BY MR. GOMEZ:

14 Q Sure. So did you just tell us that there's a chance  
15 that there are different dosages of the active ingredients  
16 in each one of the tablets at issue in these products?

17 A Not to my knowledge. Hyland's has a very formalized  
18 manufacturing procedure which is very different from what  
19 I've just described.

20 I'm talking about an individual doctor who has a  
21 bottle from another doctor and has a bottle of pellets and  
22 wants to pour some of them over and shake them up and create  
23 another bottle with active treatment.

24 Q So is it your belief that there are the identical  
25 number of nanoparticles of active ingredients in each one of

1 the pellets of this product that I'm holding in my hand,  
2 Calms Forté? Each one of them has the same number of  
3 nanoparticles of active ingredient?

4 A Based on my research there's a certain amount of  
5 variability around the number that I quoted earlier.

6 Q And so generally speaking if I am sensitive to the  
7 ingredients in one of the products that your company sells,  
8 then I will have good results even taking one of these  
9 pellets; right?

10 A It could be, yes.

11 Q And what if I'm not sensitive to one of the ingredients  
12 contained in one of these pellets, is it true I will have no  
13 relief whatsoever?

14 A If you were not sensitive -- and again I'm not talking  
15 in an adverse way. I'm not talking allergic. I'm talking  
16 about your makeup and your current illness pattern. You may  
17 not get any relief if there was no ingredient in that  
18 formula that spoke to your particular body.

19 Q Okay. So it's true that the products that Standard  
20 sells will only speak to particular consumers' bodies; true?

21 A Well, it would speak to people for whom those  
22 ingredients are relevant, are salient as I write in my  
23 professional papers.

24 Q Now, would you advise, then, writing on the front of  
25 this box for consumers "only appropriate for use with

1 certain people with bodies that are sensitive to the  
2 ingredients contained herein?"

3 A Not specifically, no.

4 Q You understand that these products are sold and  
5 representative as effective to every consumer in the  
6 American public that has these conditions; right?

7 A I understand that, yeah.

8 Q So is it true that based on what you understand about  
9 how these products are sold and marketed and your  
10 understanding as the medical director of the company that in  
11 fact these products may not in fact be appropriate for all  
12 of us?

13 A They may not be appropriate for every one of us as a  
14 general statement. They may -- at certain points in your  
15 health history they may be appropriate, yes.

16 Q And so it will even change within a single person  
17 within my health history, you know, one day; or depending on  
18 what's going on in my life, Calms Forté may help me sleep  
19 and then another day or a month later, depending on what's  
20 going on in my health history, it won't?

21 A Well, if you were drinking a great deal of coffee with  
22 actual caffeine in it and you wanted something to help you  
23 sleep, the chances are that the caffeine would override any  
24 effects of the product.

25 Q And does Calms Forté in fact contain some coffee cruda?

1 A It contains homeopathically prepared coffee cruda.

2 Q Now, have you stated that it is your professional  
3 opinion that a ten-pound child would have to ingest at least  
4 six bottles of the 125 teething tablets at once before  
5 experiencing the first mild side effects of dry mouth?

6 A I believe we have written that statement based on the  
7 input of the pharmacists at the company.

8 Q We heard yesterday -- I think it was yesterday -- from  
9 Dr. Phillips that within a 190-milligram pellet, there are  
10 only approximately .19 milligrams of active ingredients.  
11 Does that sound right to you?

12 A That's possible. I'd have to review the specifics.

13 Q Do you know?

14 A No, I don't know.

15 Q Do you believe -- would it sound about right to you  
16 that the pills that consumers pay for are 99.9 percent  
17 lactose?

18 A It would be my understanding that they are poured on  
19 lactose after they're made. What's important is that the  
20 signal of that particular ingredient get through to the  
21 individual body.

22 Q I'm going to go briefly through your theories about how  
23 these products work and then talk a little bit about the  
24 government's position, and then we'll be done, Doctor.

25 Is it true that one of your theories is there are

1 nanoparticles within these products?

2 A It is true that I believe the manufacturing process  
3 generates nanoparticles.

4 Q So are the nanoparticles that you're referring to  
5 glass; that is, silica, or actual active ingredients?

6 A Active ingredients.

7 Q Do the active ingredients adhere to the silica for a  
8 mechanism of entry into the body?

9 A Not necessarily.

10 Q Do you know?

11 A Well, most of those products like the Calms Forté  
12 you're holding are what in homeopathy is called low potency.  
13 The glassware is not always involved in manufacturing them  
14 at all.

15 Q And so silica would have no relevance to the products  
16 at issue in this case?

17 A It depends on the specific ingredient you would have to  
18 ask me about, and I would have to confirm at the company  
19 whether glassware was used in making that particular  
20 potency.

21 Q Is it true that you have said that nanoparticles have  
22 properties that overlap with the known scientifically  
23 established replicated findings about what homeopathic  
24 remedies do, and that could be due to nanoparticles or  
25 someone may come up with some other explanation? Does that

1 sound like something you would say?

2 A I'm not sure I said "or someone might come up with some  
3 other explanation."

4 Q In the interest of time, I'll ask you another question.  
5 Does it sound like you would say "so nanoparticles may or  
6 may not be there?"

7 A It's possible. I don't know the context.

8 Q We heard about nano bubbles today. Is that a second  
9 theory?

10 A It's not a theory and it's not a second theory. There  
11 are research papers coming out in the past year suggesting  
12 that nano bubbles are in fact interacting with the particles  
13 of the material and are contributing to the generation of  
14 the active material.

15 Q Are the nano bubbles interacting with nanoparticles, or  
16 are the nano bubbles interacting with bulk parts of the  
17 product?

18 A They may be interacting with both the bulk and the  
19 nanoparticles.

20 Q But you don't know?

21 A The data in the literature suggests that there are  
22 bubbles of all sizes that are present when one succuses  
23 something in a container for the purpose of creating a  
24 homeopathic potency.

25 Q A third theory is optic signals; right?



1 A Well, these are not all independent theories. These  
2 are things that are published by other people with  
3 experimental findings where they did studies and reported  
4 their data.

5 Q And what you've done is looked at those studies and  
6 tried to explain to this jury how these products could work  
7 relying upon those studies; true?

8 A In part.

9 Q How about memory of the water? Have you relied upon  
10 that theory in the past?

11 A No.

12 Q We're running out of time, so I want to finish with  
13 you. Can you go to page 1. Are you familiar with the House  
14 of Commons evidence check two on homeopathy?

15 A Yes. I believe it was done in the United Kingdom.

16 Q Yes. And so you certainly are a person that keeps up  
17 on the literature and you're aware of this document;  
18 correct?

19 A Yes.

20 Q And did you see that the House of Commons considered  
21 the input of Dr. Peter Fisher and Professor Edward Calabrese  
22 in looking at this issue?

23 A Yes.

24 Q You understand that those are both experts that we'll  
25 hear from in this case?

1 A That's my understanding, yes.

2 Q Did you see that there were aspects of the argument  
3 that like cures like that this committee was concerned  
4 about? One, it is not good scientific practice to conclude  
5 that because some substances are harmful at high doses and  
6 beneficial at low doses that all substances behave in the  
7 same way? Did you note that concern by this committee?

8 A You're pointing it out to me now. I was aware that  
9 there was such a report, but I wouldn't be able to quote you  
10 the specifics of what was stated there.

11 Q Sure. Did you see here where Dr. Fisher was asked  
12 about the specifics of the shaking, how much shaking was  
13 required? He told this committee that has not been fully  
14 investigated. Can you tell this jury how much shaking is  
15 required?

16 A Not specifically, no.

17 Q Have you been to the manufacturing facilities at issue  
18 in this case?

19 A Yes.

20 Q Did you see this where this committee concluded: In  
21 our view the systematic reviews of meta analyses  
22 conclusively demonstrate that homeopathic products perform  
23 no better than placebos?

24 MR. MARGULIES: Objection. This is beyond the  
25 scope and the Court's order on the motion in limine.

1 THE COURT: Sustained.

2 BY MR. GOMEZ:

3 Q You are a person that has looked at the literature and  
4 cited extensively from the literature that you've read to  
5 suggest to the jury that these products may work in this  
6 case, and I just want to explore a few government findings  
7 with you.

8 So we'll skip the Australian report. Do you  
9 understand that the Australian government concluded that  
10 there is no scientific evidence to support the conclusion  
11 that homeopathic products provide any effective medical  
12 relief?

13 A I know there is an Australian report. I don't recall  
14 reading it in detail.

15 Q Thank you. And this finally is what we referenced  
16 earlier, a publication by the same National Institute of  
17 Health, National Center for Complementary and Integrative  
18 Health that previously provided you funding. Do you recall  
19 that?

20 A Yes.

21 Q And you provided the results of your studies to them;  
22 true?

23 A Yes.

24 Q Do you believe that they did not give you fair  
25 consideration; that is, that they did not treat you as a

1 respected scientist?

2 A That's a difficult question to answer. They certainly  
3 treated me with respect at the time I did my studies, but I  
4 am aware that the leadership at that center changed between  
5 the time some of my grants were originally funded and the  
6 time these kind of statements were put out, that --

7 Q Go ahead.

8 A -- that the individuals who took over made public  
9 statements of that type, although I was part of a group of  
10 scientists who actually went to her facility in the  
11 Washington, D.C., area, and we gave an educational workshop  
12 sponsored by the National Center for Homeopathy to update  
13 them on the state of the science in the field.

14 We were told that they would pursue further  
15 funding, that they would think about providing research  
16 funds for more work, and they have chosen not to do so.

17 Q It's true, Doctor, that -- I want to just get you back  
18 to the products at issue in this case. Okay?

19 A Yes.

20 Q And we have to go through that quickly, but it's in  
21 evidence. It's true that you personally as the medical  
22 director of this company do not use any of the Hyland's  
23 products at issue in this case for your own medical  
24 purposes? True?

25 A For my personal medical purposes I tend not to. For

1 friends and friends of friends, yes, I do.

2 Q So not tend not to. You don't. You do not use these  
3 products; is that true? That was your testimony at the time  
4 of your deposition; correct?

5 A At the time of my deposition, I can say if I happened  
6 to get a flu and what I had in my suitcase at the time was a  
7 flu product, I would definitely use it.

8 Q Was that your testimony at the time of your deposition,  
9 that you don't use these products?

10 A It may have been. That's possible.

11 MR. GOMEZ: That's all I have. Thank you.

12 THE COURT: All right. Redirect?

13 MR. MARGULIES: Thank you, Your Honor.

14 REDIRECT EXAMINATION

15 BY MR. MARGULIES:

16 Q Why don't you use the Hyland's products, Dr. Bell?

17 A As someone trained in homeopathy, I believe that you  
18 have to have the right single ingredient for the moment and  
19 that many times you have to go through sometimes a series of  
20 individual homeopathic medicines as your response to the  
21 last medicine changes.

22 And so I use single remedies at a time most of the  
23 time. I do use combination remedies made by other  
24 companies.

25 Q Do you believe that the Hyland's remedies are not

1 effective for the reasons you've just discussed about single  
2 remedies?

3 A No.

4 Q Mr. Gomez was asking you questions about the  
5 combination remedies, and you said that one of the products  
6 might not be beneficial to everyone who takes it. Do you  
7 remember that?

8 A Yes.

9 Q All right. Is that true of conventional drugs as well?

10 A Of course.

11 Q Okay. Thank you. I don't have anything further,  
12 Dr. Bell. Thank you very much.

13 THE COURT: Recross?

14 MR. GOMEZ: Certainly not.

15 THE COURT: All right. Thank you.

16 Thank you, Dr. Bell. You may be excused.

17 All right. This is the exact time when we should  
18 adjourn, so we will resume tomorrow morning at 9:00 o'clock.  
19 And as my clerk has reminded me to remind you, please do not  
20 discuss the case with each other or with anyone else.

21 Thank you.

22 (Jury out)

23 THE COURT: Is there any need for us to resume  
24 tomorrow at an earlier time than 9:00 o'clock?

25 MR. PERSSON: I don't think on this side there's a

1 need for that. I did have one issue or one question for the  
2 Court actually, which is just -- I know no one wants to hear  
3 this question on a Friday due to its implications, but do we  
4 have a hard stop at 4:00 tomorrow? because we have two  
5 witnesses from out of town and I just want to make sure we  
6 get to them.

7 THE COURT: Well, I don't normally have a hard  
8 stop, but our jurors may. So we may need to ask the jurors  
9 how late they can stay tomorrow if you anticipate that we  
10 would go beyond 4:00.

11 MR. PERSSON: Well, I think we can reorder if  
12 necessary. I think we just had an order in mind, so that's  
13 why I asked the question. I'm not saying I'd want to stay  
14 til 5:00 or anything like that, but if we had flexibility to  
15 4:15 or something, that was more my question.

16 THE COURT: Well, why don't we ask the jurors if  
17 you are concerned in that regard.

18 MR. PERSSON: Thank you, Your Honor.

19 MR. MARGULIES: And the corollary, Your Honor, is  
20 we may end with those two witnesses before the end of the  
21 day, and it would be preferable not to put somebody on in  
22 the middle, yet another expert, and have them over the  
23 weekend. But if the Court wants us to use the full day  
24 tomorrow, we will be prepared to do that.

25 THE COURT: When is the witness for the plaintiff

1 who's being taken out of order going to be appearing?

2 MS. NELSON: Tuesday, the 15<sup>th</sup>, Your Honor.

3 THE COURT: I see. So if defendants rest  
4 tomorrow, then we would --

5 MR. MARGULIES: We wouldn't be resting. Monday is  
6 Dr. Fisher and Dr. Bellavite, who comes from --

7 THE COURT: Oh, I see. So you're not saying  
8 you're resting tomorrow. You're saying you're just finished  
9 with these particular witnesses tomorrow?

10 MR. MARGULIES: We have three queued up for today  
11 and tomorrow. The question is do I need to hold the third  
12 for tomorrow in case Mr. Persson -- I'm a little more  
13 optimistic than he is. If we finish with two and it's  
14 3:00 o'clock, should we start the third one who will be on  
15 for an hour and then have to come back on Monday, or is the  
16 Court okay with us taking off early?

17 THE COURT: I see. Why don't we cross that bridge  
18 when we get to it. I'm not as much concerned about ending  
19 early. No one will object to that. The problem is more  
20 that if we have to have the jurors stay later.

21 MR. PERSSON: And you'll see we have different  
22 interests here.

23 MR. MARGULIES: The only objections I've ever  
24 heard to ending early on a Friday have been from a judge, so  
25 I just wanted to make sure we didn't have that.



1 THE COURT: Well, I always prefer to finish a  
2 witness if we can, and in that instance I prefer to go late  
3 if we will finish a witness, assuming the jurors will stand  
4 for it. So why don't we just play it by ear. If necessary,  
5 I'll ask my clerk to ask them tomorrow morning when they  
6 come in how late they can stay.

7 MR. MARGULIES: Thank you, Your Honor.

8 MS. NELSON: Your Honor, I think there is one  
9 issue that I'd like to raise. I've not had a chance to  
10 raise this with opposing counsel. I gave them, I guess, a  
11 trailer of it, that there was an issue I did want to talk  
12 with them about.

13 I believe the first witness that they intend to  
14 call tomorrow morning is Robert Van Hasalen. And so that  
15 the Court has the construct -- and again I've not discussed  
16 this with counsel, and I know the Court has a hearing at  
17 4:00 -- Dr. Van Hasalen was only identified as a rebuttal  
18 witness as to the Taylor study and the teething tablets  
19 study.

20 I believe there was a motion in limine that was  
21 brought. That motion in limine was denied in the Court's  
22 order; however, the Court indicated that he serves a  
23 distinct purpose in rebutting a particular expert's  
24 testimony about a specific clinical trial. The Court finds  
25 that the testimony is not cumulative and denies the motion

1 as to Van Hasalen.

2 That issue related to the Hyland's teething  
3 tablets in 2010 and the assertion by Dr. Krosnick in his  
4 second report that this clinical trial challenges any claim  
5 that the product is effective. We have not had Dr. Krosnick  
6 testify on the teething tablet study. We did not have  
7 Dr. Lee testify as to the Taylor or the teething tablet  
8 study, nor did we have Dr. Rose testify on that.

9 The issue I was going to raise with defense  
10 counsel is I don't believe that Dr. Van Hasalen's testimony  
11 is now relevant since we didn't -- there's no rebuttal.

12 MR. MARGULIES: Your Honor, that's a little bit of  
13 a bait and switch. I mean, either those studies are in or  
14 they're not. I believe we're entitled to put in evidence.  
15 If they're going to try to get in evidence through innuendo  
16 and cross-examination of Hyland's witnesses, then we're  
17 entitled to present our expert as to the meaning of that  
18 study.

19 THE COURT: Is he going to be testifying tomorrow?

20 MR. MARGULIES: Yes.

21 THE COURT: Well, the way in which it was  
22 presented in the motions in limine was that he was a  
23 rebuttal witness as to those two tests. To the extent that  
24 we have had testimony referring to those clinical studies, I  
25 think that Van Hasalen is still relevant.

1           The fact that the plaintiffs chose not to have  
2 certain witnesses testify as to those studies I don't think  
3 necessarily affects my ruling.

4           MS. NELSON: I understand what the Court is  
5 saying. The reason this issue came about was because  
6 Mr. Borneman spoke about it.

7           THE COURT: As I recall, I thought we also had a  
8 videotaped deposition of Dr. Taylor himself, and we also had  
9 Dr. Bell talk about her interactions with Dr. Taylor with  
10 regard to those studies.

11           MS. NELSON: That's correct. They raised that.  
12 The testimony came in from Mr. Borneman, who testified to  
13 the teething tablets and the Taylor study. And that was  
14 then the reason that the Court allowed the videotaped  
15 deposition of Dr. Taylor.

16           THE COURT: Wasn't the videotaped deposition of  
17 Dr. Taylor presented by plaintiffs?

18           MS. NELSON: We presented it and they objected to  
19 it, and there was back and forth on the very issue with the  
20 defendant very vigorously opposing the introduction of that  
21 videotape. And ultimately, as the Court will recall,  
22 Mr. Gomez pointed out that Mr. Borneman opened the door by  
23 speaking about the Taylor study and the teething tablet  
24 study.

25           THE COURT: Well, to the extent they lost their

1 objection to the Taylor videotape, then why is it that they  
2 shouldn't be able to put on any witness who addresses that?

3 MS. NELSON: Well, I think the point being it's a  
4 rebuttal witness to our expert. That's, I guess, the point.

5 THE COURT: I understand that it was presented to  
6 me in that context. But had it been presented to me that  
7 there was going to be evidence by someone about these  
8 clinical studies, they would be entitled to have a rebuttal  
9 witness as to that.

10 The fact that the construct that was given to me  
11 in the context of the motions in limine was the anticipated  
12 testimony of the witnesses that you chose not to ask those  
13 questions of doesn't change the fact that they are entitled  
14 to rebut evidence that comes in in the plaintiff's case,  
15 whichever witness it comes from.

16 MS. NELSON: Fair enough, Your Honor.

17 THE COURT: All right.

18 MR. GOMEZ: Your Honor, just one other thing. I'd  
19 offer the whole of Exhibit 74 into evidence. I kind of  
20 rushed through obviously the doctor's testimony to get her  
21 out of here by 4:00, but she discussed it during direct  
22 examination and I think laid a foundation for it. It's the  
23 teething tablet study that Mr. Borneman was fighting me on.

24 THE COURT: Exhibit 74 is an email.

25 MR. GOMEZ: I think 74-1 is an email. The whole

1 of 74 should be the teething tablet study.

2 MR. MARGULIES: I don't think there was any  
3 questioning about that document, Your Honor. What she said  
4 was she heard from Dr. Jacobs about the study. She didn't  
5 look at this document, identify it, or discuss it in any  
6 way.

7 MR. GOMEZ: I'm sorry. We don't have the record  
8 in front of us now, so I won't burden the Court. We'll just  
9 look at the record. Thank you, Your Honor.

10 THE COURT: All right. So we will resume at  
11 9:00 o'clock tomorrow.

12 MR. MARGULIES: Thank you.

13 THE COURT: The defendants had indicated they  
14 wanted to bring a motion. When were they planning to raise  
15 that?

16 MR. MARGULIES: I am hoping we can file it  
17 tonight.

18 MR. PERSSON: I believe we will be able to file it  
19 tonight, Your Honor.

20 THE COURT: Do you want to take it up tomorrow or  
21 Monday?

22 MR. MARGULIES: I think that will depend on the  
23 timing with the two out-of-town experts tomorrow. Let's get  
24 through the experts, and maybe that's when we can --

25 THE COURT: So we may be taking it up on Monday,

1 then.

2 MR. MARGULIES: Thank you.

3 MS. NELSON: And, Your Honor, we would  
4 obviously -- if they're going to present it in writing, we  
5 would think it would be appropriate for us to be --

6 THE COURT: Well, all the more reason why we might  
7 take it up on Monday, then.

8 MS. NELSON: Thank you.

9 MR. GOMEZ: Thank you, Your Honor.

10 *(Proceeding adjourned at 4:10 p.m.)*

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**CERTIFICATE**

*I hereby certify that pursuant to Section 753, Title 28, United States Code, the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript format is in conformance with the regulations of the Judicial Conference of the United States.*

*Date: September 11, 2015*

*Lisa M. Gonzalez*  
*/s/* \_\_\_\_\_  
*Lisa M. Gonzalez, U.S. Court Reporter*  
*CSR No. 5920*

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1012-12 [1] 53/10	400 [1] 39/21	accepted [2] 5/21 22/10
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