1	UNITED STATES DISTRICT COURT
2	CENTRAL DISTRICT OF CALIFORNIA
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4	HONORABLE DOLLY M. GEE, JUDGE PRESIDING
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8	KIM ALLEN, et al.,
9)
10	Plaintiffs,)) No. 12-1150DMG
11	VS)
12	HYLAND'S, INC., et al.,
13	Defendants.)
14	,)
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16	Reporter's Transcript of Proceedings JURY TRIAL - DAY NINE
17	MORNING SESSION Los Angeles, California
18	MONDAY, SEPTEMBER 14, 2015
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1	MONDAY, SEPTEMBER 14, 2015. 9:30 A.M.
2	~ ~ ~
3	JURY TRIAL - DAY NINE
4	MORNING SESSION
5	~ ~ ~
6	(Following held outside the presence of the jury)
7	COURT CLERK: Calling Item No. 2. CV 12-1150DMG
8	Kim Allen, et cetera, et al., versus Hyland's, Inc., et al.
9	Counsel, your appearances, please.
10	MR. GOMEZ: John Gomez for the plaintiffs.
11	MS. DIXON: Good morning, Your Honor. Deborah
12	Dixon for the plaintiff.
13	MS. NELSON: Good morning, Your Honor. Gretchen
14	Nelson for the plaintiffs.
15	MR. BARTON: Kristin Barton for the plaintiffs.
16	MR. MARGULIES: Good morning. Jeff Margulies for
17	the defendants.
18	MR. PERSSON: Good morning, Your Honor. Spencer
19	Persson for the defendants.
20	THE COURT: Good morning.
21	I have reviewed the papers filed both in
22	support of and in opposition to motion for judgment as a
23	matter of law, and my tentative decision is to deny the
24	motion, but I will hear from defense counsel if they wish to
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Let me just say that I think there are triable issues of fact with regard to the parts of the motion that assert that there has been a failure to introduce sufficient evidence. And with regard to the issue of preemption, I think that the law is pretty clear that state claims can proceed as long as they are not requiring different -- or have different requirements than federal law. As far as the punitive damages issue is concerned, that is an issue on which I am thinking that I will defer my ruling, but I will hear argument. Thank you, Your Honor. I'll be MR. MARGULIES: really brief, and I really want to address myself to the first issue. In going back and reading King Bio, we would --THE COURT: Mr. Margulies, why don't you take your place at the lectern. MR. MARGULIES: I'll be happy to. Thank you. Your Honor, in reading King Bio, I was struck at the parallels of it. The King Bio case, they had an expert who testified that homeopathy isn't effective, and on that basis they submitted that the products were ineffective. And the plaintiff recognized in that case that that wasn't sufficient to go to the jury and asked for a shift of the burden, which the Court of Appeals said no,

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      that's not the case.
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                      But King Bio, when we look at this case,
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      that's all we have. We have Dr. Rose who didn't look at the
     products. He looked at homeopathy in general. We have
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      Dr. Lee who really didn't testify what homeopathy is. His
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      focus was on nanoparticles. And you have two studies,
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     neither of which have -- there is any evidence that they show
      that the two products are ineffective.
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                      So I'm just troubled at how this case is
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     different from King Bio in that it focuses on homeopathy in
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     general.
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                      I mean, and I read the opposition, and it
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      said, well, defendants market their products as homeopathics,
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      so therefore they stand and fall on that. But what if they
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     work? What if we're wrong? What if we're wrong and they
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      still work? There has been no proof that they're not
     effective. And that's really all I had to add to our papers,
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     Your Honor.
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                 THE COURT: Well, I think that King Bio, the Court
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     of Appeal decision in any event I think rested on the
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     plaintiffs' attempt to shift the burden to the defendant to
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      show that it needed to prove that the products were
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     effective.
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                 MR. MARGULIES:
                                 Right.
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                 THE COURT: And in this case, while you may
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strongly and vigorously disagree with the evidence that the plaintiffs have put forward both in the way of anecdotal evidence from plaintiffs themselves as well as from the testimony of their experts, I think the fact remains that they have put forth some evidence and that there is a triable issue as to the key issues in this case. MR. MARGULIES: Thank you, Your Honor. THE COURT: All right. MR. MARGULIES: We'll submit. THE COURT: All right. Anything further from the plaintiffs? No, Your Honor. MS. DIXON: THE COURT: Then are there any other issues that the parties would like to raise? MR. PERSSON: Yes, Your Honor. One brief issue. We would ask -- we understand that typically the Court excludes testifying witnesses that have not yet testified. We would ask that Michael Buchanan be allowed to sit in on Mr. Ackerman's testimony tomorrow. He's our damage expert. He's a true rebuttal witness. And frankly, the number we've seen thus far from plaintiffs, 350 million, is not the number that's in their reports. I understand that that's because we had updated financials. But nevertheless because this is a new number, I would ask that Mr. Buchanan be allowed to sit in as

1 a true rebuttal witness and listen to that testimony. 2 And also I might add that in the report there 3 was no evidence or no opinion by Mr. Ackerman on punitive 4 damages. So to the extent he's going to address punitive damages, that is something that even if the methodology on 5 regular damages is the same but just with a different number, 6 7 we have seen no analysis on punitives thus far. 8 THE COURT: Let me just say that my usual practice 9 is to exclude fact witnesses from the courtroom when other 10 fact witnesses are testifying; but unless the parties 11 themselves stipulate to exclude experts, that experts often 12 do sit in. 13 MS. NELSON: I -- this is the first I've heard 14 this, so I'm responding on the fly. And I would say this. 15 We will have -- we received updated financial information 16 from the defendants, and we will have updated schedules that we will provide to the defendants today, and they will have 17

I don't see a reason for Mr. Buchanan to sit through the testimony of Mr. Ackerman. I think it's all -- we're talking crunching numbers basically is all this really is.

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those.

On the issue of punitive damages, I believe Mr. Ackerman's testimony was the following, that at this point in time -- and I think that's consistent with the

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Court's view of how the case proceeds -- the jury will simply be making a decision as to whether or not the conduct was sufficient to justify an award of punitive damages. And thereafter, there would be additional testimony presented on the question of the amount of the punitive damages. Mr. Ackerman is not presenting any testimony on whether or not it's appropriate to award punitive damages in the first part of his testimony. So I'm not sure why punitive damages is any reason for --I suppose the point I'm trying to make is I don't understand why punitive damages provides any basis for having Mr. Buchanan sit in. THE COURT: So he is going to be testifying about the proposed amount --What is he going to be testifying to with regard to punitive damages? MS. NELSON: Tomorrow? Nothing. That's my understanding of how this is unfolding. Maybe I've misunderstood this. MS. DIXON: Your Honor, I apologize. If I can just interject quickly because I was working a little bit on this more recently because Ms. Nelson has several witnesses today. What we understood in speaking with defense counsel was, we've never seen any information, current

1 information about the current financial condition of the 2 company. It's not -- it's not been produced. 3 So we understood that we would discuss 4 whether Mr. Krombach, the CFO of the company, would either provide the information or testify briefly about it, or 5 somehow we would stipulate just to a simple document that 6 7 explains the current financial condition of the company. But 8 other than that, the analysis as to punitives will be argued 9 in closing, but we don't have the information from the CFO or 10 from the defense counsel about that right now. 11 So it's not Mr. Ackerman necessarily who will 12 be testifying as to the amount. 13 THE COURT: So Mr. Ackerman will not be testifying 14 about net worth? 15 MS. DIXON: That is correct -- well, as far as I 16 understood, he doesn't have the current updated information 17 to be testifying as to it, but --18 MR. GOMEZ: Can we confer one second? 19 THE COURT: Well, I don't really need to get into 20 the nitty-gritty about who you plan to put on for what issue, 21 but let me just say that typically I will allow an expert to 22 sit in on another expert's testimony. And the rule applies 23 to both sides. 24 MS. NELSON: Fair enough, Your Honor. 25 THE COURT: All right?

1	MR. PERSSON: Thank you, Your Honor.
2	THE COURT: Anything further? If not, then we
3	will recess until the jurors arrive.
4	COURT CLERK: This Court is in recess.
5	(Recess taken)
6	(Following held in the presence of the jury)
7	THE COURT: Good morning, ladies and gentlemen of
8	the jury.
9	THE JURY: Good morning.
10	THE COURT: All right. Mr. Margulies, are you
11	ready to proceed?
12	MR. MARGULIES: We are, Your Honor. The
13	defendants would call Dr. Peter Fisher.
14	THE COURT: All right.
15	COURT CLERK: Please step forward this way.
16	Please raise your right hand.
17	Do you swear or affirm that the testimony
18	you're about to give in the case now before this Court will
19	be the truth, the whole truth, and nothing but the truth, so
20	help you God?
21	THE WITNESS: I do.
22	COURT CLERK: You may be seated.
23	THE WITNESS: Thank you.
24	COURT CLERK: Please state and spell your full
25	name for the record.

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THE WITNESS: My name is Dr. Peter Antony Goodwin Fisher. Antony is spelled without an H, Fisher, F-i-s-h-e-r. DEFENDANT'S WITNESS, PETER A.G. FISHER, SWORN DIRECT EXAMINATION BY MR. MARGULIES: Good morning, Dr. Fisher. Q. Α. Good morning. Would you tell the jury please your educational Ο. background. I am a doctor. I'm an MD in the UK. In fact, Α. Yes. we call it an MBD, a different name. But I'm a doctor. I'm a fellow of the Royal College of Physicians, which is to say that I'm a senior physician. Membership of the Royal College of Physicians means that you're board certified. Fellowship is a higher level, by election, implying that you're respected -- elected by your peers. I'm a graduate of Emmanuel College Cambridge University, our leading university. Emmanuel College is in fact the alma mater of John Harvard who founded Harvard University. So I'm a graduate. My primary medical degree is from the University of Cambridge. And it says bachelor of medicine, bachelor of surgery. Ο. Is that the equivalent of an MD degree here in the U.S.? Α. Precisely. Talk to me a little bit about Cambridge. We've heard 0.

- 1 of Cambridge and Oxford. Is that kind of like the Harvard,
- 2 | the original Harvard and Yale?
- 3 A. Yes, Oxford and Cambridge -- well, I think Cambridge
- 4 is the better, but they run very close. They're certainly
- 5 | the two leading universities in the UK and in the top ten
- 6 universities in the world.
- 7 Q. And I would assume their football teams use a round
- 8 | ball, right, not an oblong --
- 9 A. All kinds of balls.
- 10 Q. Thank you. Dr. Fisher, I would ask you to turn to
- 11 Exhibit 1041 that's in the black binder in front of you.
- 12 There should be a tab 1041.
- 13 A. Oh, 1041. Yes.
- 14 Q. Do you recognize that document?
- 15 A. Yes. This is -- wait a minute. Excuse me one moment.
- 16 Yes. Sorry. Yes. Yes, this is my curriculum vitae.
- 17 MR. MARGULIES: Your Honor, defendants would offer
- 18 Exhibit 1041 into evidence.
- 19 MS. NELSON: No objection.
- THE COURT: It is admitted.
- 21 (Exhibit No. 1041 received in evidence)
- 22 BY MR. MARGULIES:
- 23 Q. Thank you, Dr. Fisher.
- I want to talk a little bit more about some
- 25 of your experience, and I've put up on the screen some of

Hospital for Integrated Medicine.

- 5 Is that --
- Are you currently the clinical director at
- 7 this hospital?
- 8 A. No. I resigned that post in January of this year, but
- 9 I was for 17 years.
- 10 Q. What is the Royal London Hospital for Integrated
- 11 Medicine?

- 12 A. The Royal London Hospital for Integrated Medicine is,
- as the name implies, a hospital specializing in integrated
- 14 | medicine, meaning can bring together the best of conventional
- 15 and complementary medicine.
- 16 It is part of University College London
- 17 | Hospital NHS Trusts, which is a large hospital group, one of
- 18 | the leading academic medical centers in the UK. It has eight
- 19 hospitals of which we are one.
- 20 Q. Is this a government-run hospital?
- 21 A. Indirectly. It's part of the National Health Service,
- 22 | so ultimately it is funded by taxpayers' money although it
- 23 has a considerable degree of autonomy.
- 24 Q. Is homeopathy practiced at the Royal London Hospital
- 25 for Integrated Medicine?

A. It is.

- 2 Q. What other types of medicine or practice is there?
- A. Well, a wide range of complementary medicines; for
- 4 instance, acupuncture, herbal medicine, nutritional
- 5 approaches, various psychological approaches. We -- spinal
- 6 manipulation, acupuncture, osteopathy, and chiropractic.
- 7 Q. Are you board certified in any specialties?
- 8 A. Yes. I am -- well, I'm -- the equivalent. In the UK
- 9 we call it on the specialist register. I am on the
- 10 | specialist register in respect of rheumatology and of
- 11 homeopathy.
- 12 Q. What is rheumatology?
- 13 | A. Rheumatology is the medical specialty concerned with
- 14 the treatment of rheumatic and arthritic conditions.
- 15 Q. Can you give us an example? Would arthritis be
- 16 something within rheumatology?
- 17 A. Yes, well, osteoarthritis. The commonest single
- 18 | condition is osteoarthritis. This is an extremely common
- 19 condition which, in fact, all of us will get probably if we
- 20 live long enough. That is the most common.
- 21 Personally I treat a lot of fibromyalgia.
- 22 This is a soft tissue condition, also very common effect, up
- 23 to five percent of the population, difficult to treat. So
- 24 | that is an area that I take a particular interest in.
- 25 Q. Are you also certified in homeopathy?

A. I am.

- Q. By whom?
- A. By the General Medical Council. I'm on the specialist
- 4 register of the General Medical Council.
- 5 Q. In your previous role from 1998 for 2015 as clinical
- 6 director at the hospital, what did you do?
- 7 A. Essentially I was responsible for the clinical
- 8 | services of the hospital to decide what services we would
- 9 provide, how we would provide them to ensure that they were
- 10 | adequately staffed, properly governed so that we knew that
- 11 | the work was a good quality, and so on.
- So I was responsible really to make sure that
- all of the clinical services were appropriate and of good
- 14 quality.
- 15 Q. What is a clinical service that you're referencing?
- 16 A. Well, one service that we introduced quite recently
- 17 | was for insomnia, sleeplessness. This is an extremely common
- 18 | condition, affects 25 to 30 percent of the population at any
- 19 one time, and for which the drug treatments are very
- 20 unsatisfactory.
- I think most family physicians are aware that
- 22 the drug treatments are short-acting. They may get you to
- 23 | sleep for a couple of hours, but then you wake up.
- 24 So this is an area where we can offer a lot
- 25 of assistance, including homeopathy but also psychological

techniques and a number of other things.

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So that was something that I introduced quite recently. We had to ensure that it was of good quality, evidence that it was properly governed. In other words, we were looking at, you know, that things were done correctly.

- Q. What did you do or what do you do as the director of research for the Royal London Hospital for Integrated

 Medicine?
- 9 A. Well, essentially direct our program of research, and
 10 our biggest current project is a clinical trial of
 11 acupuncture in cancer, not to cure cancer but to help with
 12 the side effects of cancer treatments.
- Q. Can you describe some of the other projects that have been undertaken under your leadership at the hospital.
 - A. Yes. Well, we've done meta-analyses of various topics. We have done clinical trials of homeopathy in fibromyalgia and rheumatoid arthritis. We have done a large-scale trial of acupuncture for chronic headache with a very positive result.
- Q. Thank you. And finally, it says you're a consultant physician at the hospital. What does that mean?
- A. It means I am one of the senior clinicians. We have,
 I believe, five consultant physicians, each of whom heads up
 a service. So I head up the rheumatology service.
- Q. And do you see patients as part of that?

A. Absolutely.

- Q. Do you treat patients with homeopathy or conventional medicine? Both?
- 4 A. I certainly treat with homeopathy and occasionally
- 5 | with conventional medicine. I certainly use my knowledge of
- 6 | conventional pharmacology very extensively but usually not to
- 7 | prescribe drugs but to stop drugs. Many patients come on
- 8 | very heavy drug regimes which are causing adverse effects,
- 9 and these modern drugs, they're much easier -- in general
- 10 much easier to start than to stop.
- So I spend a lot of my time working out how
- we can reduce people's excessively heavy drug regimes.
- 13 Q. Do you have information based on research or other
- 14 surveys or other means about why patients come to your
- 15 hospital?
- 16 A. Yes, we do. We've done large-scale surveys. The
- 17 | first one is that other treatments didn't work. The second
- 18 one is other treatment had adverse effects, side effects.
- 19 And the third one is personal choice. Those are the big --
- 20 | those are the three big motivations.
- 21 Q. And do you find that homeopathy, when you use it in
- 22 your practice, is effective in treating the patients that you
- 23 treat?
- 24 A. Yes.
- 25 Q. Your CV indicates you're a fellow of the Faculty of

1 Homeopathy? What is that?

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- A. The Faculty of Homeopathy is a body established by law in the UK to train, examine, regulate health professionals in the practice of homeopathy. So that means -- health professionals means doctors or pharmacists doing what
- So we train and examine and regulate health professionals in the practice of homeopathy within their domain of professional competence.

pharmacists do, veterinarians treating animals.

- Q. So you received your MD in 1975. When did you begin incorporating homeopathy into your practice as a clinician?
- A. I first used -- I suppose in the late 1970s, yes. I started to use it on a smaller scale. I have done it continuously -- it's been a continuous part of my practice
- Q. Thank you. Your CV indicates you're on the external advisory panel for the National Institute for Health and Care
- 18 Excellence. What is that?

essential role.

since 1986.

- A. The National Institute for Health and Care Excellence is an official body. It is established by the UK government essentially to advise the National Health Service on what treatments it should and should not use. That's its
- Q. You've served on World Health Organization's expert advisory panel on traditional and complementary medicine?

- 1 Yes?
- 2 A. Yes. That's correct.
- 3 Q. Okay. What was involved in that?
- 4 A. Well, the main current activity is the WHO, the World
- 5 Health Organization, has a strategy from 2014 to 2023
- 6 covering traditional and complementary medicine, indicating
- 7 | with a very strong endorsement from the Director-General,
- 8 Dr. Margaret Chan, saying that, you know, traditional and
- 9 complementary medicine is underused and has great potential.
- 10 | So my main activity in that respect is implementing the
- 11 recommendations of that strategy.
- 12 Q. And, Doctor, I understand you have a patient that most
- of us would know who she is. Who is that patient?
- 14 A. I am also physician to Her Majesty the Queen.
- 15 Q. And I understand she recently became the
- 16 | longest-serving monarch in the history of England; is that
- 17 | correct?
- 18 A. That's correct, more than 63 years.
- 19 Q. Thank you.
- Doctor, you currently serve as the
- 21 | editor-in-chief of the journal Homeopathy?
- 22 A. That's correct.
- 23 Q. Tell us what that journal is.
- 24 | A. Homeopathy is a journal, as the title implies,
- 25 | dedicated to homeopathy. It has been in continuous

- 1 publication since 1911, and I think I can say without 2 question it is the leading journal in the field. It is 3 listed in PubMed, which is the National Library of Health 4 database of publications. And so, yes -- and published between the faculty of homeopathy in Elsevier, and Elsevier 5 being a leading international publisher of scientific medical 6 7 and technical literature. 8 What types of articles are published in Homeopathy? Ο. 9 Mostly research, research on homeopathy including 10 clinical research, basic research, biological model research. 11 Are these articles peer reviewed? Q. 12 Α. Yes, absolutely. 13 Can you describe the peer-review process briefly for Ο. 14 us. 15 Well, a peer review is a process used I think by all Α. 16 respected medical journals, and it means you have a panel. 17 We have a database of some 400 people who have expertise in 18 the area. You know, in the particular method that was used, 19 they have expertise. They may or may not know anything about 20 homeopathy. In some cases they need to know about 21 homeopathy. In other cases you'd just want to know: 22 this method applied correctly? Did they use the correct 23 methods?
- 25 before they're actually published as well?

And as the editor-in-chief, do you review articles

- A. I have overall responsibility. So, of course, we -- I have always tried to send the articles to an odd number of reviewers because if you send it to an even number, you can be sure that you'll get one more publisher that no one would want. So at least you're guarantied a majority if you use an
- But, yes, the final decision is mine, but it

 is made on the basis, one can't possibly be an expert in all

 these areas, so it is made on the basis of what the peer

 reviewers say.
- 11 Q. In your -- and how long have you been the editor-in-chief of Homeopathy?
- 13 A. Since 1986.

uneven number.

- 14 Q. For how long have you been reviewing the scientific
- 15 | literature regarding homeopathy?
- 16 A. Essentially it's for the same time.
- Q. You serve on other advisory and editorial boards; is
- 18 | that correct?
- 19 A. That's correct.
- Q. What is the Cochrane Collaboration Complementary and
- 21 | Alternative Medicine?
- 22 A. Well, the Cochrane Collaboration is a very large
- 23 international collaboration across the world dedicated to
- 24 | evidence-based medicine and to reviewing evidence on all
- 25 kinds of areas, very, very large database where they look at

1 | evidence for, you name it, any kind of medical intervention.

- Q. And has Cochrane looked at homeopathic topics?
- A. Yes, absolutely it has.
- 4 Q. And have you done any of those?
- 5 A. I have been in all but two of them, I believe, yes.
- 6 Q. Thank you. Briefly -- there's a lot of your previous
- 7 appointments listed on the screen. Perhaps we could just
- 8 focus on a couple of them.
- 9 The third bullet, the clinical lead for NHS
- 10 Evidence, Complementary and Alternative Medicine. Can you
- 11 describe what that was?
- 12 A. Yes. This was a website which was run in fact by the
- organization we looked at just now, the National Institute
- 14 | for Health and Clinical Excellence, which is an official UK
- 15 government body. So it is a website dedicated to presenting
- 16 | the evidence around complementary medicine.
- 17 Q. And you were the lead on the National Cancer Research
- 18 | Institute Complementary and Alternative Medicine Clinical
- 19 | Studies Development Group, Disease Management Subgroup. What
- 20 was that?
- 21 A. Yes. So the National Cancer Research Institute is a
- 22 | large national organization. It's actually a confederation
- of a number of bodies, and they had -- well, they still do
- 24 | have a complementary and alternative medicine studies group,
- 25 and I was involved with that. I led part of it.

Q. There is a reference to being a member and deputy chair for an advisory board on the registration of homeopathic products by the Medicines Control Agency.

What is the Medicines Control Agency?

- A. The Medicines Control Agency is approximately the equivalent of the Food and Drugs Administration. It is a government body dedicated, as it says, to controlling medicines and medical devices.
- Q. And this is in the UK?
- 10 A. In the UK, yes.

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- 11 Q. And what were your responsibilities on that particular board?
- A. So this was a subcommittee of that board or still is a subcommittee, dedicated to advising on when the applications were made for registration of homeopathic products. We would take technical advice, have technical advisors to see is it prepared correctly, is the packaging correct, and, you know, are the technical aspects correct.

But then we would advise whether the claims they wish to make for the products were in line with the homeopathic literature. That was the main role.

- Q. Thank you. And then the second to the last bullet at the bottom, you were a member of the European Commission of Homeopathic Medicine Group. What was that?
- 25 A. This was set up by the European Commission in

- 1 Brussels. This is some time ago. This is now in the early
- 2 | 1990s. They brought in two directives on homeopathic
- 3 | medicines there which govern how homeopathic medicines can be
- 4 | licensed throughout the European Union. And they then wanted
- 5 a more detailed report, so we did a very full report which
- 6 was published, I believe, in 1996.
- 7 Q. Thank you. Let's talk a little bit about some of the
- 8 | clinical trial research that you've done. Have you done
- 9 clinical trials, randomized controlled clinical trials on
- 10 homeopathic medicine?
- 11 A. Yes, I have.
- 12 Q. And could you indicate by touching the screen in front
- of you which of the bullet points on our screen that's up now
- 14 | would be the publications that relate to such research.
- 15 A. So this one, this one, this one, this one, this one,
- 16 this one, this one (indicating). Yes. The others actually
- 17 | don't relate -- are randomized clinical trials but not of
- 18 | homeopathy. So the method is similar, but actually the
- 19 subject is not homeopathy.
- 20 Q. The first one you indicated, Fisher, An Experimental
- 21 | Double-Blind Clinical Trial Method in Homeopathy, what was
- 22 that study about?
- 23 A. This is a preliminary study looking at fibromyalgia.
- 24 | We looked at three different homeopathic medicines. It was a
- 25 | pilot study to see, one, whether this clinical trial that we

- were planning was feasible; and, two, which of the three different homeopathic medicines seem to work best.
- 3 Q. And is the second article, Effective Homeopathic
- 4 Treatment on Fibrositis, a report of the actual study?
- 5 A. Exactly. So we then focused on one particular
- 6 medicine and did that trial.
- 7 Q. And what were the results of that trial?
- 8 A. The results were positive. The results showed that a
- 9 particular homeopathic medicine called Rhus Toxicodendron
- 10 | improved the pain, sleep, and tender point counts of patients
- 11 with fibromyalgia.
- 12 Q. Was this a placebo controlled trial?
- 13 A. It was.
- 14 Q. The third bullet point is an article with Vickers as
- 15 | the lead author, Homeopathy for Delayed Onset Muscle
- 16 | Soreness. What was this trial about?
- 17 A. Well, this was a trial with some reports particularly
- 18 | from Norway, that a particular homeopathic medicine reduced
- 19 muscle pain after running a marathon.
- So we thought that was interesting and did
- 21 | some more work on that. So this study was actually -- this
- 22 | was not in marathon running. We had people doing bench
- 23 steps, stepping off benches, you know, until they got sore
- 24 | muscles or until they got delayed muscle soreness which came
- 25 | 36 or 48 hours later. And that seemed to be positive.

- 1 Q. Okay. And was this -- this was a placebo controlled
- 2 trial --
- 3 A. Yes.
- 4 Q. -- as the title indicates.
- 5 The next article is -- and again, Vickers is
- 6 the lead author -- Homeopathic Arnica 30X is ineffective for
- 7 | muscle soreness after long-distance running. Does that --
- 8 does the title of that article tell the story of that
- 9 particular study?
- 10 A. It does, and this was actually done in running. This
- 11 was done in the London marathon where we have large-scale
- 12 | studies on 500 participants.
- 13 Q. Randomized to arnica versus a placebo?
- 14 A. Correct.
- 15 Q. Okay. The next study is with van Haselen, R. Would
- 16 that be Dr. Robert van Haselen?
- 17 A. That's correct, yes.
- 18 O. And it's called a Randomized Controlled Trial
- 19 | Comparing Topical Piroxicam Gel with a Homeopathic Gel in
- 20 Osteoarthritis of the Knee.
- Can you -- is this a -- this is a placebo
- 22 | controlled trial?
- 23 A. No. This is a trial controlled against standard
- 24 | treatment, so this is a homeopathic gel versus piroxicam,
- 25 | which is a standard wide-used nonsteroidal gel. So it's

- 1 against -- not -- it's randomized but not against placebo,
- 2 against standard treatments.
- Q. What were the results of this trial?
- 4 A. The results showed that the homeopathic gel was just
- 5 as good, possibly better, and certainly safer.
- 6 Q. The next one is Fisher, A Randomized Control Trial of
- 7 Homeopathy and Rheumatoid Arthritis.
- 8 What was this trial about?
- 9 A. So this was a study looking at the effects of
- 10 | homeopathic treatment added on to patients who had poorly
- 11 | controlled rheumatoid arthritis.
- 12 Q. Was it placebo controlled?
- 13 A. It was.
- 14 | Q. And what were the findings in this study?
- 15 A. The findings really were that the method didn't work.
- 16 It was -- well, it was negative, but actually we had a very
- 17 | large dropout. Just about 50 percent of the patients dropped
- 18 out because they were poorly controlled and waiting to move
- 19 on to other treatments. So essentially what we found is that
- 20 | really it wasn't a very good method.
- 21 Q. And the final -- I'm sorry. The final bullet point
- 22 that you indicated was Fisher Homeopathic Pathogenetic Trials
- 23 of Acidum Malicum and Acidum Ascorbicum. Was that a
- 24 | randomized placebo-controlled trial of the effectiveness of
- 25 those remedies?

1 Α. Not of the effectiveness. This is a homeopathic 2 pathogenetic trial or approving. That means this is a basic 3 method of homeopathy where you'd find healthy volunteers, you 4 give them the substance of interest and see what symptoms 5 they get. 6 Q. Thank you. 7 You've also done what are called systematic 8 reviews? 9 Α. That's correct. 10 Q. Can you describe it to the jury? What is a systematic 11 review? 12 A systematic review means -- it's in the title, 13 really -- you review the literature systematically. So that 14 means upfront you decide: Okay, what are we going to look 15 at? What condition? What treatment are we going to look at, 16 and how exactly are we going to define that? 17 So you have to come up with a list of search 18 terms that you apply to the database, where you're going to 19 look for this name of the condition or some various synonyms 20 or contractions or acronyms and so on. You have to define 21 exactly how you're going to search your literature. 22 And then having searched it, what data -- you 23 then get your paper, you then decide, well, maybe this one wasn't. You then have exclusion maybe. All right. It looks 24

to be in the literature, but when we look at it more closely,

we see that it's not within -- not the thing we were looking at.

And then you have to define the list of criteria, define the list of things that you're going to measure and you're going to look at in the publication. So, what was the result? What was the number of patients? How good was it methodologically?

- Q. So, as an example, would a systematic review potentially be for homeopathic treatment for upper respiratory tract infection? Would that be a way of doing -- or something you might do a systematic review on?
- 12 A. Yes. Yes. Absolutely.
- Q. And then you -- what is it -- what is the -- what is the work product that you develop out of doing this review?
 - A. Well, so you have a publication or sometimes several publications which summarize the literature, you know, come to conclusions that you're on the whole, you know, the good quality study suggests that this treatment works for this condition under these circumstances but perhaps not in other people with slightly different conditions.
- Q. So the systematic review is, I guess, systematically reviewing published studies and coming to some conclusion about a general topic. Is that a fair summary?
- 24 A. Yes.

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Q. Okay. Have any of the systematic reviews that you've

done focused on the area of homeopathy?

A. Yes, several of them.

- Q. And can you indicate on the slide which of those would apply here.
- A. Well, the first one, this actually -- yes. So that
 was an overview from which actually a systematic review was
 extracted. That is actually not quite a systematic review
 itself, but the data we collected was used by a subgroup
 to produce a systematic review.

The second one is a systematic review of homeopathic, so let me show you this one of homeopathic pathogenetic trials. And this is -- this we went further. This was a similar publication. This is looking at the same data in a slightly different way.

We did systematic reviews of homeopathy in depression and in anxiety and in cancer treatments. So this is a Cochrane review. These are both Cochrane reviews, meaning they're very high quality. I think they're generally acknowledged as the highest quality systematic reviews.

And then some others and further studies.

This is the more recent one looking at the -- this is actually at this stage not a systematic review. It's an initial stage. It is finding the literature. We haven't yet analyzed it. And here we're starting to analyze it.

So this is a whole program of systematic

- 1 reviews, those two 2015 publications. Sorry, that's 2013;
- 2 | isn't it? The two recent publications, they were a part of a
- 3 comprehensive program of systematic reviews.
- 4 Q. Dr. Fisher, if I could turn your attention to the
- 5 circled bullet.
- 6 A. Yes.
- 7 Q. Is Mathie, et al., review entitled Oscillococcinum for
- 8 | Preventing and Treating Influenza and Influenza-like Illness
- 9 in the Cochrane database.
- 10 A. Yes.
- 11 | Q. We've heard a little bit about oscillococcinum in the
- 12 | course of this trial. What were the conclusions that your
- 13 systematic review reached about the effectiveness of
- 14 oscillococcinum?
- 15 A. There is some evidence that it's effective, but at
- 16 this stage it is inconclusive.
- 17 Q. Thank you.
- 18 | Can you describe for us what the key features
- of homeopathy are?
- 20 A. Yes. The main thing about homeopathy is actually in
- 21 | its name. "Homeo" in Greek means same or similar, just as in
- 22 | homogenized milk or homosexual means the same or similar.
- 23 Patho," as in pathology, means disease or suffering in
- 24 Greek.
- 25 So it is the treatment of same, like with the

1 like. Some people say it's like holding a mirror up to 2 nature. You're saying to the body, look, this is your problem. Your problem resembles the toxicity of this 4 particular substance. That is trying to give a message to the body about the nature of the disease it has. 5 We've heard a bit about Dr. Hahnemann in the 18th 6 Q. 7 century. Was Hahnemann the first to use this particular principle? 8 9 No. You can find this idea many times in many places 10 in the history of medicine. The first occurrence is actually 11 in the work of Hippocrates, what we call the Hippocratic 12 Code, because clearly they weren't all written by one person, 13 around 450 before Christ. So you can clearly find this idea. 14 You can find it in the works of Paracelsus, who lived around 15 1500. You can find it also in traditional oriental 16 medicines, both traditional Chinese medicine and Indian 17 medicine. Both have the use of very small doses of toxins as 18 stimulants. 19 0. Are homeopathic drugs thought to work like 20 conventional drugs to suppress symptoms? 21 Α. No. In a way it's the opposite. We talk about 22 the secondary action of medicine. So the primary action of 23 medicine is, if you take a blood pressure lowering drug, it 24 will lower your blood pressure obviously.

The secondary action is the body's reaction

to it, and it is very widely observed in -- for many drugs including blood pressure drugs. But if you stay on blood pressure drugs for a few weeks and then stop them abruptly, you'd get a rebound. In other words, your blood pressure is higher than it was at the beginning. This is also called rebound phenomenon or secondary action of drugs. It is actually not the action of drugs at all. It is the reaction of the body to the drug.

So they're very different things. You're not doing something directly. You're eliciting a reaction from the body.

- Q. What is the minimum dose concept in homeopathy?
- A. The minimum dose concept is the controversial part of homeopathy. The original homeopaths, which we're now back in the very early 1800s, used large doses, same sort of doses we use in contemporary medicine of the day and not surprisingly often had severe side effects. They used very large doses at that time and empirically gradually reduced their doses more and more and found they got better results. They got less of the initial effect and a bigger rebound.
- Q. And so is there a law of minimums or minimum dose in the world of homeopathy that says that the lower you go, the stronger the drug is?
- A. No, there isn't. I've seen such a thing quoted
 several times. I've never seen it referenced, which does not

1 | surprise me because it doesn't exist.

- Q. So what is meant in the world of homeopathy by the minimum dose, then?
- 4 A. Well, the smallest effective dose. So we do use this
- 5 thing called potentization whereby you dilute the medicine
- 6 | 1 in 10 or 1 in 100 and shake it vigorously and do that
- 7 repeatedly.
- 8 Q. Do you have an opinion as to whether homeopathy is an
- 9 effective treatment method?
- 10 A. I believe it is.
- 11 Q. Okay. And what are the bases for that opinion?
- 12 A. There are three main bases for that. So one is, you
- 13 know, you just sometimes say it doesn't work because it can't
- 14 | work; these dilutions cannot possibly work.
- And I agree. It does seem a little unlikely
- 16 | that these very high dilutions work. But what we can now
- 17 show is that the structure of water is altered by the
- 18 | homeopathic treatment method. Several, I think there's three
- 19 different methods at least, look -- use different physical
- 20 methods that show that for a long term, maybe even permanent
- 21 alterations of the structure of water caused by the
- 22 homeopathic preparation method.
- Secondly, we have biological research.
- 24 | That's to say research meaning cells in test tubes or animals
- 25 | which show effects on blood cells. You can take human blood

cells, test them in a test tube, and show quite consistent effects. You have now areas where multiple groups have shown the same effects.

And similarly with animals, again there are animal models -- we'll talk about one later on -- which consistently show effects due to homeopathic medicine.

And then finally the clinical research, which is in two main areas. One is controlled against placebo or against conventional treatment, rigorous control trials where we are saying, okay, here is homeopathy; here is either placebo or an alternative treatment. And we randomly assign so you don't know which patient is going to get which treatment, and we look at the outcomes.

And then also real world, which is more pragmatic. It says what happens if we add homeopathy into the mix, into the mix of medical treatment? What is the impact on medical treatment?

And the placebo effect, the placebo studies are mostly positive. The real ones, the real-world ones, are universally positive. They always show, as far as I'm aware, that adding homeopathy into the mix, into the available medical treatments, gives you better outcomes. They're either better outcomes or safer outcomes or one way or another better outcomes.

Q. Thank you. Let's now talk about some of these -- each

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of these three points. And I'll just ask you before we start. We're not going to cover the issue of hormesis, which will be discussed by Dr. Calabrese. But is that something that you also believe is consistent with your opinions? Yes. Hormesis is a related phenomenon. We will --Α. Some people sometimes say homeopathy is isolated. There is nothing like it. There is no other ideas That is not true. There are a number of concepts where you have reversed beneficial paradoxical effects from low doses of substances. Hormesis is perhaps the best known, but there are a number of others. And Dr. Bellavite tomorrow will also discuss some test Ο. tube in animal studies that you're familiar with that we're not going to discuss today. But my question is: Do you also rely on them for reaching your opinions? I do. Α. Okay. So let's talk about your first bullet, which was the physical research. We have a slide entitled Very High Energies are Generated by Succussion, and then two pictures. And perhaps you can explain to us what is in those two pictures. Yes. The reasons for putting this in, first of all, is that you might think succussion, which is this process of shaking. You just get your test tube and you shake it, mostly by a machine but you shake it vigorously, quite hard.

But you might think that's a fairly innocuous process and nothing very much is happening, but this shows that that is not the case.

So this is TEM, transmission electron microscopy, images showing nanoparticles of zinc. They're very small. You can see that's 200 nanometers, a nanometer being a millionth of a meter. They're very small particles. And what this shows is that this succussion process, what happens is you get micro, tiny bubbles, tiny vacuum bubbles which collapse, and that generates very high energies and the nanoparticles are propelled across the liquid at very high speed.

And what has happened here, this shows what has happened where two nanoparticles of zinc have collided, they have melted. You can see evidence of melting around there, which means that a temperature of around 800 degrees Fahrenheit has occurred. Very briefly, very localized, but very high energies are released by this process of succussion.

And there is a lot of -- there is no doubt that it does release very high energies due to so-called microcavitation. There is a lot of evidence of that. This is just one empirical example.

Q. So is this a picture of zinc that has been succussed to a 30C dilution?

1 Α. Yes. This is two particles -- yes, is being succussed 2 to 30C dilution, and two particles of zinc have collided and 3 melted. 4 And 30C is -- a C dilution is one part in 100; 5 correct? That's correct. 6 Α. 7 Q. So that's done 30 times? 8 Correct. Α. 9 Okay. This next slide, again, looks like a 10 complicated chart, and we're going to need help 11 understanding. It says: Low temperature thermoluminescence 12 signature of ultramolecular dilutions of NACL and LICL. 13 I think we've heard about NACL, and that's 14 table salt, sodium chloride. LICL is? 15 Α. Lithium chloride. 16 Another salt? Q. 17 Α. Yes. 18 And so what is this graph showing us? Ο. 19 Α. So this is again looking at the effects of this 20 process of succussion on the structure of water, and actually 21 you -- D20, which is deuterium oxide, which is heavy water, 22 because it gives a cleaner signal. That's why it's called 23 D20, not H20. 24 So what they do in this process, so here you

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have three different substances. So one is D20, 15CH.

1 | that's just plain water recurrently shaken.

- Q. 15CH would be 15 --
- A. That's one in 100, 15 times over.
- 4 Q. Thank you.

A. And the same thing starting off with sodium chloride and with lithium chloride, although by the time you get to 15CH, it has been diluted out. There's no more sodium chloride or lithium chloride left.

So you get these preparations and you freeze them to extremely low temperatures. So this is 70 degrees Kelvin, 70 degrees absolute. That's roughly minus 200 degrees Celsius, very, very cold. It's in fact the temperature of liquid nitrogen.

And then you bombard them with gamma rays, with hard radiation, and what that causes to happen is that the electrons, some of the electrons in the lithium and in the sodium chloride jump out of their ground state. And then as you warm it up -- so what you see along the bottom here, so this is -- starts at 70, so that's minus 200, and it goes up to minus 210 Kelvin, so that's about minus 60 Celsius.

This shows what happens as you warm it up, and it shows the emitted light. So what happens? As you gradually warm it up, it emits light. It emits literally a glow. That's what they mean by thermoluminescence.

And as you can see here, around 170, there

- 1 | are clear differences. So this is your -- the heavy water.
- 2 This is the -- sorry -- sodium chloride, and this is lithium
- 3 | chloride. The -- total amount of -- sorry. So, yes, I hope
- 4 you can see that.
- 5 The total amount of light emitted is
- 6 different, and the patent, the signal is also different. You
- 7 | have this little -- little hump here.
- 8 So there is a -- there is a clear difference
- 9 in the light emitted by these preparations.
- 10 Q. And I think you said at this particular dilution
- 11 level, you're not expecting to find any lithium or sodium
- 12 | chloride left; is that correct?
- 13 A. That is correct.
- 14 Q. Do you have an explanation for how these different
- preparations are emitting different light intensities and
- 16 | glows?
- 17 A. Yes. It has to be due to the structure of the water.
- 18 | Water is very extensively hydrogen bonded, so you have these
- 19 | little molecules, but they're all linked together. So it's
- 20 these changes to the structure of water which appear to be
- 21 mediated by tiny bubbles of gas.
- 22 Q. Okay. All right. One more complicated chart. What
- 23 | are we looking at here?
- 24 A. Right. So this is nuclear magnetic resonance.
- Nuclear magnetic resonance is essentially the same technique

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as is used in MRI scanning. You put your --
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I mean, if you're doing an MRI scanning, you put your head or whatever part of your body in a very intense radio frequency field. Here they put samples in the field, and they measure what is called the relaxation time.

So what happens in MRI, in nuclear magnetic resonance, is you excite the nucleus of -- well, you excite the nucleus, and then you measure the time that it takes to drop from its excited state back to the normal state. It emits a signal as it drops. And you're comparing the T1 and the T2, which is the horizontal and the vertical components of that signal --

13 O. So --

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- 14 A. -- for different substances here.
- 15 Q. So what is -- so we see this W over on the left side.
- 16 A. So this is plain water succussed, shaken water, and --
- 17 | no, I think this is just plain water. Sorry.
- 18 Q. All right. And over here MN --
- 19 A. This is a manganese -- MN is called -- MN is manganese
- 20 lactose, it's because it is initially triturated. That's to
- 21 | say it is -- because it's insoluable, it is ground up with
- 22 lactose and then suspended.
- 23 Q. And then here SAL, what is that?
- 24 A. That is saline.
- 25 Q. All right. And is that also succussed?

- A. That is succussed.
- 2 Q. And this is HIST?
- 3 A. Histamine, again succussed.
- 4 Q. And here S/L, what is that?
- 5 A. This is silica and lactose. Again, this is silica
- 6 vigorously -- first of all triturated, ground up, and then
- 7 suspended.

- 8 O. And --
- 9 A. And the point is you can now -- these are in the
- 10 ultra-molecular range, and you can see the difference.
- 11 Q. What do you mean by the ultra-molecular range?
- 12 A. The ultra-molecular range means they're diluted to
- 13 | the extent that there is little or no -- well, there's no
- 14 | substance of the original molecule, the original substance
- 15 persisting.
- 16 Q. And do you have an explanation or an understanding as
- 17 to how you would get a different result on the NMR for each
- of these compounds as we see in this particular chart?
- 19 A. Well, the -- yes. The explanation seems to be
- 20 consistent with the one we saw before, the
- 21 | thermoluminescence, that it is due to alterations of the
- 22 structure of water and that it does seem to be mediated by
- 23 tiny bubbles of gas.
- Q. Okay. So we've seen the pictures in the electron
- 25 | microscope. We've seen the NMR in this slide, and

the thermoluminescence in the prior slide.

2 What is this next slide showing us?

- 3 A. This is some work done by Medica Victoria earlier, was
- 4 based in Naples in Italy, who is looking at a fairly simple
- 5 measure, which is the specific conductivity of homeopathic
- 6 dilutions. So here --
- 7 Q. What is -- before you go on, what is specific
- 8 | conductivity?
- 9 A. Conductivity is basically how well it conducts
- 10 | electric.

- 11 Q. Okay. Please continue.
- 12 A. So this is the red line. This is what you would
- expect, and this is what you find with these homeopathic
- 14 dilutions. It is consistently above the line.
- 15 Q. So the red line is what -- what physics would tell you
- 16 is the answer?
- 17 A. Yes, is the predicted line, and you get higher
- 18 | specific conductivity.
- 19 Q. And what is the chart on the right describing?
- 20 A. The chart on the right shows the change in specific
- 21 | conductivity over a period of time, over something like two
- 22 years. And strangely it increases. This is very unexpected,
- and the thought is that this is due to what we call
- 24 dissipative structures.
- 25 A dissipative structure is, if you like, like

a hurricane. It is a structure which is energetically very different from its environment. Clearly a hurricane is very different from the surrounding air, and it is constantly exchanging matter and energy with the surrounding environment.

So the idea is that somehow this process creates these dissipative structures, these structure within the water that persist for a long time.

- Q. Is there experimentation going on now about the transmission of DNA information?
- 11 This is the -- the remarkable work of Luc Α. Yes. 12 Montagnier, Luc Montagnier who's got the Nobel Prize for the 13 discovery of HIV along with Gallo in 2008, and he has 14 published now a series of papers saying that essentially that 15 he takes certain bacteria -- only certain pathogenic bacteria 16 and viruses. He then shakes them up. He prepares them in the homeopathic manner, ultrafilters them, dilutes them to 17 18 way beyond the point of which any of the original substances 19 could be present, and then finds that they have -- they can 20 regenerate. They can have effect on the DNA. They can carry 21 over the DNA of the viruses and the bacteria that they were 22 originally prepared from.
- Q. And are these -- I think you said these are prepared in the homeopathic way?
- 25 A. Yes.

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- Q. Why don't we turn from some of the physical research to talk a little bit about some of the studies in the test tube.
 - A. All right.

Q. Can you discuss the next slide -- pardon me.

6 Has there been research done on the effects
7 of aspirin in homeopathic preparation?

A. Yes. So aspirin is used in conventional medicine as an anti blood-clotting agent. There are probably people in this room who are taking aspirin every day to reduce the risk of heart attacks or strokes. Very commonly used. It makes the blood less likely to clot. But we know that actually in high dilution, 15C dilution of aspirin, has the opposite effect. It increases blood clotting.

What's more, we are starting to understand the mechanism by which this works. So it has been shown that it is due to an enzyme called COX-2, cyclooxygenase-2, and it can be shown by conventional pharmacological methods. But this increasing of the blood clotting is somehow mediated by cyclooxygenase-2. So this is just beginning to understand how these things might work.

- Q. Dr. Fisher, how many or approximately how many studies do you know have been done in-vitro, you know, animal-type studies of homeopathy and homeopathic agents?
- 25 A. Quite a large number. The -- well, it depends

- 47 1 exactly what you mean. There is a systematic review of --I don't know if we have it. Do we have it? 2 3 Yes. Here it is. This is the in-vitro, 4 that's to say test tube. 5 I'm sorry. I meant animal -- I meant in-vitro. Yes. Thank you. So this is in-vitro, meaning in 6 Α. 7 glass test tube experiments, a systematic review, so they define exactly what they were looking for and they found 75 8 9 publications of which 33 were replications. The quality 10 assess them by this score, and they showed that 73 percent 11 showed an effect with dilution, including 68 percent of the 12 high quality ones, and also that the majority of replications 13 were positive. 14 This mentions in-vitro evidence of the effect of Ο. ultra-molecular dilutions. Those are the ones that are beyond the level that you would expect to find any molecules present; correct?
- 15 16 17
- 18 Correct. Α.
- 19 0. And have there also been in-vitro studies below that
- 20 level?
- 21 Α. Yes, many. Yes.
- 22 Thank you. Now let's turn a little to some of the Ο.
- 23 animal studies.
- 24 Α. Yes.
- 25 Perhaps you can describe the study on the thyroxine in Ο.

frogs.

A. Yes. So this is about amphibian metamorphosis, which sounds very complicated but it's just a process of a tadpole becoming a frog. Metamorphosis means, you know, that the tadpole becomes a frog. This process is metamorphosis. It's dependent on the hormone thyroxine, which we all have in our bodies, very widespread hormone in nature. And normally it requires thyroxine, this process of metamorphosis simply won't happen without thyroxine.

But this shows the high dilutions of thyroxine has the opposite effect. So here they're looking at different things. So the blue bars here are looking at one of the measures of metamorphosis, which is when they develop four legs as opposed to the two they have as a tadpole.

This is of the original researchers, and this is independent groups, all showing inhibition. They -- it slows down the speed of metamorphosis, the rate at which the animals metamorphose from tadpoles into frogs.

- Q. Thank you. Let's turn to the next slide. Hypericum and nerve transsection. What is this slide describing?
- A. Well, hypericum is an herb used in homeopathy typically for nerve injuries, and what they're showing here is that it appears to increase the rate of healing of nerves, of the sciatic nerve to be precise.

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                      So this is what happens. Here they're
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      looking at the axonal vine, the size of the nerve fibers.
                                                                   So
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      this is the control. As you would expect, nothing is
 4
      happening here because the nerve wasn't damaged.
 5
                      This is what happens without treatment; this
      is what happens when you add homeopathic hypericum.
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                      As you can see, it makes a big difference.
 8
      So they go back almost to normal within 12 weeks, so that is
 9
      a big difference. It may have practical implications in
10
      nerve healing.
11
             And just so we're clear, the normal, the none --
      Ο.
12
      the -- the nerve that's not been damaged, is the top line;
13
      correct?
14
      Α.
             Yes.
15
             It's the one up top.
16
             Yeah.
      Α.
             And the bottom line is the one -- it's a placebo
17
      Ο.
18
      controlled or control with no treatment?
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      Α.
             Yes.
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             And the middle line is the treatment.
      Q.
21
      Α.
             Exactly.
22
             Okay. Thank you.
      Ο.
23
                      The next line discusses anti-arthritic action
      of Rhus Toxicodendron. What is Rhus Toxicodendron?
24
25
             Rhus Toxicodendron is in fact poison ivy.
      Α.
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- 1 Q. Okay.
- 2 A. And it is traditionally used in homeopathy for various
- 3 kinds of arthritis and rheumatism, and a series of groups
- 4 have shown that it reduces not just the inflammation in the
- 5 damaged joint, but often you get what we call secondary
- 6 lesions or the damaged joint, but others come out and
- 7 typically other joints get affected.
- 8 It reduces the inflammation in both the
- 9 damaged joint and the other joints and improves the weight
- 10 gain and improves various tests, blood tests and radiological
- 11 tests. And this has been shown actually by different groups,
- 12 the group in India, Patil, but also Santos in Brazil.
- 13 Q. And these are actually using rats, and they're
- 14 | treating arthritis with the poison ivy, with the Rhus
- 15 Toxicodendron?
- 16 A. Yes.
- 17 Q. Okay. Thank you.
- 18 So let's turn now --
- 19 And there are more animal studies than the
- ones you've selected to talk to us about today?
- 21 A. Yes. Yes. Absolutely.
- 22 | O. Describe for us what the state of the literature is
- 23 | currently on clinical trials for homeopathy.
- 24 | A. Okay. So this stage is taken from something called
- 25 | CORE-Hom. CORE-Hom is a database maintained by the Carstens

1 Foundation in Stuttgart in Germany. 2 Karl Carstens actually was the president of Germany, West Germany in the 1970s, and he endowed this 3 4 foundation. 5 And they have a number of very good This is their database on clinical trials of 6 databases. 7 homeopathy. 8 When I looked at it about six weeks ago, 9 there were, as you can see 1,117 clinical trials of 10 homeopathy, of which nearly 300 were randomized controlled 11 trials, and you got the listing of -- and so this was 12 individualized homeopathy. In other words, a doctor saw the 13 patient, prescribed homeopathy, and the patient then got what 14 the doctor prescribed or placebo. 15 There were some others which looked 16 individualized versus the standard treatment, and then there 17 were some others which looked at non-individualized 18 homeopathy. So mostly that means a complex, a mixture used 19 for a particular diagnosis against placebo, and also a number 20 which looked at non-individualized versus standardized 21 treatment. 22 So non-individualized or complex, would that be Ο. 23 similar to the products that we have been discussing in this 24 case? 25 Α. Mostly, yes. Yes.

- Q. Okay. And how do they shake out in terms of whether they show an effect or not?
- 3 A. Well, roughly 45 percent are positive. Roughly 45
- 4 percent are inconclusive. Very often that's because the
- 5 trial isn't big enough or for one reason or another you can't
- 6 draw a firm conclusion. Very few were negative.
- 7 Q. Have there been systematic reviews and what are called
- 8 meta-analyses of homeopathy?
- 9 A. There have been, yes.
- 10 Q. What is a meta-analysis? You've told us what a
- 11 systematic review is. What's a meta-analysis?
- 12 A. Well, a meta-analysis really is one step beyond the
- 13 systematic review. So in a systematic review you collect of
- 14 | the information and decide how you're going to analyze it.
- In a meta-analysis you take the actual
- 16 | numbers, you crunch the numbers, you get the numbers, and
- 17 | boil them down to see what is the overall statistical
- 18 conclusion.
- Sometimes you can't do it because they're
- 20 incommensurable. You can't compare apples and pears. But
- 21 | when you can, then you can do a meta-analysis which gives you
- 22 a number.
- 23 Q. So this would be like treating a number of studies all
- 24 | as one big study and analyzing all of the data as if it were
- 25 one study?

- A. That's correct. Yes.
- 2 Q. What do these systematic reviews and meta-analyses
- 3 tell us?

- 4 A. Well, we've got here two main groups. One is
- 5 | homeopathy as a whole; in other words, homeopathy for all
- 6 conditions. And that may be a bit arguable in that you could
- 7 | say, well, you know, you've got incommensurable conditions,
- 8 but it can be done I think if you define exactly what you
- 9 | want to do, if it's legitimate. There are a total of four of
- 10 those, three as being positive and one as being negative.
- 11 Q. Okay. And you say that there are -- strike that.
- 12 Are there systematic reviews on specific
- conditions within homeopathy?
- 14 A. Yes. We've listed them here. The area that's really
- 15 | strongly positive is allergies and upper respiratory tract
- 16 infections and rhinitis -- this whole area of upper
- 17 respiratory tract, cough, cold, hay fever, that sort of
- 18 | thing. There is now, if you look at that all together, five
- 19 systematic reviews. There's a number of other areas. This
- 20 is not a comprehensive list, but we will look at some of
- 21 those.
- 22 | O. Thank you. So let's take a look at one of these
- 23 | meta-analyses that you mentioned. This is Linde.
- 24 A. Yes.
- 25 Q. Can you describe for us what we're seeing on the

1 screen right now.

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A. It looks very complicated, but actually it's not quite as complicated as it looks.

So here in this first column here, it just tells you what study we're talking about. It gives the name of the author and the number of the reference. This tells you the number of patients -- whoops --

That one tells you the number of patients.

This tells you the quality. This tells you the disease that's being treated. This tells you the treatment that was used, and this tells you what was measured. And this gives you the overall conclusion.

So this dotted line here that's marked one, I can't get -- anyway, there is one down at the bottom here, means there is no difference.

- Q. Let me see if I can't -- this line right here?
- A. That line, that is what is called an odds ratio. So that means the chances of homeopathy benefiting the patient are equal to the chances of placebo benefiting the patient.

 Anything on the right here means that homeopathy is better.
- 21 Anything on the left means the placebo is better.
- Now, as you can see, most of them form on the right. So this is the average value. This is what we call the 95 percent confidence interval.
 - Q. So the average value would be the little circle?

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placebo.

A. The little circle, and the bars are, you know, we can be 95 percent certain statistically that the real answer is between there and there.

So this top one for instance is the clear

positive. So this one, for instance, is a clear positive.

The average is on the right of the line, and the 95 percent confidence interval do not include one. This one, for instance, shows a positive trend. It is on the right of the line, but the 95 percent confidence intervals do include one. So we can't be absolutely certain that it's positive.

- 11 Q. Were these all of the studies that Linde looked at in this meta-analysis?
- A. No. I could show you another table which looks very similar to this. This is a two-page thing.
- Q. Okay. And what were the conclusions that Linde reached in his meta-analysis?
- A. So what they did then is to boil this down to a single number, which is here, the one single number. So you can see well on the right of the line with narrow confidence intervals. Essentially what that says is that homeopathy is two to three times as likely to benefit the patient as is the

And then they did what is called a sensitivity analysis. Sensitivity analysis simply means that you look at the same data in slightly different ways and see

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      if you get a different conclusion from looking at it in a
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      different way.
                      So they looked at --
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                      So this is for instance the high quality
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      studies, and they looked at them in different ways. This is
      the worst case scenario. The bottom line is any way you look
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 7
      at it, it stays positive. This is what we call a robust
      result, meaning that any way you look at it, it stays
 8
 9
      positive.
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                      And then they also looked at different kinds
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      of homeopathy. So here you have the different kinds of
12
      homeopathy, including at the bottom here complex homeopathy,
13
      which is -- I'm sorry. That's not very accurate. Let me
14
      just clear that one. Let's try it again.
15
                      So this one at the bottom here, yeah, which
16
      is complex homeopathy, which is the kind of thing we're
17
      discussing here in this trial.
18
             How many studies did Linde include in his
19
     meta-analyses overall?
20
     Α.
             89.
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      Q.
             Thank you.
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                 MR. MARGULIES: Your Honor, I don't know in terms
23
      of timing for our break whether this is a good time or if the
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      Court wants to keep going. I'm okay either way.
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                 THE COURT: How much time do you expect to have
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with Dr. Fisher more?
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                 MR. MARGULIES: Maybe 20 minutes to half an hour.
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                 THE COURT: Okay. Why don't we take a brief break
      and return at 11:15.
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                 (Recess taken.)
                 (Following held in open court and in the presence
 6
 7
      of the jury.)
 8
                 THE COURT: You may proceed.
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                 MR. MARGULIES:
                                 Thank you.
10
      BY MR. MARGULIES:
11
             Dr. Fisher, we were talking about recent -- or we were
      Ο.
12
      talking about meta-analyses and systematic reviews, and the
13
      next slide focuses or discusses the Mathie review from 2014
14
     or the meta-analysis.
15
                      What are we seeing on this particular slide?
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             Yes. This is the most recently published
      Α.
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      meta-analysis published only last December, December 2014,
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      and it is looking at the influence of the quality of the
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      study on the outcome. So again, you have in the middle here
      an odds ratio of --
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             I don't know if that pen is any better than your
22
      finger. Maybe not.
23
            Yeah. Let's do that again. Wait a minute. Let me
      Α.
24
      try.
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                      That line there just to the left, that is the
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line one. That means the chances that placebo will benefit the patient are equal to the chances that homeopathy will benefit the patient. Anything to the right means homeopathy is better.

And they took, I believe, 32 studies and then gradually filtered them down to the highest quality one. So at the bottom you have the highest quality ones, only three at the bottom. Starts off with 32 at the top; it's down to three at the bottom.

And as you can see, it does not really make a difference to the conclusion. The bars get wider. This bar gets wider because you have smaller number of patients, but actually the mean result doesn't get any worse. If anything, it gets slightly better as the quality improves. So the quality of the study does not make a difference to the conclusion.

- Q. Dr. Fisher, you had indicated earlier there were almost 300 randomized controlled trials. Why is Mathie only looking at 32 here?
- A. Because these are looking at trials of individualized homeopathy of good quality.
- Q. When you say individualized, this is the treatment by a homeopathic physician verus placebo?
- 24 A. Exactly.

25 Q. Okay. Thank you.

And the conclusion that was reached by Mathie based on this analysis was that --

- A. That trials, even the highest quality trials, yield positive results, because generally actually you expect the results to become less positive as quality improves, and that is not the case as it happens here.
- Q. Now, we've heard a little bit about the Shang
 meta-analysis that was published in 2006. You're familiar
 with that one as well?
- 10 A. I am.

- Q. What did the Shang group do? How did they do their meta-analysis?
 - A. Well, this is a meta-analysis published in a very prestigious medical journal, the Lancet. What they did is they took 110 clinical trials of homeopathy and matched them with 110 clinical trials of conventional medicine, and they matched them by diagnosis, by number of patients, and so on.

They then reduced that to higher quality trials. And the first thing to notice here is that of the 110, 21 of the homeopathic trials were of higher quality but is only 9 of the conventional trials. In other words, homeopathic trials compared to similar trials of conventional medicine are more likely -- more than twice as likely to be of high quality.

They then reduced it further to eight and six

- 1 larger higher quality trials and came to an essentially
- 2 | negative conclusion, that homeopathy doesn't work but
- 3 | conventional medicine does.
- 4 Q. So they started with 110 trials, and they ended up
- 5 | with eight; is that correct?
- 6 A. That's correct.
- 7 Q. And they based their conclusion on all of homeopathy
- 8 based on eight trials of homeopathy versus six trials of
- 9 | conventional medicine?
- 10 A. Yes, eight anonymous trials of homeopathy. We don't
- 11 know which trial -- at the time that it was published and
- 12 indeed when the very critical correspondence was published,
- we did not know which eight trials they were talking about.
- 14 Q. So what are we seeing on this next slide? Can you
- 15 describe --
- 16 Are these graphs from the Shang study?
- 17 A. These are taken from the Shang study, and as you can
- 18 | see, they look completely different. That is the right way
- around. As you can see, they're very similar. You have a
- 20 | couple of large -- so these are large scale.
- 21 Q. What are we seeing?
- 22 A. This is a scatter plot looking at the odds ratio
- again, the chances that homeopathy or conventional medicine
- 24 | will help the patient versus the chances the placebo will.
- 25 So this is the odds ratio again except it

- runs the opposite way. So this side on the left here is positive, and this is trial size.
- 3 So what you have here is -- let me just --
- 4 hang on.
- 5 Q. The trial size is this axis and effectiveness is the
- 6 bottom?
- 7 A. Exactly. So what you have here is, you know, the bulk
- 8 of the trials in both cases fall around here, fall in this
- 9 area, and they look very similar. You just have a couple of
- 10 | very large, very positive trials of conventional medicine
- 11 down there in the bottom left.
- 12 Q. And what conclusions did you draw from looking at
- 13 | these particular charts?
- 14 A. The result -- and indeed -- well, the results are very
- 15 | similar. If you look at the standard arrows, they are indeed
- 16 very similar. It's very difficult.
- So this is the whole 110 studies. It is very
- 18 | difficult looking at that to believe that there is really a
- 19 difference between those two data sets.
- 20 Q. Do these data, looking at all 110, support the
- 21 | conclusion that Shang reached that homeopathy was not
- 22 effective?
- 23 A. Well, we don't know because they didn't analyze the
- 24 | whole 110. They didn't even analyze the high quality ones.
- 25 | They only analyzed the larger higher quality studies.

- Q. And what were those studies?
- 2 A. Well, as I said, we didn't know at the time. It's
- 3 only eight of them. They didn't put the references in the
- 4 paper. They had a web appendix; they didn't put them in the
- 5 web appendix.

- This kind of behavior would not be tolerated
- 7 | in a court of law in any civilized country. You're condemned
- 8 on the basis of evidence that is concealed, and I do say
- 9 concealed.
- 10 Not just did they not include the references,
- 11 but they didn't say the name of the first author, the
- 12 | condition, the number of patients.
- I know the literature well. My colleagues
- 14 | know the literature well. If they had told you the number of
- 15 | patients, if they had told you the diagnosis, we would very
- 16 quickly have known what trials we were talking about.
- 17 Q. So I've gone back to our Linde slide. Did Shang give
- 18 | us a slide like this telling us which of these studies were
- 19 for what purpose and were included in the analysis?
- 20 A. Absolutely not. This is the huge contrast. Shang is
- 21 | extremely transparent -- sorry. Linde is completely
- 22 transparent, tells you exactly which trials you're talking
- 23 | about. Shang gives you no clue to which trials he's talking
- 24 about.
- 25 Q. So when they went down from 21 to eight, and nine of

- 1 | the regular conventional medicines to six, did they -- is
- 2 that something they decided to do when they -- when they
- 3 designed this particular study?
- 4 A. No. They didn't. It was done post-op, as we say. So
- 5 what they intended to do was to look at the high quality
- 6 studies.
- 7 Q. Those were the 21 and the nine?
- 8 A. Exactly.
- 9 Q. Did they do any analysis at all of what they said they
- 10 were going to do, which is the 21 and the nine?
- 11 A. They did not, although it has been done subsequently
- 12 by other groups.
- Q. And what have those subsequent analyses shown?
- 14 A. They show that homeopathy is indeed effective.
- 15 Q. You said one of your criticisms is there is no
- 16 sensitivity analysis. What do you think should have been
- 17 | done by the Shang group?
- 18 A. Well, they could have looked at, for instance, the
- 19 | whole 110, the 21 and nine high quality. They could have
- 20 looked at them by different diagnoses. There's a lot of
- 21 different things that not just could have been done but
- 22 | should have been done.
- 23 Q. Were there guidelines for this type of research that
- 24 | applied at the time to this publication?
- 25 | A. Yes. The quorum quidelines should have been applied.

1 Actually the quorum guidelines have now been superseded by 2 something called PRISMA, but it didn't conform to the 3 quidelines that were in force at the time. What types of things would those guidelines have 4 5 required? 6 Well, they gave no descriptive data. You had no idea, Α. 7 absolutely none. You don't know what the diagnosis was, how 8 much patients, what kind of treatment was applied. You don't 9 know if it was homeopathy or what kind of homeopathy. 10 They didn't summarize the results. They 11 didn't look at external validity. External validity means, 12 you know, what does this mean in the real world. 13 Thank you. Was there -- strike that. 14 Based on your criticisms of the Shang 15 meta-analysis, do you find that it is useful at all in 16 answering the question about whether homeopathy is effective? 17 I think it is deeply flawed. I think there is 18 only one firm conclusion that can be drawn, which is that 19 homeopathic trials are more likely to be high quality than 20 trials of conventional medicine. 21 Thank you. Let's talk a little bit about --0. You had indicated earlier there were 22 23 systematic reviews and meta-analyses for particular --24 homeopathy in particular conditions?

25

Α.

Yes.

- Q. Can you describe what some of those are for us.
- 2 A. Yes. Here we have a list. This is not a
- 3 | comprehensive list. There are a number of others, but it's
- 4 edited highlights, if you like. So, for instance, childhood
- 5 diarrhea done by Jennifer Jacobs -- we'll have a look at that
- 6 in a bit more detail I believe in a moment -- rheumatic
- 7 diseases.

- 8 But where it's really strongly positive is
- 9 this whole area of allergies, seasonal allergic rhinitis,
- 10 | which means hay fever essentially. So you have those two.
- 11 Upper respiratory tract infections and allergy, and again
- 12 upper respiratory tract infection.
- So this area of allergies, hay fever, upper
- 14 | respiratory tract infections, there is a considerable body of
- 15 evidence which is positive.
- 16 | Q. And again we have about ten systematic reviews in
- meta-analyses listed here. So those would incorporate many
- 18 studies within each of them; correct?
- 19 A. Multiple studies, yes.
- 20 Q. Okay. And there are more systematic reviews and
- 21 | meta-analysis that you didn't put on the screen?
- 22 A. This is not on this list, no.
- 23 Q. Okay. Thank you. Let's take a look at one of these
- 24 | systematic reviews. What is this next slide talking about,
- 25 | isopathy for respiratory allergies?

- A. So this is one of the studies which was mentioned in the previous slide.
- 3 So isopathy means treating the same with the 4 same.
- 5 Q. How is that different from homeopathy?
- 6 A. They are prepared, so it is prepared in the same way.
- 7 They use homeopathic medicines. If you like, it's a
- 8 | simplified form of homeopathy. It is very attractive for
- 9 doing research because it takes away the individualization.
- 10 You just work out what the patient is
- 11 allergic to by the conventional means by skin testing or
- 12 | blood testing and then give them the allergin, the thing that
- 13 they're allergic to in a homeopathic dilution.
- 14 Q. And what were the results of this systematic review?
- 15 A. Here we have four different studies, two in hay fever,
- one in asthma, and one in perennial rhinitis. In hay fever
- 17 | obviously the allergin is pollen. In asthma and in perennial
- 18 | rhinitis they tested the patients, and mostly it was house
- 19 dust mites.
- 20 Q. So this one, it looks like everything is to the left
- 21 of the line?
- 22 A. Yes. Unfortunately there is no standard way of
- 23 displaying the results. In this case left is positive for
- 24 homeopathy.
- 25 So this is what it boils down to, clearly

- 1 positive for homeopathy.
- 2 Q. So let's see if we can understand this. So in the far
- 3 left graph you see individual studies for hay fever, hay
- 4 fever, asthma, two for perennial rhinitis, and then what's
- 5 | called composite at the bottom?
- 6 A. One for perennial rhinitis.
- 7 Q. One for perennial rhinitis?
- 8 A. Two for hay fever, one for asthma, and one for
- 9 perennial rhinitis.
- 10 Q. Okay. And the pooled analysis in the second column,
- 11 this here, what is a pooled analysis?
- 12 A. So that means when you statistically combine all the
- results and you're able to do it quite legitimately here
- 14 | because they're essentially saying the same design. These
- are very homogenous studies, so one can't object that they're
- 16 | not -- they're heterogenous. They all different. This is
- 17 | not apples and pears. You're comparing apples with apples.
- 18 Q. Okay. And the composite is that all of the studies
- 19 put together into one analysis?
- 20 A. Exactly, over about 250 patients.
- 21 | Q. What was the conclusion of the composite analysis in
- 22 this meta-analysis?
- 23 A. That isopathy is effective in reducing the symptoms
- 24 | but also objective measures of allergies.
- Q. What do you mean by the objective measures of

allergies? 1 2 Well, here we have the objective measures. So this Α. one was the number of antihistamine tablets the patients 4 needed to take to relieve their symptoms. 5 This was the -- they get them to inhale histamine and to see how their bronchials reacted, and this 6 7 was nasal inspiratory flow rate. So they just sniffed through a machine to see how quickly they could inspire. And 8 9 in all case it favors the homeopathy. 10 Here they couldn't do a composite because it is apples and pears. They're different measures. You can't 11 12 boil them down to one, but in all cases they do favor 13 homeopathy. 14 Thank you. And this was one you said we were going to 15 hear about. This is a meta-analysis of homeopathy for 16 childhood diarrhea. Now we're seeing what looks like a line 17 across as opposed to up and down. Can you explain this 18 chart? 19 Α. Yes. So again you have to understand that this is 20

A. Yes. So again you have to understand that this is projected in a different way. In this case up means favorable to homeopathy, and zero means no difference between placebo and homeopathy.

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So this is a series of three studies done by Jennifer Jacobs at the University of Seattle looking at the treatment with homeopathy of childhood diarrhea.

The first two studies are done in Managua in Nicaragua. The third one here, this is done in Katmandu, Nepal. And this is what happens when you boil results down, so this is L95. So the lower range, it does not include zero. So that means it is clearly positive. This line does not include zero.

So this bar here does not overlap with zero, meaning that when you boil these results down, it is a clear

So this bar here does not overlap with zero, meaning that when you boil these results down, it is a clear positive. And again, it's legitimate because these are studies using the same methods done by the same group.

- Q. Were each of the three studies done before, were any of them statistically significant?
- 13 A. Singly not, they're not statistically significant.
- Q. But when you combine them together, is that what the meta-analysis is doing?
- 16 A. Precisely.

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- Q. And what was the conclusion that was drawn from this particular meta-analysis?
- A. That homeopathy is an effective treatment, but it's an extremely common problem of children in poorer countries.
- Q. The next one we have is a meta-analysis for Arnica for knee surgery. What are we seeing in this chart?
- A. This is a study -- again, this is projected in a similar way to the previous one. In other words, above zero is favorable to homeopathy. So anything above here is

1 favorable to homeopathy. 2 So this is a study done in Germany in the 3 Charité Medical Center, Charité University Medical Center, 4 which is actually the biggest academic medical center in Germany, very prestigious center. Looking at the rate of 5 recovery following three different kinds of knee surgery 6 7 treated with homeopathic Arnica. 8 So you have three different procedures. 9 is arthroscopy. They didn't treat it very long because it's 10 just looking into the joint. It's a minor procedure. 11 This is a whole knee replacement. It's a 12 much bigger thing, and this is repair of the ligaments. 13 all of them show favorable, show quicker recovery with 14 Arnica, and the pool becomes statistically significant. 15 So pool, when you're looking at all three together. 0. 16 Is that what you're talking about? Exactly. Yes. 17 Α. 18 Okay. Thank you. The next slide is a slide 19 discussing homeopathy versus conventional treatment in acute 20 otitis media. What's otitis media? 21 Otitis media is inflammation of the middle ear. Α. 22 very, very painful, quite common condition in children. One 23 of the biggest significances of this condition is that it is 24 very often inappropriately treated with antibiotics. 25 We have a big problem with antibiotics. We

1 are running out of antibiotics because they are used too 2 freely. 3 So this looks at homeopathy versus 4 conventional treatment. This is done in India where they 5 have very good collaboration between the homeopath and the conventional ENT specialist. 6 7 And what you can see here, so the red line is 8 the conventional treatment. The blue line is homeopathy. 9 The homeopathic treatment at least in the first week or so, 10 they recovered more rapidly. 11 At the end of it, there were a couple of 12 children in the homeopathy group who didn't fully respond. 13 What conclusions were drawn as a result --Ο. Do we have the next -- oh, is there the other one on 14 Α. 15 No. Sorry. Okay. Sorry. Go back. Sorry. that? 16 That's okay. Q. 17 Well, what the conclusion is, is that homeopathy is an 18 adequate treatment for the great majority of children with 19 acute otitis media and enormously reduces the use of 20 antibiotics. None of the children in the homeopathy group 21 got antibiotics compared to 97.5 in the conventional 22 treatment group. 23 And that is very important because acute 24 otitis media and other childhood infections are a very major

source of inappropriate use of antibiotics.

- Q. Other than the antibiotics and the homeopathy, were the treatments between the two groups the same?
- A. Yes. They were randomized, and they were assessed by the same independent conventional ENT specialist.
- Q. And we have another study on homeopathic ear drops involved with another study on acute otitis media with homeopathic ear drops. What is relayed in this particular slide?
- 9 A. Well, this is a product made by the company in
 10 question here, Hyland's, and it is looking at the rate of
 11 recovery, the pain that each of these got, the pain suffered
 12 by children who got standard treatment or who got standard
 13 treatment plus the homeopathic ear drops, randomly.

And as you can see, there is a difference here at day two, quite a big difference between the number, between the average ETG score. It speeded up recovery from this very painful, distressing condition that is often inappropriately treated.

- Q. So again, these are children who are either getting standard therapy or getting Standard therapy plus the homeopathic ear drops; is that correct?
- A. Randomly allocated, yes.

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THE COURT: For the record, what is ETG?

THE WITNESS: It is ear -- I'm sorry. It is a

measure. It is a Standard measure of pain in children. I'm

1 sorry. I can't remember what the acronym stands for. Sorry 2 about that. BY MR. MARGULIES: Study on -- has homeopathy been looked at in recurrent 4 5 upper respiratory infections? Yes. So now this is a nonrandomized study. 6 Α. 7 children were not randomly allocated, but it was done in 8 France with family physicians. They got about 500 children 9 with a good follow-up ratio. They followed up with nearly 10 all of them for six months. Some of them were treated by 11 non-homeopathic family physicians. Some were treated by 12 homeopathic family physicians. 13 And it is feasible to do this kind of study 14 in France because large numbers of family physicians practice 15 homeopathy. 16 They looked at standard outcomes including the parents' quality of life. This is not the children's 17 18 quality of life. It's the parents' quality of life. 19 And so the number -- so these are children, 20 young children between the ages of 18 months and five years 21 who were getting at least five attacks of upper respiratory 22 tract infections every year. 23 And what were the overall conclusions of this study? Ο. 24 The conclusions were that the homeopathic group did

much better. They got many fewer infections. They needed

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much less antibiotics, and the parents' quality of life was better, for equivalent costs. The costs were about the same, but the outcomes, any way you look at them, were preferable when you add homeopathy. And it's important to realize this is very pragmatic. A few of the homeopathic children got antibiotics. A few of the antibiotic children got homeopathic medicine, a few. It wasn't complete separation. But actually the ones who got the homeopathic strategy did much better, and the costs were the same. And you said the study was done in France? Ο. Α. In France. We've heard about some other countries, France and India. Are there places around the world where homeopathy is more prevalent that it is here in the United States? Yes. It is very widely used. In France, for Α. instance, essentially all pharmacies in France, 98 percent of pharmacies in France, stock homeopathy. Extremely popular in India. Germany again is not far behind France. A large portion of doctors and the patients use homeopathy. And what is quite interesting is the growth in some former Eastern Block countries. I was in Warsaw just over a year ago, May 2014. It was exactly the 25th anniversary of their Velvet Revolution when the Communist

1 regime fell. 2 And there are no accurate statistics, but you can be pretty sure that use of homeopathy in Poland in 1989 3 4 was zero or very close to zero. Now it's 30 percent; 30 percent of the population use homeopathy. So given the 5 option, people would use it. 6 7 Q. Thank you. The next study that we're looking at is comparative effectiveness of homeopathy -- oh, I'm sorry. 8 9 This is the --10 Α. This is the conclusion of the one we were looking at 11 before. Just this is in recurrent upper respiratory tract 12 infections. The homeopathic strategy was superior any way 13 you look at it. 14 Thank you. On the next slide is the result of a study 15 on homeopathy and drug use in chronic respiratory disease out 16 of Italy. What are we seeing in these charts? 17 This is data drawn from the official government 18 database of prescribing costs. So this is on the government 19 health system how much is being spent on patient's treatment 20 for upper respiratory disease. And they're looking at the 21 impact of introducing a homeopathic clinic in this town 22 called Lucca in Italy, and looking at the costs.

So what you have here, on the left here, this is the costs for specific conventional therapy, so that might mean asthma inhaler, for instance.

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And then general conventional therapy, the blue one, is the general conventional therapy. So that might mean painkillers or blood pressure tablets -- for the preceding year and then the year after they introduced this clinic, and the year after that for the patients who attended. Q. So the clinic was introduced somewhere on this line? Α. There. Exactly. And what you can see is, if you look at patients with asthma, the first year after the introduction of homeopathy you had a reduction of 71 percent in prescribing costs, and a 54 percent reduction the following year. So here, here, and here. For the patients who didn't attend -- this is the rest of the population of this town -- who were receiving these asthma drugs had an increase in both years, and the same for the general, for the blood pressure tablets, decrease in the homeopathic group, increase in those who did not attend the homeopathic clinic. What conclusions did you draw from this particular Q.

- study?
- Well, you have to be a little cautious about the conclusion. This is not a randomized study, but it does appear to show that patients who start using homeopathy achieved considerable reduction in the cost of their

- 1 medication.
- 2 Q. Do you need to have randomized controlled trials,
- 3 | placebo controlled trials, to know if something is effective?
- 4 A. To know if it's effective, no.
- 5 Q. To know if it's effective against placebo?
- 6 A. Yes. We talked about efficacy. So efficacy you do
- 7 | need a randomized study. Effectiveness, to know does it work
- 8 in the real world, you don't. You need some kind of
- 9 comparison, some kind of credible comparison. You don't have
- 10 to have placebo-controlled studies, which have many
- 11 | weaknesses. There are many problems associated with
- 12 placebo-controlled studies.
- 13 Q. Dr. Fisher, did the Swiss government contract for a
- 14 | health technology assessment of homeopathy?
- 15 A. It did.
- 16 Q. Okay.
- 17 A. So a health technology assessment is really looking
- 18 | all around at a particular health technology, in this case
- 19 | homeopathy, for a number of different conditions. This is
- 20 just one chapter in this large volume to decide, you know, is
- 21 this something that we should be using in our country, in our
- 22 state, whatever, should we be using it.
- 23 O. And what conclusions did that assessment reach?
- 24 A. Essentially positive. They found 29 trials of
- 25 | homeopathy for various different kinds of upper respiratory

tract infections and allergy. Over 24 were positive, and their bottom line was probable effectiveness of homeopathy for allergies and infectious disease of the upper respiratory tract.

"Probable" may sound a bit weak, but actually they only had a three-point scale, which is probable, possible, and likely. So probable was the most positive conclusion they could have reached. And as a result homeopathy was reintroduced actually into the Swiss national health, compulsory health insurance scheme.

- Q. And was there a study known as the EPI-3 study?
- A. The EPI-3 study is a large pharmacoepidemiological study. So this is the largest study done of homeopathy ever.

 It includes over 6,000 patients in three different groups.

So they looked at MSD, musculoskeletal disease.

They also looked at respiratory tract infections and sleep disorders and anxiety. But here we're looking at the musculoskeletal group, and what it shows very strikingly is here this is the acute patients. These are the patients who had sudden onset. These are the patients who had had the problem for a long time, mostly back pain, joint pain.

And what you see here is approximately half the number of medications are being prescribed by the homeopathic. So this is the homeopathic doctors. This is

1 the conventional doctors. They're using roughly half the 2 number of nonsteroidal anti-inflammatory drugs. This is a 3 very dangerous drug. It causes stomach ulcers. It causes 4 kidney disease. Everybody agrees they're undesirable. 5 So the homeopathic had -- the patients were 6 very similar in the two groups except the homeopathic group 7 was slightly more chronic. They'd had their conditions 8 longer. They got the same outcome, same results, same 9 improvement in their symptoms, but for half the number of 10 drugs. 11 Okay. So their results were similar, but they took Ο. 12 fewer of these conventional medicines? 13 Precisely. Nonsteroidal anti-inflammatory drugs are 14 dangerous drugs. 15 Thank you. We talked a little before about this Ο. 16 concept that you talked about the paradoxical effect of the 17 homeopathic drug. Is that something that we -- and you 18 briefly mentioned that we see in other phenomenon, similar 19 phenomenon. 20 Yes. It is sometimes said that homeopathy is Α. isolated. There is nothing like it. But actually hormesis, 21 22 you're going to hear from a world expert on hormesis, 23 Dr. Calabrese. 24 But hormesis is the paradoxical beneficial or 25 stimulator effect of the toxic, very widely observed. There

is paradoxical pharmacology which is now seriously proposed as a method of using drugs, smaller doses of drugs to achieve the opposite effect of what you would normally use them for. So those are positive uses.

There are also negative uses, rebound phenomena, very widely observed. For instance, with blood pressure drugs, very dangerous, because while you're taking them, they push blood pressure down. If you stop them, they will rebound where your blood pressure will be higher than it ever was.

So, again, this is a paradoxical reaction due to as a function of time or of dose. So it can be the dose that gives you the paradox, or it can be the timing.

- Q. So it's not unusual in science or in medicine to have drugs do the opposite of what you expect them to do in certain situations?
- A. Drugs and toxins, yes. It's very widely described,

 called by a wide range of different names, but these are all,

 I won't say the same phenomenon, but they're related

 phenomenon. They are paradoxical reactions as a function of

 either dose or time.
 - Q. Thank you. Are you familiar with the UK House of

 Commons Science and Technology Committee's evidence check on
 homeopathy?
- 25 A. I am.

- 1 Q. Did you participate in the hearings that led up to
- 2 that report?
- 3 A. I did. I gave written evidence and I spoke in person.
- 4 Q. Have you read the conclusions from the committee
- 5 report?
- 6 A. I have.
- 7 Q. Do you agree with them?
- 8 A. No.
- 9 Q. Why not?
- 10 A. Because I think they were perverse and prejudged and
- 11 unscientific. It was not written by scientists. It was
- 12 | written by MP, members of Parliament, senators if you like,
- 13 only three of them.
- 14 Q. Only three. How many members were on that particular
- 15 | committee?
- 16 A. So the committee had 13 members. Actually four of
- 17 | them voted. Three voted in favor, one against. The
- 18 | remaining nine took no interest at all. They didn't even
- 19 | formally abstain. They just weren't there.
- 20 Q. And how many members of Parliament were there at the
- 21 time?
- 22 A. Approximately 630.
- Q. And how many of them voted for this report?
- 24 A. Well, three, three of them.
- 25 Q. The report made a number of recommendations to the UK

- government. Were any of those actually adopted?
- 2 A. They made 33 recommendations, in fact, and none of
- 3 them were adopted.
- 4 Q. Thank you. Have you had an opportunity to read the
- 5 report out of the Australian government this past year on
- 6 homeopathy?
- 7 A. I have.
- 8 Q. And do you agree with it?
- 9 A. I don't.
- 10 Q. What concerns do you have about this particular
- 11 report?
- 12 A. It's a very strange document. It's a review of
- 13 systematic reviews. It was apparently written by one person
- 14 and checked by another. Who these people were, we don't
- 15 know. It has not been peer reviewed.
- 16 Q. When you say a review of systematic reviews, what does
- 17 | that mean?
- 18 A. Well, they found all the systematic reviews of
- 19 | homeopathy they could find amidst several, at least five to
- 20 my knowledge. I haven't tried to repeat their work, but when
- 21 | I read it, I thought -- I immediately spotted five that they
- 22 | had missed out.
- And so they got them, and they then, well,
- 24 | were supposed to look at what the conclusions were. But
- 25 | actually they ignored every single systematic review,

- including the Cochrane reviews which are very high quality,

 claiming the quality of the reviews is not good enough. And

 if the quality of a Cochrane review isn't good enough for

 them, then nothing is good enough for them.
- Cochrane reviews I think are universally
 accepted as the highest quality reviews, and there are three
 or four of them on homeopathy. They quoted only one review.
 They quoted it 26 times, only one review, and only a very
 partial quotation of that.
- 10 Q. How so?
- 11 A. Well, this particular -- in Cucherat they mentioned 26
- 12 times, saying that it didn't show homeopathy to be effective
- for any single condition, but they failed to mention that the
- 14 overall conclusion was that there is evidence that
- 15 homeopathic treatments are more effective than placebo. They
- 16 never mentioned that once.
- 17 O. So that was Cucherat?
- 18 A. Cucherat.
- 19 Q. And do either the UK report or the Australian report
- 20 have any effect on your opinions regarding the effectiveness
- 21 of homeopathy?
- 22 A. Not on my opinions regarding the effectiveness of
- 23 | homeopathy. They may be very depressed about human nature, I
- 24 have to tell you.
- 25 | Q. Have you had an opportunity to read the statement by

- 1 | the National Centers for Complementary and Integrative
- 2 Medicine on homeopathy?
- 3 A. I have.
- 4 | Q. And you're aware that it says there is little evidence
- 5 to support homeopathy as effective for specific health
- 6 conditions?
- 7 A. Yes. I'm also aware that that is based on a very
- 8 | incomplete look at the literature.
- 9 Q. How do you know that?
- 10 A. Well, because they list a number of reviews and they
- 11 missed out many of them.
- 12 Q. Do you agree with their conclusion that there is
- 13 | little evidence that homeopathy is an effective treatment for
- 14 any specific condition?
- 15 A. I do, and we've looked at some of the reasons why I
- 16 | think that earlier on. I've shown several systematic reviews
- 17 | and meta-analyses of homeopathy for specific conditions which
- 18 have positive results, which suggested it does work.
- 19 Q. Do you agree with their conclusion that the principles
- of homeopathy are inconsistent with fundamental concepts of
- 21 chemistry and physics?
- 22 A. I do not. And I don't think it is good enough to say
- 23 | it's inconsistent with fundamental concepts. Let them say
- 24 which fundamental concepts.
- 25 | I've heard this criticism many, many times.

- My challenge is always don't talk to me about general
 fundamental concepts; tell me which one. And I've never had
 a satisfactory answer for that.

 Q. Dr. Fisher, in summary, do you believe -Do you have an opinion about what the
 physical research on homeopathy shows?
- A. It shows several different lines of research looking at it from different angles, show that water prepared in the homeopathic manner is not plain water.
- Q. Do you have an opinion about what the biological research on homeopathy shows?
- A. There are a number of biological research experiments, and I include test tube research, for instance, done on human blood cells which you take and put in a test tube or on whole animals, and there are a number of models that consistently show that homeopathy has effect.
 - Q. And do you have an opinion about the clinical research, the studies, the systematic reviews, and meta-analyses on homeopathy?

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- A. Yes. And I would divide it into two questions, again as the biological researchers' in-vitro test tube research, and the animal research.
- With clinical research you have randomized trials, and then you also have clinical effectiveness studies, which look much more at the real world.

The randomized controlled trials broadly speaking as we've seen and most of the meta-analyses agree are positive. The clinical effectiveness research which looks at what is the effect if you introduce homeopathy into a healthcare system, which I believe is universally positive for homeopathy.

- Q. And based on all of the issues we've discussed today, do you have an overall opinion about whether homeopathy is an effective treatment method?
- A. What I've tried to do is to take an overview to say, look, this allegation that it doesn't work because it can't work because of the very high dilutions is not correct.

 There is good reason to think that that isn't true.

I have looked at some of the biological models and shown that there are biological models which consistently can show effect, and we've looked at the clinical research which, you know, broadly speaking is positive.

So, yes, my conclusion is that it is an effective treatment method and that that is supported by a spectrum, a mosaic, if you like, of evidence.

- Q. And you're aware that there are negative trials on homeopathy; correct?
- 24 A. Of course.

25 Q. And does that change your opinion?

1 Α. Of course, some you win; some you lose. Some of 2 these -- there are going to be negative trials always. I 3 would be deeply suspicious if there weren't any. And one can 4 actually look for them. There is a way of searching. You 5 can look for whether there appear to be some negative trials 6 that are not being published. And their answer is that there 7 do appear to be some in homeopathy but very far from enough 8 to change the conclusions. 9 Thank you very much, Dr. Fisher. 10 MR. MARGULIES: Thank you, Your Honor. I don't 11 have anything further. 12 THE COURT: Thank you. 13 At this time we will have our lunch break and 14 we will return at 1:15 for the cross-examination. Thank you. 15 THE CLERK: We are in recess. 16 (Noon recess taken.) 17 18 19 20 21 2.2 23 2.4 25

CERTIFICATE I hereby certify that the foregoing is a true and correct transcript of the stenographically recorded proceedings in the above matter. Fees charged for this transcript, less any circuit fee reduction and/or deposit, are in conformance with the regulations of the judicial conference of the united states. /S/Anne Kielwasser 09/15/2015 Anne Kielwasser, CSR, RPR Date Official Court Reporter 2.2 2.4

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