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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

THE HONORABLE DALE S. FISCHER
UNITED STATES DISTRICT JUDGE PRESIDING

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)	
In Re Nexium (Esomeprazole))	Case No.
Products Liability Litigation)	12 ML 2404-DSF(Ssx)
)	
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_____)	

REPORTER'S TRANSCRIPT OF PROCEEDINGS
Los Angeles, California
Monday, September 29, 2014

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1 Los Angeles, California, Monday, September 29, 2014

2 1:57 p.m.

3 -oOo-

4 THE CLERK: Calling Item No. 9, 12 ML 2404-DSF(Ssx),
5 *In Re Nexium (Esomeprazole) Products Liability Litigation.*

6 MS. FISHER: Amy Fisher, your Honor, from Ice Miller
7 on behalf of defendants AstraZeneca Pharmaceuticals LP,
8 AstraZeneca LP and McKesson Corporation.

9 MS. WINCHESTER: Your Honor, Katherine Winchester on
10 behalf of the same parties.

11 MR. STROTZ: Hi, your Honor. Peter Strotz, King and
12 Spalding, for AstraZeneca and McKesson as well. And with us
13 today, just so the Court knows, is Mr. Eric Santoro, who is
14 senior counsel, global litigation, in-house at AstraZeneca.

15 THE COURT: Thank you.

16 MR. GRIFFIN: Good afternoon, your Honor. Keith
17 Griffin on behalf of plaintiffs.

18 MR. GIRARDI: Good afternoon. Tom Girardi,
19 your Honor, plaintiffs.

20 THE COURT: Good afternoon.

21 MR. WORLEY: Don Worley with McDonald Worley for the
22 Adams and Hornsby plaintiffs.

23 MS. EDDINGTON: Good afternoon, your Honor. I'm
24 Michelle Eddington on behalf of the Adams and Hornsby
25 plaintiffs.

1 THE COURT: Is that everybody? All right. Again, I
2 apologize for the delay.

3 Now, I've looked at Dr. Bal's report and the other
4 materials, and I think the Defense argues -- and I would ask the
5 question preliminarily whether what he's done here is within his
6 expertise. So that's the first thing that I'd like Plaintiffs'
7 counsel to address.

8 MR. GRIFFIN: Thank you, your Honor. Keith Griffin
9 again for the plaintiffs.

10 Your Honor, we concede obviously Dr. Bal is not a
11 gastroenterologist, but we also believe he does not need to be
12 for the opinions he's offering in this case.

13 He is an orthopedic surgeon, extremely familiar with
14 the kinds of injuries that we are dealing with in this case. He
15 has conducted studies of his own before, not on PPIs or Nexium.
16 He is familiar with how to read studies. He is familiar with
17 how to interpret epidemiological studies and is familiar with
18 treating the types of injuries that we claim are associated with
19 Nexium use.

20 So although he is not a gastroenterologist and we
21 fully agree to that, we believe, based on his training and his
22 experience -- we submitted to the Court his resume, his CV for
23 your review -- he's a qualified expert. He's an expert in the
24 Fosamax litigation. And his opinions are entirely consistent
25 with his experience and his ability to interpret studies, which

1 is what he has done here.

2 THE COURT: All right.

3 Why don't I just parse this out and hear from the
4 Defense on that issue first.

5 MS. WINCHESTER: Sure, your Honor. Katherine
6 Winchester again for the defendants.

7 With regard to the qualifications of Dr. Bal, yes, he
8 is a physician and, yes, he is an orthopedic surgeon. However,
9 as you saw in our briefing, Dr. Bal admits that he doesn't spend
10 a lot of time reading studies in his ordinary practice.

11 What he does is he fixes fractures and he primarily
12 spends his time doing cartilage joint replacements, that being
13 hip and knee. As he says, his patients don't come to him to
14 have him read literature. They come to him to fix their
15 fractures.

16 So as the Plaintiff has said, he's familiar with these
17 kinds of injuries, sure. Dr. Bal is familiar with fractures.
18 Dr. Bal may even have some familiarity with osteoporosis, but
19 we're not here about whether Dr. Bal knows how to treat
20 osteoporosis or treat fractures. Clearly he does.

21 But we're here about general causation and whether
22 Dr. Bal has a -- the type of expertise necessary to determine
23 what causes osteoporosis and osteoporotic fractures, and that
24 was really our argument, your Honor.

25 THE COURT: All right. Thank you.

1 Let me ask the Plaintiff, because there's some -- and
2 I forget whether this was in your papers or just in his
3 deposition testimony or both, but there was some indication that
4 he had done independent research, and I was trying to figure out
5 what that meant. I couldn't figure out what that meant --
6 whether that meant he had done independent research by reading
7 all these other studies or whether he himself had done some kind
8 of research, epidemiological research or studies with regard to
9 this topic.

10 MR. GRIFFIN: Your Honor, Keith Griffin.

11 The research that he is referring to is his review of
12 the articles and the literature. He did not do his own study.

13 THE COURT: Okay. So he just determined what he
14 should read? That was his independent analysis?

15 MR. GRIFFIN: He did his own search for studies,
16 reviewed everything that was available to him, and then came up
17 with his opinions.

18 THE COURT: What does *available to him* mean?

19 MR. GRIFFIN: In other words, just as every other
20 expert does, they look for all the medical literature that is
21 available on a particular subject and review that material,
22 which is --

23 THE COURT: I just wanted to make sure that's what you
24 meant. *Available to him* could be he turned around on his
25 bookshelf, and if it wasn't there, he didn't read it.

1 MR. GRIFFIN: Correct. He -- all of the scientific
2 literature that was available, he reviewed. In other words,
3 there wasn't something that he specifically excluded to review.

4 THE COURT: Okay.

5 Tell me how that testimony then satisfies the relevant
6 epidemiological methodology.

7 MR. GRIFFIN: Well --

8 THE COURT: Because that's what we're looking at;
9 right? I have to determine whether he has followed an
10 appropriate methodology.

11 MR. GRIFFIN: Correct.

12 He, as other experts in his field do, reviewed
13 peer-reviewed literature and --

14 THE COURT: Well, you keep saying *as other experts in*
15 *his field*, and I'm not sure what his field is in this context.
16 I'm not sure other orthopedic surgeons do whatever it is that he
17 did, so I'm --

18 MR. GRIFFIN: I understand, your Honor.

19 THE COURT: And stop saying *as other experts*. Just
20 tell me what he did.

21 MR. GRIFFIN: Okay.

22 He reviewed all of the epidemiological studies that
23 were available to him relating to PPIs causing osteoporosis and
24 other bone injuries, reviewed those studies, compared those with
25 his own experiences and his own training and came up with the

1 opinion, as the studies did, as the FDA did, that in fact use of
2 PPIs, including Nexium, cause or contribute to the development
3 of osteoporosis and other bone-related injuries.

4 THE COURT: What was his own experience and training
5 that he applied here? I'm not sure what --

6 MR. GRIFFIN: His own experience and training as
7 related to the injury side of that opinion, specifically his
8 familiarity with osteoporosis, with hip fractures, with bone
9 fractures. That's where his experience lies.

10 And his experience with reviewing medical literature
11 and medical studies, which is what he did here. He went out and
12 looked at the available literature, agreed with it, agreed with
13 the FDA, and opined that the use of Nexium is causally related
14 to the development of osteoporosis.

15 THE COURT: So you're saying there was nothing in his
16 training or experience that suggested any of those was wrong?

17 MR. GRIFFIN: Correct.

18 THE COURT: Because I'm not really getting how his
19 training and experience would suggest they were right.

20 MR. GRIFFIN: Well, I --

21 THE COURT: He sees fractured bones and he does
22 something with cartilage. I'm not sure how that follows up from
23 these studies.

24 MR. GRIFFIN: Well, there's nothing specific to his --
25 his work as an orthopedic surgeon that relates to these

1 particular studies, but as a physician, as a doctor, as someone
2 who has written and participated in his own studies, he has the
3 qualifications and the ability to review a study, interpret it
4 and then opine on it, which is what causation experts in
5 pharmaceutical cases do.

6 He reviewed the literature, came up with an opinion,
7 which is supported by the literature, and that's what he did.

8 THE COURT: Okay. But there's nothing specific about
9 his training or experience that I've missed in here that he
10 said, *Oh, yes, Mrs. Jones came in to me, and now that I see this*
11 *study, now I know exactly what happened to Mrs. Jones.*

12 MR. GRIFFIN: No, your Honor. His job is as an
13 orthopedic surgeon.

14 THE COURT: Okay. I just want to make sure I'm not
15 missing anything.

16 All right. So did he do some -- does he have in his
17 report some discussion of the strength of the correlation, for
18 example?

19 MR. GRIFFIN: Well, your Honor, he does review a
20 number of different studies on the correlation between Nexium or
21 PPI use and osteoporosis and other bone-related injuries. There
22 are studies -- the Vestergaard study was a 2006 study that he
23 refers to which indicated a doubling of the risk of spinal
24 fractures --

25 THE COURT: But I'm trying to figure out -- he's

1 applying his expertise, so I'm trying to figure out how he
2 applied his expertise, which is different from telling me what's
3 in the studies; right?

4 MR. GRIFFIN: Correct. And, your Honor, his -- his
5 expertise, he's a doctor --

6 THE COURT: I got that part of it. He is also
7 apparently a lawyer.

8 MR. GRIFFIN: He is.

9 He has participated in studies and he's familiar with
10 the types of injuries that are at issue here. That's the
11 experience that we're --

12 THE COURT: Okay. In his report, is there a
13 discussion of the strength of the correlation?

14 MR. GRIFFIN: The strength of the correlation, yes, as
15 identified in the studies that he reviewed. That's the
16 correlation that he -- that he discusses. In other words, he
17 didn't do his own study, so the correlation and the strength of
18 the correlation is based on the studies that he has reviewed.

19 THE COURT: What's his analysis in that regard?

20 MR. GRIFFIN: His analysis is that there is a causal
21 connection between the use of Nexium and other PPI drugs when
22 taken for at least one year, causing osteoporosis and other
23 osteoporotic fractures. That is essentially his opinion in
24 summary form.

25 THE COURT: All right. Did he look for any contrary

1 studies?

2 MR. GRIFFIN: Again, he looked for all of the
3 literature that was available to him.

4 THE COURT: You keep saying *that was available to him*,
5 and that's a phrase that's causing me concern. What does that
6 mean? Is there a Westlaw or Lexis for medical -- how does he do
7 that?

8 MR. GRIFFIN: Well, for instance, your Honor, he did
9 review a study by the Defense expert, who is Dr. Targownik, who
10 found that although there was a connection between Nexium and
11 osteoporosis -- their own expert agrees with that fact.
12 However, that study -- the author said well, it takes five years
13 and, yes, so that is different than his opinion, which is one
14 year.

15 So, yes, he has reviewed studies that are different
16 than his own opinion. However, based on the totality of the
17 studies, he believed that one year was the accurate duration of
18 dose. And that's consistent with the Vestergaard study and the
19 Yang study.

20 THE COURT: Okay. Now, what about the fact that not
21 all of these studies included Nexium and apparently some of them
22 we don't even know whether Nexium was one of the drugs that was
23 looked at. Does he have the expertise to decide whether that
24 factor would make a difference?

25 MR. GRIFFIN: Well, your Honor, the opinions of

1 these -- of the studies that are out there are that this is a
2 class-wide effect. That there is nothing different about Nexium
3 that would make this analysis any different.

4 All of the PPI drugs have this same causal mechanism,
5 which is essentially inhibiting the uptake of calcium by
6 reducing the amount of acid. That's what happens --

7 THE COURT: So he has no independent expertise. He's
8 just looking at the studies. And so to him it doesn't matter
9 whether the studies included Nexium or not because whoever was
10 doing the study said it doesn't matter?

11 MR. GRIFFIN: That's right.

12 THE COURT: Okay. All right.

13 But the studies talk in terms of association; right?

14 MR. GRIFFIN: Yes.

15 THE COURT: And *association* does not necessarily mean
16 *cause*?

17 MR. GRIFFIN: Well, association does mean a
18 relationship that is more than trivial. I think that's
19 clinically how *association* is defined.

20 THE COURT: Was my statement true or not true?

21 MR. GRIFFIN: Yes, it is true, that it does not
22 necessarily mean *cause*.

23 THE COURT: Okay. So how does he get from the studies
24 to his opinion?

25 MR. GRIFFIN: Well, because I think he evaluated the

1 totality of the evidence, all of the studies. Obviously this is
2 not just one study we're talking about; this is many, many
3 studies that all show an association, which is the term that's
4 used in the studies, association --

5 THE COURT: So five associations equals causation?

6 MR. GRIFFIN: No. But I think the totality of the
7 evidence, when you have all of these studies -- and there are
8 very few studies that do not find a connection between use of
9 Nexium and osteoporosis. I mean, their own expert's study shows
10 a connection between the two.

11 The FDA reviewed all these studies and agreed there
12 was a connection between the two.

13 THE COURT: Could be because old people have
14 osteoporosis and old people take Nexium. So it wouldn't
15 necessarily mean that there was a causal relationship.

16 MR. GRIFFIN: That's -- that is true, your Honor.

17 THE COURT: Where does he get the expertise to make
18 that -- you'll call it a link. I think the Defense would
19 probably call it a jump, but --

20 MR. GRIFFIN: Sure. I think the same place that their
21 own expert has, the --

22 THE COURT: I didn't even look at their expert. I
23 didn't think that was relevant in my analysis of what your
24 expert --

25 MR. GRIFFIN: I understand. Your Honor, I only bring

1 it up because that is one of the key articles that he relies on,
2 is their expert's study that shows the relationship and the
3 causal connection between Nexium and osteoporosis.

4 THE COURT: The association.

5 MR. GRIFFIN: Correct. Association. Association.

6 THE COURT: Which we know doesn't mean causation
7 because you just told me I was correct.

8 MR. GRIFFIN: That's correct. But his opinion is
9 actual causation and his opinion is based on his review of the
10 totality of the studies.

11 THE COURT: Well, it seems to be -- I don't even know
12 what word to call it.

13 Again, maybe it is a jump. It doesn't seem that he
14 really explored that second issue to me. I mean, we have all
15 these studies, and let's say I assume that this doctor, maybe
16 any doctor, certainly a doctor that works with bone fractures,
17 could look at epidemiological studies and figure out what they
18 say. How does he get the expertise then to go beyond that
19 without really solid studies on that next step?

20 He doesn't really seem to have explored how plausible
21 this hypothetical mechanism conclusion that he reaches is, other
22 than sort of just basic level, I guess would be one way of
23 putting it.

24 MR. GRIFFIN: Again, his analysis is simply based on
25 that which is found in the literature, that which is found by

1 Dr. Targownik, the same mechanism of injury. There really isn't
2 any dispute on the mechanism of injury, the manner in which
3 Nexium and other PPIs inhibit calcium uptake.

4 So his review is based on -- his opinion is based on
5 his review of the literature.

6 THE COURT: Okay. Has he done anything -- at least it
7 didn't seem to me to show -- on the issue of dose
8 responsiveness, other than mentioning the FDA warning?

9 MR. GRIFFIN: His opinion on dose is -- and
10 duration -- let me make sure I answer your question correctly.

11 Did you ask me specifically about dose? And, no, he
12 didn't have a specific opinion as to the amount of dose. His
13 opinions were more related to duration.

14 THE COURT: Okay. And did he rely on anything other
15 than what we have before us?

16 MR. GRIFFIN: Simply the medical literature. And, of
17 course, his own expertise.

18 THE COURT: Well, again, his own expertise on what? I
19 haven't seen anything about his expertise in deciding -- does he
20 give people medicine to be treated for these fractures? I
21 thought he was a surgeon.

22 MR. GRIFFIN: He is a surgeon, your Honor. He is a
23 surgeon that has been published --

24 THE COURT: Just answer my question. Has he
25 prescribed Nexium? Does that fall within the kind of thing -- I

1 don't know what orthopedic surgeons do. I have never been to
2 one.

3 Does that fall within the kinds of things he would do?

4 MR. GRIFFIN: No, he doesn't himself prescribe Nexium,
5 but he certainly treats patients that have been prescribed
6 Nexium by other doctors.

7 THE COURT: But I'm trying to figure out -- you keep
8 mentioning the studies that he read and then you talk about
9 training or experience, etc., and I'm trying to figure out
10 whether you just keep saying that because it sounds better or
11 whether you're saying that because he has some expertise above
12 and beyond what he's read in the studies.

13 And a conclusion -- what is the -- if it's not in the
14 study, what is the conclusion -- the basis for any other
15 conclusion that he reaches? Does he have a separate expertise?
16 Does he prescribe some medications other than Nexium?

17 MR. GRIFFIN: No, your Honor, he does not -- that is
18 not within his job. He doesn't prescribe Nexium-related drugs
19 or PPIs. He treats patients that are taking Nexium or other
20 PPIs.

21 THE COURT: So what are you saying? That people come
22 in to him and they have a bone fracture and he says, *Have you*
23 *been taking PPIs*, and they say, *Yes*, and he says, *Well, for over*
24 *or under a year*? And then he just -- that's -- I'm trying to
25 figure out what it is that you are trying to tell me is the

1 extra.

2 MR. GRIFFIN: I'm just trying to tell you -- the Court
3 how he is experienced with osteoporosis.

4 THE COURT: That's my question. How? What is the
5 connection between that experience and the Nexium conclusion --
6 the conclusion he reaches? I'm not saying there isn't one; I'm
7 just trying to figure out what it is.

8 MR. GRIFFIN: It is related to his review of the
9 literature as a medical scientist.

10 THE COURT: Stop there. Review of the literature.
11 Now, what else, if anything?

12 MR. GRIFFIN: Other than the fact that he's a doctor
13 who treats patients for osteoporotic injuries who are also
14 prescribed Nexium and other PPIs.

15 THE COURT: Does he ask them about that?

16 MR. GRIFFIN: Oh, sure, your Honor.

17 THE COURT: What do you mean *oh, sure*?

18 MR. GRIFFIN: I'm sure it's part of his general workup
19 on the case --

20 THE COURT: Do you know that it is?

21 MR. GRIFFIN: I don't know for sure that that's part
22 of his clinical workup.

23 THE COURT: So as I sit here, I have no idea and
24 apparently you have no idea whether he even asks anybody who
25 comes in, who needs his help with orthopedic surgery, *By the*

1 way, have you taken a PPI drug?

2 MR. GRIFFIN: No, your Honor. I don't know that
3 that's important necessarily to his role in --

4 THE COURT: Well, it may not be, but I'm asking the
5 question, so I get to decide what's important to me. So the
6 answer is you don't know the answer.

7 MR. GRIFFIN: I don't.

8 THE COURT: Okay. All right.

9 So we have he's looked at studies that show a
10 correlation between PPIs and these various conditions and then
11 he comes up with this hypothesis about how PPIs could reduce
12 calcium uptake and then that then would be the cause, the
13 reduction in the calcium uptake would be the cause -- because we
14 need to get to a cause here -- of these problems.

15 MR. GRIFFIN: Correct. A cause or substantial factor.

16 THE COURT: Is there anything else in -- I mean, is
17 that basically the summary of his opinion?

18 MR. GRIFFIN: Yes. Yes, it is.

19 THE COURT: Okay. And doesn't he have to have done at
20 least some investigation of whether this calcium uptake
21 hypothesis is supported by the literature?

22 MR. GRIFFIN: He did do that, your Honor, and in fact
23 it is supported by the literature.

24 THE COURT: As a cause?

25 MR. GRIFFIN: Yes, it is. As a mechanism of injury.

1 THE COURT: Where is that?

2 MR. GRIFFIN: That's found in their expert's study,
3 the 2008 Targownik study.

4 THE COURT: Their expert says it doesn't cause it at
5 all so how could the expert have said how it was caused?

6 MR. GRIFFIN: Well, your Honor, I understand that's
7 what their expert says now, but the study itself actually says
8 that the most likely cause is in fact the same mechanism of
9 injury, namely, a problem with the uptake of calcium. That's
10 the Targownik study called *The Use of Proton Pump Inhibitors and*
11 *Risk of Osteoporosis*.

12 THE COURT: Okay. And that's what he's based that
13 conclusion on, the Targownik study?

14 MR. GRIFFIN: Yes.

15 THE COURT: Anything else?

16 MR. GRIFFIN: Well, your Honor, I believe it's also
17 in -- in the other studies. However, that's the study that --

18 THE COURT: All the other studies. But they also say
19 there is an association, not causation. I thought he said he
20 was basing his opinion on some intuitive conclusion he had
21 reached.

22 MR. GRIFFIN: Your Honor, if you're waiting for a
23 response from me, he refers in his report to the mechanism of
24 injury and cites to the Targownik study and also cites to the
25 Endsrud study, *The Study of Osteoporotic Fractures*, Research

1 Group, 2000 publication.

2 THE COURT: Okay. Thank you.

3 For the Defense, we're not -- as I indicated, we're
4 not in a battle of the experts here. If it is a battle, then
5 they get to battle it out in front of the jury. So for that
6 reason, as I said, I didn't spend time looking at your expert's
7 report for the purposes that -- I guess you indicated in your
8 papers what you were and were not submitting it for.

9 But in any event, I didn't really pay much attention
10 to that because I didn't think it was relevant to what I am
11 supposed to be doing here.

12 So why is this man with a medical degree, never mind
13 his JD degree -- I don't know how he found the time -- who's
14 been practicing in the area of orthopedics and is an orthopedic
15 surgeon -- why is he not qualified to give an opinion here?

16 MS. WINCHESTER: Well, your Honor --

17 THE COURT: It might be a weak one. The jury may not
18 believe it. They might think your person is much better able to
19 give an opinion, but --

20 MS. WINCHESTER: Fair enough. Katherine Winchester
21 again for the defendants.

22 And we understand the standard, your Honor, in the
23 Ninth Circuit for judging the admissibility of experts and we
24 understand that this isn't a battle, and if ours is better,
25 their's doesn't come in if their's meets the standard. So we

1 understand that.

2 But why is Dr. Bal unqualified? Well, he's
3 unqualified, as I said earlier, because all he is for these
4 purposes is an MD. That's it. He probably took an epidemiology
5 class in first year med school, but other than that, he doesn't
6 have any specialized training to bring to the methodology that
7 he used here.

8 We're not talking about a case where it's an issue of
9 how to repair a hip and he might have expertise in that area.
10 Here what he did was read a handful of studies and regurgitate
11 back what he thought those studies meant, when the studies are
12 all epidemiologic and he is not an epidemiologist, and so he
13 doesn't have any particular training in that area.

14 THE COURT: Well, but after telling counsel not to
15 tell me what other experts do, I'm going to tell you what other
16 experts do, and oftentimes what they do is they read studies and
17 they say, *Now that I've read this study, here's my expert*
18 *opinion.* And assuming the methodology is correct and assuming
19 the studies are relevant to the case, then that's helpful to the
20 jury because obviously the jury isn't going to read all those
21 studies, and even if they did, probably would not be able to
22 come up with a reasoned conclusion.

23 So let's skip over that issue because I'm not sure I
24 need to reach that issue. Why don't you address for me your
25 opinion on the methodology and whether Dr. Bal did or did not

1 follow it sufficiently to make this opinion admissible in the
2 Ninth Circuit.

3 MS. WINCHESTER: Sure, your Honor.

4 His methodology was simple. As we have already
5 discussed today, he read a number of studies. Plaintiff has
6 said several times that he read the literature that was
7 available to him. Significantly, your Honor, a number of the
8 studies that have been raised today and that were submitted by
9 the plaintiffs in opposition to summary judgment Dr. Bal never
10 read.

11 Dr. Bal never read Vestergaard, he never read Yang.
12 Dr. Bal never read Targownik 2008, which is the study that we
13 heard much about today. He never read Corely. And he never
14 read Yu. And he doesn't rely on any of those studies for
15 purposes of his report.

16 So even to the extent his methodology, even if we were
17 willing to accept that someone with no specialized training,
18 other than an MD, is capable of reading studies and parroting
19 back those to the jury and that that's sufficient, he really
20 didn't even do that in this case. There were a number of
21 studies we addressed at the deposition he had never heard of,
22 including the Targownik 2008 study. So with regard to his
23 methodology, we think that's inappropriate.

24 Second of all, he says he relied on the FDA's
25 pronouncement. Well, the FDA, when they set warnings, they

1 don't make determinations about causality, as your Honor knows,
2 and similarly, even this particular warning, the FDA doesn't say
3 cause. They simply note the fact that there was an association
4 in these other studies.

5 And I think your Honor was asking counsel about
6 strength of the association, dose response, etc., and I think
7 what -- what I heard from that was a request for the Bradford
8 Hill criteria application or some other similar methodology, and
9 what we know here is that there is simply no evidence before us
10 whatsoever that Dr. Bal did any type of analysis.

11 He read the studies and he, to some extent, parroted
12 back what was in them, but there's no indication whatsoever that
13 he did any type of analysis to determine whether they met those
14 criteria such that he could imply causation, because it's my
15 understanding that that is the way good epidemiology is done.

16 You look at epidemiologic studies and then you
17 determine whether you can imply causation from that,
18 particularly when the studies themselves -- none of them say
19 causation themselves.

20 So you've got someone who's not an epidemiologist
21 who's reading these studies to imply causation and he's having
22 to make a leap from something the studies don't say to something
23 that he wants them to say.

24 And I think, as you brought up already, the studies
25 either don't study Nexium or they study it in a group, and,

1 frankly, that might be appropriate methodology if you've got a
2 scientist who's willing to come in and say, *I can extrapolate*
3 *from one drug to the next and this is how I do it.* We don't
4 have that here.

5 In fact, what Dr. Bal testified is that his opinion is
6 not generalizable to all PPIs. It's specific to Nexium only.
7 Regardless of that, he applied a methodology where he looked at
8 studies of all kinds of drugs where Nexium may or may not have
9 been a part of it, and so we would submit that is inappropriate
10 methodology.

11 What else here? There was also a comment that
12 Dr. Bal's methodology was reading the studies and then looking
13 at the totality of the evidence, and I guess I just wanted to
14 follow up on that.

15 To the extent totality of the evidence means something
16 other than epidemiologic studies and maybe the FDA's
17 announcement, there's no evidence that Dr. Bal relied on
18 anything else. He didn't rely on any company documents. He
19 didn't do any of his own research. And, in fact, with regard to
20 research he's done himself, there's no indication any of it is
21 epidemiologic research. It's other types of research.

22 THE COURT: My other question had to do with his
23 conclusion about the -- or his hypothesis perhaps about the
24 reduction of calcium uptake issue.

25 MS. WINCHESTER: Yeah. Thank you, your Honor. Two

1 points on that.

2 First of all, Dr. Bal testified that he got his
3 mechanism of action from reading the epidemiologic studies.
4 Now, what the epidemiologic studies look at is users and
5 non-users and is there any risk, increased risk between one
6 group versus another, and what epidemiologic studies always do
7 is if they find any kind of increased risk at all, no matter how
8 small, then what the authors often do is they say well, if in
9 fact it's causal, it might be due to this. If, in fact, it's
10 causal, it might be due to this: A, B, C, D. But they don't do
11 anything that's not part of epidemiology. They don't do
12 anything to try to prove whether that's true. It's merely
13 coming up with ideas for further research, and that's what
14 Dr. Bal read.

15 However, Dr. Bal didn't do any independent research to
16 determine whether those things had already been studied and what
17 the results were. And in fact, as we cited in our briefing,
18 your Honor, there are two studies out there where it's been
19 studied in patients whether taking a PPI makes it more difficult
20 to absorb calcium, and what both of those studies found was the
21 answer was no.

22 Dr. Bal wasn't familiar with those. We asked him
23 about it at his deposition. He hadn't read them and didn't feel
24 he needed to do that research.

25 THE COURT: All right. Thank you.

1 Mr. Griffin, did you want just another minute or two
2 on that subject before we move on?

3 MR. GRIFFIN: Your Honor, just one comment on the
4 mechanism of injury.

5 Because I heard counsel say that epidemiologists come
6 up with these theories and then say *might be* or *this could be*,
7 *this is something to study further*, and I just wanted to make
8 sure the record was clear on that. And this is from the --
9 their expert's study that says --

10 THE COURT: Which he didn't rely on; right?

11 MR. GRIFFIN: He did not rely on it at the time he
12 wrote his report. He relied on the later version, the 2013
13 version of their expert's report -- study.

14 But the study says, *The mechanism by which extended*
15 *use of proton pump inhibitors increases the risk of fracture is*
16 *unknown. However, it is most likely due to the acid inhibiting*
17 *effects of proton pump inhibitors accelerating the rate of bone*
18 *mineral loss.*

19 THE COURT: So I need to look at the methodology, if
20 any, that was used to put that statement in the study, if I were
21 going to look at it at all, which I don't know why I would do if
22 he didn't rely on it.

23 MR. GRIFFIN: I guess I wanted to raise for the Court
24 that there really is no dispute about that, seeing as their own
25 expert agrees to that mechanism.

1 THE COURT: Well, I don't know that they have to agree
2 to everything their expert says, and I'm sure that they wouldn't
3 agree that there's no dispute about it, but I think we've
4 probably had enough on this subject.

5 Let me go on to the choice of law here, and I'll just
6 tell you that if I need, for some reason, to reach the
7 independent plaintiff issues, both of you are going to have to
8 go back and reorganize your evidence, or if we do get to that,
9 maybe I would just have you come in and go over this -- find it
10 yourself in the papers as we're sitting here because it just
11 would take too much of my time and my law clerk's time to be
12 trying to find the things in the documents or look at all the
13 documents to conclude there is no such thing.

14 But right now let's just talk about the choice of law,
15 and perhaps, Mr. Griffin, or one of your colleagues can tell me
16 what the possible interest of California is in the Texas
17 plaintiffs' cases beyond whatever connection McKesson might have
18 to this case.

19 MR. GRIFFIN: Thank you, your Honor. Keith Griffin.

20 California's interest is clearly not only in
21 protecting its own citizens but also ensuring that its laws are
22 enforced and deterring bad conduct against other citizens of its
23 own state.

24 Here we have the involvement of McKesson, a California
25 corporation --

1 THE COURT: Wasn't McKesson just a middleman
2 distributor? It didn't have a connection with the development
3 of the drug? Or am I misunderstanding.

4 MR. GRIFFIN: They're certainly the distributor of the
5 drug, and, however, I don't -- for purposes of the product
6 liability case, I don't know that it matters whether or not they
7 were involved in the development or not of the drug.

8 If they are distributing a drug that is harmful to the
9 citizens of the State of California, then I'd offer to
10 your Honor that the State of California has a serious interest
11 in protecting --

12 THE COURT: In dealing with the California plaintiffs.
13 I'm trying to figure out why that would override whatever
14 interest Texas has in dealing with Texas plaintiffs' cases.

15 MR. GRIFFIN: I would say that, your Honor, candidly
16 that Texas has no interest whatsoever in applying the law of
17 this case. It has no defendant corporations to support or
18 protect.

19 The only interests that Texas does have is in
20 protecting the plaintiffs, and if we're doing an analysis of
21 California law versus Texas law, clearly California law is more
22 protective of these plaintiffs than Texas law would be.

23 There's no other interest that Texas would have in
24 finding -- using its own heightened standard of causation
25 because it's not serving to protect anyone. There is no Texas

1 citizen who would benefit from that in this litigation.

2 In fact, its residents would be hurt if the Court used
3 a heightened level of scrutiny against the Texas plaintiffs.

4 So it's for that, your Honor, that we believe
5 California law should apply.

6 THE COURT: All right. I'll hear from the Defense.

7 MS. WINCHESTER: Thank you, your Honor. Katherine
8 Winchester again.

9 Would you like to hear about California law or Texas
10 interests, either one? It doesn't matter?

11 THE COURT: Either order is fine.

12 MS. WINCHESTER: First with regard to California's
13 interest, your Honor, there are a number of cases that have
14 addressed this issue and found when you're dealing with
15 non-residents and regardless of whether it's an in-state
16 defendant or not, California's interests are, I think the word
17 is, attenuated as it relates to non-residents, and particularly
18 the Ninth Circuit's opinion in the *Mazza* case I think is quite
19 instructive here.

20 Can I elaborate for a moment on *Mazza*?

21 THE COURT: Sure.

22 MS. WINCHESTER: *Mazza* was a case involving a class
23 action of Honda users, and the Court there was considering a
24 nationwide class action of Honda users for fraudulent
25 advertising, and the District Court certified a nationwide

1 class, and as part of that, determined that California law under
2 California's choice of law principles should apply to the entire
3 class.

4 And the reasons for that, the Court found that of
5 course it's a class action and so the Court had contacts --
6 California had contacts with all the claims, so that was
7 important. But also Honda's headquarters were in California and
8 the ad agency which issued the fraudulent ads was in California.
9 And so those three things -- and a fifth of the class members,
10 by the way, were all from California. So all of those things
11 the District Court felt justified applying California law to the
12 entire class.

13 Well, it went up to the Ninth Circuit after class was
14 certified, and in fact the Ninth Circuit reversed that and found
15 that it was error for the District Court to have applied
16 California to all of those plaintiffs because California has
17 limited interests in the other state residents, and as well,
18 each one of those states has an interest, a federalism-type
19 interest in having its own laws applied to its own residents.
20 In that case, its own consumer protection statute.

21 Here it's very similar. Texas, for whatever reason,
22 good or bad, has decided that rule of law for Texas means that
23 you have to have heightened evidence when you're going to use
24 epidemiologic evidence, like we have here, to prove your case.
25 And they've already made the balance.

1 If you look at the *Havner Garza* -- excuse me -- the
2 *Havner* case, then you look at the *Garza* case, and they
3 specifically talk about the balancing. And they've already done
4 it, not only in general, but with regard to this issue, they
5 recognize it's a balance between consumer protection and rule of
6 law.

7 And in this case, they feel that this is the balance
8 that Texas has struck for its own residents, and it would be --
9 it would not further that policy if a Texas resident gets a
10 lower standard of proof when they file outside the state than
11 when -- if they file in the state. And it really has little to
12 do with protecting Texas corporations.

13 I mean, those cases, *Havner* and *Garza*, weren't about
14 Texas corporations. They weren't about protecting Texas
15 corporations from frivolous litigation. It was really about
16 rule of law.

17 But even if we wanted to talk about corporate
18 protection in particular, protection of pharmaceutical
19 companies, in addition to the *Havner* and *Garza* cases, you can
20 also look at the Texas legislature has issued particular
21 statutes. We cite them in our brief, which are the -- the aim
22 is to keep FDA-approved medications for Texas residents at fair
23 price.

24 So whether you consider it rule of law or whether you
25 consider it protectionism for pharmaceutical companies, it

1 doesn't matter. Either way, Texas has expressed a distinct and
2 important interest in having its law applied, regardless of
3 where the Texas residents are and regardless of what choice of
4 law rules apply.

5 Similarly, Texas has consistently said that they want
6 their law applied, and it's done -- even MDLs have applied
7 *Havner* even when the MDLs have sat outside of Texas.

8 So therefore for those reasons, we think Texas has
9 expressed a clear interest which outweighs California's minimal
10 interest in protecting non-California residents.

11 And for a moment on the McKesson issue, as you noted,
12 McKesson is a wholesaler. Their principal place of business is
13 in California. However, 22 of the 35 remaining Texas plaintiffs
14 never sued McKesson. And even those who sued McKesson, there is
15 maybe one sentence in the Complaint about them. No discovery
16 has been taken of McKesson and little has been done at all with
17 regard to McKesson.

18 And McKesson was a wholesaler who had no active duty
19 and -- or no active involvement in the product development
20 process and they couldn't have changed the warnings if they
21 wanted to, and that's really the issue that we're here about
22 today.

23 And again if you go back to where we started, which
24 was the *Mazza* case, in the *Mazza* case, Honda, the primary target
25 defendant, as well as the ad agency, were both from California,

1 and nevertheless the application of the California governmental
2 interest test properly applied resulted in not having California
3 law apply to those out-of-state residents.

4 THE COURT: All right. Thank you.

5 Anything else?

6 MR. GRIFFIN: Your Honor, may I defer my response to
7 Mr. Worley?

8 THE COURT: Certainly.

9 MR. WORLEY: Your Honor, Don Worley with McDonald
10 Worley in Texas, by the way.

11 I want to take just a moment, if possible, and talk
12 about the -- in the Hornsby and Adams plaintiffs -- actions, we
13 did not include McKesson, so it was between Texas residents and
14 AstraZeneca, and I would argue I'm not here today from Texas to
15 tell you who California should protect, but I would humbly
16 suggest that if it's a choice between citizens from Texas or a
17 pharmaceutical company from Delaware, that the residents of
18 Texas add more to the California economy.

19 But I also wanted to talk briefly about *Havner*.
20 *Havner* does not say if you don't have -- and I understand I'm
21 going into applying Texas law instead of applying California
22 law, but if you'll give me just a moment -- it doesn't say if
23 you don't have two independent studies that have a doubling of
24 the risk, you lose. It says if you have those, you win. But it
25 doesn't say you lose on summary judgement.

1 You have to look at the totality of the evidence in
2 the matter. If you don't have those studies, you have to look
3 at the studies you have, and what we have to meet our burden
4 today of a fact issue to be able to go to the jury with, not
5 trying our case or trying the experts, but whether we have a
6 fact issue, we have the studies, and Dr. Bal did review -- if it
7 helps the Court, I'm not trying to get back into the Dr. Bal
8 argument, but I'm trying to offer this to be helpful to the
9 Court.

10 He said on page 9 of his deposition that he reviewed
11 his report, the literature that he looked at, and he also looked
12 at some material online at PubMed and MEDLINE, and so the Court
13 knows, those are databases that contain the published
14 peer-reviewed medical literature compiled by the National
15 Library of Medicine database, including all published studies.

16 And on that note, on behalf of the Adams and Hornsby
17 plaintiffs, I would like to say that it's not -- the studies
18 that were reviewed by Dr. Bal for you to review and under a
19 *Havner* situation, I think the word *association* -- first I would
20 argue that means fact issue. But a quote from the study that
21 they were discussing earlier said *We found that use of protein*
22 *pump inhibitors increase the risk of hip fractures after five or*
23 *more years of continuous exposure and the risk of any*
24 *osteoporotic fracture was increased after at least seven years*
25 *of continuous exposure to protein pump inhibitors.*

1 So there's a fact issue on how long the exposure is,
2 but Dr. Bal considered that and he considered that AstraZeneca
3 voluntarily changed their warning label of May of 22 -- May of
4 2010 to include the injuries that we're talking about today.

5 And as an orthopedic surgeon, the plaintiffs in Adams
6 and Hornsby feel that he's qualified to testify as to what
7 causes the injuries that he treats.

8 So all that -- you have to take the whole totality of
9 the evidence under a *Havner* decision to decide -- and here is
10 their quote, if it's helpful to the Court. *The court should*
11 *allow a party to present the best available evidence and only*
12 *then should a court determine from a totality of evidence*
13 *whether there is legally-sufficient evidence to support a*
14 *judgment.*

15 So you have to look at the totality of the evidence:
16 The FDA warning, the change of the label to include these
17 injuries by the FDA, Dr. Bal's independent study, his
18 testimony -- studies that he reviewed and that are at issue
19 today and the totality of the evidence that we have today to
20 consider that.

21 And so in closing, I would just argue that California,
22 in my humble opinion, has an interest of protecting residents
23 from all states, especially Texas and not --

24 THE COURT: Especially Texas?

25 MR. WORLEY: Especially Texas, as that's where I'm

1 from, your Honor.

2 And not to say a defendant can hurt someone in
3 California as long as they're from Texas.

4 Thank you.

5 THE COURT: All right. I will get my ruling out as
6 soon as possible. Thank you.

7 (Proceedings adjourned at 2:46 p.m.)

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CERTIFICATE OF OFFICIAL REPORTER

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I, Pamela A. Batalo, Federal Official Realtime Court Reporter, Registered Professional Reporter, in and for the United States District Court for the Central District of California, do hereby certify that pursuant to Section 753, Title 18, United States Code, that the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Date: October 1, 2014

/s/ Pamela A. Batalo
Pamela A. Batalo, CSR, FCRR, RMR
Federal Official Court Reporter

