

In The Matter Of:

Pledger v.

Janssen

(Jury Trial-PM Session)

Vol. V

January 30, 2015

John J. Kurz, RMR-CRR, Official Court Reporter

City of Philadelphia

First Judicial District Of Pennsylvania

100 South Broad Street, 2nd Floor

Philadelphia, PA 19110

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IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: RISPERDAL® LITIGATION :
March Term, 2010, No. 296 :
----- :
Phillip Pledger, et al., :
Plaintiffs, : APRIL TERM, 2012
v. : NO. 01997
: :
Janssen Pharmaceuticals, Inc., :
Johnson & Johnson Company, :
and Janssen Pharmaceutical :
Research & Development, :
L.L.C. :
Defendants. :

- - -
FRIDAY, JANUARY 30, 2015
- - -

COURTROOM 425
CITY HALL
PHILADELPHIA, PENNSYLVANIA
- - -

B E F O R E: THE HONORABLE RAMY I. DJERASSI, J.,
and a Jury
- - -

JURY TRIAL - VOLUME V
- AFTERNOON SESSION - (AMENDED)

REPORTED BY:
JOHN J. KURZ, RMR, CRR
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

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- I N D E X -

WITNESSES	CROSS
DAVID A. KESSLER, M.D.	
By Ms. Sullivan	19

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1 (The following transpired in open
2 court outside the presence of the jury, at
3 1:45 p.m.):)

4 - - -

5 COURT CRIER: Come to order.

6 THE COURT: All right. You can be
7 seated.

8 All right. Before we are ready to
9 proceed on cross-examination, before we do
10 so, let me just give you some guidelines
11 regarding these issues.

12 You know what, Dr. Kessler, why don't
13 you just step out just for a moment.

14 (Witness, Dr. Kessler, exited the
15 courtroom.)

16 THE COURT: All right.

17 First of all, in relationship to the
18 question regarding the fee situation, how
19 cross-examination may proceed, I am going to
20 follow the Mohn versus Hahnemann Hospital
21 case, at 357 Pa. Super 173, 815 A.2d 920,
22 1986, and specifically as a guide. I've made
23 a copy of this for defense counsel.

24 Judge Rau's opinion at Molinaro
25 versus Ramoska, 2006 WL 620 9929, April 12,

1 2006, I think she had a real good guide there
2 on Page 10 out of 19, which we just printed
3 out. And in that case, I agree with her, she
4 thought it was -- extensive cross-examination
5 she permitted as follows: The total number
6 of cases he has testified; the number of
7 cases per year; the percentage of plaintiff
8 versus defense; the number of states in which
9 the witness has testified in; what portion of
10 the expert witness's work is part of his
11 income. Those were all permitted.

12 As long as we don't get into the
13 numbers, the specific numbers for anything
14 outside of this case, that is the guideline,
15 all right?

16 And that will be strictly enforced.

17 Here is for, I guess, the defense
18 team is that little portion on Page 10 out of
19 19, and I kept one for the other counsel.
20 Same procedures would follow for any defense
21 witnesses. For any --

22 MS. SULLIVAN: And, Your Honor, I
23 just would note that Mr. Kline went into that
24 precise subject with Dr. Kessler on direct,
25 so I think the door's been opened here on

1 that.

2 THE COURT: Well, the door has not
3 been opened to specific numbers of fees
4 generated by other cases. That is specific.
5 And I will admonish you in front of the jury
6 if you attempt to do that here with this
7 specific guidance that I'm providing.

8 And now as to the other question
9 having to do with Mr. Kline's very late
10 motion, there are some issues that need to be
11 addressed. Essentially, the motion is
12 basically saying that the Pennsylvania Rules
13 of Evidence in its peculiarity forbids or
14 precludes the admission of US documents.

15 And I believe that would be under,
16 what was that, under Section 6104 by statute,
17 42 Pa. C.S.A. Section 6104. It wasn't by
18 Rules of Evidence. It was by statute.

19 However, what was neglected to be
20 mentioned to the Court is the existence of
21 Section 5328 of the same title, "Proof of
22 Official Records."

23 Now, that particular statute does
24 permit a court to introduce certified --
25 self-authenticated certified documents of the

1 US government.

2 Do we have those?

3 MS. SULLIVAN: Yes, Your Honor.

4 THE COURT: Okay.

5 MS. SULLIVAN: I'm sorry, Judge.

6 THE COURT: Let me just see one of
7 them and make sure that they are
8 self-authenticated and then we may proceed.

9 MS. SULLIVAN: You want an FDA
10 document?

11 THE COURT: Anything that you intend
12 to use, they do have to be
13 self-authenticated.

14 MS. SULLIVAN: And, Judge, there's
15 two grounds for admission -- one is the
16 public records exception, and the other is
17 the business records exception -- because
18 Janssen maintains these FDA documents in the
19 ordinary course of business. They're
20 attached to all of their FDA approvals, all
21 the medical reviews, and it's part of their
22 business records, and --

23 THE COURT: Well, I haven't been
24 asked to review the business record nature of
25 the documents. The objection has been based,

1 at the moment, on whether or not these are
2 public documents or official records that may
3 be admitted.

4 MS. SULLIVAN: I --

5 THE COURT: If you have another
6 grounds for admission, fine. But as far
7 as -- we can end the discussion if you have
8 certified documents.

9 MS. SULLIVAN: Well, I have -- I
10 don't have a stamped certified. But I have
11 an FDA heading signed by an FDA official on
12 all of these documents.

13 THE COURT: No.

14 MS. SULLIVAN: Then, Your Honor, I
15 submit they should be admitted as business
16 records. I'll have a witness come. They all
17 are maintained by Janssen in the ordinary
18 course as part -- and they're --

19 THE COURT: Well, the problem here,
20 of course, is that by filing this late, after
21 a motion in limine, it should have been filed
22 before trial. You were not given the chance
23 to comply with the technicality of Section
24 5328. So now I need to know exactly what
25 documents you are intending to use.

1 MS. SULLIVAN: Sure.

2 THE COURT: In much the same fashion
3 as we did for the plaintiff, so I can limit
4 this discussion before the jury.

5 MS. SULLIVAN: Sure, Your Honor. And
6 I can pull up --

7 THE COURT: All right. Let's see the
8 documents.

9 MS. SULLIVAN: And they are -- and we
10 can get them -- but they are FDA approval
11 letters, FDA medical review officer --

12 THE COURT: Well, how many of them
13 are there?

14 MS. SULLIVAN: There's been six or
15 seven different approvals, so there's
16 several.

17 THE COURT: Well, let's see them.
18 Let's get them marked and do it hopefully
19 within ten minutes and get rolling here.

20 MS. SULLIVAN: Your Honor, this,
21 again, this was sprung on us right before
22 cross-examination. It's going to take awhile
23 to get this stuff together.

24 THE COURT: Well, do you plan to use
25 it during cross-examination?

1 MS. SULLIVAN: I do, Your Honor.

2 THE COURT: All right.

3 - - -

4 (Pause.)

5 - - -

6 MR. KLINE: May I be heard just
7 briefly?

8 MS. SULLIVAN: Your Honor --

9 THE COURT: Well, you may be heard,
10 otherwise then we're going to have to go into
11 the business records. Maybe everything will
12 come in.

13 MS. SULLIVAN: Yeah. Your Honor, you
14 permitted Mr. Kline to use all these e-mails
15 subject to --

16 THE COURT: I want to know ahead of
17 time what the evidentiary disputes are so we
18 don't get into a situation where every single
19 document is being contested before the jury,
20 requiring sidebar and interruptions.

21 MS. SULLIVAN: May I make a
22 suggestion, Judge? Why don't we start the
23 cross-examination and then we can break at a
24 point --

25 THE COURT: Very well.

1 MS. SULLIVAN: I think I can get a
2 fair amount --

3 THE COURT: As long as you don't use
4 these documents --

5 MS. SULLIVAN: So they can --

6 THE COURT: As long as you don't use
7 these documents before the break.

8 MS. SULLIVAN: Thank you, Your Honor.

9 THE COURT: All right. Now let's go.
10 Yes, sir.

11 MR. KLINE: Your Honor, my point,
12 respectfully, was not to spring anything on
13 anyone. I simply -- I simply thought that
14 rather than standing up and objecting, that a
15 bench memo would suffice.

16 All I was suggesting was that rather
17 than running to sidebar the first time, that
18 I would do it this way.

19 I don't believe that it is kind of
20 the "motion in limine" material. My view of
21 it was, respectfully, that it was when we try
22 complicated cases, that we occasionally say
23 to the court -- just like I did with the
24 Kessler money thing -- hey, here are the
25 cases in advance. I think this is going to

1 come up. So I would hope the Court would not
2 think that I was trying to do something.

3 THE COURT: No.

4 MR. KLINE: Second --

5 THE COURT: I am glad we are able to
6 resolve it so that we are not interrupted.

7 MS. SULLIVAN: Your Honor, there was
8 25 in limine motions. This is the core of
9 our case, and they spring this on us now,
10 come on.

11 THE COURT: Well --

12 MR. KLINE: It's not --

13 THE COURT: -- in any event, we
14 are -- I have reviewed the law on it, and I'm
15 confident that this stuff was admissible, you
16 know, if it had notice.

17 MR. KLINE: Here's my -- but some of
18 it I do believe is admissible, and my point
19 in the memo was this -- my point was simply
20 this: That there are certain documents,
21 there are certain things that they want --
22 there are certain documents that they would
23 like to put before the witness, which are
24 third-party documents, which are out-of-court
25 statements, which are hearsay.

1 My only point in this whole memo, my
2 core point in the memo was that, to that
3 extent, I didn't believe that under
4 Pennsylvania law, a court can allow those
5 type of statements. And, again, two or three
6 more sentences.

7 I'm not suggesting that they can't
8 say that the FDA approved this drug -- my
9 word, I've said. They can't -- they're
10 not -- that's a fact. Facts in these reports
11 are allowable. Opinions of others are not.
12 And so all I was saying to the Court was
13 rather than being a jumping jack during
14 cross-examination, that it would be
15 well-advised for me not to spring something
16 on somebody, but simply say to the Court,
17 Hey, we're now going to have an issue which
18 has to do with things that they're going to
19 read to the FDA, like didn't you know that
20 the FDA thought that it was this and that?
21 That's a third-party statement. It's out of
22 court. It's not subject to
23 cross-examination.

24 And for whatever the quirk is in
25 Pennsylvania law, we have a different view of

1 803.6 than the feds. And so my only point in
2 doing this was to say, Hey, ahead of time, I
3 believe, Your Honor, that hearsay statements
4 in FDA documents are not admissible.

5 By the way -- by the way, Your Honor,
6 I'm not here to try to put the defendants to
7 the task of bringing in a copy with a ribbon
8 on it. That's not what this is all about.
9 And this is not about trying to hold up the
10 trial or do something silly. It's just to
11 alert the Court to the fact that I believe
12 that based on the cross-examinations that
13 I've seen of Ms. Sullivan in other
14 pharmaceutical matters -- and I'm not -- I'm
15 not disparaging it. I'm just saying that I
16 know that she's going to say: Isn't it true
17 that FDA, Ms. Woodcock, thought this? And
18 isn't it true that FDA executive so-and-so
19 thought that?

20 And my only point is that as to
21 facts, as to the facts, was it approved or
22 not approved, that's fair game.

23 As to what FDA officials were
24 thinking, I don't believe comes in under
25 either Pennsylvania hearsay, the hearsay

1 rule, which is somewhat different, at least
2 as I understand it, than the federal rule
3 that allows a much more expansive view. My
4 only point was it's not a motion. It's not a
5 last-minute ditch effort. It's to say I
6 don't want to be at sidebar, Judge. That's
7 all I was trying to do.

8 THE COURT: All right. Well, if
9 we're at sidebar on hearsay issues, then
10 we're at sidebar on hearsay issues.

11 MR. KLINE: Okay.

12 THE COURT: The memorandum that I
13 read had to do with the public record, proof
14 of official records, and actually no mention
15 of the effect of official records generally.
16 One of these statutes wasn't even cited. So
17 I'm fine with the hearsay.

18 I will say this: That as a general
19 matter, we are going to be hopefully looking
20 at Dr. Kessler's cross-examination in the
21 same way we were addressing his direct
22 examination. If, of course, you open the
23 door to asking him what he thinks was going
24 on in the FDA's mind, you will then be
25 opening the door to a rebuttal that was not

1 permitted during direct examination,
2 Ms. Sullivan.

3 MS. SULLIVAN: And, Your Honor, just
4 on the public records, these are official
5 conclusions not of one person, of the FDA.

6 THE COURT: I haven't seen the
7 documents yet, so let's go forward. You're
8 saying you're going to think it over on a
9 break and we'll look at it. I don't know
10 what the documents are.

11 But I'm not afraid of any kind of
12 objections involving hearsay. But, again, we
13 permitted hearsay in terms of the
14 out-of-state documents that -- out-of-court
15 documents that were admitted in relationship
16 to these e-mails, so that is not very
17 persuasive.

18 It has to do with what you're asking
19 Dr. Kessler to do, and all I'm saying is if
20 the rule is good for one, it's good for the
21 other.

22 Namely, if you want Dr. Kessler to
23 start telling the jury what he thinks was
24 going on in the minds of the FDA or whatever,
25 if that's the situation that we're going to

1 have, then that's a fair prompting for
2 rebuttal.

3 MR. KLINE: Okay.

4 THE COURT: All right.

5 MS. SULLIVAN: Understood, Your
6 Honor.

7 MR. KLINE: Your Honor, Page 2 of the
8 memo talks about 803.

9 THE COURT: I have 803, Mr. Kline,
10 right here. I have Bernstein's version.

11 MR. KLINE: I was just saying it
12 was his -- I have the yellow one.

13 THE COURT: Have a seat, Dr. Kessler.

14 MR. KLINE: He likes when counsel has
15 it in their hand.

16 THE COURT: I have it right in my
17 hand.

18 COURT CRIER: All rise as the jury
19 enters the courtroom.

20 - - -

21 (The following transpired in open
22 court in the presence of the jury:)

23 - - -

24 (Whereupon the jury entered the
25 courtroom at 2:01 p.m.)

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THE COURT: All right. Good
afternoon everybody.

JURY PANEL: Good afternoon.

THE COURT: Be seated.

All right. We're now going to begin
the cross-examination on behalf of Janssen
Pharmaceuticals.

Ms. Sullivan, you may proceed.

MS. SULLIVAN: Thank you, Your Honor.
Good afternoon everyone.

JURY PANEL: Good afternoon.

- - -

CROSS-EXAMINATION

- - -

BY MS. SULLIVAN:

Q. Good afternoon, Dr. Kessler. How are you?

A. I'm well. Good afternoon.

Q. Dr. Kessler, you and Mr. Kline spent awhile
going through numbers and statistics and things on
Dr. Findling's article; do you remember that?

A. The Janssen pooled analysis.

Q. Yes.

A. Yes.

Q. And you've also read Dr. Mathisen, the

1 prescribing physician's deposition in this case; you
2 mentioned that the other day?

3 A. Yes.

4 Q. And you know, Dr. Kessler, that Dr. Mathisen
5 never saw the article that you two have been
6 spending hours talking about, right?

7 A. You'd obviously have to ask Dr. Mathisen. I
8 have no reason to dispute that statement.

9 Q. But you have his deposition. Did you see his
10 testimony, sir, where he said I never saw the
11 Findling article?

12 A. Yes. But I would rather not talk about
13 deposition testimony when you have a witness. But,
14 yes, I agree with you. That's what I read.

15 Q. You read that he never saw the Findling
16 article?

17 A. Yes; the Janssen pooled analysis, yes.

18 Q. And, Dr. Kessler, you spoke to -- you gave a
19 little speech to our jurors yesterday about the
20 importance of telling the whole truth, right?

21 A. Yes.

22 Q. And, Dr. Kessler, you haven't told our jurors
23 the whole truth in this case, have you, sir?

24 A. Tell me what question -- and I've been on the
25 stand for now two days. Tell me what I've not told

1 the whole truth.

2 Q. All right. Dr. Kessler, let's start with
3 Plaintiff's Exhibit 45.

4 If I could have the ELMO, Ken.
5 (Document P-45 displayed on the
6 screen.)

7 BY MS. SULLIVAN:

8 Q. And, Dr. Kessler, you remember going through
9 this e-mail --

10 A. Can I see a copy, please?

11 Q. Oh, I'm sorry. Sure. Of course.

12 THE COURT: All right. Yeah. This
13 is another thing, which -- is this in
14 evidence now? What number is it?

15 MS. SULLIVAN: Yes, Your Honor. It's
16 Plaintiff's Exhibit 45.

17 THE COURT: Can we have 45, the court
18 copy shown to -- the hard copy shown to
19 Dr. Kessler.

20 COURT CRIER: Yes, Your Honor.

21 MR. KLINE: May we follow with the
22 Bates number? Because on redirect I want to
23 pull up the Bates that we were doing.

24 THE COURT: Well, the Bates number --
25 you know, whatever the Bates number is, let

1 me see it.

2 The Bates No. is 03892170.

3 COURT CRIER: P-45 to the witness.

4 BY MS. SULLIVAN:

5 Q. And, Dr. Kessler, do you have it?

6 A. I do.

7 Q. Okay. And this is an e-mail -- looking at the
8 bottom -- November 2002, from Carin Binder. Do you
9 see that?

10 A. I see a November 18. Am I reading that wrong,
11 ma'am?

12 Q. Yeah. November 18, 2002.

13 A. Yes.

14 Q. And you know, Dr. Kessler, that Carin Binder
15 is a Janssen person in Janssen Canada, right?

16 A. In Toronto, yes.

17 Q. Yes.

18 And she's writing to Gahan Pandina
19 and the US group -- she's actually writing to these
20 people at Janssen saying Gahan and the US group
21 convened a child and adolescent advisory board on
22 November 15th. Do you see that?

23 A. Yes. The meeting in New York, I believe, yes.

24 Q. And you know, Dr. Kessler, that the US group
25 refers to Janssen's scientists in the US working on

1 these prolactin and Risperdal issues, right?

2 A. I assume so, yes.

3 Q. Yeah.

4 So the US group at Janssen convened
5 an advisory board, and the advisory board are the
6 outside advisors that you talked about, right?

7 A. Yes; Dr. Rapoport, et cetera.

8 Q. And they're talking about this manuscript that
9 you and Mr. Kline talked about. The authors have
10 just finished reviewing this Findling manuscript on
11 the prolactin issues, right?

12 A. Right.

13 Q. And it goes down to say, "Secondly, the US
14 group" -- and that's referring to the Janssen US
15 scientists, right? -- "the US group recommended that
16 the manuscript list all cases of gynecomastia in
17 males and state whether prolactin levels were normal
18 or elevated as well as state the new rates of
19 gynecomastia as identified by the endos." Do you
20 see that?

21 A. Yes.

22 Q. And, Dr. Kessler, it goes on to state that
23 they felt -- referring to the Janssen US
24 scientists -- that applying the endos' position of
25 gynecomastia in boys in puberty not being SHAP

1 without listing all gynecomastia was hiding the
2 data. Do you see that?

3 A. I see that exactly.

4 Q. And so, Dr. Kessler, when you and Mr. Kline
5 were suggesting to our jurors that it was the
6 outside scientists saying it would be hiding the
7 data not to include all gynecomastia, the truth is
8 it was Janssen saying we've got to include all
9 gynecomastia in the manuscript?

10 A. If you can give me back my exact sentence, I
11 think I said he said what it says.

12 Q. Yeah. And so what it says, Dr. Kessler, is
13 that the US scientists at Janssen were saying we
14 have to put all of the gynecomastia cases in this
15 study, right?

16 A. That -- that's what that says.

17 Q. Yeah.

18 A. And the meeting minutes also say that was
19 based on what your outside expert said.

20 Q. And what you didn't tell our jurors and what
21 Mr. Kline and you skipped over was the fact that the
22 outside scientists, the pediatric endocrinologists
23 who were on the Findling study, including some
24 pretty famous people, did not want to include the
25 SHAP (A) stuff because they thought it was not good

1 data because so many boys get gynecomastia
2 naturally, right?

3 A. No, I don't think that's in fact what I saw
4 happen.

5 Q. Well, let's look at what the document actually
6 says.

7 A. Right.

8 Q. And so -- and just to go back, Dr. Kessler, on
9 the Findling. The jury has heard -- and we can
10 remind them -- that there were outside authors on
11 this paper in addition to Janssen folks, right?

12 A. Yes. There were four -- there were four
13 outside experts.

14 Q. And there were actually two pretty
15 well-respected pediatric endocrinologists, right?

16 A. There were.

17 Q. Yes. And one was actually the chief of
18 pediatric endocrinology at CHOP here in
19 Philadelphia, right?

20 A. Who's no longer living, I believe.

21 Q. Yeah, unfortunately. Otherwise he could
22 actually come in and tell us what this means.

23 MR. KLINE: Oh, objection, Your
24 Honor. Objection.

25 THE COURT: That's sustained, as to

1 what he can tell us.

2 MR. KLINE: And he --

3 THE COURT: Go ahead.

4 MR. KLINE: -- might have told us the
5 opposite.

6 MS. SULLIVAN: And, Your Honor,
7 Mr. Kline has a habit of having a running
8 commentary during questioning. I would just
9 ask that --

10 THE COURT: Well, you did say
11 "unfortunately." We don't know whether it
12 was fortunate or not fortunate, Counsel.
13 Just go ahead.

14 BY MS. SULLIVAN:

15 Q. The fact is, Dr. Kessler, that Dr. Moshang who
16 was the chief of endocrinology and one of the
17 authors on this paper can't come in here to talk to
18 us about what was actually said and why, right?

19 A. Yes, he cannot, unfortunately.

20 Q. And you weren't involved personally in any of
21 this stuff?

22 A. No, that's correct.

23 Q. You're coming back ten years later saying I
24 think this is what this means, these are what these
25 documents say and giving your opinions, right?

1 A. No, I don't think it's what I think. It's
2 what I see in the documents.

3 Q. Yeah. But --

4 A. And the data that I see in the documents and
5 the calculations that I saw in the documents that
6 are not in the final document.

7 Q. But, Dr. Kessler, why things are included and
8 why they weren't, you weren't there and you weren't
9 part of those discussions?

10 A. Motive I can't talk about.

11 Q. Yeah.

12 A. So why people left the data out, okay. But it
13 is important at this meeting that --

14 Q. And, Doctor --

15 A. -- that this group of advisors never saw, from
16 what I can see, the data.

17 Q. And, Dr. Kessler, you know that's not true;
18 and we'll look at it.

19 A. So they saw these -- the statistically
20 significant finding?

21 Q. Yes. And we're going to show the jury that,
22 Dr. Kessler. But stick with me on this, okay?

23 A. Of course, ma'am.

24 Q. And, Dr. Kessler, you agree it's not good
25 science and it's not right to just cherry-pick out

1 pieces of information and not tell the whole story,
2 right?

3 A. Well, so I've heard that --

4 Q. Can you answer that, Dr. Kessler? Do you
5 agree it's not right to cherry-pick out pieces of
6 information and not tell the whole story?

7 A. When it comes to safety -- let's say you have
8 a red leg, your leg is all red and inflamed -- and I
9 don't mean to be personal, right -- I have to look
10 at that leg, okay. So of course my attention is
11 selected on when there is a positive result, okay.

12 When you're talking about
13 effectiveness, if you're talking about causation,
14 right, I agree you want to look at the totality of
15 everything.

16 Q. Yeah.

17 A. When you're dealing with safety, you have to
18 look at what's salient.

19 Q. Okay. And, Dr. Kessler, even when it comes to
20 reading e-mails, it's good to look at the whole
21 story, not to cherry-pick out a line here or a
22 document here, right?

23 A. I -- I -- show me anything you want to show
24 me.

25 Q. Let's do that, Dr. Kessler.

1 And so here it talks about the fact
2 that the -- it talks about the endos, right? The
3 endos' position of gynecomastia in boys. So it says
4 they felt that applying the endos' position -- and
5 that's talking about the pediatric endo authors
6 outside the company, right? Dr. Findling -- I'm
7 sorry, Dr. Daneman and Dr. Moshang, right?

8 A. Yes.

9 Q. Okay. And saying that the endos' position --
10 they felt the endos' position of gynecomastia in
11 boys in puberty not being SHAP without listing all
12 gynecomastia was hiding data. Do you see that?

13 A. (No response.)

14 Q. And so what Janssen is saying in this e-mail
15 is that we think that the pediatric endocrinologists
16 outside the company, their suggestion about not
17 including the boys over 10 would be hiding data so
18 we'd like to include it, right?

19 MR. KLINE: Object.

20 BY MS. SULLIVAN:

21 Q. That's what they're saying.

22 THE COURT: Wait. Is there an
23 objection, sir?

24 MR. KLINE: Yes. First of all, to
25 yelling.

1 THE COURT: First of all, there is an
2 objection?

3 MR. KLINE: Yes. The objection is,
4 first of all, to the yelling.

5 The second --

6 THE COURT: That's overruled. Go
7 ahead.

8 MR. KLINE: The second --

9 MS. SULLIVAN: I didn't think I was
10 yelling. I apologize.

11 THE COURT: All right. Go ahead.

12 MR. KLINE: The second objection is
13 to the interpretation of this, the same as we
14 discussed --

15 THE COURT: Well, that I had
16 sustained, unless you want to change the
17 procedures, Ms. Sullivan. I agree; you're
18 asking him now to comment himself on what was
19 going on in the minds of the people who wrote
20 this and we did not permit him to do that
21 during direct examination.

22 MS. SULLIVAN: Okay.

23 BY MS. SULLIVAN:

24 Q. Well, we can look at what the words say,
25 Dr. Kessler, and what the words say is that Janssen

1 US recommended that the manuscript list all cases of
2 gynecomastia and that the endos' position -- these
3 outside authors -- not listing all cases and just
4 listing boys not in puberty would be perceived as
5 hiding data. That's what Janssen is saying, right?
6 That's what it says.

7 A. Uhhh, it says what it says. There are
8 pronouns. You can certainly interpret that the way
9 you wish.

10 Q. Yeah. And --

11 A. It is about -- the issue is hiding data.

12 Q. Yeah. And Janssen is saying the outside
13 endocrinologists, including one of the leading
14 experts in endocrinology who was at CHOP --

15 MR. KLINE: Objection.

16 BY MS. SULLIVAN:

17 Q. -- had suggested not including boys in
18 puberty?

19 THE COURT: There's an objection.

20 However, it was mistimed. It was during a
21 question. All right. Overruled.

22 Go ahead.

23 BY MS. SULLIVAN:

24 Q. So just to back up, Dr. Kessler, there is a
25 background rate of gynecomastia in the general

1 population. Gynecomastia has been around a long
2 time before Risperdal, right?

3 A. Could you -- could you be a little more
4 specific in that question? A little more -- when
5 you say a "background rate," are you talking about
6 adults? You talking about kids?

7 Q. Boys.

8 A. Talking about in puberty?

9 Q. Yeah. Boys during puberty get gynecomastia;
10 it happens?

11 A. Uhmm...

12 Q. And percentages would range anywhere from 20
13 to 90 percent in the medical literature. Are you
14 aware of that, sir?

15 A. So I've gone back; I've read the studies. I
16 read the CAM studies going back into the 1960s.
17 There is -- we saw a description of that in the
18 e-mails, and you just have to be careful with the
19 term "gynecomastia" and what's transient and what
20 disappears and what is permanent. So just -- you
21 have to be careful on the definitions that are used.

22 Q. And, Dr. Kessler, one of the things, looking
23 at the documents and looking at the depositions of
24 some of the authors on this paper, you know that
25 they were concerned by the background rate of

1 gynecomastia in the public; that is, if you include
2 adolescent boys in the study, it will mess up your
3 study.

4 A. No. You're missing Janssen -- the
5 significance of the Janssen study, Ms. Sullivan,
6 because you have two groups. You have an above the
7 upper limit of normal, right, and you have within
8 the normal level. So, in essence, you have a
9 comparison. So you should have, if you're right,
10 that there is -- I mean, it's messing up the study,
11 right. You have a built-in control, in essence. So
12 I'm happy to discuss about that.

13 Q. No. We'll look -- why don't we look at some
14 of the things the authors of the study actually say,
15 Dr. Kessler.

16 A. Sure.

17 Q. And so this e-mail in 2002 notes that the
18 authors have just finished reviewing the manuscript,
19 right?

20 A. (No response.)

21 Q. Do you see that in the first bullet?

22 A. I assume this is the -- yes, I see that.

23 Q. Okay.

24 A. I'm not sure exactly who that refers to. I
25 assume it's the authors of the Janssen pooled --

1 whether that's Janssen employees or outside
2 employees.

3 Q. And it refers to some of the outside authors'
4 position, the outside pediatrics' position of not
5 including gynecomastia in all boys, right?

6 A. No. Ma'am, you're -- you're --

7 Q. Dr. Kessler, can you try to answer my
8 question?

9 A. I am. I don't think those are the two -- I
10 don't think that overlaps.

11 If you take out the attendees, if you
12 could -- would be so kind, the attendees at the New
13 York meeting, Ms. Rapoport, Peter Jensen, I can pull
14 the list, those are not the authors.

15 So, again, I'm not sure, you know,
16 which groups we're talking about when you're talking
17 about the endos' position or the authors' position
18 or whether you have the advisors' position. So we
19 just have to be exact.

20 Q. Yeah. And, Dr. Kessler, you know the endos
21 were the outside authors. They were the only endos
22 on this study, right? Dr. Moshang and Dr. Daneman,
23 those are the outside authors?

24 A. Those are the authors -- those were the two
25 endos on the paper.

1 Q. Yeah. Exactly.

2 A. But --

3 Q. And so this document refers to the endos'
4 position of not including SHAPs of boys going
5 through puberty, right? That was the outside
6 authors' suggestion. And Janssen said "we can't do
7 that." That's what this says.

8 A. After your other group of advisors said it
9 would not be transparent.

10 Q. Yeah. And then --

11 A. Wait.

12 Q. Just to be clear, Dr. Kessler --

13 THE COURT: You know, what I need
14 here is if you're going to ask questions that
15 invite an answer of some length, then we're
16 going to permit that answer to be made.

17 MS. SULLIVAN: Okay. I understand,
18 Your Honor.

19 BY MS. SULLIVAN:

20 Q. And, Dr. Kessler, one of the things that you
21 and Mr. Kline didn't do when you had this document
22 up is show the whole story, right?

23 A. Please, I -- I --

24 Q. Well, you got --

25 A. I very much want, show the entire story.

1 Q. You guys didn't turn the page, did you?

2 A. Ma'am, with all due respect, I wasn't asking
3 the questions.

4 Q. Yeah. But you didn't correct Mr. Kline or
5 Mr. Kline didn't show the jury --

6 THE COURT: Counsel.

7 BY MS. SULLIVAN:

8 Q. -- the page.

9 MR. KLINE: Come on, Your Honor.

10 THE COURT: Is that a question?

11 MS. SULLIVAN: Yeah.

12 THE COURT: Please get to the
13 question.

14 BY MS. SULLIVAN:

15 Q. And if you had actually turned the page,
16 Dr. Kessler --

17 THE COURT: What page? What document
18 is this now, P-40...

19 MS. SULLIVAN: This is P-45.

20 THE COURT: We have that. All right.

21 BY MS. SULLIVAN:

22 Q. If you had turned the page, Dr. Kessler, it
23 talks about the fact that Carin Binder, one of the
24 authors on the paper, says I have no problem, I have
25 no problem adding in gynecomastia in boys over 10

1 and keeping the pediatric endo analysis in the
2 manuscript. Do you see that?

3 A. It -- it says that, yes.

4 Q. Yes.

5 So Janssen is saying here that even
6 though the outside authors want just this analysis
7 without the pubertal boys, we have no problem
8 putting it all in there, right?

9 A. No, ma'am.

10 Q. That's what she said.

11 A. No, ma'am. May I explain?

12 Q. Well, let's look at the Findling --

13 A. May I explain why I think you're wrong?

14 MR. KLINE: Yes.

15 BY MS. SULLIVAN:

16 Q. Well, I'm sure Mr. Kline will ask you a lot of
17 questions about why I'm wrong.

18 MR. KLINE: Can we save the time,
19 Your Honor, by letting him answer the
20 question.

21 THE COURT: Well, we'll permit you to
22 move on. It is apparent that we will have a
23 redirect, so that's correct.

24 MR. KLINE: Your Honor, just on
25 procedure, may I have the Bates number when

1 she puts something up?

2 MS. SULLIVAN: He has copies, Your
3 Honor.

4 THE COURT: Well, again, if there's a
5 document there, Mr. Gomez, please help out
6 Mr. Kline on that front, please.

7 MR. GOMEZ: I will, Your Honor.

8 THE COURT: Thank you.

9 BY MS. SULLIVAN:

10 Q. And, Dr. Kessler, let's look at the actual
11 study, if we can, Plaintiff's Exhibit 49.

12 A. May I have a copy?

13 THE COURT: You have it, P-49.

14 MS. SULLIVAN: Yes.

15 THE COURT: Is this --

16 THE WITNESS: I'd be happy to go find
17 them in my book.

18 THE COURT: No, no. Where is this
19 document?

20 MS. SULLIVAN: It's a plaintiff's
21 exhibit.

22 BY MS. SULLIVAN:

23 Q. And, Dr. Kessler, this paper, in addition to
24 being reviewed by outside authors outside the
25 company, also went through something that's called

1 the peer-review process.

2 A. That's a good point. I looked for those in
3 the database, and I didn't see them.

4 Q. Well, we'll talk about that.

5 A. Great.

6 Q. Didn't you see the comments from the authors
7 in the manuscripts you reviewed? Did you skip
8 those?

9 A. I asked -- I saw the comments in the draft
10 manuscript, yes.

11 Q. Yeah. By the authors, outside authors?

12 A. We don't know exactly who made which comments.
13 But what I don't have, just to be clear, is I don't
14 have the -- when this manuscript was submitted, I
15 don't have the peer review. That was not in the
16 database that I could find from Janssen.

17 Q. Yeah. We wish we had it, too. The outside
18 authors apparently didn't keep it, and we don't have
19 any copies.

20 MR. KLINE: See, now, Your Honor,
21 objection.

22 THE COURT: Again --

23 MR. KLINE: You see, that's a
24 problem. Janssen --

25 COURT REPORTER: Excuse me.

1 (Counsel speaking overtop of each
2 other and the Court.)

3 THE COURT: You may be seated.

4 That is sustained as to some kind of
5 testimony about why some document is not
6 present.

7 You may proceed, Ms. Sullivan.

8 BY MS. SULLIVAN:

9 Q. And, Dr. Kessler, we know that on this paper,
10 in addition to the Janssen authors, there's four
11 authors outside the company, right?

12 A. Yes.

13 Q. And it's also -- this paper also went through
14 the peer-review process?

15 A. I have no doubt of that.

16 Q. Yeah.

17 And that process is -- in order to
18 get an article published in the scientific journal,
19 you have to submit it to a journal's board and some
20 outside doctors and scientists review it, give you
21 comments, make sure it's good science and legitimate
22 and decide whether you can have it published or not,
23 right? That's generally the peer-review process,
24 right?

25 A. No, that's incorrect.

1 Q. Okay.

2 A. Can I explain?

3 Q. And, Dr. Kessler, we talked about the fact
4 that we had Dr. Daneman from Toronto, and we have
5 Dr. Moshang from the Children's Hospital of
6 Philadelphia who are the two outside
7 endocrinologists, right, as the authors?

8 A. Yes.

9 Q. And we also have an outside author,
10 Dr. Kusumakar from Nova Scotia from the university
11 there, right?

12 A. Yes.

13 Q. And Dr. Findling who is a leading psychiatrist
14 out of Case Western, right?

15 A. He's now at Hopkins, yes.

16 Q. Yes.

17 And, by the way, right in the front
18 page of this paper, the outside authors at Janssen
19 talk about the fact that elevated prolactin has also
20 been associated with gynecomastia, right?

21 A. Just point --

22 Q. Page 1.

23 THE COURT: Wait. Again,
24 Ms. Sullivan, you must let him answer.

25 MS. SULLIVAN: Sure. I'm sorry, Your

1 Honor.

2 THE COURT: Take your time, you know.

3 THE WITNESS: Yes. There's a general
4 discussion here. Okay.

5 BY MS. SULLIVAN:

6 Q. On Page 1?

7 A. In the -- in the background.

8 Q. Yeah. On Page 1, though.

9 A. That says there -- let's point to the exact
10 sentence.

11 It says, "Elevated prolactin has also
12 been associated with gynecomastia."

13 Q. Right.

14 A. And then it keeps on going.

15 Q. Right.

16 A. And then it goes -- I mean, but the purpose
17 was to see whether there was an association, yes.

18 MR. KLINE: Like turn the page.

19 MS. SULLIVAN: And --

20 THE COURT: Doctor, I would like to
21 say one thing, in the interest of the
22 proceedings here.

23 I'm going to ask, Doctor, that you
24 answer her questions as asked, because in the
25 end, Mr. Kline will have an opportunity to go

1 over this testimony again with you for your
2 clarifications. So nothing is going to be
3 left out. But for purposes of procedure and
4 also for time --

5 THE WITNESS: Sure.

6 THE COURT: -- it's preferable to go
7 this route.

8 BY MS. SULLIVAN:

9 Q. And, Dr. Kessler, we can agree that just
10 because something is associated with something else
11 doesn't mean it causes it, right? There's a
12 difference between causation and association?

13 A. Yes.

14 Q. In other words, so if you do a study to see if
15 a medicine causes gray hair, you don't want a lot of
16 people over 50 because there's a big background rate
17 for gray hair in people over 50, right?

18 A. It depends how you design the experiment if
19 you have an internal control.

20 Q. And so one of the things that the outside
21 authors, the pediatric endocrinologists, were
22 worried about is that if you have a background rate
23 of pubertal gynecomastia in boys, you won't be able
24 to tell whether any elevated prolactin is associated
25 with Risperdal or is associated with puberty, right?

1 That was one of the concerns.

2 A. That was not one of the concerns when the
3 article -- when they were first convened.

4 Q. Well, let's take a look at the paper itself,
5 Dr. Kessler.

6 And the paper talks about the fact
7 that many of the side effects --

8 A. What page are you on, ma'am?

9 Q. I'm sorry. I'm on Page 1366.

10 A. Thank you.

11 Yes.

12 Q. And, Dr. Kessler, it says, "Many of the side
13 effects hypothetically attributable to elevation in
14 prolactin levels are also commonly seen during
15 puberty," right? See that? That's what it says?

16 A. I see it. Yes, I see that.

17 Q. And it also says, "Many of the children and
18 adolescents in this analysis were at the age of
19 puberty, so the cause of SHAP could be uncertain,"
20 right?

21 A. If it was uncontrolled, yes.

22 Q. And so it says -- and, Dr. Kessler, this was
23 not a controlled study?

24 A. Well, you had -- you had two groups, right.
25 So you have, in essence -- I mean, it is --

1 Q. The analysis was two groups, but --

2 THE COURT: All right. I'm going to
3 permit him to answer that question.

4 MS. SULLIVAN: Sure.

5 THE WITNESS: So, yes, in the
6 traditional sense of it didn't have a placebo
7 and a drug, but you had two groups.

8 MS. SULLIVAN: Right.

9 THE WITNESS: And the two groups
10 should have all the same characteristics
11 except for one. So it's controlled, the two
12 groups. Their only difference is they have a
13 higher elevation of prolactin. So you've
14 controlled for the incidence of kids going
15 through and age and everything else. So you
16 have a built-in control, in essence.

17 BY MS. SULLIVAN:

18 Q. And, Dr. Kessler, the authors of the study are
19 saying that since many kids going through puberty
20 have these prolactin-related events, we're going to
21 do two analyses, right? It tells the reader in the
22 paper that's what's going to happen, right?

23 A. Yes. I have no problems with that.

24 Q. Okay. And if we look at the next page,
25 Dr. Kessler, there's no question that this paper

1 contains all of the gynecomastia events that
2 happened in these five studies, right? It lists
3 them.

4 A. Yes. I don't question that the 5.1 percent
5 and the 30 and the 22 are correct numbers. I don't
6 contest that at all.

7 Q. So when you and Mr. Kline were going through
8 in the paper and it didn't include boys over 10, 11,
9 12, 13, 14, the truth is, the first analysis,
10 SHAP (A), includes all the kids, boys over 10 and
11 boys under 10, right?

12 A. Uhmm, actually, I think the testimony is that
13 point does, but the abstract does not.

14 Q. Yeah. But let's -- we're talking about Table
15 2, right?

16 So in the paper, we saw the e-mail,
17 we have no problem including all the kids in the
18 study. They do include, in Table 2, all the kids in
19 the study, right, in the paper?

20 A. Not in the abstract, ma'am.

21 Q. Right, in the paper?

22 A. Well, which part of the paper are we talking
23 about?

24 Q. So, Dr. Kessler, can you answer my question?
25 In the published paper, for the world to see, in a

1 table on top of this page, are all the kids in all
2 of these studies, 10 and above, 10 and below who got
3 gynecomastia; true?

4 A. Yes. And one place in the paper and not in
5 another.

6 Q. Okay. Can you -- in the paper.

7 THE COURT: Well, all right. The
8 jury, you're going to determine what this all
9 means in only one page or not another. It's
10 up to you to decide what's going on.

11 BY MS. SULLIVAN:

12 Q. And it also, Dr. Kessler, includes the right
13 incidence rate in all of the kids, 5.1, right?

14 A. Just show me where -- just show where it's
15 saying that.

16 Q. In the primary analysis. I have it circled.

17 A. That circle I have no doubts about.

18 Q. Yeah.

19 And so this is a completely accurate
20 table?

21 A. No.

22 Q. Table -- SHAP (A)?

23 A. No. We went through the percentages. The
24 percentages are wrong.

25 Q. Well, let's talk -- 5-point --

1 A. Let me get my notes, if I may.

2 Q. And, Dr. Kessler, I thought --

3 THE COURT: Wait. Hold on one
4 second, please.

5 MS. SULLIVAN: I'm sorry.

6 THE WITNESS: I'm sorry. Just give
7 me a second.

8 Yes, ma'am. Thank you.

9 THE COURT: All right. You may
10 proceed, Ms. Sullivan. Go ahead.

11 BY MS. SULLIVAN:

12 Q. Dr. Kessler, every boy who got gynecomastia in
13 this study was included in Table 2, correct?

14 A. (Pause.)

15 Q. Can you answer that yes or no?

16 A. You're pointing at a number, so you're -- tell
17 me what number you're pointing at.

18 Q. I'm pointing at the ITT column and the primary
19 analysis column. It shows all the boys who got
20 gynecomastia in the study, over 10 and under 10.

21 A. So -- yes.

22 Q. Okay.

23 A. But -- yes, the 22 is correct. The 3.7, I
24 don't think is correct.

25 Q. And the 5.1 you've already testified was

1 accurate, right?

2 A. Yes. I believe that's correct, ma'am.

3 Q. Okay. So that's the total. And so the total
4 incident rate of gynecomastia in boys in this study
5 over 10, under 10, all the kids, was right there for
6 everybody to see in Table 2; they included all the
7 data?

8 A. I -- I -- I cannot agree that it's there, that
9 everyone sees that, no.

10 Q. Okay. Anybody who read this article would see
11 Table 2, right on top.

12 A. If --

13 Q. All the kids with gynecomastia, under 10, over
14 10.

15 A. Everyone who reads this paper -- every
16 physician who reads this paper -- I studied this
17 paper for days; I see this.

18 Q. Okay.

19 A. That number -- that point is correct. I don't
20 dispute that.

21 Q. You're saying that other doctors aren't as
22 smart as you?

23 A. Please, I have enormous respect for other
24 doctors.

25 Q. Yeah.

1 A. But I know, okay, that not -- the reality is
2 that not every doctor is going to have the time to
3 be able to go figure out every data point that's put
4 there and understand the significance. That's why
5 there's an abstract.

6 Q. And, Doctor, going further in the paper, the
7 paper makes clear that it's the outside
8 endocrinologists, Dr. Moshang and Dr. Daneman, who
9 want to exclude in the analysis to do SHAP(B) boys
10 going through puberty, right; it says that?

11 A. It does say, okay, the first analysis,
12 SHAP(A), used a more inclusive definition of SHAP.
13 In the second analysis, SHAP, excluded additional
14 symptoms that the pediatric endocrinologist
15 attributed to the puberty.

16 Q. And so right in the paper it makes clear --
17 and just to back up, neither you or Mr. Kline told
18 our jurors that it was the outside endocrinologists
19 who wanted to do SHAP(B)?

20 MR. KLINE: Your Honor --

21 BY MS. SULLIVAN:

22 Q. They wanted to exclude gynecomastia in
23 adolescent boys; and it says it right in the paper.

24 MR. KLINE: Objection, Your Honor.

25 THE COURT: Objection sustained, for

1 a lot of reasons.

2 MR. KLINE: Yes.

3 BY MS. SULLIVAN:

4 Q. Dr. Kessler --

5 THE COURT: Including compound.

6 BY MS. SULLIVAN:

7 Q. Dr. Kessler, it says in the paper that the
8 pediatric endocrinology authors, Dr. Moshang and
9 Dr. Daneman, wanted to do a second analysis
10 excluding events attributed to puberty. That's what
11 it says, right?

12 MR. KLINE: I'm sorry, where are we
13 pointing?

14 THE WITNESS: It says that they --
15 the way I read this is that there should be a
16 SHAP (A) analysis and a SHAP (B) analysis per
17 those endocrinologists.

18 BY MS. SULLIVAN:

19 Q. Right. And we saw on the e-mail before, from
20 the beginning the pediatric endocrinologists wanted
21 to exclude boys going through puberty because they
22 thought it would mess up the test.

23 MR. KLINE: Objection.

24 THE COURT: Wait a minute.

25 MR. KLINE: She's testifying to her

1 interpretation, not what the words say.

2 THE COURT: No. No. That's

3 overruled on those grounds.

4 You may proceed.

5 Can you rephrase the question again

6 or have it reread.

7 THE WITNESS: Just repeat it again.

8 MS. SULLIVAN: Sure.

9 BY MS. SULLIVAN:

10 Q. Dr. Kessler, looking at the e-mail before and

11 looking at the study, it's clear that it wasn't

12 Janssen, but it was the outside endocrinologists,

13 including the chief of endocrinology at CHOP, who

14 said we got to exclude the boys who are over 10 --

15 MR. KLINE: Objection.

16 BY MS. SULLIVAN:

17 Q. -- in our analysis, right?

18 THE COURT: All right. That's

19 overruled.

20 If you can answer that, Doctor. Only

21 if you can answer that truthfully. If you

22 don't know, say "I don't know."

23 THE WITNESS: Can I just ask that it

24 be read back? I'm sorry.

25 - - -

1 (Whereupon the court reporter read
2 back the previous question as follows:

3 "Question: Dr. Kessler, looking at
4 the e-mail before and looking at the study,
5 it's clear that it wasn't Janssen, but it was
6 the outside endocrinologists, including the
7 chief of endocrinology at CHOP, who said we
8 got to exclude the boys who are over 10?")

9 - - -

10 THE WITNESS: I don't think that's a
11 full -- fully correct statement. I saw
12 Janssen do SHAP (B) to the endocrinologists --
13 to the advisory board. So I --

14 BY MS. SULLIVAN:

15 Q. But, Dr. Kessler -- well, maybe you don't
16 know, Dr. Kessler.

17 MR. KLINE: Now that --

18 THE COURT: Well, I'm going to permit
19 him to answer the question.

20 MS. SULLIVAN: Well, I thought he was
21 finished, Judge.

22 THE WITNESS: I don't -- the way I
23 interpret this -- and there would be -- I
24 have no problems -- is not to exclude it, not
25 to exclude the association, okay, in -- I

1 mean, it would boggle my mind to think that
2 the two endocrinologists would want to
3 exclude a statistically significant
4 association. They may want to present all
5 the data and present it both SHAP (A) and
6 SHAP (B), but not -- it would boggle my mind
7 to believe that two eminent endocrinologists
8 would not publish a statistically significant
9 finding.

10 BY MS. SULLIVAN:

11 Q. And the truth is, Dr. Kessler, you don't know.
12 You're just speculating.

13 A. No. I read Dr. Daneman's e-mail --
14 deposition.

15 Q. And, Dr. Kessler, we could --

16 A. No. I read Dr. Daneman's deposition, okay.

17 Q. And we're going to play it for the jury, so
18 why don't we wait to hear him say it instead of you.

19 MR. KLINE: Why doesn't he --

20 THE COURT: Are you cutting him off?

21 MS. SULLIVAN: I didn't mean to,
22 Judge.

23 THE COURT: All right. You may
24 answer.

25 MR. KLINE: You read Daneman's

1 deposition is where you're at.

2 THE WITNESS: I read Daneman's
3 deposition, and I took away from that
4 deposition that an endocrinologist would want
5 to make sure that statistically significant
6 associations were not hidden.

7 BY MS. SULLIVAN:

8 Q. And, Dr. Kessler, this paper makes clear that
9 the SHAP(B) analysis was done at the insistence of
10 the outside endocrinologists, right? It refers to
11 Dr. Moshang and Dr. Daneman attributing events to
12 puberty.

13 A. I -- I think it would be best, okay, to allow
14 the fact witnesses to testify exactly who prompted
15 who to do what.

16 Q. Well, Dr. Kessler, we can read what it says.
17 It says that SHAP(B) excluded additional symptoms
18 that the pediatric endocrinology authors -- these
19 are the outside authors, Dr. Moshang and Dr.
20 Daneman -- attributed to puberty. That's what it
21 says.

22 A. But you -- but that -- and let's take that as
23 a true statement. That doesn't mean that Janssen
24 didn't in fact push those endocrinologists and
25 present data selectively.

1 So that statement does not tell you
2 who drove what to do -- who drove who to do what.

3 Q. Actually, but, Doctor, if we look at this
4 e-mail, it's clear that the US scientists at Janssen
5 wanted to put everything in, but they're saying that
6 the pediatric endocrinologists outside the company
7 think that SHAP(B) is the more clinically relevant
8 analysis.

9 MR. KLINE: Objection.

10 BY MS. SULLIVAN:

11 Q. Right? That's what the e-mail says?

12 THE COURT: Whatever the e-mail says
13 is what it says. That's what it says,
14 whatever it says. It says what it says.
15 Anything else on this, on that document?

16 BY MS. SULLIVAN:

17 Q. And, Dr. Kessler, you testify a fair amount,
18 don't you, sir?

19 A. I do.

20 Q. And I think Mr. Kline and you talked about at
21 least 25 times over the last five years.

22 A. In depositions, 23, something like that, yes.

23 Q. And a thousand dollars an hour?

24 A. Yes.

25 Q. And you've testified against a bunch of pharma

1 companies, right?

2 A. A bunch of pharma companies? I -- there --
3 pharma companies have been on the other side; and
4 several I've testified for pharma.

5 Q. Well, Doctor, you have testified, sir, against
6 Merck, right?

7 A. In Vioxx.

8 Q. And you've testified against Bayer?

9 A. Hold on a second.

10 So I was called by the --

11 Q. Can you just answer my questions?

12 A. Yes.

13 THE COURT: No. I'm going to permit
14 him to -- if you're now -- this goes to the
15 doctor's own reputation. He's permitted to
16 explain or discuss or whatever.

17 You're saying about Merck now.

18 THE WITNESS: So I was asked by the
19 Attorney Generals in the state of Louisiana,
20 Utah and Kentucky, right, to testify in cases
21 that the State on behalf of citizens brought
22 against Merck.

23 BY MS. SULLIVAN:

24 Q. You've also testified against Merck in
25 individual plaintiffs' suits, in Fosamax litigation?

1 A. I have testified on a preemption question, on
2 a relatively narrow question in Fosamax because of
3 the expertise on preemption.

4 Q. And you've testified against C.R. Bard in an
5 individual plaintiff's case for plaintiff's lawyers?

6 A. That was an MDL, yes.

7 Q. And you've testified --

8 A. Not in court. In a --

9 MR. KLINE: He's allowed to answer.

10 BY MS. SULLIVAN:

11 Q. And you testified against Allergan for
12 plaintiffs' lawyers?

13 A. In two cases of botulism the children got.

14 Q. And you've testified against Eli Lilly for
15 plaintiffs' lawyers?

16 A. What case is Lilly, please?

17 Q. You've testified against Takeda and Eli Lilly
18 in litigation for plaintiffs' lawyers?

19 MR. KLINE: Your Honor, objection.

20 Plaintiffs' lawyers represent clients and we,
21 on behalf of clients, hire expert witnesses.

22 THE COURT: Well, no. Again, there's
23 going to be a chance for redirect, and all of
24 this, if it takes us till kingdom come, can
25 be explained.

1 BY MS. SULLIVAN:

2 Q. And, Dr. Kessler, the truth is you've
3 testified against pharmaceutical companies so much
4 you just cut and paste your report and stick in the
5 companies, the different company's name, your expert
6 report, right?

7 A. There are certain essential aspects of Food
8 and Drug law that apply to all those companies, and
9 I do not repeat the aspects of law that apply
10 generally.

11 Q. And so you take your expert report and you
12 just stick in Merck. Oh, this time it's Johnson &
13 Johnson. Oh, this time it's Bayer. Oh, this time
14 it's Allergan, and you cut and paste --

15 MR. KLINE: Your Honor, objection.

16 THE COURT: That's sustained.

17 BY MS. SULLIVAN:

18 Q. -- you cut and paste the paragraphs of your
19 report.

20 THE COURT: That's sustained.

21 Frankly, Ms. Sullivan, I think you
22 would know better than that.

23 MS. SULLIVAN: Your Honor, may I show
24 his reports to show how he's cut and pasted
25 his opinions?

1 THE COURT: No, ma'am, unless it's
2 germane to some issue that you're raising.

3 MS. SULLIVAN: Well, it goes to the
4 bias, Your Honor.

5 THE COURT: I haven't seen the
6 document. So anything you want to do, I can
7 look at.

8 MS. SULLIVAN: Okay.

9 BY MS. SULLIVAN:

10 Q. And, Dr. Kessler, it's true that each and
11 every time you've come into a court where the issue
12 is did the pharmaceutical company adequately warn,
13 you have said each and every time that the pharma
14 company didn't warn? Bayer didn't warn; Merck
15 didn't warn; Allergan didn't warn; Janssen didn't
16 warn, et cetera, right?

17 Each and every time where the issue
18 has been did the pharmaceutical company adequately
19 warn, each and every time you've raised your hand
20 for a thousand dollars an hour and said "they didn't
21 warn," right?

22 MR. KLINE: Oh, my word, Your Honor,
23 I object.

24 THE COURT: Is there an objection to
25 that compound question?

1 MR. KLINE: Yes.

2 THE COURT: To that speech that was
3 being asked.

4 MR. KLINE: Yes. I object to the
5 speech.

6 THE COURT: Sustained.

7 MS. SULLIVAN: Doctor --

8 MR. KLINE: I object to the --

9 THE COURT: Counsel, I advise you to
10 be careful.

11 MS. SULLIVAN: Your Honor, I'll
12 rephrase it.

13 BY MS. SULLIVAN:

14 Q. Each and every time you've come in to testify
15 against a pharmaceutical company, Dr. Kessler, where
16 the issue is did the pharmaceutical company
17 adequately warn, each and every time you've raised
18 your hand and said, "No, they didn't warn," right?
19 Each and every time?

20 A. That they didn't warn? I think that would be
21 a general statement. I think -- I mean, if you look
22 at certain --

23 Q. Can you just answer that yes or no?

24 MR. KLINE: No.

25 THE WITNESS: I think that --

1 THE COURT: Is there an objection
2 there?

3 MR. KLINE: I only would like him to
4 be able to finish the answer.

5 THE COURT: I would think so. I
6 would think so.

7 You're asking him a question about
8 each and every time. How many times are we
9 talking about?

10 MS. SULLIVAN: And, Your Honor, I'll
11 put up the impeachment --

12 MR. KLINE: He's testified in court
13 seven.

14 THE COURT: Seven times?

15 MR. KLINE: Yes. Three for
16 plaintiffs; other times for others.

17 MS. SULLIVAN: Your Honor --

18 THE COURT: I just don't know. He's
19 allowed to answer the question so he can
20 explain this question.

21 BY MS. SULLIVAN:

22 Q. Dr. Kessler, it's true, sir, that in every
23 single case where the subject was: Did the pharma
24 company's label adequately warn of the risk, in
25 every single case you were working for a plaintiff's

1 lawyer and you said the labels didn't adequately
2 warn? You said the same thing every time?

3 A. First of all, no, I did not say the same thing
4 every time.

5 Q. Can we --

6 A. No, no, no.

7 Q. I want to show you your --

8 A. Let me finish, please.

9 So let's just understand. I've
10 testified seven times in court that I have in my
11 head, between 2010 and 2014, over the last five
12 years. Three of those cases were cases that involve
13 failure to warn, okay. This would be the fourth in
14 court, okay.

15 Each one of these cases, as you can
16 see, is a very complex case. There's an enormous
17 amount of details. I may have in all three cases
18 concluded that the label was in some way inadequate.
19 In one case, I think I remember, sitting here, that
20 the label was improved at a certain point.

21 Q. And, Dr. Kessler --

22 MR. KLINE: Are you finished?

23 MS. SULLIVAN: I'm sorry.

24 THE COURT: Let him finish and then,
25 you know, you will put up whatever you have

1 to put up. But I think he's entitled to
2 explain this question of yours.

3 THE WITNESS: But to say that I've
4 testified each and every time the same way, I
5 mean, I've been here for three days, I can
6 assure you, no case has been like this.

7 BY MS. SULLIVAN:

8 Q. Dr. Kessler, my question was, every time --
9 and it's more than three. We can get your
10 reports -- you said Merck failed to warn; you said
11 Bayer's failed to warn; you said Takeda failed to
12 warn; you said Allergan failed to warn; you said Eli
13 Lilly failed to warn; and each and every time --

14 A. I'm sorry. You're -- you're -- in some of
15 those cases, you're taking a case and there may be
16 multiple defendants, so you're listing -- I believe
17 there were three -- before here, there were three
18 plaintiffs' failure-to-warn cases that I've
19 testified for trial.

20 Q. I'm not just talking about plaintiffs, Doctor.

21 THE COURT: Counsel, I'm going to ask
22 you to move on, because at this point you're
23 inviting us to litigate all those other
24 cases, and we'll be here through next year.
25 Move on, please.

1 MS. SULLIVAN: Yes, Your Honor.

2 BY MS. SULLIVAN:

3 Q. And, Dr. Kessler, you haven't worked for the
4 FDA in about 20 years?

5 A. That's correct.

6 Q. And you're not authorized to speak on behalf
7 of the FDA?

8 A. That's correct.

9 Q. And the truth is, Dr. Kessler, you know the
10 FDA disagrees with you here, right?

11 A. On what point, ma'am?

12 Q. Well, I'm asking you a question. The truth
13 is, you know the FDA disagrees with you?

14 A. No. Let's -- would you like me to discuss
15 this?

16 Q. Well, let me ask you a question.

17 Dr. Kessler, the FDA disagrees with
18 you about the safety of this drug. They don't agree
19 that this drug is unsafe, right?

20 A. Oh, hold it. Could you do me a favor and tell
21 me exactly where I said this drug is unsafe.

22 Q. Okay. Well, then, we don't --

23 A. Or where the FDA -- please use my words
24 exactly right.

25 Q. Okay. Yeah. Well, maybe I misunderstood, Dr.

1 Kessler.

2 So you're not suggesting to this jury
3 that Risperdal is unsafe when used as labeled,
4 right?

5 A. Let me be very clear. The issue that I'm
6 testifying about is what a doctor needs to know in
7 order to safely prescribe that medicine. I thought
8 that's been the subject of the testimony. I am not
9 here to testify on the safety and effectiveness of
10 Risperdal, I mean, for any particular indication.
11 This is a question of whether under certain
12 circumstances, of Janssen's certain conduct in doing
13 certain things, they adequately warned. That's what
14 I thought I'm here testifying.

15 Q. And, Dr. Kessler, do you agree with the FDA
16 that this drug is safe when used as labeled?

17 A. At what point in time are we talking about?

18 Q. At any point. Do you agree with the FDA that
19 this drug is safe when used as labeled?

20 A. No.

21 Q. Okay.

22 A. May I explain?

23 Q. I'm sure Mr. Kline will ask you to explain.

24 Do you agree with the FDA that
25 this drug --

1 MR. KLINE: Do I have to go back?

2 THE COURT: Well, yes. You're going
3 to have to go back.

4 But I'm concerned about these
5 questions in terms of confusing the issues in
6 this case as to -- because I really think you
7 need to ask at what point. This case is
8 related to a specific patient and a specific
9 time or time period. So these questions
10 about whether FDA, whether it's safe or not,
11 I need to pin down so it's relevant to this
12 case.

13 BY MS. SULLIVAN:

14 Q. And, Dr. Kessler, the truth is, the FDA during
15 the time of this case never concluded that Janssen
16 failed to adequately warn, correct? They never --
17 they've never concluded what you're telling this
18 jury, that Janssen failed to adequately warn?

19 A. The --

20 Q. Can you answer that one yes or no?

21 A. Just give me a second.

22 No. I mean, yes, you're correct.
23 But Janssen didn't know -- I mean, sorry, FDA didn't
24 know what Janssen was doing.

25 Q. Well, Dr. Kessler, there's no issue in this

1 case that Janssen gave FDA --

2 MR. KLINE: Objection.

3 BY MS. SULLIVAN:

4 Q. -- all of the events of gynecomastia and all
5 their studies; true?

6 THE COURT: Is there an objection?

7 MR. KLINE: No.

8 THE COURT: No.

9 THE WITNESS: Yes. But you didn't
10 give the association of --

11 BY MS. SULLIVAN:

12 Q. And, Doctor --

13 THE COURT: Again, you're cutting him
14 off, Counsel. Please.

15 MS. SULLIVAN: I'm sorry.

16 BY MS. SULLIVAN:

17 Q. And, Dr. Kessler --

18 A. There's two missing pieces, okay, that FDA
19 doesn't have, all right. One was Janssen said there
20 was no correlation. I didn't see Table -- the data
21 in 21 being told to the FDA in the documents, in the
22 safety updates, in the text.

23 Two, right, what Janssen was doing
24 with Dr. Mathisen -- and, again, I want to be
25 careful, Your Honor, because it goes to the issue

1 of, I mean, going into an office on a use that's not
2 on the label. That raises a whole set of issues.
3 And I just want to be respectful of what I can say.

4 THE COURT: Well, answer her
5 questions. I'm going to give you permission,
6 of course, to elaborate to some degree, but
7 right now it is her cross-examination, so we
8 just need to have her questions answered
9 and --

10 MS. SULLIVAN: And --

11 THE COURT: -- we'll go forward.

12 BY MS. SULLIVAN:

13 Q. And, Dr. Kessler, you know that the FDA knows
14 all about your opinions in this case about the
15 statistical association; and they disagree with you.

16 MR. KLINE: Your Honor, objection.

17 THE COURT: All right. That --

18 MR. KLINE: That's --

19 THE COURT: So that's sustained.

20 MR. KLINE: May we see Your Honor at
21 sidebar?

22 THE COURT: That is sustained, unless
23 you have evidence from the FDA that's coming
24 in live in this case on that point.

25 MS. SULLIVAN: I have a letter to the

1 FDA from them, telling them all about
2 Dr. Kessler.

3 MR. KLINE: Your Honor, may we see
4 you at sidebar? May we see you at sidebar.
5 I have a motion to make, a significant
6 motion; or can we take a break now?

7 THE COURT: Yeah. We'll take a
8 break.

9 COURT CRIER: All rise as the jury
10 exits.

11 THE COURT: Please don't discuss this
12 matter with each other.

13 - - -

14 (Whereupon the jury exited the
15 courtroom at 2:48 p.m.)

16 - - -

17 (The following transpired in open
18 court outside the presence of the jury:)

19 - - -

20 THE COURT: All right.

21 MR. KLINE: Your Honor, I move for an
22 admonishment and a -- and an instruction.

23 THE COURT: I was afraid you were
24 moving for a mistrial.

25 MR. KLINE: This counsel was told,

1 she was told --

2 THE WITNESS: Do you want me to --

3 THE COURT: I'm going to ask,
4 Dr. Kessler, that you take a break yourself.

5 MR. KLINE: She was instructed that
6 the Citizens Petition here --

7 THE COURT: Well, wait. Hold it.

8 MR. KLINE: What she's trying to get,
9 that, quote, letter, that's --

10 THE COURT: Let's let Dr. Kessler
11 take a break himself and we'll straighten it
12 out.

13 (Whereupon the witness, Dr. Kessler,
14 exited the courtroom.)

15 MR. KLINE: May I be heard?

16 THE COURT: Sure.

17 MR. KLINE: Counsel was told after
18 argument, reargument, re-reargument and
19 re-reargument and re-reargument that the
20 issues raised when Mr. Sheller sent
21 Dr. Kessler's letter to the FDA and the FDA
22 disagreed about it being a serious adverse
23 event was not to be part of this case, not to
24 be suggested, not to be -- not to be
25 interjected into the case.

1 And in fact that Petition, Your
2 Honor, is currently the subject of a lawsuit
3 in Federal Court against the FDA involving
4 significant issues.

5 Now, we had a discussion about
6 whether that was going to be allowed, and
7 she, in violation of what the instructions
8 were, suggested to the jury that his opinions
9 were told to the FDA and the FDA disagreed.

10 MS. SULLIVAN: And, Your Honor --

11 THE COURT: All right.

12 MR. KLINE: And that is --

13 THE COURT: I understand it.

14 MR. KLINE: And that is wrong. And
15 it shouldn't be countenanced by the Court.

16 THE COURT: Well, before we hear from
17 Ms. Sullivan about this, what I don't know
18 is -- this Court was not a party to any such
19 agreements or any such motions, so I'm a
20 little bit in the dark. Why doesn't
21 somebody, Mr. Murphy, why don't you fill me
22 in to what we're talking about.

23 MR. MURPHY: I beg your pardon?

24 MS. SULLIVAN: Your Honor --

25 THE COURT: I don't know of any

1 statement -- I've never ruled on any in
2 limine motion --

3 MS. SULLIVAN: I agree; exactly.

4 THE COURT: -- regarding a
5 settlement.

6 MS. SULLIVAN: Exactly, Your Honor.

7 MR. KLINE: Yes, you did, Your Honor.

8 MR. MURPHY: No.

9 MR. KLINE: Your Honor, respectfully,
10 respectfully.

11 MS. SULLIVAN: No.

12 MR. KLINE: We had this whole issue
13 as to whether the "Citizens Petition" and
14 whether the information that was provided to
15 Dr. Kessler in 2013, which has nothing to do
16 with the label from 2002 to 2006, which is
17 the issue here, the 2002 label, and
18 Mr. Sheller going to the FDA last year
19 submitting a lot of information to the FDA
20 and telling the FDA that the 2013 label
21 should contain a "black box warning" and the
22 FDA saying certain things to Mr. --

23 THE COURT: Everyone sit down,
24 please.

25 MR. KLINE: -- to Mr. Sheller back,

1 that has nothing to do with this case. And
2 what she wants to do -- what she wants to try
3 to do here is to try to interject a document
4 which she was told has nothing to do with
5 this case.

6 THE COURT: Well, if you have an
7 objection based on the document, that's
8 different from an admonishment or anything.
9 We haven't seen the document. I've never
10 seen it. So I don't think that there's any
11 real grounds for anything for us to do at
12 this point.

13 But I will say this, and I'll hear
14 from Ms. Sullivan, but I will say this: You
15 are on a very slippery slope, in my view, in
16 terms of bringing up what government actions
17 have or have not been taken against your
18 client.

19 MS. SULLIVAN: Well, this -- Your
20 Honor, my question -- I understand that
21 point, Your Honor.

22 THE COURT: And so you continue --

23 MS. SULLIVAN: I moved on.

24 THE COURT: If you continue, it's
25 very, very possible that some kind of

1 rebuttal will be permitted about government
2 action against Johnson & Johnson in the last
3 year or so on a particular drug named
4 Risperdal.

5 MS. SULLIVAN: And, Your Honor, this
6 was a different issue. This was --

7 THE COURT: Well, I don't know. The
8 way you're carrying on about this invites
9 that kind of rebuttal.

10 MS. SULLIVAN: And, Your Honor, on
11 the Citizens Petition issue, Your Honor, he
12 specifically said the FDA never saw this
13 analysis. The truth is, they know all about
14 it. His opinion was given to the FDA and
15 that's relevant cross-examination.

16 THE COURT: But it's not a relevant
17 point in this trial unless you make it so.
18 What the FDA thought or did not think is not
19 relevant to the stated issues in this case,
20 unless you make it so. And if you make it
21 so, that it's about what the government had
22 in mind regarding Johnson & Johnson and
23 Merck, that opens a whole new case.

24 MS. SULLIVAN: Well, Your Honor, then
25 that puts us in a position where you can't

1 even defend yourself.

2 THE COURT: You can't have it both
3 ways, Ms. Sullivan, is what I'm trying to
4 tell you.

5 MS. SULLIVAN: Well, Judge, it sounds
6 like the Court is not going to permit Janssen
7 to even defend themselves.

8 THE COURT: Well, I haven't seen the
9 document.

10 MS. SULLIVAN: The fact is, on these
11 narrow issues, the FDA does disagree with
12 Dr. Kessler. That's cross.

13 THE COURT: Well, then present
14 evidence to that point. Present evidence to
15 that point. It's not coming in through a
16 letter.

17 MR. KLINE: So Your Honor knows, what
18 she's trying to do is interject what the FDA
19 said in 2013 about whether a "black box
20 warning" is needed on the current label. I
21 have no --

22 THE COURT: I want to see a direct
23 examination, the cross-examination on that
24 point, otherwise it won't -- that is hearsay,
25 unless it is something that is admissible

1 here, just like the other documents, the
2 e-mails and everything else were admitted.
3 If this document is admitted by the actual
4 testimony and introduction of the person who
5 wrote it or did it or was deposed about, then
6 they are --

7 MS. SULLIVAN: Well, Your Honor, the
8 problem is we can't bring in the FDA.

9 THE COURT: I'm sorry, then.

10 MS. SULLIVAN: Judge, this is an
11 official document that we can authenticate
12 through our FDA expert, and it's --

13 THE COURT: I don't know. Let me see
14 the document.

15 MS. SULLIVAN: It's clear that the
16 FDA disagrees with Dr. Kessler.

17 THE COURT: I'll take a look at the
18 document. But we have the same rules for
19 both parties. And those rules are that the
20 materials need to be independently
21 authenticated and admissible.

22 MS. SULLIVAN: And, Your Honor, I
23 hadn't used the document. Right now I just
24 wanted to ask --

25 THE COURT: Well, you'll have to show

1 it to this witness in terms of trying to
2 impeach him for something, and I need to see
3 the document. And, frankly, when you do
4 that, you are opening the door to trouble.

5 MS. SULLIVAN: Well -- and, Your
6 Honor, I understand your ruling, but it puts
7 Janssen in a position where it can't even
8 defend themselves by saying the FDA disagrees
9 with this hired gun. They looked at these
10 very issues and said that Dr. Kessler is
11 wrong. He's wrong on serious adverse event.

12 THE COURT: But it's not about what
13 the FDA thinks or not. It's about whether or
14 not the evidence that he's presenting about
15 the so-called manipulation of data is true or
16 not. Ask him about that. Not through --

17 MS. SULLIVAN: And, Your Honor --

18 THE COURT: -- not through a letter
19 by the FDA. Have the FDA person come in here
20 and refute what Dr. Kessler has said here.
21 But don't do it that way or else you're going
22 to open the door to how the government has
23 viewed Johnson & Johnson on this drug in
24 other matters.

25 MS. SULLIVAN: It's a separate issue,

1 Your Honor. And the FDA's concluded that
2 this statistical analysis he's basing their
3 whole case on is bologna. It's just -- it's
4 no clinical significance.

5 THE COURT: Well, you're testifying
6 now. Then have the FDA person come in and
7 say that.

8 MR. KLINE: Your Honor --

9 MS. SULLIVAN: You can't drag -- I
10 wish I could, Judge. I wish I could bring
11 them down here because they completely
12 disagree with Dr. Kessler.

13 THE COURT: So what are you saying
14 now; that this is an out-of-court statement
15 that is admissible because it's not
16 available?

17 MS. SULLIVAN: It's a public record;
18 and, yeah, they're unavailable.

19 THE COURT: Well, I don't know. Let
20 me see the document. What kind of public
21 record is this?

22 MS. SULLIVAN: Here it is, Judge.

23 MR. KLINE: The document goes to the
24 2013 label. It has nothing to do with the
25 2002 label's adequacy. That's the problem

1 here. She wants to throw -- and you're going
2 to now see weeks of it -- anything possible
3 up against the wall.

4 MS. SULLIVAN: That's not true.

5 MR. KLINE: This is highly
6 inflammatory and prejudicial.

7 MS. SULLIVAN: It's not, Your Honor.

8 MR. KLINE: It has nothing to do with
9 the 2002 label at issue in this case.

10 MS. SULLIVAN: It has to do with the
11 safety of the medicine.

12 MR. KLINE: It has to do with --

13 MS. SULLIVAN: It has to do --

14 MR. KLINE: When she yells over me to
15 get her way.

16 COURT REPORTER: One at a time.

17 THE COURT: You know, I was asked by
18 our court reporters that counsel not speak
19 over each other or over me when talking
20 because they have a lot of difficulty in
21 recording what's been said.

22 MR. KLINE: You might want to look at
23 it on a recess, Your Honor.

24 THE COURT: I mean, I don't --

25 MR. KLINE: And you'll see --

1 THE COURT: Frankly, the issue that I
2 have is one of relevance, and including --
3 it's your choice whether to potentially open
4 the door to prior conduct that could be
5 admissible here.

6 As far as this particular discussion
7 is concerned, I'll read the letter. I'll
8 read it, and so I won't make a definitive
9 ruling.

10 As far as an admonishment is
11 concerned, I don't think it's necessary at
12 this point, a public admonishment.

13 What I can say, though, is that this
14 case is about the state action of a -- a
15 negligence action. It is clearly not about
16 what the FDA did or did not do, because that
17 is a situation of what did the FDA know and
18 when did it know it. And unless you are
19 prepared to go down that route, Ms. Sullivan,
20 I would suggest that you not bring up this
21 particular issue now.

22 MS. SULLIVAN: Well, Your Honor, it's
23 a preemption. I mean, the FDA has --

24 THE COURT: There is no preemption
25 involved here.

1 MS. SULLIVAN: And, Your Honor, this
2 is where they alerted the FDA to
3 Dr. Kessler's opinion in this case.

4 THE COURT: All right. Well, you can
5 present whatever is available evidence to you
6 that's admissible. This is not admissible
7 from what I can tell right now.

8 MS. SULLIVAN: Can I, Your Honor,
9 cross him on the fact that they have sent or
10 told the FDA about his opinion?

11 THE COURT: What are you trying to --
12 I mean, are you saying the FDA is not
13 permitted to testify here?

14 MS. SULLIVAN: They can't. We can't
15 bring them in. There's a prohibition.

16 THE COURT: So what does the federal
17 law say about the admissibility of their
18 letters in this court? Anything?

19 MS. SULLIVAN: It's clear, Your
20 Honor, they come in in every case. We --

21 THE COURT: You have to peg this
22 issue to some state evidentiary rule.

23 MR. KLINE: Yes.

24 MS. SULLIVAN: It's public records,
25 too.

1 THE COURT: Which one is it? This is
2 a public record? A letter from the FDA to a
3 law firm is a public record?

4 MS. SULLIVAN: A business -- it's a
5 conclusion. Your Honor, they reviewed it for
6 two years, teams of FDA experts, and they
7 reached conclusions on specific regulatory
8 issues. This is a response to a Citizens
9 Petition. It's a formal action which the
10 FDA --

11 THE COURT: What Citizens Petition is
12 that?

13 MS. SULLIVAN: Mr. Sheller's firm
14 sent a letter to the FDA all about these
15 allegations.

16 THE COURT: That's what I'm trying to
17 tell you. If you want to raise these kind of
18 issues, then we can all get into all kinds of
19 issues involving Johnson & Johnson and
20 Risperdal and the Department of Justice.

21 MS. SULLIVAN: But, Your Honor --

22 MR. KLINE: Your Honor, if you
23 will --

24 MS. SULLIVAN: -- the difference is
25 this related specifically to their

1 allegations in this case.

2 THE COURT: Well, that is denied
3 then. Okay. I have reasons that I do not
4 want this case to go into mistrial-land based
5 on evidence of prior actions, prior
6 activities of issues that are not relevant
7 here based on a 2013 label, unless it is
8 relevant. And so far I haven't seen that
9 it's relevant.

10 MS. SULLIVAN: And, Your Honor, it
11 goes back --

12 THE COURT: What the FDA thinks
13 about Dr. Kessler's testimony is not relevant
14 to what the jury might think about it, unless
15 you are anticipating that the government
16 itself is going to come in and testify one
17 way or the other about this case.

18 MS. SULLIVAN: Well, I wish they
19 could, Your Honor, but --

20 THE COURT: All right. Well, so do
21 I, but that's the law.

22 MS. SULLIVAN: Your Honor, but it's
23 probative on the issue of --

24 THE COURT: It may be. But the
25 government, the FDA for some reason has this

1 law. And now we're stuck with Pennsylvania
2 law. And I'm telling you it's not relevant;
3 and also in my judgment it is potentially
4 prejudicial to the plaintiff because of the
5 nature of the relevancy itself. And also I'm
6 very concerned that it will end up in
7 exploding this case to issues that are really
8 prejudicial to both parties here, especially
9 to the defendant.

10 Let's face it, this particular
11 company has been the subject of a massive
12 judgment outside of this courtroom relating
13 to this particular drug.

14 MS. SULLIVAN: That was overturned,
15 Your Honor, on appeal.

16 THE COURT: Well, there's a lot of
17 findings involved in that case that are
18 germane to the issue here. And I don't want
19 to go into issues that were elsewhere. And
20 I'm not sure that we need to get into all of
21 that.

22 And, by the way, the conduct involved
23 in this particular case as it relates to
24 Johnson & Johnson, I'm not going to permit it
25 to be used by the plaintiff as to other

1 conduct by Johnson & Johnson with other drugs
2 which have not been overturned.

3 MR. MURPHY: Your Honor, if I might.
4 I've heard you and I understand you.

5 I would ask you to consider under
6 Rule 902 that this is in fact a
7 self-authenticating document. There are
8 rules regarding public pamphlets published by
9 the government; and as you'll see in some of
10 the commentary, public pamphlets now are
11 outdated. Websites are what are at issue.

12 The Citizens Petition here at issue
13 was posted at the FDA's website; the response
14 posted at the FDA's website. And I would ask
15 you to consider that, Your Honor.

16 MR. KLINE: Janssen's response wasn't
17 posted.

18 But, Your Honor, the fundamental
19 touchstone of this, putting aside anything
20 else, is that -- there are two things: One,
21 this was ruled upon in limine and the Court
22 eliminated it based on everything we've done.
23 And my objection to start with was how she
24 just blurts it out.

25 Number two, this document has nothing

1 to do with the issues in this case. It is a
2 2013 letter that raises a totally different
3 issue which is whether a black box needs to
4 be put on the drug.

5 MS. SULLIVAN: And there --

6 MR. KLINE: And -- and the fact of
7 the matter is --

8 THE COURT: Well, we'll take a recess
9 for a few minutes and we will review the
10 document. If you're so persistent in wanting
11 this document, and Mr. Murphy has spoken, I
12 will take a look at it very carefully under
13 902.

14 MS. SULLIVAN: Thank you, Your Honor.
15 It also refers to the issue of whether a
16 different warning is required, because this
17 is a serious adverse event. The FDA
18 concludes that gynecomastia is not a serious
19 adverse event.

20 MR. KLINE: Exactly what you ruled
21 out.

22 MS. SULLIVAN: That's not true.

23 MR. KLINE: Exactly what you ruled
24 out days ago.

25 MS. SULLIVAN: He's never looked at

1 the document.

2 MR. KLINE: And, by the way, in the
3 face of that ruling --

4 THE COURT: See, that's the problem,
5 Ms. Sullivan. This is a difficult case for
6 any jury to really -- to take ahold of. And
7 I am afraid that the procedure here of
8 bringing in the FDA's own analysis of this
9 outside a court, which is not subject to
10 cross-examination, is inherently unfair. So
11 I'll take a look at the document and --

12 MR. KLINE: Two things as you're
13 looking at the document.

14 One, have you heard Dr. Kessler say
15 that there needed to be a "black box
16 warning"? No.

17 THE COURT: I know that --

18 MR. KLINE: Have you heard Dr.
19 Kessler say it's a serious adverse event?
20 No.

21 MS. SULLIVAN: Dr. Mathisen said it.

22 THE COURT: Dr. Mathisen testified
23 that he did not read the particular
24 prescription after it came out in October
25 2006. He wishes he had. But he didn't see

1 it in the black box, didn't see it in the
2 warnings. Whether that's relevant to this, I
3 don't know. I have to read the document.

4 MR. KLINE: What you have learned
5 here, Your Honor, is in the face of a ruling
6 of a document being out, instead of even
7 going to sidebar, she blurts it out.

8 MS. SULLIVAN: It wasn't ruled out.

9 THE COURT: Well, everybody has their
10 style. Everyone has their style.

11 MR. KLINE: That's not style, Your
12 Honor, respectfully.

13 THE COURT: All right.

14 MS. SULLIVAN: I, first of all --

15 MR. KLINE: That is -- that is
16 improper. It's not style.

17 THE COURT: Now, I understand that.
18 But, again, you know, we're having late
19 motions in limine. We're having all kinds of
20 things going on here, so let me just take a
21 few minutes and we'll look at this and we'll
22 come right back.

23 MS. SULLIVAN: Thank you.

24 - - -

25 (Whereupon a recess was taken.)

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(Whereupon an off-the-record discussion was held.)

- - -

(The following transpired in open court outside the presence of the jury:)

- - -

THE COURT: I'd like to go back now on the record to address some of the more recent points and then get back, hopefully, to the cross-examination.

First of all, I just want to be very clear that I am not mistaken. I'm not necessarily concerned about the outcome of a particular DOJ or FDA. I'm concerned about what prior acts could be brought into a courtroom in rebuttal of issues involving the government.

So, for example, Ms. Sullivan, I am wondering now whether the multi-billion-dollar settlement of November 2013 has been rescinded.

MS. SULLIVAN: I'm sorry, Your Honor. The settlement with the federal government, it involves a different --

1 THE COURT: It involved marketing and
2 Risperdal and some --

3 MS. SULLIVAN: No; for a completely
4 different indication. It has nothing to do
5 with autism.

6 THE COURT: Well, then that gets me
7 to this thing here of the black box. It's
8 irrelevant to this case. It's out.

9 MS. SULLIVAN: Dr. Mathisen raised
10 it, Your Honor.

11 THE COURT: As far as this witness is
12 concerned. You had the opportunity to
13 cross-examine Dr. Mathisen about that. The
14 black box issue, is that being raised here in
15 some way?

16 MS. SULLIVAN: Well, here's the
17 issue: Dr. Mathisen is not a regulatory
18 expert. Maybe their way to solve it,
19 Judge --

20 THE COURT: The problem is that this
21 particular document is written in
22 relationship to a label that was not seen by
23 Dr. Mathisen. Dr. Mathisen was talking about
24 October 2006.

25 MS. SULLIVAN: But he --

1 THE COURT: Does this document relate
2 to an October --

3 MS. SULLIVAN: Yes, yes, Your Honor.
4 Here's the relation: The definition for
5 serious adverse event is the same now as it
6 was then, and the FDA said this does not rise
7 to that level. They've concluded this -- it
8 was the same definition --

9 THE COURT: Then present that
10 evidence, I beg you to. If you wish to, that
11 is a defense that you may raise to your own
12 evidence.

13 MS. SULLIVAN: Understood, Your
14 Honor.

15 And, Your Honor, I may ask for an
16 instruction at the end of the case that only
17 the FDA can initiate a black box;
18 manufacturers can't.

19 THE COURT: Well, let me tell you
20 something else that I want to say about the
21 black box, the matter of the black box: I'll
22 be happy to look at any jury instructions at
23 any time, but the reality of the matter is,
24 is that this Court is going to be very
25 diligent, and I believe I have been up to

1 now, and I will continue to do so, in making
2 sure the jury understands the difference
3 between a state negligent, failure-to-act
4 cause of action. And a review for whatever
5 reason, black box, label, precautions or
6 anything else under the FDA, they are two
7 different -- they are apples and oranges.

8 MS. SULLIVAN: The problem for
9 manufacturers, Judge, is on the labeling side
10 and on every side, they have to follow the
11 FDA regulations.

12 THE COURT: Well, you know, again,
13 this Court has been through one of these
14 before where that particular argument was
15 very unsuccessful with the jury, so, you
16 know, bear that in mind. We are familiar
17 with Wyeth. We are familiar with the cases.
18 We know the distinctions between a generic
19 and a brand. This one is a brand, so you
20 know...

21 MS. SULLIVAN: No. And, Your Honor,
22 the reason that all this is relevant, it's a
23 negligence case, and FDA is the industry
24 standard that we have to follow.

25 THE COURT: Well, you make that

1 argument to the jury and present it as part
2 of your case, not through a irrelevant
3 cross-examination that invites prior bad acts
4 by your client into evidence on rebuttal.

5 MS. SULLIVAN: Your Honor, we'll do
6 it through our witnesses. Thank you.

7 THE COURT: All right. Fine. Now,
8 bring the jury back.

9 - - -

10 (Whereupon an off-the-record
11 discussion was held.)

12 - - -

13 THE COURT: All right. Let's have
14 the jury come back.

15 (Pause.)

16 - - -

17 (Whereupon an off-the-record
18 discussion was held.)

19 - - -

20 THE COURT: I would also like to put
21 on the record there is one other reason why
22 I'm not permitting this document to be used,
23 and that is because it refers to a different
24 case entirely, Docket No. FDA 2012, P-0857.

25 COURT CRIER: All rise as the jury

1 enters the courtroom.

2 - - -

3 (The following transpired in open
4 court in the presence of the jury:)

5 - - -

6 (Whereupon the jury entered the
7 courtroom at 3:20 p.m.)

8 - - -

9 THE COURT: All right. You may be
10 seated everybody.

11 All right. Members of the jury, we
12 will continue now with Ms. Sullivan's
13 cross-examination.

14 MS. SULLIVAN: Thank you, Your Honor.

15 BY MS. SULLIVAN:

16 Q. Dr. Kessler, I'm going to go back and put up a
17 demonstrative that you and Mr. Kline were talking
18 about involving the 2002 and 2006 labels, okay. It
19 should come up on your screen, I think.

20 A. Thanks.

21 (Document displayed on the screen.)

22 (Counsel conferring with technician.)

23 BY MS. SULLIVAN:

24 Q. And, Dr. Kessler, you remember this, talking
25 to Mr. Kline about this demonstrative?

1 A. Yes, ma'am.

2 Q. And this is a section of the 2002 label and a
3 section of the 2006 label, and the two of you were
4 comparing them for the jury, right?

5 A. Yes.

6 Q. But these are for two completely -- the 2002
7 label was an adult label, right?

8 A. (No response.)

9 Q. In 2002 Risperdal was not approved for
10 children?

11 A. Uhmm, that's correct.

12 Q. And so the data in the 2002 label related to
13 adults, the safety data, right? Studies in --
14 safety studies in the adult population.

15 A. The data, yes, I see that.

16 Q. It was an adult label.

17 And it was in 2006 for the first time
18 that Risperdal was approved for children and
19 adolescents, correct?

20 A. Uhmm, yes.

21 Q. Okay. And so there are two different patient
22 populations, adults and children, and the safety
23 data was different for each, right, on a variety of
24 issues?

25 A. Sure.

1 Q. Yeah.

2 A. Generally, that's fair.

3 Q. And you read Dr. Mathisen's deposition. He
4 knew that the 2002 label, that the medicine was not
5 approved for children, right? He knew he was
6 prescribing off-label?

7 A. I believe so, yes.

8 Q. Yeah.

9 And there is actually some other
10 sections of the label that you and Mr. Kline didn't
11 talk about that I wanted to put up. If we could
12 give counsel -- it's part of the label, counsel, and
13 we can give you the demonstrative. We'll mark this
14 as Defense Exhibit 14.

15 And, Dr. Kessler, in the 2002 label
16 for adults, it was clearly stated in the label that
17 safety and effectiveness in children had not been
18 established, right?

19 A. That's exactly what it said.

20 Q. Yeah.

21 And you know, because you've seen his
22 deposition, that Dr. Mathisen, Mr. Pledger's
23 prescriber, knew that, that safety in children had
24 not been established?

25 MR. KLINE: Your Honor, objection.

1 Objection to the testimony about Dr. Mathisen
2 and all about it. We've had him here.

3 THE COURT: Well, no. That's
4 overruled.

5 But I just want to make sure that I
6 understand where this label is coming from.
7 Where is this --

8 MS. SULLIVAN: This is the labels,
9 Judge, that are already --

10 THE COURT: What is our marking on
11 this?

12 MS. SULLIVAN: This is Defense
13 Exhibit 14.

14 THE COURT: Okay. Just mark that
15 down. And the first one was?

16 MS. SULLIVAN: That was Plaintiff's
17 Exhibit 11.

18 MR. KLINE: Everything has been in
19 front of the jury, Your Honor.

20 THE COURT: All right. But Marianne
21 is the keeper of our records here and she
22 likes it this way, and we're going to call it
23 the "Marianne rule." Okay.

24 (Laughter.)

25 Everything that's flashed up there,

1 Marianne needs to know. So Plaintiff 11 was
2 the first thing. And then now we have
3 defense, what is it?

4 MS. SULLIVAN: Fourteen, Your Honor.

5 THE COURT: Fourteen. Okay.

6 BY MS. SULLIVAN:

7 Q. And so, Dr. Kessler, it was clear to
8 prescribers in 2002 that the medicine had not been
9 proven safe and effective in children yet; that's
10 what it says.

11 A. You'd have to, again, if we're talking about
12 Dr. Mathisen, it would be great -- I certainly
13 remember that Dr. Mathisen said he knew that it was
14 off-label. I wasn't here when he testified.

15 Q. Okay.

16 A. I know that. I wouldn't want to characterize
17 Dr. Mathisen's testimony exactly on safety and
18 effectiveness, but he certainly knew it was
19 off-label.

20 Q. Fair enough. And our jurors have heard from
21 Dr. Mathisen.

22 But no dispute, Dr. Kessler, that
23 right in the 2002 label, it told prescribers that
24 safety and effectiveness in children had not been
25 established?

1 A. Yes, it says that.

2 Q. And --

3 MR. KLINE: Let him --

4 MS. SULLIVAN: Oh, I'm sorry. I
5 didn't mean to cut you off.

6 THE WITNESS: The -- there's a "but."

7 BY MS. SULLIVAN:

8 Q. I'm sorry?

9 A. There's a "but." But I'll let you decide.

10 MR. KLINE: Just --

11 THE WITNESS: Yes, it says that. But
12 it doesn't put in the safety data -- the
13 safety concerns about kids.

14 BY MS. SULLIVAN:

15 Q. And, Dr. Kessler, you agree that the
16 information in the 2002 label was adequate for the
17 indication, right?

18 A. For which indication?

19 Q. For what it's approved for, for adults; that
20 this label was correct and truthful?

21 A. So maybe the -- so, no, I don't think that
22 would be correct, because the issue is -- and again,
23 this is an FDA term -- what the intended use was.
24 If the intended use, if Janssen's intended use was
25 for pediatrics, then this was not an adequate label.

1 If the intended use was for adults,
2 right, if that's what Janssen's intended use was,
3 then this would be adequate.

4 Q. And, Dr. Kessler, it was only FDA approved at
5 that time in 2002 for adults, correct?

6 A. Yes. But that doesn't determine the intended
7 use. You have to look at the totality of evidence.

8 Q. Well, we're going to talk about that.

9 But certainly in 2002, the medicine
10 was only approved for adults and said plainly in the
11 label that safety in children had not been
12 established, correct?

13 A. Yes, that's correct.

14 Q. And it also talked about gynecomastia being
15 rare, right?

16 A. Yes.

17 Q. And that was true in terms of the indication
18 it was approved for; in other words, the studies in
19 adults showed that it was rare?

20 A. Yes. It was approved -- if the intended use
21 was for adults, then that would be correct.

22 Q. Okay.

23 A. If the intended use was for children and
24 adolescents, that would not be correct.

25 Q. And, Dr. Kessler, you know that the indication

1 in 2002, the FDA approved it only for adults with
2 psychosis and schizophrenia, right?

3 A. Yes. That was exactly what FDA approved it --

4 Q. Okay. And, Dr. Kessler, you know that there
5 was no indication in 2002 for -- it had not been
6 approved for children in 2002?

7 A. It was widely -- yes. It was not approved,
8 but that doesn't mean the intended use wasn't for
9 kids.

10 Q. And, Dr. Kessler, you know that Janssen -- I
11 think you talked about the fact that -- and let me
12 back up.

13 When it says "safety and
14 effectiveness in children has not been established,"
15 FDA does not mean to say that the medicine is
16 unsafe, just that the studies haven't been done
17 sufficient to get approval for kids yet, right?

18 A. Please understand, this is Janssen's label
19 that gets reviewed and approved or cleared by FDA.
20 So be careful when you say the FDA is saying this.
21 These are Janssen's words as reviewed and approved
22 by FDA.

23 Q. Yeah. Dr. Kessler, you know that you can't
24 get a medicine approved unless the FDA says --
25 concludes that your label is okay; and they often

1 make changes and dictate that you say different
2 things as part of the approval process?

3 A. It's a negotiation.

4 Q. Yeah.

5 A. That's correct. It's a back-and-forth. But
6 in the end, it's the company's label.

7 Q. Well, it is -- the FDA makes the final
8 decision at the approval stage. In other words,
9 companies can't just say anything they want in their
10 label at the approval stage. The FDA makes very
11 clear -- and we can pull out some of the FDA
12 conclusions, if the Court permits -- when they
13 approve a medicine, they attach the label to the FDA
14 approval letter and says you have to say exactly
15 this, right?

16 A. Yes. But if you have safety information at
17 any point in time and you're the manufacturer, that
18 should be disclosed. Nothing prevents you from
19 disclosing safety information.

20 Q. And we're going to talk about that. But at
21 least -- and you know that the FDA approved
22 Risperdal not just twice, but Janssen did a ton of
23 studies on this medicine, comparatively speaking,
24 right?

25 They did -- this is, Dr. Kessler, you

1 would agree, the most studied antipsychotic in
2 history as it relates to child and adolescent
3 medicines, right?

4 A. Ummm, a ton is a weight measure. This was
5 extensively studied and there were a lot of
6 findings, safety findings also.

7 Q. Along the way?

8 A. Yes.

9 Q. And you're not criticizing Janssen for doing
10 the hard science, doing the studies, and getting
11 this medicine approved for kids with autism who have
12 serious problems?

13 A. (No response.)

14 Q. Are you critical of Janssen for doing that?

15 A. No.

16 Q. Okay.

17 A. I have no problems with doing studies. But if
18 you find certain results, you have to make those
19 results known.

20 Q. And --

21 A. That's part of the FDA rule.

22 Q. Yeah.

23 A. So I am -- I think it's fair to say, I am
24 critical because Janssen, in my opinion, did not
25 make the -- an important finding known.

1 Q. And we're going to talk about your Table 21,
2 Dr. Kessler, but --

3 MR. KLINE: Your Honor, can we have a
4 lack of that "we're going to talk about it"
5 every time he answers and just go on to a
6 next question?

7 MR. MURPHY: Is there an objection?

8 THE COURT: It's a style.

9 MR. KLINE: It's a style?

10 THE COURT: It's a style. I'd like
11 to get there, though, yes.

12 MS. SULLIVAN: We'll get there,
13 Judge. We'll get there.

14 THE COURT: It is a style.

15 MS. SULLIVAN: We'll get there.

16 BY MS. SULLIVAN:

17 Q. Dr. Kessler, you know that Janssen sought --
18 and we'll look at the document -- that Janssen asked
19 FDA if they could put safety data in the medicine as
20 it related to dosing for children, right?

21 A. In 1996 they asked my colleague, Paul Leber,
22 when I was at the FDA, if they could put dosing
23 information, and he concluded that the data was too
24 meager.

25 Q. Yeah. Because Janssen had just started

1 studying the medicine for children at that time.
2 They had not finished all of their pediatric studies
3 yet, right?

4 A. A fair point.

5 Q. Yeah.

6 But nonetheless, Janssen knew that
7 the medicine was being prescribed in children, and
8 they wanted to put some safety information about
9 dosing in the label even before it was approved,
10 right, for kids?

11 A. Well, you're mixing two things, okay. There's
12 safety information, okay, and there's dosing
13 information. Now, dosing can be safety information.

14 Q. Of course.

15 A. But there's also safety information that is
16 not dosing. Dosing implies this is the dose you
17 give if you want to use it. If you have adverse
18 events in kids, that's different from dosing.

19 Q. Yeah. But dosing with safety -- you don't
20 want kids to have an overdose on Risperdal. You
21 don't want kids to take too high a dose so they have
22 side effects. So what Janssen wanted to do, it says
23 we know we haven't done enough studies to get
24 approval yet, but let's give doctors information
25 about pediatric dosing.

1 A. Something that I encouraged very strongly when
2 I was at the FDA, but, again, it has to be based on
3 the data.

4 Q. And so I'm putting back up Plaintiff's Exhibit
5 15.

6 And this is an August 15, 1996 letter
7 from Janssen to the FDA, right?

8 A. Yes.

9 Q. And in this letter Janssen talks about -- they
10 give whatever safety data they had in pediatric --
11 in the pediatric age group at that time, right?

12 A. Yes. Yes. Exactly.

13 Q. And in 1996, this is ten years before the
14 medicine was approved by the FDA in kids, and so
15 they had just started to do those studies, right?

16 A. Yes.

17 Q. And so they gave the FDA, you know, what they
18 had, and they wanted to give doctors safety
19 information about dosing in kids, right?

20 A. Yes.

21 Q. And --

22 A. But, again, for what indication?

23 Q. They wanted to give them dosing indication for
24 anything, right?

25 A. Well, that's the problem.

1 Q. And let's talk about -- let's look at this.

2 So in 1996, the medicine had just
3 been approved for adults, not for children, right?

4 A. Yes.

5 Q. But Janssen knows it's being prescribed in
6 children?

7 A. Yes.

8 Q. And they're doing the studies. And, by the
9 way, Dr. Kessler, it takes a really long time to get
10 a medicine approved by FDA, doesn't it, sir?

11 A. Uhmm, it takes a long time to develop a
12 medicine. I have approved important medicines in 45
13 days.

14 Q. You're talking about the NDA approval process.
15 But all the studies, doing all the studies, the
16 animal studies, the lab studies, the patient
17 studies, it takes years?

18 A. I've -- yes. But that's on the company's
19 time.

20 Q. Right.

21 A. And it did -- back before I got to the FDA,
22 FDA took a lot of time in reviewing applications;
23 and we accelerated that, the FDA review portion.

24 Q. And it generally on average takes between 8
25 and 11 years to get a drug to the new drug approval

1 stage to the FDA. It takes companies on average
2 about 8 to 11 years to get a medicine ready to get
3 approval, right?

4 MR. KLINE: Objection. Objection;
5 relevancy.

6 THE COURT: Overruled.

7 THE WITNESS: That's -- it takes a
8 long time. Again, in certain instances, when
9 a company is efficient and there's an
10 important national priority, we've been
11 able -- we did this in a matter of a few
12 years when it came to important drugs like
13 HIV.

14 BY MS. SULLIVAN:

15 Q. Yeah. But it takes years?

16 A. Yes, of course.

17 Q. And looking at Page 2 of Plaintiff's Exhibit
18 15. Janssen talks about the fact that they know
19 that their request to add something about kids in
20 the label in terms of dose, that they don't have the
21 studies yet for kids because they just started them.
22 "Although this submission does not contain data
23 which the Agency would normally characterize as
24 substantial evidence, we are nonetheless [sic] aware
25 that Risperdal is being utilized in children and

1 adolescents. See summary. Hence, we believe that
2 the Agency's alternative labeling options would not
3 adequately and safely reflect this fact," right?

4 A. Yes, I see that.

5 Q. So they're asking the FDA, they're saying we
6 know we don't have all the studies yet done in kids
7 and we know the medicine is only approved in adults,
8 but can we please give doctors dosing information so
9 they could use it safely in their patients, right?
10 That's what they're asking?

11 A. I think that's a fair statement.

12 Q. And if we could see -- and I'll pull it out
13 and give my colleague a copy, take a look at the
14 FDA's response.

15 It's 221.

16 A. May I just trouble somebody for copies?

17 Q. Of course, Dr. Kessler.

18 MR. KLINE: Your Honor, objection to
19 the FDA document generally, to the extent
20 there's hearsay in it.

21 If I could have a continuing
22 objection.

23 THE COURT: Well, first of all, is
24 this a document that has been marked already?

25 MS. SULLIVAN: This is the first

1 time, Your Honor.

2 THE COURT: What is this?

3 MS. SULLIVAN: It's been premarked by
4 us, but it's the first time we're using it in
5 the trial, Judge.

6 THE COURT: It's exhibit what?

7 MS. SULLIVAN: It's Defense Exhibit
8 221.

9 COURT CRIER: Fifteen.

10 THE COURT: All right. Let's do
11 that.

12 COURT CRIER: It will be D-15.

13 MS. SULLIVAN: And if we could have
14 copies for the Judge and for Dr. Kessler,
15 yes. Thank you. And for Mr. Kline.

16 MR. KLINE: Yes. Thank you.

17 THE COURT: What is the purpose of
18 this inquiry?

19 MS. SULLIVAN: Your Honor, the
20 plaintiffs introduced this request for
21 pediatric dosing. And this is the FDA's
22 conclusion about whether they could add it in
23 the label or not.

24 I mean --

25 THE COURT: About the dosing?

1 MS. SULLIVAN: Yeah. The issue in
2 this case is whether you can add safety data
3 to the label even though it's not approved,
4 and I want to show the FDA's response to that
5 inquiry.

6 THE COURT: That's not an issue.
7 That's sustained. That's -- that's
8 understood. We're going to instruct the jury
9 to that.

10 MS. SULLIVAN: And, Your Honor --

11 BY MS. SULLIVAN:

12 Q. And, Dr. Kessler, you know, without using the
13 document, you know, Dr. Kessler, that the FDA did
14 not allow Janssen to use -- to put the pediatric
15 dosing information in their label, right?

16 A. Uhhh, yes, because they were concerned that
17 that would promote the use of the drug.

18 Q. Exactly. They didn't want any information in
19 there -- even safety information -- that would
20 indicate that this medicine had been approved for
21 children because it hadn't been, right?

22 A. No. There's a difference --

23 Q. The --

24 A. -- in terms of the -- may I finish?

25 So the FDA's specific concern was

1 putting in the dose would -- and I happen to have
2 this -- would in fact run the risk of promoting the
3 drug, the use of this drug in pediatric patients
4 without any justification.

5 Q. Yes.

6 A. That's if you -- that's if you put the dose
7 in. If you put a warning in, that's different than
8 the dose.

9 So, again, just be careful, all
10 right. You can't promote. You can't market, all
11 right. You can't -- you know, you can't promote and
12 you can't market, but you can -- you can warn, if
13 this were a warning. A dose is not a warning.

14 Q. And, Dr. Kessler, you know that there are FDA
15 officials and former FDA officials who vehemently
16 disagree with your opinion --

17 MR. KLINE: Objection, Your Honor.

18 BY MS. SULLIVAN:

19 Q. -- that you can warn about an off-label risk?

20 MR. KLINE: Objection under many
21 Rules of Pennsylvania Evidence.

22 THE COURT: Well, I don't know.

23 Dr. Kessler is also opening the door to this
24 kind of thing, and I'm going to permit that.

25 BY MS. SULLIVAN:

1 Q. Dr. Kessler, you know that there are FDA
2 officials who work at the FDA now and who were
3 former FDA officials who absolutely would disagree
4 with your opinion in this case that companies can
5 warn about an off-label risk? They think you're
6 just flat wrong about that.

7 MR. KLINE: Same objection.

8 BY MS. SULLIVAN:

9 Q. Under the regulations.

10 THE COURT: Overruled.

11 BY MS. SULLIVAN:

12 Q. Can you answer my question?

13 A. Yes. Just give me one second.

14 Q. Can you answer that question or do you know?

15 A. I'm just looking for the 1979 Federal Register
16 where the Commissioner specifically states -- and
17 I'll do this from memory, okay.

18 MR. KLINE: Doctor, take the time.

19 THE WITNESS: There is nothing --
20 there is nothing that prevents a warning from
21 happening. There is no limitation on
22 warning.

23 Dr. Robert Temple signed an affidavit
24 and stated that. And --

25 MS. SULLIVAN: Okay. Doctor --

1 THE WITNESS: As you know. And
2 furthermore, I would surmise that -- I mean,
3 you can only prevent a warning if it's false
4 or misleading, okay. That's the only -- and
5 then it would be misbranding.

6 And, Ms. Sullivan, I will assure you
7 that there is no judge in this -- in the
8 United States, certainly in my opinion,
9 right, that would prevent the company from
10 making a true warning about safety
11 information in order to protect kids.

12 BY MS. SULLIVAN:

13 Q. And, Dr. Kessler, I'm talking about the FDA
14 here. They wouldn't -- the FDA in this instance
15 said, no, you can't put the safety information about
16 dosing in your label because it's an off-label use,
17 right? They said no.

18 A. Because the dose, right, would serve as
19 promotion. It would serve as use.

20 Q. Yeah.

21 A. It's not warn that something bad is going to
22 happen.

23 Q. But that's --

24 A. Those things are different.

25 Q. But that's the concern of FDA about any risk

1 information. What the FDA doesn't want is companies
2 using the guise of a warning to say, look, our
3 medicine is approved for kids because we have
4 something about kids in there. They don't let you
5 do that.

6 A. They always let you warn. You can't use it as
7 a guise, but a true warning is always allowed.

8 Q. Well, in this instance, Dr. Kessler, the FDA,
9 when Janssen asked, didn't let them warn about the
10 dosing levels, right?

11 MR. KLINE: Objection; asked and
12 answered.

13 THE COURT: All right. That's
14 sustained. Now, that was about the dose as
15 opposed to a warning about safety for
16 children; did I get that right?

17 THE WITNESS: Exactly, Your Honor.

18 THE COURT: Move on, please.

19 BY MS. SULLIVAN:

20 Q. And just so we're clear, this is about as the
21 FDA -- as the documents you reviewed indicate,
22 Dr. Kessler, this dosing issue was a safety issue,
23 FDA said that, and the company said that, right? A
24 safety issue?

25 A. Let me just give the support for my position,

1 if I may. Thank you.

2 And perhaps --

3 Q. And --

4 A. Maybe --

5 Q. And, Dr. Kessler, you never did answer my
6 question about --

7 THE COURT: Well, right now we
8 have -- this question is on the floor.

9 What was the question there, John?

10 MS. SULLIVAN: My question was that
11 the documents in the case that he's reviewed
12 indicate that this was a safety issue. The
13 FDA said it and Janssen said it.

14 THE COURT: No. What was the last
15 question that we had?

16 MS. SULLIVAN: That was the last
17 question.

18 - - -

19 (Whereupon the court reporter read
20 back the previous question as requested.)

21 - - -

22 THE WITNESS: FDA did not allow them
23 to warn about the dosing levels for fear that
24 the dosing levels would cause the drug to be
25 promoted, and that would not be permissible.

1 FDA did say, when it looked at the
2 data, there are no specific safety findings
3 of sufficient concern among the meager safety
4 data submitted to justify adding any
5 information to the labeling about safety
6 experience.

7 So you can always warn about safety,
8 and that's well-established. And I'd be
9 happy to cite the Federal Register right now.

10 BY MS. SULLIVAN:

11 Q. And, Dr. Kessler, you know the FDA disagrees
12 with you on that, the real FDA, not -- you were
13 there 20 years ago.

14 MR. KLINE: Objection, Your Honor.
15 Objection, Your Honor.

16 THE COURT: What's the question?

17 MR. KLINE: The "real FDA" disagrees
18 with you. We have to bring the "real FDA" in
19 to do that, because I know different, Your
20 Honor, too.

21 THE COURT: Well, I'm only concerned
22 with the time period -- Doctor, you can say
23 yes or no -- the time period between 2002 and
24 2006 or 2007, I think it was prescribed.

25 THE WITNESS: Right.

1 THE COURT: During that time period,
2 what is your answer?

3 THE WITNESS: During that time
4 period, the federal regulations that governed
5 that time period, Your Honor, that were in
6 effect, were written and promulgated in a
7 final rule on June 26, 1979, and that was in
8 effect through 2006, 2007.

9 And that Federal Register -- and I'm
10 quoting from Page 37447, and this is the FDA,
11 right, and it's the FDA that governs that
12 time period in this federal regulation. It
13 says, "The Commissioner also advises that
14 these labeling regulations" -- because that's
15 what's in effect through 2006 -- "do not
16 prohibit a manufacturer, packer, relabeller,
17 or distributor from warning healthcare
18 professionals whenever potentially harmful
19 adverse effects associated with the use of
20 the drug are discovered."

21 BY MS. SULLIVAN:

22 Q. That doesn't talk about an off-label use,
23 though, does it, Dr. Kessler?

24 A. This -- this --

25 Q. That refers to on-label.

1 MR. KLINE: She has two questions now
2 going. Can he answer the first?

3 THE WITNESS: It refers to the
4 intended use. If Janssen's intended use and
5 is marketing for off-label, it has an
6 obligation to warn. But all -- this applies
7 to everything. This applies to all warnings.

8 It doesn't make sense -- it will not
9 make sense to anyone to say if I have a
10 warning and I got to let that doc know, of
11 course I got to be able to read that. You
12 just can't promote the use. You can't
13 encourage the marketing, but I can always
14 warn.

15 BY MS. SULLIVAN:

16 Q. And, Dr. Kessler, that refers to intended use
17 which means the approved indication.

18 A. Wrong.

19 Q. Well, then, the FDA disagrees with you.

20 A. No.

21 MR. KLINE: See, Your Honor,
22 objection again.

23 THE WITNESS: I mean --

24 THE COURT: Well, no, no. That's
25 overruled.

1 You may answer, Doctor.

2 BY MS. SULLIVAN:

3 Q. You know, Dr. Kessler, that the FDA disagrees
4 with you?

5 A. No.

6 MR. KLINE: See, Your Honor,
7 objection again.

8 THE COURT: The FDA disagrees with
9 what? When?

10 BY MS. SULLIVAN:

11 Q. Dr. Kessler knows that the FDA, as indicated
12 by this denial of the pediatric dose and safety
13 information, among other things, disagrees with your
14 opinion that you could just say anything you want in
15 your label about an indication that it's not
16 approved for.

17 A. Ma'am, I have -- I have studied intended use
18 for 30 years, okay. And it's a key aspect of our
19 law, right. And Janssen by going in 20 times to
20 that doctor who was a pediatric neurologist, the
21 totality of the evidence was the intended use was
22 for pediatrics, okay. And certainly you have a
23 duty, if your intended use is to make sure that
24 you're not -- you tell not just the good, but the
25 whole story.

1 But in any case, in any instances,
2 right, no one can credibly say you can't warn. That
3 just defies all logic. It defies any humanity.

4 Q. Although the FDA told Janssen exactly that
5 when it came to the safety information about dosing
6 because it hadn't been approved for kids yet.

7 MR. KLINE: Objection.

8 THE WITNESS: No. Ma'am, that's not
9 what FDA is saying. The FDA is saying -- let
10 me read it. There were no --

11 THE COURT: All right. What document
12 is this?

13 MS. SULLIVAN: This is the document,
14 Your Honor, Defense Exhibit --

15 MS. BROWN: We had premarked it, Your
16 Honor, as D-221.

17 THE COURT: Which one is it?

18 MS. SULLIVAN: It hasn't been
19 admitted, Your Honor.

20 THE COURT: If the witness is going
21 to read from it, then it's got to be
22 admissible.

23 MS. SULLIVAN: Thank you, Your Honor.

24 MS. BROWN: Then it will be Defense
25 15, Your Honor, for our purposes.

1 COURT CRIER: Sixteen.

2 THE COURT: Sixteen.

3 (Counsel and court crier conferring.)

4 COURT CRIER: It's D-15, Your Honor.

5 THE COURT: What is it, D-15?

6 COURT CRIER: Yes, Your Honor.

7 THE COURT: All right. Let me see it
8 again.

9 - - -

10 (Whereupon Exhibit D-15 was marked
11 for identification.)

12 - - -

13 THE COURT: All right. You may
14 continue.

15 MS. SULLIVAN: Thank you, Your Honor.

16 BY MS. SULLIVAN:

17 Q. And, Dr. Kessler, this was FDA's -- this is
18 official FDA letterhead, right?

19 A. Yes.

20 Q. And this is FDA's response, and it talks about
21 Food and Drug Administration, right?

22 A. Yes.

23 Q. And this is FDA's response in 1997 to
24 Janssen's request to add safety data about dosing in
25 their adult label for kids -- let me rephrase that.

1 This was FDA's response to Janssen's
2 effort to add information about pediatric dosing in
3 their adult label, right?

4 A. Yes.

5 Q. And the FDA says that -- they basically say
6 no, right?

7 A. If you turn to the second page, yes.

8 Q. And they say that -- basically telling Janssen
9 you acknowledge that you've not provided substantial
10 evidence from adequate and well-controlled trials to
11 support a pediatric indication nor developed a
12 rationale to extend the results of those studies
13 conducted in adults to children, right?

14 A. Yes.

15 Q. And they say -- and we talked about the fact
16 that Janssen was just starting to do studies, they
17 didn't have a lot of studies yet, right?

18 A. They were early in the development, yes.

19 Q. And it says, your rationale for proposing this
20 supplement appears to be simply that since Risperdal
21 is being used in pediatric patients, this should be
22 acknowledged in some way in the labeling. That's
23 what the FDA says, right?

24 A. Not -- that does not say, as you point out,
25 that you want to include safety information, right.

1 So that -- that's the point. It's --

2 MR. KLINE: I think the witness is
3 talking about something that's not on the
4 screen.

5 THE COURT: Do you want to read the
6 whole document into the record; any of you?

7 MS. SULLIVAN: I'm sorry?

8 THE COURT: You want to read the
9 whole document or should I read the whole
10 document into the record?

11 MS. SULLIVAN: I'm going to read --

12 THE COURT: Read the whole thing, or,
13 you know, because again we're going to pick
14 apart. And the document at this point can
15 speak for itself.

16 MS. SULLIVAN: Okay.

17 Although I will note, Judge, that the
18 plaintiffs were able to read a lot of
19 documents.

20 THE COURT: Well, I mean, you know,
21 again, this doctor wanted to answer your
22 question by reading from a specific paragraph
23 in this document. May he do so?

24 MS. SULLIVAN: I'm sorry? Of course.

25 THE COURT: All right. What is it

1 that you were going to read to us,
2 Dr. Kessler, from this document?

3 THE WITNESS: If you could kindly go
4 to the paragraph that starts "accordingly."
5 And what Dr. Leber is saying beginning with
6 the sentence, "There were no specific safety
7 findings of sufficient concern among the
8 meager safety data submitted to justify
9 adding any information to the labeling about
10 safety experience with this drug in the
11 pediatric age group. To permit the inclusion
12 of the proposed vague references to the
13 safety and effectiveness of Risperdal in
14 pediatric patients and the nonspecific
15 cautionary advice about how to prescribe
16 Risperdal for the unspecified target
17 indications would only serve to promote the
18 use of the drug in pediatric patients without
19 any justification."

20 MS. SULLIVAN: Yeah.

21 THE COURT: That's what you wanted to
22 read?

23 THE WITNESS: Yes.

24 THE COURT: All right. You got it.

25 BY MS. SULLIVAN:

1 Q. And, Dr. Kessler, so what they're saying
2 here -- the FDA is saying is that we're looking at
3 your safety data and we don't see enough adverse
4 reactions to justify a pediatric dosing?

5 MR. KLINE: Objection. What the FDA
6 is saying he just read.

7 THE COURT: Again, we now had the
8 thing read into the record and now it speaks
9 for itself. Counsel, you may either go to
10 another question or move on.

11 MS. SULLIVAN: And --

12 THE COURT: But this was to
13 explain -- the reason I permitted him to do
14 this was for him to explain an answer which
15 is consistent with this particular statement.

16 MS. SULLIVAN: Yeah. And then this
17 particular statement says that we're looking
18 at your data and we don't see any safety
19 issues to justify -

20 MR. KLINE: Objection.

21 MS. SULLIVAN: -- this change.

22 THE COURT: Sustained. Sustained.
23 You might want to move on or if you want to
24 go to the first page, I don't know. But that
25 particular paragraph was consistent --

1 MS. SULLIVAN: I'll move on.

2 THE COURT: -- with his statement
3 here.

4 MS. SULLIVAN: I'll move on, Your
5 Honor.

6 BY MS. SULLIVAN:

7 Q. And so, Dr. Kessler, bottom line, the FDA said
8 no, you can't add pediatric dosing?

9 MR. KLINE: Objection. It speaks for
10 itself.

11 THE COURT: Again, sustained as to
12 the bottom line. Everything's nuance in this
13 case.

14 Go ahead.

15 BY MS. SULLIVAN:

16 Q. Dr. Kessler, I want to talk more about the
17 Findling article and the studies.

18 A. The Janssen pooled analysis, yes.

19 Q. Well, it was the Janssen studies, but
20 Dr. Findling, Dr. Moshang and Dr. Daneman, outside
21 authors, were also involved in looking at the data
22 and in the publication; true?

23 A. At Janssen's request, yes.

24 Q. Yeah.

25 And in fact they've testified, and

1 you've read their depositions, about their
2 involvement in this process, right?

3 A. Yeah, I've read their depositions, yes.

4 Q. Yes. And --

5 MR. KLINE: It's not Dr. Moshang.

6 MS. SULLIVAN: Fair enough.

7 THE COURT: I'm sorry. I don't know
8 where we are right now.

9 MR. KLINE: Objection to the question
10 which said --

11 THE COURT: We haven't heard the
12 question, Mr. Kline.

13 MR. KLINE: Well, the last question,
14 Your Honor, I'm sorry. The last question
15 suggested that there were depositions of
16 Moshang, Daneman and Findling, to my
17 knowledge.

18 MS. SULLIVAN: I stand corrected,
19 Dr. Moshang.

20 THE COURT: Well, whoever. Let's do
21 one at a time so that we're on target.

22 MS. SULLIVAN: And, Your Honor, and
23 I'll give counsel a copy, I want to put up a
24 demonstrative that just summarizes the number
25 of events in the five -- I don't think this

1 will be controversial -- the five studies
2 that were involved in the -- that were the
3 basis for the Findling analysis.

4 COURT CRIER: It's going to be marked
5 D-16, Your Honor.

6 - - -
7 (Exhibit D-16 marked for
8 identification.)

9 - - -
10 MS. SULLIVAN: And it's Defense
11 Exhibit 16.

12 THE WITNESS: May I get a copy?

13 THE COURT: Do you have copies?

14 THE WITNESS: I can look at the
15 screen, if it's simple.

16 BY MS. SULLIVAN:

17 Q. And, Dr. Kessler, we have put in here, and
18 it's from the studies, and I don't think it will be
19 controversial, the five studies and the incident
20 rate of gynecomastia in each; do you see that?

21 A. Uhmm, I'm a little off on some of my number of
22 patients on Risperdal. But I'd be happy to, you
23 know, I assume that's correct.

24 Q. Yeah.

25 A. I mean, I -- I have different numbers. But

1 the incidence of -- the gynecomastia rate is
2 correct.

3 Q. That's consistent with your recollection?

4 A. Yes.

5 Q. Okay. And just to go back to remind our
6 jurors, what -- so the Findling analysis was not a
7 clinical trial. It was an analysis about data that
8 had already been gathered in other clinical trials,
9 right?

10 A. So, yes, it took data from other clinical
11 trials and asked a new question.

12 Q. Right.

13 And the question it asked wasn't
14 specific to gynecomastia. It was, let's take a look
15 at whether there's some relationship between
16 prolactin elevation and prolactin-related events.

17 A. Don't mean to quibble, Ms. Sullivan, but the
18 word was "any" relationship.

19 Q. Yeah. Fair enough.

20 In other words, they weren't just
21 looking at gynecomastia. They were looking at any
22 kind of prolactin-related events?

23 A. Yes.

24 Q. And if we could just -- if I can use this
25 board for a second. See if people can still see it

1 when it's back here.

2 MS. SULLIVAN: Can you see that all
3 the way down there?

4 - - -

5 (Jurors nodding.)

6 - - -

7 MS. SULLIVAN: You can. Thanks.

8 BY MS. SULLIVAN:

9 Q. So just so -- let's see if there's any pages
10 left here.

11 Just so we're kind of in a basic
12 fashion for my own benefit, Dr. Kessler, what they
13 were looking at was -- and so prolactin, as we
14 talked about, is a hormone in the body that both men
15 and women have, right?

16 A. Yes, ma'am.

17 Q. And so what the authors of the study were
18 looking at was whether elevations in prolactin have
19 some event -- have some relationship to these
20 events, these symptoms or events, right, like
21 gynecomastia or not having your period or some of
22 the other things that we talked about, right?

23 A. I think we're -- I'm not sure what the -- what
24 these two graphs are.

25 Q. So this is just a bar representing -- so then

1 what they did is they tested the blood -- in the
2 studies they tested the blood of the patients to see
3 what their prolactin levels were at various points
4 during the time periods.

5 A. Yes.

6 Q. And some people had normal prolactin, some
7 people had abnormal prolactin levels; true?

8 A. Some of the children, yes.

9 Q. Yes.

10 And what they wanted to do is to
11 see -- so we'll call this "normal," and we'll call
12 this "elevated."

13 And what they wanted to see was
14 whether there was any relationship to having
15 elevated prolactin, whether that had any
16 relationship to symptoms, right, or events?

17 A. Yes.

18 Q. Okay. And what they found was that in many
19 cases, the people who had the events had normal
20 prolactin. They had no relationship to the events.
21 Prolactin had no relationship to the events, right?

22 A. Yes.

23 Q. And we'll look at that.

24 A. Well, why don't we look at the actual numbers.

25 Q. We will.

1 A. Let's look at the numbers. But, yes, there
2 were those. But as we know, there also was that
3 association that --

4 Q. Yeah. And believe me, Dr. Kessler, we're
5 going to get to Table 21.

6 But part of the studies showed that
7 many, many people who had absolutely normal levels
8 of prolactin, people who Risperdal didn't elevate
9 prolactin on, actually did have things like
10 gynecomastia and some of the other events we talked
11 about, right?

12 A. Yes.

13 Q. So even people who had normal prolactin had
14 gynecomastia, right?

15 A. Yes.

16 Q. And part of the --

17 A. There were -- but there were fewer of those
18 than who had elevated.

19 Q. And we're going to look at the data.

20 And part of the reason that normal --
21 people who had no elevation in prolactin had
22 gynecomastia is that it's a fairly common condition
23 in puberty.

24 A. I think you're testifying. I'll leave that
25 for the endocrinologist to testify.

1 Q. Fair enough. Fair enough.

2 But they found gynecomastia in people
3 that had nothing to do with prolactin?

4 A. Yes. But more with -- the whole in that -- in
5 the statistically significant time frame there were
6 more with those above.

7 Q. We're going to talk about Table 21, I promise
8 you, Dr. Kessler. But --

9 A. Okay.

10 Q. And just going back, just because you find an
11 association between -- just because people develop
12 an event while they're on a drug doesn't mean the
13 drug caused that event.

14 A. That's why you -- well, first, you're mixing
15 up several things, okay. You switched sort of the
16 question.

17 Q. Well, let me rephrase the question.

18 A lot of things happen to patients in
19 studies, sometimes from the drugs and sometimes not?

20 A. That's why -- that's why you have studies.
21 You try to control for that study.

22 Q. So just because somebody develops an event on
23 a study doesn't mean that it was necessarily
24 associated with a drug?

25 A. That's correct.

1 Q. And so, for example, if you have a -- say you
2 have a bunch of six-year-olds in a study and you
3 want to see if a medicine causes you to lose your
4 teeth, you're going to have a lot of kids losing
5 their teeth at that age that have nothing to do with
6 the drug?

7 A. That's one example. But if you give me a
8 medicine and all of a sudden I start flying across
9 the room, it depends on the uniqueness of the event
10 the commonality of the event.

11 Q. Yes.

12 A. I mean, I take your point.

13 Just giving a medicine and seeing a
14 side effect doesn't mean that it's causally related.
15 That's why you study this.

16 Q. Exactly.

17 And just because somebody developed
18 gynecomastia during the study doesn't necessarily
19 mean that the drug caused the gynecomastia?

20 A. That's -- well, what kind of study are we
21 talking about?

22 Q. Any study.

23 A. Well, so, again, that's -- the reason why if
24 you have two groups and they're, in essence, control
25 for everything else, age, and the only difference is

1 prolactin, that's why you control it, to see whether
2 the association is related to the thing that is the
3 variable.

4 Q. Do you remember my question, Dr. Kessler?

5 A. Yes.

6 Q. My question was, just because somebody
7 develops gynecomastia on a medicine doesn't mean the
8 medicine caused gynecomastia?

9 A. That is true.

10 Q. And that's especially true because we know
11 that there's a background rate for gynecomastia.
12 And you're going to defer to the endocrinologist
13 about how many or what percentage. But we know that
14 boys develop gynecomastia with or without Risperdal.

15 A. As we saw, there is increased breast tissue
16 for some in puberty. According to Janssen, it
17 disappears.

18 Q. And -- well, have you -- and you're not an
19 endocrinologist, Doctor. But have you seen studies
20 that show in 20 percent of the cases it doesn't
21 disappear?

22 A. Yeah. I've looked at -- I've tried to look
23 for that data, and that data is not very clear to
24 me. But, again, let me leave it to the pediatric
25 endocrinologist to discuss that.

1 Q. All right. And so going back to the Findling
2 study, so they had -- so this -- these studies that
3 made it into this manuscript that you and Mr. Kline
4 spent a long time talking to the jury about, was
5 made up of these five studies, right?

6 A. Yes.

7 Q. And in four of the studies -- in three of the
8 studies there was no gynecomastia at all. Nobody on
9 the medicine got gynecomastia, right?

10 A. That's correct.

11 Q. And in one study, one person out of 107 had an
12 adverse event?

13 A. 1 percent, yes.

14 Q. And basically, almost all of the events in
15 this manuscript came from one study?

16 A. I think we discussed that when we were talking
17 about it.

18 Q. Yeah.

19 A. Yes. Two of those studies are short-term, for
20 example. We went through that.

21 Q. A couple of them are long-term?

22 A. Two are long-term, I believe.

23 Q. Yeah.

24 A. I mean, three are long-term.

25 Q. But 99 percent of the events in the Findling

1 paper that we talked about came from this one study,
2 this INT-41, right?

3 A. Yes. The one that Mr. Kline --

4 Q. Spent a long time talking about.

5 A. And it was labeled as special attention.

6 Q. Yeah. I'm going to show you the special
7 attention.

8 Do you remember, Dr. Kessler, that in
9 that document they paid special attention to a lot
10 of different things, not just prolactin? Special
11 attention to --

12 A. EPS.

13 Q. Special attention to other things, glucose?

14 A. There were three things that I believe had
15 special attention, and you applauded them for that.

16 Q. Yeah. Right.

17 A. That's a good thing. Because if you're
18 looking to do a long-term safety, you want to look
19 for those results. So those were all important --
20 prolactin-related, glucose, and this thing called
21 extrapyramidal syndrome.

22 Q. And the truth is, Dr. Kessler -- and after
23 these studies, actually, you know that Janssen did
24 13 more pediatric clinical trials?

25 A. It supported the autism, yes.

1 Q. Yes.

2 A. They were part of the autism protocol, yes.

3 Q. Yes.

4 And you know that in all 18 studies,
5 they collected prolactin data and they looked at
6 whether there was a relationship between prolactin
7 and the events?

8 A. You know, I read the FDA review, and I think
9 prolactin data was primarily collected in the DBD
10 studies, but we'd have to go back and double-check.
11 I mean, I have that actually in my notes. But I
12 think FDA -- I don't think a number of the autism
13 studies collected prolactin. We'd have to
14 double-check.

15 Q. Do you remember at least that most of them
16 did?

17 A. I have a list, if you want to go through each
18 one.

19 MR. KLINE: Yes.

20 BY MS. SULLIVAN:

21 Q. We can -- it looks like we're going to be
22 back, Dr. Kessler, so I'll make sure I have it for
23 Monday.

24 But the fact is, Dr. Kessler, in all
25 of the 18 studies, it was really just INT-41, this

1 one study, that they found anything close to a
2 significant number of events, right?

3 A. No. When the data was pooled, the
4 significance, right, was based on the pooled data,
5 right.

6 So the statistical significance was
7 not just based on INT-41. The statistical
8 significance was based on all five of those studies.

9 Q. But, Dr. Kessler, if there's no events in
10 three and only one event in one, the statistical
11 significance is caused by the one study that has all
12 the events. That's like kind of common sense,
13 right?

14 A. The statistical significance was based on the
15 pooled data. The number of adverse events, positive
16 adverse events, come from INT-41.

17 THE COURT: All right. May I see
18 counsel at sidebar, please?

19 MS. SULLIVAN: Sure.

20 - - -

21 (The following discussion transpired
22 at sidebar out of the hearing of the jury:)

23 - - -

24 THE COURT: All right. So we all
25 know that this witness is coming back on

1 Monday. I have a note from the jury that if
2 Dr. Kessler is coming back, the jury would
3 like to leave soon.

4 MS. SULLIVAN: Good. I'm fine.

5 THE COURT: So why don't we adjourn
6 in five minutes. Wrap it up for the day and
7 let him try to catch his flight.

8 MR. KLINE: Okay.

9 MS. SULLIVAN: Okay. Sure. Sounds
10 good.

11 - - -

12 (Sidebar discussion concluded.)

13 - - -

14 (The following transpired in open
15 court in the presence of the jury:)

16 - - -

17 THE COURT: All right. Members of
18 the jury, we are going to permit a few more
19 questions and then we are going to adjourn
20 for the day.

21 (Counsel conferring with technician.)

22 THE COURT: You have this document up
23 there. You may want to wrap it up on this
24 one.

25 MS. SULLIVAN: Thank you, Your Honor.

1 BY MS. SULLIVAN:

2 Q. And, Dr. Kessler, there is such a thing as
3 controlled studies and studies that are open-label
4 or not controlled, right?

5 A. Yes. Exactly.

6 Q. And controlled studies are when you have
7 people on the drug and people not on the drug and
8 you compare them?

9 A. That's -- well, no. You can have controlled
10 studies when people are on one drug and people are
11 on another drug.

12 Q. Fair enough.

13 A. And you can have built-in controls.

14 Q. Fair enough.

15 What the FDA requires for you to get
16 a medicine approved is that you do what's called
17 placebo-controlled studies?

18 A. We'd use up your couple of remaining minutes
19 to answer that. Not always, ma'am, not always.
20 You --

21 Q. Generally.

22 A. It's usually the best way to show
23 effectiveness, but it's not always required.

24 Q. It's viewed as the gold standard,
25 placebo-controlled studies, for showing

1 effectiveness and for analyzing safety?

2 A. But all oncology studies are not placebo
3 controlled. What you're referring to as the gold
4 standard is randomized, double-blind, controlled
5 studies, but not always the placebo.

6 Q. But INT-41 didn't have a control group, right?
7 It was an open-label study; it didn't have a
8 comparison group?

9 A. In and of itself, yes.

10 Q. And INT-41, when you say open-label, that's a
11 study where everybody knows what you're taking. The
12 doctors know you're on Risperdal and the patients
13 know you're on Risperdal?

14 A. Well said.

15 Q. And there's nothing to compare it to?

16 A. That's why Findling did the experimental. The
17 Janssen pooled analysis was designed the way it was,
18 so there was something to compare.

19 Q. And I want to show you -- I think Mr. Kline
20 had it up -- the Croonenbergh study. Jed, if we
21 could put it up.

22 And so, actually, INT-41 was
23 published, and we talked about it. You and
24 Mr. Kline talked about the actual publication,
25 right?

1 A. The 2005, if I remember.

2 Q. Yeah.

3 A. Right.

4 Q. And you know, Dr. Kessler, that Janssen
5 published all of their pediatric studies, right?

6 A. I don't think -- I think there were a few
7 foreign studies that I didn't see published. Let me
8 just see. I have my list here.

9 So I'm not sure whether, for
10 example -- it's a small point. Bell 22. I mean,
11 there are some small studies. We just have to go
12 through them.

13 Q. Yeah. And we can talk to another witness
14 about it, but they published the bulk of their
15 studies.

16 A. I think that's fair.

17 Q. At that time there was no obligation for
18 companies to publish their data, but Janssen did it,
19 right?

20 A. So it's not Findling?

21 Q. I'm sorry?

22 A. So it's not Findling?

23 THE COURT: Which one are you asking
24 about, Counsel? We're going to try to wrap
25 this up.

1 MS. SULLIVAN: Your Honor, I'm happy
2 to let our jurors --

3 THE COURT: We'll come back to this.
4 I think you were asking about INT-41, right?

5 MS. SULLIVAN: Yeah. I can do it
6 Monday.

7 THE COURT: All right. I think he
8 has a plane to catch, and I think the jury
9 wants to go, so we'll do it that way.

10 MS. SULLIVAN: Okay. Fair enough,
11 Your Honor.

12 THE COURT: Thank you very much.

13 All right. Members of the jury,
14 we're going to adjourn now for the --
15 Dr. Kessler needs to see if he can make a
16 flight. And I don't know if he will make it
17 or not, but we'll see, hopefully. And we are
18 going to adjourn for the weekend. Come back
19 here on Monday at 9:15.

20 The rules are the same. Please wear
21 the yellow badges. Please remember to keep
22 an open mind in this case. We are not done.
23 And I was going to say by any stretch, but,
24 no, we're not done. And we are going to ask
25 you, again, not to talk to anybody about the

1 case, friends, family, neighbors, anyone.
2 And, again, it's extremely important that we
3 not listen to any media or read any media,
4 probe any media, do anything with TV,
5 newspapers or computers in any way to relate
6 to this case, okay? Very important for the
7 reason that I said before.

8 This is our case and we're getting
9 the real thing here, all right? No reason to
10 go anywhere else, all right?

11 With that, enjoy the Super Bowl, and
12 we'll see you on Monday morning.

13 COURT CRIER: All rise as the jury
14 exits the courtroom.

15 - - -

16 (Whereupon the jury exited the
17 courtroom at 4:11 p.m.)

18 - - -

19 (The following transpired in open
20 court outside the presence of the jury:)

21 - - -

22 THE COURT: All right. So,
23 Dr. Kessler, you're excused, sir. Please do
24 not discuss the case with your lawyers. You
25 can discuss it with your wife or anyone else

1 you want, but not with any press or anybody
2 like that, and we will see you on Monday.

3 THE WITNESS: What time on Monday,
4 sir?

5 THE COURT: Well, I mean,
6 realistically I just told them 9:15. So if
7 you can make it here at 9:15, fine. If not,
8 I will -- we'll play it by ear, okay?

9 THE WITNESS: All right.

10 MR. KLINE: You're taking the redeye.
11 I don't want to talk to him at all in
12 public. Are you taking the redeye?

13 THE WITNESS: That may make the
14 judgment of whether I stay in town or not.

15 MR. KLINE: All right.

16 THE COURT: Okay. You got it.

17 THE WITNESS: May I e-mail them just
18 so they know whether I'm in --

19 THE COURT: Yes. All right.

20 MS. SULLIVAN: Thank you very much,
21 Your Honor.

22 MR. KLINE: Thank you, Your Honor.

23 THE COURT: Thank you. Have a great
24 weekend.

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(Pause.)

- - -

(Whereupon an off-the-record discussion was held.)

- - -

THE COURT: I think that for the record, I want to be clear that one of these documents, the one from the -- the document from the FDA response, we're marking that as court something, Court-2. It was not admitted, but it's certainly part of the record.

The other document, there was another one from Mr. Sheller's office out. I did not make a formal ruling on that. I did not study that for the purpose of admissibility. So it's still out there and subject to be looked at again.

MS. SULLIVAN: Thank you, Your Honor.

THE COURT: There was something about Dr. Kessler's opinion in that particular document related to 2003. I did not rule on that. I don't want to have it recorded that I made a ruling on something that I haven't.

MR. KLINE: You mean Mr. Sheller's

1 actual letter to the FDA?

2 THE COURT: Yeah. There's something
3 in there about Dr. Kessler's 2003 opinion.
4 And since I haven't read that, and I wasn't
5 making a ruling about that, it's still out
6 there.

7 MR. KLINE: Well, Mr. Sheller, who's
8 the author of it, would be available. And
9 Ms. Sullivan could cross-examine him. That
10 would be worth the price of admission.

11 THE COURT: No. No.

12 - - -

13 (Whereupon an off-the-record
14 discussion was held.)

15 - - -

16 MR. SHELLER: I want you to know that
17 there's cases in federal court now; Duane
18 Morris.

19 MR. KLINE: Right.

20 THE COURT: Duane Morris handled
21 that?

22 MR. KLINE: Yeah. Yeah.

23 The federal court case involving that
24 Petition is pending now in front of Judge
25 Savage -- the ruling challenging the FDA's --

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what they did, which we believe is illegal.

THE COURT: Well, that case, I see that going upstairs, so, you know, it's not relevant here because it's not decided.

All right.

- - -

(Whereupon an off-the-record discussion was held.)

- - -

(Court adjourned at 4:20 p.m.)

- - -

In The Matter Of:

Pledger v.

Janssen

(Jury Trial-PM Session)

Vol. VI

February 2, 2015

John J. Kurz, RMR-CRR, Official Court Reporter

City of Philadelphia

First Judicial District Of Pennsylvania

100 South Broad Street, 2nd Floor

Philadelphia, PA 19110

1 IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
2 FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
 CIVIL TRIAL DIVISION

3 -----
4 IN RE: RISPERDAL® LITIGATION :
March Term, 2010, No. 296 :
 :
5 Phillip Pledger, et al., :
 Plaintiffs, :
 :
6 v. :
 :
7 Janssen Pharmaceuticals, Inc., :
Johnson & Johnson Company, :
8 and Janssen Pharmaceutical :
Research & Development, :
9 L.L.C. :
 Defendants. :
 :
10 -----

11
12 - - -
13 MONDAY, FEBRUARY 2, 2015
14 - - -

15 COURTROOM 425
 CITY HALL
16 PHILADELPHIA, PENNSYLVANIA

17 - - -
18 B E F O R E: THE HONORABLE RAMY I. DJERASSI, J.,
 and a Jury
19 - - -

20 JURY TRIAL - VOLUME VI
21 - AFTERNOON SESSION - (AMENDED)
22

23 REPORTED BY:
24 JOHN J. KURZ, RMR, CRR
 REGISTERED MERIT REPORTER
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Also Present:

Priscilla M. Brandon, Esq., Sheller, P.C.
Marianne Mari, Tipstaff
Cory Smith, Display Technician

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- I N D E X -

WITNESSES	CROSS	REDIRECT	REXCROSS
DAVID A. KESSLER, M.D. (Continued)			
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By Ms. Sullivan	10	--	114

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- - -

1 (The following transpired in open
2 court outside the presence of the jury at
3 2:11 p.m.):

4 - - -

5 COURT CRIER: Come to order, please.

6 THE COURT: All right. Good
7 afternoon.

8 MR. KLINE: Your Honor, may we see
9 you at sidebar?

10 THE COURT: Right here.

11 - - -

12 (The following discussion transpired
13 at sidebar out of the hearing of the jury:)

14 - - -

15 MR. KLINE: Your Honor, as the Court
16 knows, this case has a long history here.
17 And we have -- we exchanged expert reports
18 quite awhile ago. A deposition was taken of
19 my pediatric endocrinologist -- I should say
20 the pediatric endocrinologist who's going to
21 come and testify -- a Dr. Goldstein from
22 Missouri.

23 I was handed today for the first time
24 a motion which has apparently been either
25 filed with the Court or about to be given to

1 Your Honor, which seeks to preclude his
2 testimony.

3 The defendants and the plaintiffs
4 both had pediatric endocrinologists examine
5 this young man who's at issue here, Austin
6 Pledger.

7 The Sheller firm sent Dr. Goldstein
8 from Missouri down to Alabama. We're now
9 told for the first time something unbeknown
10 to me, totally new to me, by the way. And I
11 haven't yet even had a chance to look at
12 whether the law recited is correct.

13 But on its face, they say that
14 Dr. Goldstein, by doing an examination
15 without a local physician present in Alabama,
16 committed a crime. And they say that he was
17 in the unauthorized practice of medicine and
18 that it would subject him to up to as a
19 felony, I believe they say, Class C. I don't
20 know if any of this is accurate. I'm only
21 reciting what's in their papers.

22 First of all, it wasn't brought to
23 our attention ever. It wasn't brought to our
24 attention at the motion in limine stage.
25 It's now sprung on us here at the last

1 minute. And they will tell you that they had
2 a local doctor examine the young man for that
3 reason. And their firm, I might add, have
4 known all along that they were going to do
5 this.

6 THE COURT: First of all, let me
7 interrupt you.

8 Is Dr. Goldstein testifying today?

9 MR. KLINE: No; tomorrow.

10 THE COURT: So we will adjourn on
11 this matter and we will review it after,
12 until we finally get Dr. Kessler off the
13 stand.

14 MR. KLINE: The only reason I bring
15 it to your attention -- and I understand the
16 need to get him off the stand --

17 THE COURT: I'm having a lot of
18 difficulty with our jury.

19 MR. KLINE: Okay. My --

20 THE COURT: I understand.

21 MR. KLINE: -- my issue was to give
22 myself some time.

23 THE COURT: Understand. I will
24 examine the law.

25 MR. KLINE: You now know the issue.

1 THE COURT: I'll examine the law.
2 But, frankly, I really need to get
3 Dr. Kessler off the stand.

4 MR. MURPHY: Your Honor, one other
5 issue since while we're at sidebar. Juror
6 No. 6, Mr. Eugene, had been napping quite a
7 bit.

8 THE COURT: Well, we're watching him.
9 We are aware of him.

10 MR. MURPHY: Okay.

11 THE COURT: Our policy is, you know,
12 what appears to be napping sometimes is just,
13 you know, closing eyes, because whenever you
14 go over there, he wakes up or he -- you know,
15 we're watching him.

16 MR. MURPHY: Fair enough, Your Honor.

17 MR. KLINE: Did the Court get a copy
18 of this?

19 MR. MURPHY: He didn't.

20 MR. KLINE: He should have one.

21 MR. MURPHY: That's fine.

22 - - -

23 (Sidebar discussion concluded.)

24 - - -

25 (Pause.)

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MR. KLINE: And, Your Honor, while you're looking at the issue, and we're prepared to talk about --

THE COURT: I hope so. There are some Philadelphia civil rules, procedural rules involved here, and I'm not going to breach those.

Alabama authorities can do whatever they want to do.

COURT CRIER: All rise as the jury enters the courtroom.

- - -

(Whereupon the jury entered the courtroom at 2:17 p.m.)

- - -

(The following transpired in open court in the presence of the jury:)

- - -

THE COURT: All right. Please be seated everybody.

All right. We may proceed.

MS. SULLIVAN: Thank you, Your Honor. Good afternoon everybody.

JURY PANEL: Good afternoon.

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CROSS-EXAMINATION (Continued)

BY MS. SULLIVAN:

Q. Good afternoon, Dr. Kessler.

A. Good afternoon, Ms. Sullivan.

Q. Back on the Dr. Findling study.

So, Dr. Kessler, before the lunch break, you and I were talking some more about this study that looked at prolactin levels and potential side effects from prolactin in five of the Janssen studies, right?

A. Exactly, ma'am.

Q. And I think you and I made clear to our jurors that the Findling study was just -- just looked at five of these 18 because the other 13 hadn't been done yet, right, back at the time the Findling analysis was done?

A. Well, I don't think that's true. Didn't -- what were there, like MED-8, and some of the earlier studies were small studies; I think those were done, right?

Q. Many of them hadn't been done yet. Many of the studies hadn't been done yet. And these were chosen because they had prolactin levels and they

1 had side effects in some instances.

2 A. They were a cohort of studies that were, as I
3 understood it, that were identified as the
4 developmental -- disruptive behavior cohort.

5 Q. Yeah. And we don't have to quibble about it,
6 but the point is it was five -- this Findling study
7 just involved five of the total number of studies?

8 A. That's what Janssen selected, yes.

9 Q. And we talked about the fact that the Findling
10 analysis contained side effects from these five
11 studies and that all of them except one in terms of
12 gynecomastia came from this one study, INT-41,
13 right?

14 A. Exactly, ma'am.

15 Q. And we also talked about the fact that there
16 was no control group, placebo control group?

17 A. In INT-41?

18 Q. Right.

19 A. Yes. Exactly.

20 Q. And you know, Dr. Kessler, that after doing
21 the study, the Janssen folks ran a whole bunch of
22 different analysis. They looked at the data many
23 different ways.

24 A. I think that's a pretty loose way to say it.

25 Q. They analyzed, they ran statistics on many

1 different things. They looked at it by gender.

2 They looked at it on efficacy. They looked at it by
3 age. They looked at it several different ways?

4 A. So as I understand it, there was a May set of
5 data runs; is that a fair way to say it?

6 Q. Okay.

7 A. And that May set of data runs, May 15th data
8 runs, had a number of tables that looked at, you're
9 exactly right, a number of variables.

10 Q. And it had about 50 different tables. They
11 looked at the data in a number of different ways?

12 A. Yes. I'm not sure exactly that number, and
13 then there was another run in September, we know
14 that.

15 Q. And it's a good thing for scientists to run
16 data and look at various things to figure out what's
17 going on?

18 A. No.

19 Q. Okay. It's not a good thing for scientists to
20 do a lot of statistical analyses to try to figure
21 out what's going on?

22 A. No. You don't change things.

23 So what's important is you ask the
24 question, you give certain parameters to the
25 statisticians, you get back certain results. You

1 then don't re-run the data without making, I mean,
2 one, making that explicit. Two, being very careful.
3 You don't get -- you don't run data, get back
4 certain results and then change, you know, for
5 whatever reason. I don't want to go into motive.
6 You don't re-run the data unless it's part -- unless
7 there's very special reasons to do that.

8 Q. And you know here the special reasons to
9 re-run the data was that the outside
10 endocrinologists didn't think you should have
11 pubertal boys in the analysis?

12 A. No, ma'am. Because what we do know is that
13 the outside endocrinologists were involved from the
14 beginning. They met in Toronto in January. They
15 were part of the analysis plan, that very short
16 document. They set certain parameters. The
17 endocrinologists and/or Janssen shouldn't have just
18 re-run it once they got results that they didn't
19 like. You got to do it up front.

20 Q. You know, Dr. Kessler, based on your review of
21 the documents, that the outside endocrinologists
22 were concerned about all of the background rate of
23 gynecomastia in pubertal boys?

24 A. Fair, from the beginning.

25 Q. Yeah.

1 A. And they set certain parameters and they ran
2 the data, got certain results, then you just don't
3 re-run the data.

4 Q. But you know -- whether you think it's right
5 or not, you know it was the outside endocrinologists
6 not Janssen that said let's look at the data without
7 the pubertal boys?

8 MR. KLINE: Objection.

9 THE COURT: Sustained.

10 BY MS. SULLIVAN:

11 Q. Do you know, Dr. Kessler, that that's a fact;
12 that the outside endocrinologists were the ones who
13 suggested to Janssen --

14 MR. KLINE: Same question.

15 BY MS. SULLIVAN:

16 Q. -- look at the data without the pubertal
17 boys?

18 THE COURT: All right. That's
19 sustained, because I don't recall -- we have
20 a document. That's all we have.

21 MS. SULLIVAN: I'm asking, Your
22 Honor, if he knows.

23 THE COURT: Then you're really
24 opening the door, Ms. Sullivan, to him
25 interpreting for himself what was really

1 going on behind closed doors.

2 BY MS. SULLIVAN:

3 Q. Dr. Kessler, let's take a look at what's been
4 marked previously as Plaintiff Exhibit 46.

5 And this is --

6 A. Can I just get a copy or tell me kindly where
7 it is in the binder.

8 Q. Sure. It was used by Mr. Kline with you.
9 It's Plaintiff Exhibit 46.

10 A. I just don't have -- that's meaningless. I
11 have certain tabs in my binder. I apologize.

12 COURT CRIER: Did you say 46?

13 MS. SULLIVAN: 46, Marianne. Thank
14 you.

15 MR. KLINE: We'll find it.

16 BY MS. SULLIVAN:

17 Q. Dr. Kessler, did you not keep a set of the
18 stuff that you used with Mr. Kline?

19 A. I have it, but I don't have it by plaintiff's
20 exhibit number.

21 MR. KLINE: We have it. Look in Tab
22 21. It's draft four.

23 COURT CRIER: P-46.

24 THE COURT: P-46, we have it.

25 MR. KLINE: It's the nauseating...

1 MS. SULLIVAN: Yes. Let's talk about
2 that.

3 BY MS. SULLIVAN:

4 Q. Dr. Kessler, this is a draft manuscript being
5 circulated by Janssen, right?

6 A. I have the cover page, yes.

7 Q. And it has the line that Mr. Kline has
8 repeated many, many times during this trial about
9 the revisions now include a nauseating amount of
10 information on SHAP, specifically gynecomastia, et
11 cetera, right?

12 A. Yes.

13 Q. And it says "nauseating amount of
14 information," right?

15 A. It says exactly that.

16 Q. Yeah. And you know there is a ton of
17 information in this analysis about different ways
18 they looked at the data, by gender, by age, by
19 whether it has a relationship -- whether prolactin
20 has a relationship to how well the drug works,
21 whether prolactin levels had anything to do with
22 other side effects like these neurological side
23 effects. They looked at a whole bunch of different
24 things. There was a lot of information.

25 MR. KLINE: Your Honor, objection.

1 It's not a question. I have it in front of
2 me.

3 THE COURT: Sustained. Sustained.
4 Yes. Rephrase it.

5 MS. SULLIVAN: Sure.

6 BY MS. SULLIVAN:

7 Q. Dr. Kessler, you'll agree they looked at a lot
8 of information in terms of prolactin and its
9 relationship to a lot of different things in this
10 paper?

11 A. Yes. I mean --

12 Q. Okay.

13 A. -- the specific thing that you pointed me to
14 was the stuff on SHAP. But I agree that there were
15 a lot of different variables looked at. There were
16 different variables looked at.

17 Q. And this draft also includes the 8- to 12-week
18 statistically associated finding that you think is
19 so significant, right?

20 A. Not just me. It's -- it's in there. It was
21 made --

22 Q. Right.

23 A. It was -- even Janssen said it was notable or
24 significant.

25 Q. My question was, this contains that finding?

1 A. Exactly, and then it disappears.

2 Q. And you see here that the authors -- the
3 Janssen author of this e-mail says that "there's
4 nothing to find, people," no matter how you look at
5 the data, right?

6 A. Exclamation point.

7 Q. Right. Even with the 8- to 12-week; in other
8 words, Dr. Kessler, the authors -- and incidentally,
9 Dr. Kessler, this contains the author's comments,
10 right?

11 A. Again, let the sentence read as it does,
12 because it talks about some minor text. It says
13 exactly that.

14 Q. Yes. And the authors -- and Janssen concluded
15 that this 8- to 12-week thing that you think is a
16 red flag was not clinically meaningful --

17 MR. KLINE: Objection.

18 BY MS. SULLIVAN:

19 Q. -- right?

20 MR. KLINE: Objection. The e-mail --

21 THE COURT: All right. That's
22 sustained. I mean --

23 MR. KLINE: The e-mail doesn't have
24 an author on it.

25 THE COURT: All I know is the

1 objection is sustained.

2 This document has been read by and
3 commented upon for its language. I don't
4 know that there was any specific data
5 attached to this that you have attributed to
6 right now.

7 BY MS. SULLIVAN:

8 Q. Well, Dr. Kessler, it contains the information
9 that you think is so clinically relevant, right,
10 this 8- to 12-week stuff that's on Page 084?

11 A. This manuscript, right, has the data put back
12 in and then it disappears. And I do think, as I
13 think Janssen said in earlier draft, that this was
14 notable or significant.

15 Q. And, Doctor, well, you know that Janssen
16 wanted to -- you know Dr. Pandina from Janssen
17 wanted the 8- to 12-week data information in the
18 manuscript?

19 A. So, no. I have Dr. Pandina's presentation to
20 the advisory committee board, right. That's a few
21 weeks earlier than this. And he didn't present any
22 of that to the advisory committee board.

23 Q. Because, Dr. Kessler, you know that the
24 outside authors didn't want SHAP(B) at all, never
25 mind the 8- to 12-week data -- I mean SHAP(A) at

1 all, never mind the 8- to 12-week data --

2 MR. KLINE: Objection.

3 BY MS. SULLIVAN:

4 Q. -- because it was filled with pubertal boys
5 who had gynecomastia from puberty?

6 MR. KLINE: Objection; her version of
7 the world.

8 THE COURT: All right. That question
9 is sustained.

10 And remember, ladies and gentlemen,
11 the question is not evidence.

12 BY MS. SULLIVAN:

13 Q. The truth, Dr. Kessler, is --

14 MR. KLINE: Objection to these
15 questions with the truth.

16 THE COURT: I don't know what the
17 truth is, Counselor.

18 BY MS. SULLIVAN:

19 Q. The fact is, Dr. Kessler, that it was the
20 outside authors, including the pediatric
21 endocrinologists from CHOP, who didn't want to look
22 at SHAP (A) at all?

23 MR. KLINE: Objection.

24 BY MS. SULLIVAN:

25 Q. They didn't want that Table A in the paper; it

1 was Janssen that put it in the paper?

2 MR. KLINE: Objection. She tries to
3 do what she's told not to do.

4 THE COURT: Again, Counselor, this
5 now is getting into what exactly has been
6 discussed before. He wasn't in the meetings.

7 MS. SULLIVAN: Fair enough.

8 THE COURT: Okay.

9 BY MS. SULLIVAN:

10 Q. And that's the truth, Doctor, you don't know
11 because you weren't there?

12 MR. KLINE: Objection to "that's the
13 truth." Objection to asking the same thing
14 again.

15 BY MS. SULLIVAN:

16 Q. You weren't there, Dr. Kessler?

17 MR. KLINE: Like she owns the truth.

18 THE COURT: Were you there,
19 Dr. Kessler?

20 THE WITNESS: There, define "there."

21 THE COURT: Were you at the meetings,
22 at these meetings yourself?

23 THE WITNESS: No.

24 THE COURT: All right. Move on
25 please, Counsel.

1 MS. SULLIVAN: Yes, Your Honor.

2 BY MS. SULLIVAN:

3 Q. And, Doctor, I want to look at some of the
4 statistical analysis that you talked about, this
5 Table 21 and Table 20.

6 A. Sure.

7 Q. I think you told our jury that you are a
8 professor, but you're not a statistician, correct?

9 A. I think I am a professor of biostat. I
10 certainly have studied biostat, especially in the
11 pharma -- in the context of statistics and drugs. I
12 can hold my own. But in the end, the fact is that I
13 rely on statisticians and would do that routinely
14 when I worked at FDA.

15 Q. Can you answer my question, Dr. Kessler?
16 You're not a statistician?

17 A. I'm a professor of biostatistics. I don't --
18 I certainly rely on others who know a lot more
19 statistics than I do.

20 Q. And you're not a statistician?

21 THE COURT: Well, Counsel, again, I
22 mean, he has not -- ladies and gentlemen,
23 this gentleman has not been qualified as an
24 expert in statistics. He, however, has been
25 qualified as an expert in biostatistics,

1 right.

2 BY MS. SULLIVAN:

3 Q. And, Dr. Kessler, at least you've acknowledged
4 in the past that you're not a statistician, correct?

5 A. Others know certainly more -- have much more
6 knowledge about mathematical statistics than I do.

7 Q. And, Dr. Kessler, I want to look at and talk
8 to you a little bit about this Table 20 and 21 from
9 the five Findling studies.

10 And so Table 20 is all of the --
11 taking a look at this -- Table 20 looks at the data
12 over five different time periods in addition to
13 before dosing, right?

14 A. Exactly.

15 Q. And it includes all the kids?

16 A. Table 20 as I understood --

17 Q. I'm sorry. This is SHAP(B).

18 A. Thank you, ma'am.

19 Q. Yes. And this is the table where boys over 10
20 are excluded?

21 A. Yes. And there probably is a footnote that we
22 can point to.

23 Q. Yeah. And so this took out boys who were
24 going through puberty, this analysis?

25 A. This took out boys greater than 10.

1 Q. Yeah.

2 A. Greater than 10, and you assume that that was
3 the -- that correlated with puberty, whether it was
4 8- or 9-year-olds.

5 Q. Yeah, right.

6 And because you saw the outside
7 endocrinologists found that there was a background
8 rate of 50 percent for gynecomastia in boys in
9 puberty?

10 A. I don't --

11 MR. KLINE: Objection. Objection.

12 THE COURT: What's the basis?

13 MR. KLINE: Asked and answered at
14 least a dozen times.

15 It's the same question.

16 THE COURT: All right. I'll permit
17 it one more time. Overruled.

18 BY MS. SULLIVAN:

19 Q. You saw in the paper that they noted a
20 background rate of 50 percent?

21 A. They noted it.

22 Q. Yeah.

23 A. That doesn't mean --

24 MR. KLINE: Objection. Objection, if
25 I may. Objection. Her last question was

1 20 percent and one question was 90 percent.

2 MS. SULLIVAN: No, no. It's always
3 50. You didn't listen --

4 MR. KLINE: So even -- no. I'm
5 listening and I'm watching. So that has to
6 be consistent, Your Honor.

7 THE COURT: What is the question,
8 Counsel?

9 MS. SULLIVAN: I thought I always
10 said 50, Judge.

11 BY MS. SULLIVAN:

12 Q. The paper says 50 percent, right, Dr. Kessler,
13 that the outside experts put the frequency of
14 puberty in boys -- the frequency of gynecomastia in
15 boys at 50 percent, right?

16 A. Yes. It's important -- let me just look at it
17 as you have this up. It's not talking specifically
18 about this study --

19 Q. Right.

20 A. -- in 50 percent.

21 Q. It's talking about a background rate in the
22 population of boys going through puberty.

23 MR. KLINE: May he answer?

24 THE COURT: Counsel, are you going to
25 have any experts of your own in this case?

1 MS. SULLIVAN: Sure are.

2 THE COURT: All right. Why don't you
3 move on, then.

4 MR. KLINE: Asked and answered.

5 MS. SULLIVAN: Well, Your Honor, this
6 is relevant to this whole --

7 THE COURT: Well, it has been asked
8 and answered repeatedly.

9 MS. SULLIVAN: Okay.

10 BY MS. SULLIVAN:

11 Q. And, Dr. Kessler, so one way to take out this
12 background rate to figure out if the drug is
13 associated with gynecomastia -- with
14 prolactin-related events like gynecomastia is to
15 take out the boys who might have gynecomastia
16 because of puberty?

17 A. It could have been done that way. But that's
18 not the way it was -- the rules were set up front.

19 Q. And Table 20 does that. It takes out the boys
20 who might have gynecomastia from puberty?

21 A. Yes, after the fact.

22 Q. Yes.

23 And you would expect, Dr. Kessler, if
24 the medicine had some association with gynecomastia,
25 you'd expect to see it in SHAP(B) as well, right?

1 A. I'm not giving an opinion specifically on
2 that. You can ask the endocrinologist that.

3 Q. So -- okay.

4 So if Risperdal was associated with
5 gynecomastia or caused gynecomastia, you would
6 expect to see it in this population as well, the
7 boys under 10, right?

8 A. And you do. You do see cases of gynecomastia,
9 right. Add up the number of cases. We do see that.

10 Q. But you actually see more in the normal
11 population?

12 A. The issue is, right, you do see gynecomastia,
13 right, in these cases.

14 Q. Right.

15 A. This is an analysis. It is what it is. It's
16 an analysis. It was done after the fact.

17 Q. But what --

18 A. I --

19 THE COURT: Wait. You know, Counsel,
20 I am going to ask -- if you're asking these
21 questions repeatedly, please allow him to
22 answer his questions repeatedly.

23 MS. SULLIVAN: Sure. I didn't mean
24 to interrupt.

25 THE COURT: Otherwise, you know, we

1 will start cutting off questions.

2 MS. SULLIVAN: I didn't mean to

3 interrupt, Your Honor.

4 BY MS. SULLIVAN:

5 Q. So, Dr. Kessler, Table 20 looks at boys under
6 10 and finds no difference in any of the weeks in
7 terms of a greater statistical relationship between
8 the medicine and gynecomastia as compared with the
9 boys who had normal prolactin levels, right?

10 A. That's correct, if one takes a statistical .05
11 rate. But as you see, that in weeks 8 to 12, you
12 still have three times more. It's not significant
13 at the .05 level.

14 Q. And statistical significance is used by
15 scientists to try to eliminate the play of chance?

16 A. Sure.

17 Q. And so when you look at weeks 4 to 7, no
18 statistical relationship, right?

19 A. Not after the fact.

20 MR. KLINE: It's not being --

21 THE WITNESS: Not after the fact.

22 MR. KLINE: Your Honor, the whole
23 thing's not being displayed, and you'll see
24 that it's 90 percent.

25 THE COURT: No, I don't see anything.

1 But I would ask that the entire document be
2 displayed.

3 MS. SULLIVAN: Of course.

4 THE COURT: And I'm very happy with
5 going through this cross-examination on these
6 points. This is the crux of it.

7 BY MS. SULLIVAN:

8 Q. And, Dr. Kessler, there is also no
9 relationship in weeks 8 to 12 when you take out the
10 pubertal boys, right, statistically?

11 A. You have three times the incidence. You have
12 a 90 percent of P at point -- 90 percent
13 probability, not 95.

14 Q. Not statistically significant?

15 A. It depends on -- it depends on how you define
16 statistically significant. It's three times.

17 Q. A p-value that --

18 MR. KLINE: Let him finish, please.

19 THE COURT: That -- really, we're now
20 going through this finally, the crux of it,
21 as far as this particular issue is concerned.
22 Allow him to answer the question.

23 MS. SULLIVAN: Sure.

24 THE COURT: It's only fair for both
25 sides to have this all aired out.

1 MS. SULLIVAN: Yes, Your Honor. I
2 was just trying to move it along, but --

3 THE COURT: No, no, no. Let him
4 answer this question. You want to ask him,
5 he'll answer. You ask him, he'll answer.

6 THE WITNESS: So this is an analysis,
7 Table 20, that is done after you have a
8 statistical association, right. You found a
9 statistical association on May 15, right, and
10 then you -- and then Janssen ran this after
11 it had that result, which is not proper.

12 BY MS. SULLIVAN:

13 Q. In your view?

14 A. No. Ma'am, no one changes the rules of the
15 game once you have the data and not report the
16 initial results.

17 Q. And, Dr. Kessler, in fact, there is no
18 statistical significance for any time period in this
19 table, right?

20 A. It -- the issue is what level of statistical
21 significance, but it makes no difference. Once you
22 have a statistically significant result on the
23 May 15, right, running it again, you can -- you can
24 change the rules and find results that are not
25 statistically significant. It doesn't negate the

1 statistically significant finding in May. That's
2 what counts. You can't change the rules.

3 Q. Can you answer my question, sir?

4 MR. KLINE: Your Honor, he answered
5 it.

6 THE COURT: All right. That's
7 sustained. He's answering your questions the
8 best he can. If you don't like the answer,
9 then ask him a different question or move on
10 to some other subject.

11 MS. SULLIVAN: Your Honor, my
12 question was very simple.

13 THE COURT: Well, then ask him a
14 question in a direct, leading way that gives
15 him no chance to --

16 MS. SULLIVAN: John, John, can you
17 repeat my question. Thank you.

18 COURT REPORTER: May I, Your Honor?

19 THE COURT: Yes.

20 And, Doctor, you are basically
21 instructed to answer the question.

22 THE WITNESS: Thank you.

23 - - -

24 (Whereupon the court reporter read
25 back the previous question as follows:

1 "Question: And, Dr. Kessler, in
2 fact, there is no statistical significance
3 for any time period in this table, right?")

4 - - -

5 THE WITNESS: At the .95 level,
6 that's correct.

7 BY MS. SULLIVAN:

8 Q. And the convention and the statistics is
9 typically .05 in terms of statistical significance?

10 A. That's true, but not necessarily all the time.

11 Q. So according to the convention, none of these
12 time periods at all were statistically significant,
13 true?

14 A. I think I just answered -- I answered that.

15 Q. Okay. And this is the table where you exclude
16 the boys going through puberty, right?

17 MR. KLINE: Objection. That is asked
18 and answered over and over again.

19 THE COURT: I, frankly, did not hear
20 it. So, John, repeat the question.

21 MS. SULLIVAN: And, Your Honor,
22 Mr. Kline had Dr. Kessler on the stand for
23 three days.

24 THE COURT: Well, you've had -- you
25 know, I'm not counting the hours at the

1 moment. So let me hear the question.

2 - - -

3 (Whereupon the court reporter read
4 back the previous question as follows:

5 "Question: And this is the table
6 where you exclude the boys going through
7 puberty, right?")

8 - - -

9 MR. KLINE: That was also --

10 THE COURT: And "this is" the --
11 again, I'm directing you not to answer that
12 question unless we have a more specific
13 explanation of what "this" is.

14 BY MS. SULLIVAN:

15 Q. Table 20, Dr. Kessler, we can agree excluded
16 the boys over 10, the boys in puberty?

17 A. As well as some other exclusions.

18 Q. Yeah. But it excluded the boys in puberty?

19 A. Among other exclusions, yes.

20 Q. And so when they excluded the boys in puberty,
21 there was no statistical significance for any time
22 period, right?

23 A. I think I answered that. But I'm happy to
24 answer that question. At the .95 level, that's
25 correct.

1 Q. And, Dr. Kessler, even in -- and incidentally,
2 Dr. Kessler, there was actually, in many of the time
3 periods, there were more people in the normal groups
4 percentage-wise that had events hypothetically
5 related -- that had side effects that hypothetically
6 could be prolactin related that had normal prolactin
7 levels, right?

8 A. Yes. The 8 to 12 had more in the upper limit
9 of normal.

10 Q. But there are several time periods where
11 actually the people that had the elevated prolactin
12 had fewer side effects than the people that had
13 normal prolactin levels?

14 A. Yes, that's exactly correct.

15 Q. Which is the opposite of what you'd expect?

16 MR. KLINE: Objection.

17 THE WITNESS: No.

18 THE COURT: Objection?

19 MR. KLINE: Yes.

20 THE COURT: Sustained.

21 BY MS. SULLIVAN:

22 Q. And then, Dr. Kessler, looking at Table 21,
23 this is where you include the pubertal boys, right,
24 the boys going through puberty?

25 A. Let's be specific. These are the boys greater

1 than 10.

2 Q. Yes. Which would include boys going through
3 puberty.

4 A. Yes.

5 Q. And even when you do that, you have no
6 statistical significance for all of the time periods
7 except for 8 to 12, right?

8 A. That's exactly correct.

9 Q. And it's also true, sir, that if you look at
10 all of the data for Table 21, if you pull all of the
11 time periods, there's no statistical significance
12 overall?

13 A. Just show me that on this table and the next
14 table.

15 Q. I'm asking you, do you know?

16 A. I have not run that myself --

17 Q. You have --

18 A. One second. I went through this data set,
19 right, and I don't see it.

20 Q. But you know that's true?

21 A. Show me it, please.

22 Q. Do you not know?

23 A. I looked for it several times in this data
24 set. It doesn't exist.

25 Q. But my question is do you know, sir, that when

1 you look at all the time periods, there's no
2 difference?

3 A. If you have that data, I'd like to see it.

4 Q. I'm asking if you know, sir.

5 A. I have not seen that data. And I have looked
6 for it in these data sets. It doesn't exist.

7 Q. And, Dr. Kessler, and if you actually add up
8 the events, 60 versus 63, there's no way there's any
9 difference statistically, right?

10 A. I'm not doing post hoc, post hoc analysis --

11 Q. Yes.

12 A. -- as you're doing here. These are
13 statistical analyses that Janssen got at a point in
14 time.

15 Q. So, Dr. Kessler, you're not going to
16 acknowledge to the jury that when you look at the
17 data overall, all of the time periods, there's no
18 difference?

19 A. I am perfectly willing to acknowledge to the
20 jury, and this is what's important, is the
21 statistically significant finding in 8 to 12 weeks,
22 and that time period is of critical importance.

23 Q. And, Dr. Kessler, the only way you get there
24 is if you ignore 9 of 10 data points and just pick
25 out that one period?

1 A. Ma'am, I didn't ignore anything. Look at the
2 Janssen manuscripts. They point out this is a
3 significant and notable finding.

4 Q. And if you -- and so you have to ignore weeks
5 4 to 7, 6 to 24, 28 to 36, 40 to 48, and all of the
6 other time periods including 8 to 12 in the boys
7 without puberty, right?

8 A. None of that justifies throwing out the
9 statistically significant results and hiding it.

10 Q. Well, Dr. Kessler, you and Mr. Kline keep
11 talking about hiding data. But the fact is, you saw
12 the e-mail that it was Janssen that wanted the
13 gynecomastia rates in the Findling article?

14 MR. KLINE: Objection.

15 THE COURT: All right. That's
16 sustained. The jury is going to have to
17 determine that themselves, not from an expert
18 witness on, you know -- this witness has
19 offered a particular opinion, and we've had
20 about four days of testimony back and forth
21 on the substance of that opinion. And that's
22 for the jury to decide whether or not to
23 accept his opinion.

24 BY MS. SULLIVAN:

25 Q. Dr. Kessler, I'm going to put up Plaintiff's

1 Exhibit 37 which is a call-out from one of the
2 manuscripts here. And I want to just ask you about
3 a statement in there.

4 A. Can you just tell me which version of the
5 manuscript? What the date is.

6 Q. It's the July 16, 2002 version, Plaintiff's
7 Exhibit 37, and it looks like it's on Page 741.

8 A. Let me get it, please. Thank you.

9 MR. KLINE: Is this from draft one?
10 July 16.

11 THE WITNESS: So I have it -- correct
12 me if I'm wrong, this is from Bates No. 740
13 and 741; is that correct?

14 MS. SULLIVAN: Yes, sir.

15 THE WITNESS: Thank you.

16 MS. SULLIVAN: You got it.

17 THE WITNESS: I have it exactly in
18 front of me.

19 BY MS. SULLIVAN:

20 Q. And it talks about the fact that 7.8 percent
21 of patients who had prolactin above the upper limit
22 of normal had SHAP at some point during the trial,
23 right?

24 A. Exactly.

25 Q. And what that means is that some of the side

1 effects could have -- for example, some of the boys
2 could have gotten gynecomastia before they had the
3 elevated prolactin. That's how the data was
4 collected?

5 A. That's exactly how Janssen designed the study,
6 yes.

7 Q. Yeah. So some of the gynecomastia events
8 could have occurred before prolactin was even
9 elevated?

10 A. It -- it measured them independently of each
11 other.

12 Q. Right.

13 A. Exactly, ma'am.

14 Q. So many of the events counted in the Findling
15 article and in Table 21 could have occurred before
16 prolactin was even elevated?

17 A. That's a -- that's a correct statement. I
18 don't know -- you added the word "many." I don't
19 have that data.

20 Q. Okay. Dr. Kessler, I want to go back to
21 INT-41, the actual study report. And it's
22 Plaintiff's Exhibit 20, briefly.

23 A. And if I can just get a copy.

24 (Pause.)

25 Yes, I have it.

1 Q. And, Dr. Kessler, and this is the study
2 report, the final one for INT-41, right?

3 A. Yes. That's what it looks like.

4 Q. And this is the kind of thing that companies
5 and Janssen did here submit to the FDA after a study
6 is done, right?

7 A. Yes.

8 Q. And I think you and Mr. Kline --

9 A. Hold on. Sometimes. Sometimes it's part of
10 an application. It had -- each of these have
11 their -- they get submitted at different times. So
12 I just don't want to represent exactly when it was
13 submitted.

14 Q. And, Dr. Kessler, you and Mr. Kline kept
15 calling this the quote-unquote special attention to
16 prolactin study, right?

17 MR. KLINE: Your Honor, objection. I
18 asked him questions. He answered the
19 questions. It's not me, him and Mr. Kline.
20 It's so silly what she tries to do, and I
21 object.

22 THE COURT: Okay. Mr. Kline, my
23 preference is, of course, if you have an
24 objection and then a short statement of what
25 the objection is.

1 MR. KLINE: That was my --

2 THE COURT: You're saying that this
3 is irrelevant?

4 MR. KLINE: Yes.

5 THE COURT: All right. It's not --
6 that's overruled.

7 But, again, I don't mean to be fussy
8 about this, but what is this document number?

9 MS. SULLIVAN: This is Plaintiff's
10 Exhibit 20, Your Honor.

11 THE COURT: All right. We've seen
12 this before, correct?

13 MS. SULLIVAN: Yes, Your Honor.

14 MR. KLINE: Yes.

15 THE WITNESS: May I answer that
16 question?

17 THE COURT: Yes, Dr. Kessler, please
18 answer her questions regarding this document.

19 THE WITNESS: So you don't have to
20 take my word for the use of the word "special
21 attention." Turn to 159, assuming this is
22 Bates, the same as my copy.

23 BY MS. SULLIVAN:

24 Q. Yeah. And let's look at that, Doctor.

25 In fact, Dr. Kessler, the company was

1 paying special attention to a few different side
2 effects, not just prolactin?

3 A. You asked me that question, I believe,
4 yesterday.

5 Q. And let's take a look at that.

6 THE COURT: No; that was Friday.

7 THE WITNESS: Oh, I'm sorry.

8 BY MS. SULLIVAN:

9 Q. And I asked you -- but we didn't have the
10 document to show our jurors. We now do. And they
11 were paying special attention to these neuromuscular
12 side effects, right, extra EPS?

13 A. The extrapyramidal, the neuromuscular, with --

14 Q. You see that on Page 58 there? They were
15 paying special attention to that, too, right?

16 A. 58. I'm sorry. I was on 59.

17 So, yes, it says special attention
18 was given, yes, and it says exactly what it does.

19 Q. And they were also paying special attention to
20 glucose, right?

21 A. Yes.

22 Q. And they also were paying special attention to
23 prolactin?

24 A. Yes. That's what it says.

25 Q. And so they were looking for and paying

1 attention to different side effects?

2 A. Yes.

3 Q. This wasn't a prolactin-only study, by any
4 means?

5 A. No.

6 Q. And going back, Dr. Kessler, to Page 193 of
7 this document where they talk about adverse events.
8 And this is INT-41, right? Your red flag.

9 They say this is no serious adverse
10 events that were related to the increase in
11 prolactin levels, right?

12 A. Just show me where --

13 MR. KLINE: Where are you?

14 MS. SULLIVAN: 193.

15 MR. KLINE: 193.

16 THE WITNESS: Give me one second,
17 please.

18 MS. SULLIVAN: I'm sorry, Jurors,
19 making you dizzy here.

20 (Displaying document.)

21 So --

22 THE WITNESS: So can you show me
23 that, please?

24 BY MS. SULLIVAN:

25 Q. On Page 193 it says that there are no serious

1 adverse events that were related to the increase in
2 prolactin levels. Do you see that?

3 A. Yes.

4 So that's inconsistent with the table
5 that I have which is the actual listing for
6 RIS-INT-41, which is a table that says a narrative
7 or tabulis summary showing the most frequent and
8 most serious adverse experiences by body systems and
9 that has gynecomastia -- and labels gynecomastia.

10 So just to be -- yes. There
11 certainly are serious adverse events in INT-41.

12 Q. And we're going to look at the table. But in
13 terms of serious adverse events, that's what the CSR
14 says, related to prolactin?

15 A. (No response.)

16 Q. In other words, they looked at the people who
17 had adverse events to see if the serious ones had a
18 relationship to elevated prolactin and they found
19 none, right?

20 MR. KLINE: Your Honor, same
21 objection. The words say what they say, not
22 what she says they say.

23 THE COURT: Yeah. Sustained as to
24 "they." I think we need to be specific
25 again. Who wrote this document?

1 MS. SULLIVAN: This is a Janssen
2 Clinical Study Report --

3 MR. KLINE: Janssen.

4 MS. SULLIVAN: -- to the FDA.

5 THE COURT: Ah, okay. Overruled.

6 As long as we understand it's a
7 Janssen -- Janssen's "they," right?

8 MS. SULLIVAN: Sure.

9 THE WITNESS: So I see Janssen also
10 saying there's serious adverse events of
11 gynecomastia, right, and --

12 BY MS. SULLIVAN:

13 Q. But, Doctor, I think we're missing each other.
14 So there were events of gynecomastia, but what this
15 says, the serious events were not related to the
16 elevated prolactin levels. When you looked at the
17 people who had elevated prolactin, they didn't have
18 the serious events, right?

19 A. No. This says -- there's no question, I
20 believe. You're not saying that -- I'm not
21 interpreting you to say gynecomastia is not related
22 to increased prolactin levels. From the beginning
23 gynecomastia was defined by Janssen as
24 prolactin-related adverse event. So it has -- I
25 mean, it is a related event.

1 Q. Potentially.

2 MR. KLINE: Objection, Your Honor.

3 THE WITNESS: No. It's --

4 THE COURT: Well, no. I take that,
5 Ms. Sullivan, that's a question. Is that
6 potentially true or that is true?

7 BY MS. SULLIVAN:

8 Q. Dr. Kessler, can you just answer my question?
9 The fact is, in INT-41, they found that the people
10 who had the serious adverse events did not have
11 elevated prolactin, right?

12 A. They are making that statement.

13 Q. Yeah.

14 A. Okay. They are also saying that there's
15 serious adverse events of gynecomastia, and they are
16 defining -- Janssen's defining PRAE and gynecomastia
17 as definitely causally related to prolactin levels.

18 Q. But, Dr. Kessler, we've already established
19 that boys can have gynecomastia from puberty, right?

20 A. There certainly can be increased breasts from
21 puberty, yes.

22 Q. And so Janssen was looking at whether
23 gynecomastia and any other serious adverse events
24 were related to prolactin elevations and they didn't
25 find any that were related to the prolactin

1 elevations, right?

2 When they measured prolactin, the
3 serious adverse events didn't correlate?

4 A. Well, I don't think that's -- that data is not
5 shown there. Show me that data there, ma'am.

6 Because the table on gynecomastia does not say which
7 ones correlate and which ones don't correlate.

8 Q. And, Doctor, it goes on to say in most
9 patients hyperprolactinemia was a lab finding that
10 had no clinical symptoms, right?

11 A. There is hyperprolactinemia, but the fact is
12 that when you -- there is no data that I've seen,
13 right, that those cases of gynecomastia were not --
14 if you look at that table, right --

15 Q. And let's look at the table that you want to
16 look at.

17 A. -- the table does not state that they were not
18 related to hyperprolactinemia.

19 Q. Well, let's look at the --

20 A. There's no analysis.

21 Q. Let's look at the -- did you not look at the
22 appendices to this CSR, Doctor?

23 A. I looked at a lot of the study, yes, ma'am.

24 Q. Do you know, sir, that the elevated prolactin
25 levels were not correlated with the serious adverse

1 events?

2 A. I looked for the evidence of correlation,
3 right, and I don't see -- certainly in this
4 discussion, I don't see the correlation.

5 Q. And, Doctor, here is the chart you're talking
6 about where the outside investigators grade the
7 severity of the adverse event, right?

8 A. Be careful with that, okay.

9 That's probably true. But this study
10 report is authored not just by the outside
11 investigators, it's also authored by the Janssen
12 employees who obviously scrutinize.

13 Now, I assume, right, that those are
14 directly off of investigator reports. We can go
15 check, but this is --

16 Q. Of course they are. You don't have any
17 evidence that there's anything to the contrary?

18 A. Well, the --

19 Q. In other words, the outside investigators
20 write "mild, moderate, severe" and Janssen reports
21 that to the FDA?

22 A. Janssen employees wrote this report. As you
23 know, that there are times when companies scrutinize
24 what the investigators do. So you have to be
25 careful.

1 What we know is -- and I'm certainly
2 willing to speculate -- that that's by the
3 investigators; and what Janssen did was they
4 reported what the investigators said. And I'm
5 comfortable with that.

6 Q. And what the investigators said is that the
7 side effects were moderate, mild, moderate, mild,
8 moderate, mild. In fact, none severe in these
9 tables, right? No serious adverse events here?

10 A. No; because you're confusing two things.
11 You're confusing the degree of severity, right, with
12 the way -- if you look here, I have 22 of the most
13 serious adverse events. So they're considering all
14 the adverse events as serious. There's different
15 degrees of severity here. But Janssen on certainly
16 the way it is submitted to the FDA and did the
17 tabulation considered these the most serious adverse
18 experiences.

19 Q. And for none of them, in terms of
20 gynecomastia, did the outside investigators rate
21 them as severe, right, for none of them?

22 A. Again, I'm not sure we -- just let us look at
23 the footnotes and see if we have the scale.

24 Q. I'm just asking you to look --

25 A. No, no. I just -- you asked me a question.

1 We would be able to tell that by looking at the
2 footnotes to see what the -- what the options were.

3 MR. KLINE: Is that down there?

4 THE COURT: Is there a footnote here?

5 MS. SULLIVAN: I don't know what he's
6 talking about, Your Honor. He's just making
7 stuff up.

8 THE WITNESS: No.

9 THE COURT: No.

10 MR. KLINE: Oh, my word, Your Honor.
11 Did you hear that? The suggestion -- did you
12 hear that, Your Honor, what she mumbled under
13 her breath?

14 THE COURT: If you don't know --
15 excuse me. Sustained.

16 Have a seat, please.

17 If you don't know, that means the
18 jury doesn't know. So let's look at the
19 footnote.

20 MS. SULLIVAN: I don't know what he's
21 talking about, Your Honor.

22 THE COURT: What exhibit are you
23 talking about, Doctor?

24 THE WITNESS: So go to the first
25 page.

1 MR. KLINE: Your Honor, may we -- if
2 it's a good time for a break, may we see you
3 at sidebar?

4 THE COURT: It's not a good time for
5 a break. I want to see this footnote.

6 MS. SULLIVAN: I don't know what he's
7 talking about.

8 MR. KLINE: I would request that
9 counsel doesn't mumble under her breath about
10 making things up.

11 THE COURT: No; that's a different
12 matter.

13 MR. KLINE: Because making things up
14 is her forte.

15 THE COURT: I'm asking you, however,
16 to please be seated. And I do want to see
17 the footnote; because if counsel doesn't
18 know, that means the jury doesn't know, which
19 means the Judge doesn't know. And this
20 witness is saying he can explain through a
21 footnote. I'm happy to look at a footnote.

22 MS. SULLIVAN: Me, too, Judge.

23 THE WITNESS: So if you look, okay,
24 there are, right, there are footnotes that go
25 to the C and B and O.

1 BY MS. SULLIVAN:

2 Q. What page are you on, Dr. Kessler?

3 A. On 82.

4 MR. KLINE: 82.

5 THE WITNESS: And that describes --
6 that will give you --

7 THE COURT: Is that Page 82?

8 THE WITNESS: No. The table is 82.

9 THE COURT: I think we were on Page
10 82 originally.

11 THE WITNESS: No.

12 MS. SULLIVAN: I don't know what --

13 THE COURT: Marianne, let me see the
14 report. What number is this?

15 THE WITNESS: I'm sorry.

16 THE COURT: Plaintiff's 20. He has
17 it.

18 BY MS. SULLIVAN:

19 Q. Doctor, did you find your footnote?

20 A. Yes. There is a footnote on 82.

21 Q. 82 by Bates number or --

22 A. No. That's Page 82. And there's a footnote.
23 You see that footnote.

24 Q. Yes.

25 A. C, Caucasian, B...

1 Q. Yes, sir.

2 A. So on severity, you asked me how they graded
3 it. And I'm looking to see if there was an
4 explanation in the footnote.

5 Q. Okay. And I'm showing the footnote here.

6 (Displaying document.)

7 And it says there's an asterisk if
8 there's a serious adverse event, right?

9 A. Yes.

10 Q. And nobody on this table has an asterisk in
11 terms of gynecomastia, right?

12 A. Well, it clearly means something because it's
13 there.

14 Q. In any event, Doctor, the severity rating from
15 the investigators runs from mild to moderate,
16 correct?

17 A. Exactly.

18 Q. And it looks like many of the kids recovered,
19 reversed, during the course of the study, right,
20 from the --

21 A. So let's be -- let's go through this, okay?

22 Q. Uh-huh.

23 A. So I think we know from the report that there
24 were about 15 or 16 that didn't recover; is that --

25 Q. Yeah. We'll talk about the ones --

1 A. So --

2 Q. Can we stick first -- we'll talk about those
3 as well. But can we stick first to many of the kids
4 recovered from whatever prolactin-related events
5 including gynecomastia?

6 A. So just zero in, if you could, on the chart
7 and just go to the beginning on Table 7.8, the first
8 page.

9 Q. Uh-huh.

10 A. We can do this. Just so, again, the jury can
11 see exactly. And just zero in on the first patient,
12 for example.

13 Q. Uh-huh.

14 A. Right. So if you go to the top, it says not
15 recovered.

16 Q. Right. And that does --

17 A. So what we could do -- so the table speaks for
18 itself. And, exactly, we don't have to guess, you
19 can count up which ones were recovered and which
20 ones were not recovered.

21 Q. Right. And the study was just a year long, so
22 we don't know which of the patients recovered after
23 the study, right?

24 A. The data are the data.

25 Q. Yeah. And it's certainly possible that

1 several or many or all or none recovered after the
2 study?

3 A. Speculation.

4 Q. Right. And you don't know the answer?

5 A. Don't know the answer.

6 Q. And also it looks like many of these events
7 happened -- I think I heard you say that Janssen was
8 wrong to include the short-term studies in the
9 incident rate for gynecomastia in the 2006 label?

10 A. No, I didn't say -- I don't think I said
11 "wrong," okay. I think you would not necessarily
12 expect your endocrinologists -- Janssen's
13 endocrinologists have testified -- I mean, have
14 stated that they would not expect them in the
15 short-term studies. There are some in the
16 short-term studies. It's not as good as the year
17 studies. It's not as comprehensive. I don't think
18 I would use the word "wrong."

19 Q. I thought you said yesterday that you don't
20 see gynecomastia in six weeks from the medicine, so
21 it was a mistake to include those studies in the
22 2006 label.

23 A. Do me a favor, just give me -- just read back
24 my testimony so we can be very exact.

25 Q. Maybe after a break we'll pull it out. We'll

1 go back to this point, Doctor.

2 But certainly some of the events
3 happened in the short term, in 22 days, in three
4 days, in 18 days after taking the medicine, right?

5 A. Yes, and very much so.

6 Q. And just so we're clear, just because someone
7 develops a side effect on the medicine like
8 gynecomastia doesn't mean it's necessarily from the
9 medicine?

10 A. Exactly.

11 Q. And we don't know, looking at this chart, how
12 many of these gynecomastia, for example, were
13 pubertal?

14 A. Nor do we have prolactin levels, that's
15 correct.

16 Q. And when I say "pubertal," we don't know how
17 many of these events of gynecomastia on this table
18 were caused by puberty; we don't know that?

19 A. Janssen -- Janssen didn't design the study to
20 do that.

21 Q. There were other studies done by Janssen that
22 were placebo controlled where you could tell that?

23 A. Ummm, we'd have to go back and review exactly
24 what you can tell.

25 Q. And you're aware, Dr. Kessler, that there is

1 no placebo-controlled study that shows a higher
2 incident rate in boys getting gynecomastia as
3 associated with Risperdal as compared to boys taking
4 nothing; there's no study that shows that?

5 A. I would -- the two autism studies did not show
6 that.

7 Q. Right. So when -- and in the large
8 placebo-controlled studies that controlled for
9 puberty, you did not see an increased rate of
10 gynecomastia on Risperdal; fair?

11 A. There weren't that -- I mean, I have -- I
12 don't think that would be correct. I have the
13 medical reviewer's analysis of those studies, and
14 she says that prolactin data were not available from
15 the placebo-controlled autism studies, right. So
16 I'm not sure which studies you're referring to.

17 Q. You're not aware, Dr. Kessler, of any of the
18 placebo-controlled studies done by Janssen or anyone
19 else showing an increased rate of gynecomastia on
20 Risperdal?

21 A. That's correct.

22 Q. And I also wanted to go back to INT-70, which
23 was one of the studies you and Mr. Kline talked
24 about, right?

25 A. Yes.

1 Q. And INT-70 was an extension study to INT-41,
2 the one that you spoke a lot about?

3 A. Well said.

4 Q. And I think you corrected -- I think Mr. Kline
5 put on the easel that there was a 12 percent
6 incidence of gynecomastia in INT-70, but you
7 corrected him and said it's actually 6 because there
8 was some double counting going on?

9 A. Well, don't blame -- I'm not --

10 Q. I'm not blaming. I'm just saying it was
11 wrong.

12 A. I was -- one table did say 12.5. One table
13 said 6, and I was trying to sort that out. Those
14 were Janssen's -- those were Janssen's numbers.

15 Q. And the 12-point -- the only way you get to
16 12.5 is if you double count. If you count the
17 INT-41 events and the INT-70 events, right?

18 A. Could we just put up that table or give me
19 that table so I have it?

20 Q. Sure.

21 This is -- I have the full study, so
22 I'm going to mark it, Judge, as Defense Exhibit --
23 Ms. Brown, what's our next number?

24 MS. BROWN: It's like 25.

25 MS. SULLIVAN: 25. If you could give

1 Dr. Kessler and Mr. Kline and the Court a
2 copy, Lamia. Thank you. It's 546.

3 THE COURT: What document is this?

4 COURT CRIER: D-25.

5 - - -

6 (Exhibit D-25 marked for
7 identification purposes.)

8 - - -

9 MR. KLINE: Is this just RIS-70 as
10 previously marked? I used the topline.

11 MS. SULLIVAN: No. This is a more
12 complete copy, Counsel. Remember you had
13 some pages that weren't there.

14 MR. KLINE: Oh, yeah, I do remember.
15 Okay.

16 COURT CRIER: May I show it to the
17 witness?

18 (Showing the witness.)

19 THE COURT: All right. The witness
20 is now looking at D-25.

21 BY MS. SULLIVAN:

22 Q. And, Dr. Kessler, can you -- I'm not sure what
23 table you want to look at, but I think it's 831.

24 A. So I'm looking at 859, assuming we're looking
25 at the same pagination, the same document.

1 THE COURT: Why don't you use, for
2 our sake right now, Doctor, the actual page
3 number in the real document, because we're
4 all at different numbers now.

5 THE WITNESS: Sure.

6 I have something called Table 4,
7 incidence of all adverse events. And, Your
8 Honor, I don't have a page number. I have a
9 Bates number on the copy I'm looking at. I
10 can try to find -- if you try to find Table
11 4.

12 BY MS. SULLIVAN:

13 Q. Maybe we can shorten this, Dr. Kessler. The
14 fact is that the total events in INT-70 is
15 6 percent, not 12 and a half percent?

16 THE COURT: Well, wait one second.
17 One second. I'm not satisfied with that,
18 okay. In other words, we're not shortening
19 anything. Nobody's been worried about that
20 up to now. So where is this document?

21 MR. KLINE: I'm just lost. Point me
22 wherever.

23 THE COURT: I need it by the JJRE
24 number.

25 MS. SULLIVAN: I'm not sure what he's

1 looking at, Your Honor.

2 THE COURT: I'm looking at --

3 MS. SULLIVAN: I have Defense Exhibit
4 25, but I'm not sure what page he's
5 interested in, Judge.

6 THE WITNESS: May I give you,
7 Ms. Sullivan?

8 MS. SULLIVAN: If you want to tell me
9 what the page is.

10 THE WITNESS: Yeah. So let me just
11 tell you what I have.

12 THE COURT: Here, why don't you show
13 it to -- Dr. Kessler, let me see it, please.
14 Give it to Marianne and I'll find it.

15 THE WITNESS: Okay. That was the
16 table that I was referring to.

17 THE COURT: Where is it?

18 COURT CRIER: That one.

19 THE COURT: This page here?

20 COURT CRIER: Yes.

21 THE COURT: Table 4?

22 For the record, that's on 00061859.

23 MS. SULLIVAN: I think that's a
24 different exhibit, Judge. I'm not sure what
25 he's got here.

1 THE COURT: It might be.

2 BY MS. SULLIVAN:

3 Q. Is that -- that's not on the INT. You're
4 looking at a different exhibit, Dr. Kessler.

5 A. So I'm looking at something called topline
6 results, RIS-INT-70.

7 Q. Yes. I was looking at the final study report,
8 Dr. Kessler, but --

9 A. So I'm looking at the topline results. And
10 the topline results in Table 4 -- happy to give it
11 to you so you can project it, not my numbers -- have
12 gynecomastia, and for -- it has three columns,
13 INT-41, INT-41-INT-70, and INT-70, and it says
14 12.5 percent. Again, Janssen's numbers. And then
15 there's another table that's Table 7 that has
16 6 percent.

17 Q. You're right.

18 But, Dr. Kessler, you know you only
19 get to 12 and a half percent if you double count
20 people that got gynecomastia in the first study,
21 INT-41, and continued into INT-70?

22 MR. KLINE: Objection. It's not
23 double counting, and she knows it. It's an
24 extension of one year after another.

25 THE COURT: You know, I'm going to

1 allow him to answer, but then what's going to
2 happen is we're going to have a redirect of
3 about 10 minutes duration, 15 minutes
4 duration, and 15 minutes duration on the
5 other side, and we're going to call it a day
6 and a witness. That's how we're going to
7 proceed in this matter.

8 MS. SULLIVAN: You're cutting off
9 cross-examination, Your Honor?

10 THE COURT: I'm not cutting off your
11 cross-examination. But what I'm saying to
12 Mr. Kline is that when it gets to his turn to
13 clear all this up, he's got 15 minutes and
14 then you'll have 15 minutes on recross.

15 MS. SULLIVAN: Understood, Your
16 Honor.

17 BY MS. SULLIVAN:

18 Q. Well, Dr. Kessler, we don't have to spend a
19 lot of time on this, but do you agree that the real
20 rate was 6 percent, not 12 and a half?

21 A. I see two different numbers that Janssen are
22 reporting.

23 Just for INT-70, if you want to show
24 this, INT-70 says on this table 12.5 percent. It
25 says 6.3 on the other. And this is -- please, if

1 you want to project this so people can see what I'm
2 talking about.

3 THE COURT: That's not going to be
4 done through this -- through this attorney.
5 It might be done through your own attorney,
6 Dr. Kessler.

7 BY MS. SULLIVAN:

8 Q. Just so it's clear, Doctor, you're not going
9 to agree that the only way you get to 12 and a half
10 is if you double count?

11 A. The word "double counting," again, I'm not
12 doing any double counting. Janssen's doing the
13 counting. On one table they say 12.5, and that's
14 solely the way they list it as INT-41. When they
15 have a column for double counting -- not double
16 counting, but INT-41 and 70, and there they got
17 8.3 percent. So, again, the document needs to speak
18 for, you know, the document --

19 Q. Sounds like you're not going to agree,
20 Dr. Kessler. I guess we'll have to let somebody
21 else talk about it.

22 MR. KLINE: Objection, Your Honor.
23 Objection. Really.

24 MS. SULLIVAN: Okay.

25 THE COURT: Is there an objection?

1 MR. KLINE: Yes. Really.

2 MS. SULLIVAN: Judge --

3 MR. KLINE: Really.

4 MS. SULLIVAN: -- we could pull up
5 his direct testimony. He told Mr. Kline it
6 was -- he's changing his testimony.

7 MR. KLINE: No, he is not. See --

8 THE COURT: Counsel, Counsel, at this
9 point, I've been, I think, pretty generous in
10 the leeway that's been given to counsel. If
11 you're going to cross-examine a witness and
12 he has a document he wants to show himself
13 that may counter your point, he should be
14 allowed to do that. But we'll allow that on
15 redirect.

16 MS. SULLIVAN: Of course.

17 BY MS. SULLIVAN:

18 Q. And, Dr. Kessler, if you can turn to Page 64
19 on INT-70.

20 A. This is Bates No. 64.

21 Q. It's Page No. 64, Bates No. 834, and it's
22 Defense Exhibit 25. This is the Clinical Study
23 Report for INT-70.

24 A. Yes.

25 Q. And one of the things when you and counsel

1 were talking about the study to the jury that you
2 guys didn't highlight was the fact that there was no
3 apparent link between the occurrence of gynecomastia
4 and prolactin levels, right?

5 A. That says exactly what it says.

6 Q. And because it's true?

7 A. I -- that document says what it says.

8 Q. That the prolactin levels in the subjects who
9 experienced gynecomastia remained within the normal
10 range and were not highest during the occurrence of
11 the AE of gynecomastia, right?

12 A. That's exactly what that says.

13 Q. And you don't dispute that?

14 A. I'm not disputing that at all.

15 Q. And so what that says is that the people who
16 had gynecomastia didn't have elevated prolactin?

17 A. The document says exactly what it says. Yes.

18 Q. Which is the opposite of what you'd expect if
19 Risperdal was causing gynecomastia, right?

20 A. I am not opining on causation. If you'd like,
21 I'd be happy to.

22 Q. What this says is that the people who had
23 gynecomastia had normal prolactin levels?

24 A. The document says exactly that.

25 MR. KLINE: Would you just tell me

1 the page on the bottom.

2 THE COURT: Pardon me?

3 MR. KLINE: I just need the bottom of
4 the page because she blows it --

5 THE COURT: All right. What page is
6 this? I'd like that, too.

7 MS. SULLIVAN: This is Page 64 of the
8 study report.

9 MR. KLINE: Wait.

10 THE COURT: Wait. In our lingo, is
11 this a plaintiff exhibit? What number is
12 this?

13 MS. SULLIVAN: This is a defense
14 exhibit, Your Honor.

15 THE COURT: Well, it's also a
16 plaintiff exhibit, I believe.

17 MS. SULLIVAN: No. There was a -- it
18 didn't have all the pages.

19 THE COURT: So what's this --

20 MR. KLINE: Ours was -- that's not
21 true either. It was the topline report.
22 They have the final report.

23 THE COURT: All right. We're going
24 to straighten it out. I agree. What's this
25 now? Because this looks familiar to me. I

1 think I've seen something like this before.

2 COURT CRIER: D-25.

3 THE COURT: D-25.

4 MR. KLINE: All I've asked is for her
5 to show the page number.

6 THE COURT: What document is it? And
7 what page on D-25 is this?

8 MS. SULLIVAN: Sixty-four.

9 THE COURT: And this document, may I
10 see the cover page to this document right
11 here?

12 MS. SULLIVAN: Yes, Your Honor. This
13 is a Clinical Study Report from INT-70.

14 THE COURT: Okay.

15 All right.

16 BY MS. SULLIVAN:

17 Q. And, Dr. Kessler, looking at Plaintiff's
18 Exhibit 27, which is the published -- the published
19 version of this trial INT-70, right?

20 A. Yes.

21 Q. And it has --

22 A. Let me just get my copy, if you could give me
23 one second, please.

24 Or if you can give me a copy, that
25 would be helpful.

1 I should be able to find it in a
2 second.

3 Q. I'm sorry, Doctor, I didn't realize you didn't
4 have the plaintiff's exhibits.

5 A. Yeah. No, I just don't have it in...

6 Thank you.

7 Q. And, Doctor, this was also done by an outside
8 author by Janssen, Dr. Croonenberghs?

9 A. Yes.

10 Q. And it went through peer review and it was
11 published in the Journal of Child and Adolescent
12 Psychopharmacology, right?

13 A. 2006.

14 Q. And the published article with the outside
15 author and after peer review says the same thing as
16 the Clinical Study Report; that the gynecomastia was
17 severe, but it was not related to elevated
18 prolactin, right?

19 A. Six -- so that's pretty amazing, right.
20 Because there it says -- first of all, you're right,
21 two cases of gynecomastia were rated as severe. But
22 then it says importantly, right, as previously
23 observed by Findling, it says the occurrence of
24 gynecomastia was not related to increases in serum
25 prolactin levels. And yet we know from the Findling

1 study, that Table 1 did in fact show that they were
2 related. So this study is not reporting on the
3 result that Janssen had.

4 Q. This study, Dr. Kessler, and we talked about
5 the Findling study and everybody's heard your views
6 on it, but this comment relates to INT-70 which was
7 not part of the Findling analysis, right?

8 A. No. It says, As has been previously observed
9 by Findling" -- right -- "there was nothing related
10 to increases -- that gynecomastia was not related to
11 increases in serum prolactin."

12 Findling, in fact, the data found a
13 relationship. So this is not -- this is again --

14 Q. I understand.

15 A. -- repeating --

16 THE COURT: Please do not cut him
17 off.

18 MS. SULLIVAN: I didn't mean to, Your
19 Honor.

20 THE WITNESS: This is repeating,
21 right, the erroneous statement in Findling.

22 BY MS. SULLIVAN:

23 Q. I understand that your opinion is that
24 Findling is erroneous. But this is talking about
25 INT-70. And in INT-70 the fact is that they didn't

1 find any relationship between --

2 THE COURT: Counsel, this document
3 speaks for itself. You've got to move on.
4 It says importantly, as has been previously
5 observed, and that is in reference to the
6 Findling.

7 MS. SULLIVAN: But, Your Honor, the
8 findings --

9 THE COURT: Okay. It may be used in
10 talking about this document, but let's not
11 belabor a point that is on the screen itself.

12 BY MS. SULLIVAN:

13 Q. Dr. Kessler, it's true that the people that
14 got gynecomastia in INT-70 had normal prolactin
15 levels?

16 A. We'd have to -- if you put up the appendix in
17 the prior, I can double-check that, right. I
18 don't -- I'm not disputing that. The INT-70 said
19 there was no apparent link. But, again, we'd have
20 to put up the appendix to be sure.

21 Q. You're not disputing that?

22 A. I have no reason to dispute that.

23 Q. You're not disputing the fact that the kids
24 who had severe gynecomastia had absolutely normal
25 prolactin?

1 A. I -- in -- that's what that says. That's not
2 in fact the case with Findling.

3 Q. This is talking about INT-70, though, not
4 Findling, this study right here?

5 A. It's talking about both, that paragraph that's
6 highlighted.

7 Q. But the findings of gynecomastia and the
8 normal prolactin levels are from INT-70?

9 MR. KLINE: Objection.

10 THE COURT: All right. That's
11 sustained. I'm saying it again, sustained.

12 BY MS. SULLIVAN:

13 Q. And, Doctor --

14 MR. KLINE: Does that count against
15 my 15 minutes?

16 THE COURT: Well, you might get your
17 15 minutes tomorrow.

18 MR. KLINE: At the rate it's going,
19 it's running out the clock.

20 MS. SULLIVAN: Come on.

21 THE COURT: I'm being careful right
22 now with the amount of redirect and recross,
23 or else we'll never get out of here.

24 MS. SULLIVAN: Your Honor, he did
25 take a long time --

1 THE COURT: I have no problem with
2 the cross-examination as long as it takes.

3 MS. SULLIVAN: It won't take that
4 long, Your Honor.

5 BY MS. SULLIVAN:

6 Q. Doctor, you know that there is a
7 government-funded study that found the exact same
8 thing as the Dr. Findling study found, right?

9 A. The NIH study; is that what you're --

10 Q. Yes.

11 A. -- referring to?

12 Q. Yes.

13 A. I don't see the NIH study looking for an
14 association with upper limits of normal. I didn't
15 see that.

16 Q. Well --

17 A. Prolactin levels.

18 Q. Let's talk about that.

19 So, Dr. Kessler, in 2006, 2007, the
20 National Institute of Health funded a study in
21 children with autism, right?

22 A. Yes.

23 Q. And --

24 A. Can I have it?

25 Q. I'm sorry?

1 A. Could you kindly show it to me?

2 Q. Sure.

3 Can we give Dr. Kessler a copy,
4 Lamia. It's D-530 for identification.

5 Ms. Brown.

6 MS. BROWN: It's 26.

7 MS. SULLIVAN: 26. And give a copy
8 to the Court and a copy to Mr. Kline. Thank
9 you.

10 THE COURT: All right. You know
11 what, I'm going to take a recess right here.
12 I think we all need a recess and we'll
13 resume, all right. We're going to take a
14 break for about ten minutes and then we'll
15 come back.

16 We are going to adjourn today around
17 4:30, so we may not get the redirect in today
18 and the recross. That's fine. I have no
19 problem with that, okay. So we're not
20 rushing the cross-examination, by heavens,
21 no. So we'll take a ten-minute recess.

22 COURT CRIER: All rise as the jury
23 exits.

24 - - -

25 (Whereupon the jury exited the

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courtroom at 3:20 p.m.)

- - -

THE COURT: All right. Ten minutes.

MS. SULLIVAN: Thank you, Your Honor.

- - -

(Whereupon a recess was taken.)

- - -

(Whereupon an off-the-record discussion was held.)

- - -

THE COURT: Everyone please be seated.

COURT CRIER: All rise as the jury enters.

- - -

(Whereupon the jury entered the courtroom at 3:44 p.m.)

- - -

THE COURT: All right. You may be seated.

All right. To our juror who has child-care issues, be aware that I have spoken personally now with Ms. Osterweg, or whatever her name is, and she knows of our situation. And she's expecting you no later

1 than 5:30. No later than 5:30. So we are
2 going to try to complete the
3 cross-examination today if we at all possibly
4 can.

5 MS. SULLIVAN: Yes, Your Honor.

6 BY MS. SULLIVAN:

7 Q. Homestretch, Dr. Kessler. Get you out of
8 here.

9 A. Thank you very much, Ms. Sullivan.

10 Q. Talking about this --

11 A. I don't have it yet.

12 Q. Oh, I'm sorry. If we could give Dr. Kessler
13 Defense Exhibit 26. It's 530, the Anderson study.

14 Oh, he's got it.

15 COURT CRIER: Do you have this,
16 Counsel?

17 MR. GOMEZ: Yes.

18 MR. KLINE: Yes, we're fine.

19 COURT CRIER: D-26 to the witness.

20 BY MS. SULLIVAN:

21 Q. And, Dr. Kessler, this was a study done not by
22 Janssen, correct?

23 A. You referred to this as an NIH study earlier,
24 but I think this is a Yale Child Study Center.

25 Q. Funded by the NIH, correct?

1 A. I'm sure there was an NIH grant, but it wasn't
2 done by the NIH.

3 Q. So a study funded by the NIH, National
4 Institute of Health, the government, done by Yale
5 and some other outside investigators, not done by
6 Janssen, correct?

7 A. That's correct. Hold on a second. Yes,
8 that's correct.

9 Q. And so the government funded this organization
10 called the -- it's a actually famous organization --
11 the RUPP Autism Network, right? Are you familiar
12 with it?

13 A. I am. Although this lists the Child Study
14 Center, as well as Kennedy Krieger and UCLA, yes.

15 Q. And the RUPP Autism Network is a group of
16 outside investigators from some universities across
17 the country that do research in autism?

18 A. Yes.

19 Q. And the government funds some of their work?

20 A. Yes.

21 Q. And they funded part of their study?

22 A. Yes. It says it's funded in the back.

23 Q. And this is a study on about 101 kids ages 5
24 to 17 who had autism, right?

25 A. Yeah. If I'm correct, there was a short-term

1 period and then an open-label period.

2 Q. Yes, exactly. It was an eight-week
3 placebo-controlled period and then a four-month
4 open-label period, right?

5 A. Exactly.

6 Q. And they looked at prolactin levels in these
7 autistic kids and side effects, right?

8 A. Yes, exactly.

9 Q. And they had physical exams during the study
10 at various points; that the kids taking the
11 Risperdal went in to doctors and they were examined
12 at three different -- at least at three different
13 points in the study?

14 A. Yes. So let's just check those three points.
15 That's what I'm looking for. I don't have that.

16 Q. Yes. It's on the bottom of the second page,
17 Page 546. It talks about -- let me just put this
18 up.

19 A. Thanks.

20 Q. And we're showing the jury Defense Exhibit 26,
21 the Effects of Short- and Long-Term Risperidone
22 Treatment on Prolactin Levels in Children. And we
23 see that the study's funded by an NIH grant, right?

24 A. Yes.

25 Q. Okay. And we also see that in the study --

1 let me make sure that everybody can see here -- that
2 there are physical exams, right?

3 A. Well, let's be exact in that. It says the
4 screening included a physical exam.

5 Q. Right.

6 A. And then there was weekly follow-up, was a
7 review of adverse effects, right.

8 Q. Right.

9 A. And just show me what else it says.

10 Q. So they had an exam and baseline, and then
11 they had follow-up visits where they had a detailed
12 review of adverse effects, right?

13 A. Yes. But I'm just looking for the follow-up.

14 Q. And then on the bottom it talks about they
15 also had physical examinations and blood draws at
16 various intervals, including at 8 weeks, 6 months,
17 and 22 months, right?

18 A. So they did it at three intervals. That's
19 what I was looking for.

20 Q. Yeah.

21 A. Thanks for the help.

22 Q. Yeah.

23 A. Yes.

24 Q. And they had weekly visits where they asked
25 patients do you have elevated; do you have excessive

1 breast growth; do you have problems with your
2 period, sort of detailed review of symptoms?

3 A. Exactly.

4 Q. And they also actually did physical exams at
5 least three different intervals in the study?

6 A. Right. They did it at -- exactly at those
7 three intervals, yes.

8 Q. And the authors found that -- and they also --
9 and when they took blood, they also measured
10 prolactin, right?

11 A. I believe so, yes.

12 Q. And they reported on their findings, right?

13 A. Yes.

14 Q. And what they found, Dr. Kessler, is that, in
15 this government-funded study, was that prolactin
16 levels were not associated with clinical complaints
17 or physical exam findings, right, that's what they
18 found?

19 A. So just to be exact, I mean, that's correct,
20 but read the next sentence.

21 Q. The side effects review form administered at
22 weeks 1 to 8, 3, 4, 6 and 22 contained specific
23 questions about galactorrhea, gynecomastia, and
24 menstrual problems, right?

25 A. Right. But that was not the physical exam

1 necessarily. That was a form.

2 Q. But certainly on physical exam, they would
3 have examined the chest, breasts, et cetera, right?

4 A. They say they did it at three periods of time.

5 Q. Right.

6 A. It was a physical exam. They don't say
7 exactly what they were looking for, if I'm correct.

8 Q. What they found is there was no relationship
9 to prolactin elevations from Risperdal and side
10 effects, right?

11 A. That's correct.

12 Q. That's what the government study found?

13 A. That's the government's?

14 Q. The government-funded study.

15 A. It's not the government. It's these
16 investigators.

17 Q. Yeah. Funded by the government, from the
18 Autism Network.

19 A. Yes.

20 Q. Not associated with Janssen?

21 A. That's correct.

22 Q. Okay. And they report in the study that they
23 found exactly what Dr. Findling found, right?

24 A. Well, let's read their conclusion.

25 Risperidone treatment was associated

1 with two- to fourfold mean increases in serum
2 prolactin in children with autism. And although the
3 risperidone increases tended to diminish with time,
4 further research --

5 MR. KLINE: Excuse me. Is what
6 you're reading up on the screen?

7 MS. SULLIVAN: I don't know where
8 he's reading from.

9 Where are you reading from, Doctor?

10 MR. KLINE: She's putting that up
11 there.

12 MS. SULLIVAN: I was referring to the
13 statement where they found that their data
14 was consistent with Dr. Findling's.

15 THE COURT: No. Is there an
16 objection?

17 MR. KLINE: Yes.

18 THE COURT: Sustained.

19 You asked a question regarding the
20 Findling as maybe an aside in your question.
21 But he's now responding to that by, I
22 believe, by reading from the Findling
23 article; is that what you're doing?

24 THE WITNESS: No.

25 MS. SULLIVAN: No, no. He's reading

1 from this article. I just don't know where
2 you're reading from.

3 MR. KLINE: This is a different --

4 THE COURT: Then I really need one at
5 a time. And if he wants to put something up
6 there, he may, if you're willing to,
7 Ms. Sullivan. If not, then I guess he will
8 be coming back tomorrow.

9 BY MS. SULLIVAN:

10 Q. Doctor, my question was the RUPP
11 investigators, these outside investigators, found
12 exactly the same thing Janssen found. They found no
13 relationship between prolactin elevations from
14 Risperdal and side effects?

15 A. I was reading from the conclusion of the paper
16 in the abstract.

17 Q. Okay.

18 A. That's what I was reading from, Your Honor.

19 Q. We can do that first.

20 THE COURT: Excuse me. Reading from
21 the conclusion of the abstract in which paper
22 was that?

23 THE WITNESS: This paper, I'm sorry.
24 I thought you had asked me what these
25 investigators found.

1 BY MS. SULLIVAN:

2 Q. Well, I can ask you that question. But my
3 question was, isn't it true they found exactly what
4 Dr. Findling and Janssen found in terms of prolactin
5 elevation from Risperdal not being associated with
6 prolactin-related side effects?

7 A. I think that they used the word "fairly
8 consistent" in the paper.

9 Q. Yeah.

10 A. If I'm correct.

11 Q. Yeah.

12 A. Yes.

13 Q. Exactly.

14 So these outside investigators found
15 the same thing, no association between Risperdal
16 elevations in prolactin and side effects of
17 gynecomastia?

18 A. The paper speaks exactly for what the paper
19 speaks for.

20 Q. Okay.

21 MR. KLINE: I thought we were on the
22 abstract, though.

23 THE COURT: No, no. He -- this
24 was -- if you want to go back to the
25 abstract --

1 MS. SULLIVAN: I'm happy -- if he
2 wants to read the abstract, Doctor --

3 MR. KLINE: Just look at the
4 conclusions.

5 MS. SULLIVAN: -- I'm happy to read
6 the abstract.

7 BY MS. SULLIVAN:

8 Q. So the conclusion in the abstract says:
9 Risperidone treatment was associated with two- to
10 fourfold mean increases in prolactin in children
11 with autism, right; that's what it says?

12 A. Exactly.

13 Q. And although risperidone increases tended to
14 diminish --

15 (Reading fast.)

16 COURT REPORTER: Excuse me, counsel,
17 please, a little slower.

18 BY MS. SULLIVAN:

19 Q. [Reading]: Further research on the
20 consequences of long-term prolactin elevation in
21 children and adolescents is needed.

22 A. Exactly what they write.

23 Q. And what they found is, and we talked about
24 it, that these elevations in prolactin from
25 Risperdal didn't have an association with any of the

1 side effects like gynecomastia?

2 A. That's exactly what they found.

3 Q. And, Doctor, by the way, I want to talk a
4 little bit in five minutes, before I turn you over
5 to Mr. Kline, about the FDA.

6 A. Sure.

7 Q. You agree, Dr. Kessler, that the FDA is the
8 most important consumer protection agency in the
9 world?

10 A. You're probably quoting me.

11 Q. I probably am.

12 A. Thank you.

13 Q. And you agree that all of the FDA's employees
14 share a commitment to protect and enhance the public
15 health?

16 A. "All" is a pretty big statement, but, yeah, I
17 think that's correct. Very dedicated employees.

18 Q. And you --

19 A. Do we have a few clunkers? I'm sure, but like
20 any organization, but very dedicated employees.

21 Q. And that the FDA has served the American
22 public well in ensuring the remarkable standard of
23 product safety, and that's been maintained?

24 A. It sure tries.

25 Q. And it's the gold standard across the world,

1 the FDA's review and when they decide something's
2 safe and effective?

3 A. We can be very proud of it.

4 Q. And the FDA, as you've mentioned, is filled
5 with doctors, scientists, toxicologists, dedicated
6 professionals?

7 A. Absolutely.

8 Q. Well-trained and highly trained and some of
9 the best specialists in the world?

10 A. People who could earn multiple incomes in
11 other jobs that are as smart as anyone I've ever
12 met, yes.

13 Q. And, Dr. Kessler, you've acknowledged or said
14 that the doctors and scientists at FDA are as smart
15 and as talented as any that you've ever seen?

16 A. Exactly.

17 MR. KLINE: Look.

18 THE WITNESS: At least I'm
19 consistent.

20 THE COURT: Is there an objection?

21 MR. KLINE: No. I'm saying "look."

22 BY MS. SULLIVAN:

23 Q. And, Dr. Kessler, throughout your professional
24 career, you've always and continue to have every
25 reason to trust the judgment of the officials of the

1 FDA?

2 A. Yes. But I have to add a footnote. They're
3 only as good as what a manufacturer gives them.

4 Q. And, Dr. Kessler, you agree that all medicines
5 have risks?

6 A. We can spend probably a day talking about
7 that, but sure.

8 Q. None are a hundred percent safe? None have no
9 side effects, unfortunately?

10 A. Your definition of "safe," yes, medicines are
11 powerful. Some medicines are even more powerful.

12 Q. And doctors have to weigh the risks and
13 benefits of a medicine before they prescribe it?

14 A. Absolutely. And a company has to give the
15 docs the information.

16 Q. And doctors -- and the FDA spends a fair
17 amount of time reviewing and editing the labels for
18 a medicine as part of the FDA approval process?

19 A. Yes. Up through 2006, it was a negotiation.
20 FDA couldn't order changes, it could negotiate.
21 That doesn't sound right that the FDA couldn't order
22 it and Congress changed the law in 2006 to allow
23 that.

24 Q. Well, when it comes to drug approval, though,
25 the FDA could say we're not going to approve your

1 drug unless you say exactly what we want you to say
2 on the label; true?

3 A. At that moment in time, that probably could be
4 said. But I think it's fair to say FDA has always
5 viewed the label as a negotiation.

6 Q. And, Doctor, you've seen in this case where
7 the FDA's marked up the Janssen letter and said you
8 got to say this as a condition of approval?

9 A. It's a general statement. There's a -- there
10 was -- there's a negotiation certainly back and
11 forth in the 2006 label.

12 Q. And, Doctor, you expect when the FDA approves
13 a drug label that doctors actually will read it,
14 right?

15 A. Which version?

16 Q. The final label.

17 A. How many -- there were -- I counted up some 25
18 different versions of the label between 1993 and
19 2006 that Janssen printed.

20 Q. Well, Doctor, I'm talking -- let's -- we'll
21 talk about Janssen. But generally do you expect --
22 does the FDA expect that the doctors will actually
23 read drug labels?

24 MR. KLINE: Objection.

25 THE COURT: Objection to that

1 question. Overruled.

2 BY MS. SULLIVAN:

3 Q. That's what they're for, right?

4 A. We would be living in a fantasy if we thought
5 that a doctor always read the most current version
6 in entirety. That's why FDA in 2006 put the
7 highlights section in the label, because it
8 understands that doctors have limited time. And
9 especially when you realize that there were so many
10 different versions here. You have to take that into
11 consideration.

12 Q. Well, Dr. Kessler, there was a lot of versions
13 because Janssen kept doing studies and kept getting
14 approvals for different things, for bipolar
15 disorder, for schizophrenia, for autism. They kept
16 doing the studies and getting the approval from the
17 FDA for a variety of different things and that
18 results in label changes.

19 A. There are some 25 different versions. Some of
20 them are due to that; others are due to other
21 reasons.

22 Q. And the FDA and companies take care in putting
23 together prescribing information for doctors to
24 guide them in their decision-making in terms of what
25 medicines to prescribe?

1 A. For the approved indications. What is at
2 issue here is not for the approved indications, but
3 the fact is this drug was being off-label used and
4 the label was never designed for those off-label
5 uses because that off-label use was beyond the
6 statute.

7 Q. And, Dr. Kessler, you've reviewed some
8 information in this case, but you'll agree that the
9 FDA -- you left in 1997, and there's been 20-plus
10 more years of research on Risperdal since you've
11 left the FDA?

12 A. By definition.

13 Q. Yeah. And so all of the subsequent
14 approvals -- in fact, we put up the 1993 label. You
15 were actually there at the FDA when Risperdal was
16 first approved?

17 A. Absolutely.

18 Q. You didn't take any issue with the label at
19 the time?

20 A. I took no issue with the label at the time.

21 Q. And since that time, Dr. Kessler, the FDA has
22 reviewed and approved Risperdal for other
23 indications and reviewed a ton --

24 MR. KLINE: Objection.

25 BY MS. SULLIVAN:

1 Q. -- of scientific data?

2 THE COURT: Basis?

3 MR. KLINE: Objection. Basis, of
4 what they approved today. It has nothing to
5 do with the case. This is a 2002 --

6 THE COURT: I thought it was going to
7 be "asked and answered."

8 Overruled.

9 You can go into a question that
10 you've asked before, if you wish.

11 MR. KLINE: That wasn't asked, Your
12 Honor. The question of indications now --

13 THE COURT: I didn't hear anything
14 about now. Are you asking about now,
15 Counsel?

16 MR. KLINE: Yes.

17 MS. SULLIVAN: No, Your Honor.

18 MR. KLINE: Since '06, that's her
19 question.

20 MS. SULLIVAN: Well, there were
21 many --

22 MR. KLINE: Nothing to do with the
23 case.

24 MS. SULLIVAN: Are you done?

25 BY MS. SULLIVAN:

1 Q. There were indications, Dr. Kessler, and
2 you'll agree, between 2002 and 2007 when this
3 plaintiff stopped taking Risperdal, there were other
4 indications for Risperdal that was approved?

5 A. There were indications in 2006 for autism and
6 then later in bipolar and then schizophrenia in
7 young people for which there were applications that
8 were approved, yes.

9 Q. And they also got approval for an oral
10 solution during that time frame?

11 A. Different formulations.

12 Q. And a disintegrating tablet and things like
13 that?

14 A. Exactly.

15 Q. And every time that happens, the FDA has
16 occasion to review more safety data and occasion to
17 look and approve the label?

18 A. Uhmm, yeah. I think it's -- it's really on
19 the big indications when there's new clinical trial
20 data that can have clinical importance, then the
21 medical officers tend to review the data.

22 Q. And, Doctor, at no time during the 20 years or
23 so since you've left the FDA, while FDA is reviewing
24 all of this additional safety data, did FDA ever
25 conclude that Janssen failed to warn about a safety

1 risk; true?

2 A. I have to go back and look at that. Again,
3 there's a complicated off-label history here. And
4 are you talking about the on-label uses or the
5 off-label?

6 Q. Or anything, Dr. Kessler. It's true that the
7 FDA has never concluded in 20-plus years that
8 Janssen failed to adequately warn about a safety
9 risk?

10 A. I think that's probably correct the way you
11 phrase it.

12 MS. SULLIVAN: Nothing further.

13 Thank you, Your Honor.

14 - - -

15 REDIRECT EXAMINATION

16 - - -

17 BY MR. KLINE:

18 Q. Yeah. But what would be the full -- may I,
19 Your Honor?

20 THE COURT: Yes.

21 Like I said, I would like to conclude
22 today at 4:30. So I'm giving you -- if you
23 want to go forward with redirect, then I
24 would say about a 20-minute or 15-minute
25 redirect and then 15 minutes for the other

1 side.

2 MR. KLINE: In the alternative?

3 THE COURT: Or the alternative is not
4 to have any redirect whatsoever and no
5 recross and just call it a day.

6 MR. KLINE: Okay. And the third
7 alternative?

8 THE COURT: The third alternative,
9 frankly, is to spend another two days of
10 Dr. Kessler's life in this courtroom.

11 MR. KLINE: I want to try about three
12 or four areas in 15 minutes.

13 THE COURT: All right. Go ahead.

14 - - -

15 BY MR. KLINE:

16 Q. And one of the things is before we left off,
17 which is -- hi, again. It's me.

18 The -- I'm back.

19 What was just said, is that the full
20 story, that very last question and answer about the
21 FDA never safety -- you know, never said anything
22 about safety?

23 A. No, it's not the full story.

24 I think Ms. Sullivan was correct in
25 the way she phrased that question narrowly. But

1 let's -- I mean, there's a, you know, a big elephant
2 here is that it was off-label --

3 MS. SULLIVAN: Your Honor, can I have
4 a sidebar?

5 THE COURT: Pardon me?

6 MS. SULLIVAN: May I have a sidebar,
7 Your Honor?

8 THE COURT: Sidebar, no, unless
9 there's an objection to something.

10 MS. SULLIVAN: Yeah. I object, Your
11 Honor. Because he's about to get into things
12 that the Court has ruled out of this case.

13 THE COURT: I don't know. You must
14 be a mind reader. I don't know.

15 Overruled.

16 BY MR. KLINE:

17 Q. You were saying, off-label...

18 A. If you're in a doctor's office marketing the
19 drug 20 times and you're going to -- so the FDA has
20 not given you approval, you can't look to the label
21 for what you have to do when you're doing that
22 off-label that you shouldn't be doing.

23 Q. And that takes us -- next exhibit number.

24 That takes us to something you were
25 talking about two days ago, sir, about intended use.

1 What you really need to look at is what is the
2 intended use?

3 A. Exactly.

4 Q. And I have a document of Janssen's, a business
5 record of Janssen's which talks about how many
6 children were getting this drug in 2002, which is
7 what we're looking at. It's marked as Plaintiff's
8 Exhibit No. 57. It has the JJRE number 0082146.
9 I'm going to hand that to counsel. It simply tells
10 us the number of prescriptions that were being
11 actually written at that time, so we can talk about
12 what the -- put this in some context.

13 With the Court's permission, I'll
14 display it to the jury. I'll hand a copy to the
15 witness.

16 THE COURT: All right. Is there any
17 objection now from the defense, P-57?

18 MS. SULLIVAN: Your Honor, if this
19 was a Janssen document, I would have no
20 problem. But this is a hearsay document from
21 some outside service, so I would object.

22 THE COURT: Overruled. Go ahead.

23 MR. KLINE: It's a Janssen-produced
24 document.

25 THE COURT: Overruled. Go ahead.

1 BY MR. KLINE:

2 Q. Sir, can you look at this? You're familiar
3 with these kinds of charts.

4 Would you look at the -- in 2002, do
5 you see that?

6 A. Yes.

7 Q. I'm not interested in the other atypical
8 antipsychotics. What I want to know here is you see
9 how this is stated in thousands, estimated treatment
10 prescriptions, volume?

11 A. Yes.

12 Q. Okay. When you're talking about the intended
13 use here and what the label needed to say, how
14 many -- you see here it says one million six hundred
15 and sixty-nine doses were being prescribed to
16 children in 2002?

17 A. I see that.

18 Q. One million six hundred and sixty-nine.

19 Now, sir, as far as measuring the
20 conduct of the company and what they should do,
21 which we've been talking about with you for four
22 days, is that measured in part against how it was
23 really being used and the population in which it was
24 being used?

25 A. That's what's key. If the drug is being

1 marketed for children, that's the intended use.

2 Q. When this doctor --

3 A. I didn't finish. Can I just finish?

4 Q. Yes, sir.

5 MS. SULLIVAN: And, Your Honor, again
6 I'm going to object. There's no evidence in
7 this case that Dr. Mathisen, the prescriber,
8 was marketed to off-label. In fact, the
9 opposite is true.

10 MR. KLINE: He was in the office --
11 we'll see him tomorrow. We'll see the
12 salesman tomorrow. He was in the office 20
13 times with the samples.

14 THE COURT: First of all, as to the
15 question of marketing, that is going to be up
16 to the jury to decide as to what was going on
17 in Dr. Mathisen's office. So I don't need an
18 expert opinion about that from this witness.

19 MR. KLINE: Okay.

20 BY MR. KLINE:

21 Q. Next item, sir, let's take this down. I want
22 to do this in 15 minutes.

23 You were asked a question on
24 cross-examination from the company lawyer about
25 the -- about whether other labels of other drugs in

1 the relevant time period warned about gynecomastia,
2 and you mentioned Striant, correct?

3 A. Yes.

4 Q. S-T-R-I-A-N-T, correct, sir?

5 A. Yes.

6 Q. And I'd like to hand copies to counsel. We've
7 marked it as P -- this is the second of about four
8 things I intend to do. That's all.

9 MS. SULLIVAN: Can we have a date,
10 Counsel?

11 MR. KLINE: Yes. I can tell you.
12 Mr. Gomez looked it up. What year label is
13 it, Mr. Gomez?

14 MR. GOMEZ: 2003.

15 MR. KLINE: 2003 label.

16 And do you have it in your machine?

17 BY MR. KLINE:

18 Q. Let's look at Page 7 under Warnings.

19 COURT CRIER: P-58.

20 - - -

21 (Whereupon Exhibit P-58 was marked
22 for identification.)

23 - - -

24 BY MR. KLINE:

25 Q. Do you have a copy in front of you?

1 A. I've just been handed one. Yes.

2 Q. What was -- what drug company was Striant?

3 A. It was manufactured for Columbia Laboratories.

4 Q. Okay. Let's look at when you told the jury
5 earlier today that other drugs had such warnings;
6 let's look right down here at number 5.

7 Gynecomastia develops frequently and occasionally
8 persists in patients being treated; do you see that?

9 A. I do.

10 Q. Those words were missing from this label where
11 the drug risperidone frequently caused gynecomastia,
12 correct?

13 MS. SULLIVAN: Objection. Objection.
14 That's leading and argumentative, Your Honor.

15 THE WITNESS: Yes.

16 THE COURT: As far as -- as far as
17 the question, that's sustained. I mean --

18 MR. KLINE: Was this --

19 THE COURT: -- again --

20 MR. KLINE: I would rephrase it, Your
21 Honor.

22 BY MR. KLINE:

23 Q. Was a warning similar to this on the Risperdal
24 label?

25 A. No.

1 Q. Was Risperdal eventually admitted in the 2006
2 label to have a 2.3 percent incidence of
3 gynecomastia?

4 A. Yes.

5 Q. And is that something that's frequent, sir?

6 A. Yes.

7 Q. And in this drug when it's frequent, is it
8 right there in the warning?

9 A. Yes. And can I also add, this drug had the
10 warning on gynecomastia, this is in adults. So
11 especially gynecomastia in kids warrant the same
12 kind of warning.

13 Q. Now, let's talk about something else that was
14 raised.

15 Do you recall your discussion with
16 the company lawyer about the question involving
17 whether there was a placebo-controlled study,
18 whether there was a placebo-controlled study? Do
19 you recall that discussion?

20 A. Yes.

21 Q. And whether there's any study that measured
22 kids getting Risperdal against kids that were just
23 getting a sugar pill; namely, a placebo. Do you
24 recall that discussion?

25 A. Yes.

1 Q. All right. Let me show you a table to RIS-79.

2 It's JJRE0498189.

3 MS. SULLIVAN: And, Your Honor, I
4 would just ask that we use the whole CSR
5 instead of pulling a page out.

6 MR. GOMEZ: We can do it like we did
7 the other things.

8 THE COURT: Well, first of all, what
9 document is this from?

10 MR. KLINE: It's from RIS-79, the
11 Clinical Study Report of RIS-79. I want to
12 go right to the table. I copied the one key
13 page.

14 THE COURT: All right. What page is
15 the table on?

16 MR. KLINE: The table is on Page 123
17 of this long study. It is JJRE0498189.

18 THE COURT: All right.

19 MR. KLINE: I have a copy for the
20 Court.

21 THE COURT: Okay.

22 MR. KLINE: And we've marked it as
23 Plaintiff's Exhibit --

24 MR. GOMEZ: 59.

25 MR. KLINE: -- 59.

1 THE COURT: Very well.

2 - - -

3 (Whereupon Exhibit P-59 was marked
4 for identification.)

5 - - -

6 MR. KLINE: Does the witness have a
7 copy, or are you shorthanded?

8 MR. GOMEZ: Shorthanded.

9 MR. KLINE: Your Honor, can we watch
10 up here?

11 THE COURT: Sure.

12 MR. KLINE: Can I have the Court
13 indulge me on this one?

14 And may I go behind the witness?

15 THE COURT: This is P-59. This is
16 Page 123. And it's from a document that is
17 admissible, so you may proceed.

18 MR. KLINE: Okay.

19 You don't have it?

20 VIDEO TECHNICIAN: No, I don't have a
21 copy.

22 MR. KLINE: You want the JRE number
23 again. Okay. Here we go. I'm trying to be
24 done at 4:15 or 4:20.

25 It is JJRE0498189.

1 BY MR. KLINE:

2 Q. I'm displaying a table which is the result of
3 a clinical trial of Janssen.

4 A. Yes.

5 Q. Ms. Sullivan suggested to you that there was
6 no other study -- no study where they had the kids
7 on the sugar pill versus the kids on the
8 risperidone, correct?

9 A. Yes.

10 Q. They did such a very study right here on this
11 table. It shows the results, correct?

12 A. Yes.

13 Q. Does it surprise you, sir, that when they got
14 the risperidone, they got the gynecomastia?

15 MS. SULLIVAN: Objection, Your Honor,
16 to the form. It's argumentative.

17 MR. KLINE: Let's look at --

18 THE COURT: Well --

19 MR. KLINE: Yeah, I could ask that.

20 But let me ask it this way.

21 BY MR. KLINE:

22 Q. Let's look at the study. There were, very
23 quickly -- and I am rushing -- there are placebo
24 versus risperidone treated. There were 163 on the
25 sugar pill. Do you have it highlighted?

1 A. Not yet.

2 Q. We will. Right up above, Cory. I know I'm
3 rushing, placebo number 163. And maybe you can just
4 zero in on the top, right there. That's where we
5 want to look (indicating).

6 (Technician complies with request.)

7 MR. KLINE: Yes. There you go.

8 BY MR. KLINE:

9 Q. They had 163?

10 A. Yes.

11 Q. And they have the placebo. That means the
12 kids on the sugar pill, in their very study. This
13 is a Janssen study with which you're familiar?

14 A. Yes.

15 Q. When you went through all those boxes, this
16 was one of the pages of the millions of pages,
17 correct?

18 A. It's in my notes here.

19 Q. And you see here it says they gave the ris --
20 the placebos had no gynecomastia, correct?

21 A. That's exactly what the data showed here.

22 Q. And you're going to have to take this down and
23 show me the whole slice of the top.

24 Go to the top, please.

25 (Technician complies with request.)

1 MR. KLINE: The full top, there.

2 I hope you can see.

3 BY MR. KLINE:

4 Q. So what you have is potential
5 prolactin-related treatment, emergent adverse events
6 by sex and age during maintenance treatment.

7 So they had the total number of
8 subjects. They gave some the placebo, which is just
9 a sugar pill, and they gave some risperidone,
10 correct?

11 A. Exactly what they did here.

12 Q. And what they found was none on the sugar
13 pill, correct?

14 A. Yes.

15 Q. Five on the risperidone, correct?

16 A. Yes.

17 Q. Once again, about three in a hundred kids are
18 getting gynecomastia when they're on the
19 risperidone, correct?

20 A. Three in 150, 170, yes, exactly.

21 Q. Three in a hundred, in this study, against the
22 placebo group.

23 And, by the way, who designs these
24 studies, the good folks at the FDA or the good folks
25 at Janssen?

1 A. The studies are designed by the folks at
2 Janssen.

3 Q. So in this study, the placebo-controlled
4 study, remember when Ms. Sullivan was questioning
5 you for maybe a half an hour on the question of
6 whether there were no placebo control studies. This
7 is RIS-41, was just all kids in a "open label"
8 study?

9 A. This shows exactly that there were zero in the
10 placebo and three in the Risperdal-treated children.

11 Q. Yes. In a placebo-controlled study. And what
12 year was this known to them, sir?

13 A. INT study was known in September 2000 -- the
14 study was completed in September '03 is what my
15 notes say.

16 Q. September '03.

17 A. When the study was complete.

18 Q. Yes.

19 So in addition to everything else
20 that you've testified about on direct examination,
21 we hadn't gotten to mention this: And this was
22 known by September of 2003 in its final results,
23 correct?

24 A. The study was complete. We have to look
25 exactly when it was available. I think it was

1 available subsequently.

2 Q. Yes.

3 And, sir, let me see if I can do one
4 more thing quickly with you.

5 You've mentioned that you've reviewed
6 a whole lot of deposition testimony and the like.

7 A. I did.

8 Q. And do you remember your discussion with
9 Ms. Sullivan about the authors of the study and the
10 authors, the outside authors of the study; remember
11 you talked repeatedly about that?

12 A. Yes.

13 Q. And how it wasn't just Janssen, it was the
14 outside study; do you remember?

15 A. Yes.

16 Q. Do you know as to that thing that you said was
17 key, the question of whether there was a correlation
18 between what they call SHAP now and elevated
19 prolactin levels?

20 A. Right.

21 Q. And as part of what you've read, did you also
22 read -- we don't display deposition testimony in
23 this courtroom.

24 Did you also read what Dr. Daneman
25 has to say about that study now --

1 MS. SULLIVAN: Objection.

2 BY MR. KLINE:

3 Q. -- under oath?

4 MS. SULLIVAN: Objection, Your Honor.

5 Let him play the whole thing of Dr. Daneman

6 instead of taking a line out and having

7 Dr. Kessler agree with him. I object to it.

8 THE COURT: Well, I'll permit this.

9 This is his direct examination, correct?

10 MR. KLINE: Yes. It's on the point.

11 THE COURT: Of Dr. Daneman.

12 BY MR. KLINE:

13 Q. Sir, when asked about the very study which has

14 his name, it says -- the question was asked: "So

15 you would agree with me that that sentence that I

16 just read" -- this is in the Findling article -- "No

17 correlation was found between SHAP and prolactin

18 levels even when male gynecomastia during puberty

19 was included, is incorrect?"

20 And what did he say?

21 A. He answered, "Is inaccurate."

22 Q. And what you have told the jury today and

23 yesterday and the day before, to say that there's a

24 lack of correlation or a lack of an association,

25 that would be an inaccurate statement, as the author

1 of the article under sworn deposition testimony
2 himself says, like you, correct?

3 MS. SULLIVAN: Objection, Your Honor.
4 Leading. And he should play the whole
5 deposition.

6 MR. KLINE: We will.

7 THE COURT: Well, as far as the
8 leading, overruled as far as the leading at
9 this hour.

10 BY MR. KLINE:

11 Q. Is that correct?

12 A. Yes. Dr. Daneman, who published, who was one
13 of the authors, the sentence that I -- the point
14 that I was concerned about, and you saw Janssen's
15 realizing that it was significant, he in his
16 deposition under oath said it was inaccurate.

17 Q. Just like you told them?

18 A. Yes.

19 MR. KLINE: Okay.

20 THE COURT: I think it would be
21 helpful, though, counsel, if we do have, for
22 the record, from this witness who this
23 particular doctor is.

24 MR. KLINE: Yes.

25 BY MR. KLINE:

1 Q. Dr. Daneman, let's look at the Findling
2 article and we can wrap up, the Findling article.
3 That's a good point because a point was made about
4 it earlier.

5 The Findling article, while we're
6 getting it out, has two of the authors are Janssen
7 people. One of whom is this Ms. Binder, the MBA,
8 correct?

9 A. Yes.

10 He's the third author on the paper.

11 So if you look at the author --

12 Q. Let's put it back up, if I may, for a minute.

13 A. Sure.

14 Q. It is Ms. -- we'll learn the plaintiff's
15 number in a minute. The JJRE number is
16 JJRE03839224.

17 A. Yes. He's the third author -- the first
18 author on the second line.

19 Q. Yes. He's from the University of Toronto in
20 Toronto, Canada, correct?

21 A. Yes. He was one of the pediatric
22 endocrinologists.

23 Q. Denis Daneman?

24 A. Yes.

25 Q. And he, like you, says that statement is

1 incorrect?

2 A. He says it's inaccurate, yes, incorrect.

3 Q. And so we know, you've read his whole
4 deposition, correct?

5 A. Yes; I've studied it.

6 Q. So when the questions were asked, you have to
7 pick one thing out of the thing, as to the issue
8 that we have here, the issue as to whether the
9 Janssen Pharmaceutical Company provided the full and
10 complete story on the drug, as to that statement in
11 that article and that statement which was made to
12 the FDA, it is inaccurate, so the author -- one of
13 the authors himself says, correct?

14 A. That's --

15 MS. SULLIVAN: Objection; leading,
16 Your Honor.

17 BY MR. KLINE:

18 Q. Is that correct?

19 THE COURT: That's overruled. That's
20 overruled because of the hour.

21 THE WITNESS: He says it's
22 inaccurate.

23 MR. KLINE: Thank you.

24 And, Your Honor, thank you for
25 letting me get through it quickly.

1 THE COURT: All right. Thank you.

2 MS. SULLIVAN: If I may, Your Honor.

3 THE COURT: All right. Recross.

4 Last recross.

5 - - -

6 RECROSS-EXAMINATION

7 - - -

8 BY MS. SULLIVAN:

9 Q. Dr. Kessler, you read Dr. Daneman's
10 deposition. You know that he disagrees with you
11 that the 8- to 12-week data is clinically
12 meaningful, right?

13 A. I have the deposition right here, if you want
14 to show me.

15 Q. Do you know, sir?

16 A. I looked at that. I do know that I've read
17 subsequently that he once did --

18 Q. Can you answer my question, you know, Dr.
19 Kessler --

20 MR. KLINE: He was finishing --

21 THE COURT: Well, right now are you
22 asking about the deposition?

23 MS. SULLIVAN: Yes.

24 MR. KLINE: But he was in the middle
25 of an answer, Your Honor.

1 MS. SULLIVAN: I'm just asking about
2 the deposition.

3 THE COURT: Okay.

4 BY MS. SULLIVAN:

5 Q. You know, Dr. Kessler, that in that deposition
6 Dr. Daneman says the 8- to 12-week data is not
7 clinically meaningful, right?

8 A. If you have an exact quote, please show me.

9 Q. We're going to play it for the jury. But you
10 don't remember that?

11 A. I don't have that exact quote, that exact
12 line.

13 I do know that he said it was
14 inaccurate.

15 Q. Now, Dr. Kessler, Mr. Kline showed you this
16 placebo-controlled study. But what you guys didn't
17 talk about is that the fact that there's no -- there
18 was more people in the risperidone arm and that the
19 difference is not statistically significant, right?

20 A. There are about nine additional people, but
21 there's three additional cases of gynecomastia.
22 Again, I think to -- if I can say what I've said
23 before, the data are the data. You see zero in the
24 placebo; three in the risperidone arm. There is no
25 statistics on that chart that I see.

1 Q. But you know, Dr. Kessler, that that's not a
2 statistically significant finding?

3 A. Show me --

4 MR. KLINE: Objection. There's no
5 statistics run.

6 THE COURT: Wait. Excuse me.

7 MR. KLINE: And it's their study.

8 THE COURT: That's sustained. I
9 think he answered that question.

10 BY MS. SULLIVAN:

11 Q. Do you know, sir?

12 A. I know there's no statistics on that table.

13 Q. Do you know whether that's statistically
14 significant or not?

15 A. I know that it's not -- I did not run the
16 statistics. I've read the table. There are no
17 statistics on the table.

18 Q. So you don't know whether it's statistically
19 meaningful or not?

20 A. Oh, please, you've just changed the
21 terminology.

22 Q. I didn't. You don't know whether it's
23 statistically significant or not?

24 A. Right. But then you talked about whether
25 something is meaningful.

1 Q. Statistically meaningful.

2 A. Right.

3 So Janssen didn't run -- didn't show
4 the statistics on this table. They could have.

5 Q. And Mr. Kline didn't bring in the whole --

6 COURT REPORTER: I'm sorry, counsel,
7 repeat.

8 BY MS. SULLIVAN:

9 Q. Mr. Kline didn't bring in the whole --

10 MR. KLINE: Your Honor, can we not
11 try the case on that?

12 THE COURT: Well, again --

13 MR. KLINE: Can we try the case on
14 the facts?

15 THE COURT: -- I don't believe that
16 was a question, Ms. Sullivan. So just please
17 ask questions. It's okay.

18 BY MS. SULLIVAN:

19 Q. And, by the way, Dr. Kessler, in all of these
20 studies, the overwhelming majority, even in INT-41,
21 95 percent of the kids didn't have any side effects
22 at all --

23 MR. KLINE: Objection.

24 BY MS. SULLIVAN:

25 Q. -- right?

1 MR. KLINE: Beyond the scope of
2 redirect.

3 THE WITNESS: So if you --

4 THE COURT: Wait a minute.
5 95 percent did not have what?

6 MS. SULLIVAN: So --

7 MR. KLINE: It's the same
8 cross-examination from before, Your Honor.
9 It's beyond the scope of redirect.

10 MS. SULLIVAN: Your Honor --

11 THE COURT: I don't know. It depends
12 on the question. I didn't catch that.
13 95 percent of what?

14 BY MS. SULLIVAN:

15 Q. Dr. Kessler, in the study that you and
16 Mr. Kline just looked at, 98 percent of the kids
17 didn't have any side effects at all, right, in terms
18 of the prolactin?

19 A. You have to put up the numbers. In Findling,
20 I think it was, what, 7.8 percent, right?

21 Q. 98 percent didn't have any side effects,
22 right, or more?

23 A. You have -- again, that's not the way you look
24 at safety data. You compare the two arms, right.
25 So you're looking how many got gynecomastia who were

1 treated versus how many got it in the placebo arm.

2 That's what your end point is.

3 Q. And the one label that Mr. Kline showed you
4 that had gynecomastia in the warnings, that was a
5 steroid drug, right? It's a steroid.

6 A. And it had gynecomastia in the one --

7 Q. Yeah. It's not a prolactin-elevated drug.
8 It's a steroid.

9 A. It's not an antipsychotic.

10 Q. And it's not a prolactin-elevated medicine?

11 MR. KLINE: Objection. The whole
12 point was to show --

13 THE COURT: No, no, no. Objection?

14 MR. KLINE: -- you have gynecomastia
15 you warn about.

16 THE COURT: Hold it.

17 MR. KLINE: Not the kind of drug it
18 was.

19 THE COURT: No. The objection is
20 overruled.

21 BY MS. SULLIVAN:

22 Q. This is a steroid?

23 A. Yes.

24 Q. And it's not a prolactin-elevated medicine?

25 A. Ask your endocrinologist for the role -- the

1 interrelationship.

2 Q. And even though kids take steroids, it doesn't
3 have it on the warning for kids, right, for
4 pediatrics in this label?

5 MR. KLINE: Objection.

6 THE COURT: An objection, one second.

7 Ms. Sullivan, which drug is this that
8 you're talking about?

9 MS. SULLIVAN: This is Mr. Kline's
10 label, the Striant.

11 THE COURT: Okay.

12 MR. KLINE: The one that has the
13 gynecomastia.

14 THE COURT: Oh, the one that has that
15 on a warning?

16 MR. KLINE: Yes.

17 THE COURT: Yes. Overruled.

18 BY MS. SULLIVAN:

19 Q. And there is no -- and steroids are used
20 off-label by young men and women?

21 A. There's no evidence that I have that the
22 company was promoting it for children.

23 Q. And there is no warning for pediatrics in this
24 label for gynecomastia, right?

25 A. It had a warning for gynecomastia.

1 Q. But not for pediatrics?

2 A. It was in the warning. If you look at the
3 warning, it says gynecomastia, I believe.

4 Q. But your claim in this case, Dr. Kessler, is
5 that the company could and should have warned about
6 an off-label risk. In fact, the label Mr. Kline
7 showed you doesn't have that kind of a warning.

8 A. If you sell it for an off-label use to kids,
9 for use in kids, then you have to warn.

10 Q. And you're telling the jury kids don't use --
11 teenagers don't use steroids?

12 A. I am not --

13 MR. KLINE: Your Honor, that's --

14 THE COURT: That's sustained.

15 Sustained. That's argumentative.

16 MR. KLINE: Nor is there proof that
17 they were selling a million prescriptions of
18 it.

19 THE COURT: All right. It's
20 argumentative. All right. Sustained.

21 BY MS. SULLIVAN:

22 Q. And, Dr. Kessler, true that Risperdal has
23 helped millions of children?

24 MR. KLINE: Objection; beyond the
25 scope; irrelevant. And I will show you all

1 the ones it hasn't helped.

2 THE COURT: Will this end the recross
3 soon?

4 BY MS. SULLIVAN:

5 Q. We've established that it's widely prescribed?

6 THE COURT: Sustained. Sustained.

7 BY MS. SULLIVAN:

8 Q. Doctor, it's widely prescribed because it
9 works in kids, right?

10 MR. KLINE: Objection. He just
11 sustained it.

12 THE COURT: I don't think that's an
13 issue that's been raised on redirect.
14 Sustained.

15 BY MS. SULLIVAN:

16 Q. And, Doctor, the FDA has actually found that
17 Risperdal has helped millions of autistic children
18 and their parents and other caregivers, right?

19 MR. KLINE: Same objection.

20 THE COURT: All right. Same,
21 sustained.

22 The same warning or reminder to the
23 jury that questions are not evidence.

24 BY MS. SULLIVAN:

25 Q. The FDA when it approved -- well, you read the

1 review memos, Dr. Kessler. The FDA when it approved
2 Risperdal found that there were no treatments for
3 these kids and that Risperdal could be an important
4 medicine to help autistic kids and their parents;
5 that's what the FDA --

6 MR. KLINE: Same, same objection,
7 Your Honor.

8 BY MS. SULLIVAN:

9 Q. That's in the FDA review.

10 MR. KLINE: When does she stop?

11 THE COURT: That's sustained.

12 You're going to have your own
13 witnesses on all of this, aren't you?

14 MS. SULLIVAN: Yes, Your Honor.

15 But --

16 THE COURT: All right. Then please
17 restrict it to what the redirect was.

18 BY MS. SULLIVAN:

19 Q. And, Dr. Kessler, on the labeling front, you
20 know, sir, that the FDA does not agree with your
21 opinion?

22 MR. KLINE: Same objection.

23 THE COURT: All right. That's
24 sustained. It has been asked. It's not in
25 evidence in this case, and so it is

1 sustained.

2 MS. SULLIVAN: May I use the FDA
3 conclusion --

4 THE COURT: You're going to have your
5 own witnesses testify about what the FDA did
6 or did not do, so get it through them.

7 MS. SULLIVAN: Thank you.

8 No further questions, Your Honor.

9 THE WITNESS: Thank you,
10 Ms. Sullivan.

11 MR. KLINE: All right.

12 THE COURT: Anything else?

13 All right. Dr. Kessler, you've made
14 it. You've made it. Congratulations to you,
15 sir. And you are formally excused as soon as
16 you are ready. Thank you very much for being
17 in Philadelphia.

18 THE WITNESS: Thank you, Your Honor.

19 MR. KLINE: Thank you for coming,
20 sir.

21 (Witness left the stand.)

22 THE COURT: All right. Members of
23 the jury, we have accomplished something, so
24 we're going to rest right there, okay?

25 So we are going to take our

1 adjournment right here. It should give us
2 enough time to get up to the after-school.
3 And I am asking that that particular juror,
4 to please work on it as far as helping us out
5 to pick up, all right? So enough said for
6 that.

7 Please wear your yellow badges,
8 again, when you come in. Keep an open mind
9 in this case, obviously. Please do not talk
10 to anybody about this case, yourselves or
11 anybody else.

12 Again, a big reminder, not to conduct
13 your own investigation whatsoever on this
14 case, and also not to read or review any
15 media reports about this case, if there are
16 any, any newspapers, any radio, any magazines
17 any Internet coverage, anything at all,
18 television, anything at all, all right?

19 For all the reasons that I've said
20 before, which I'm not repeating now. It's
21 time to go home, all right?

22 So you are excused. We'll see you
23 tomorrow. Please try to come in at 9:15 and
24 we'll get started as soon as all of you are
25 here.

1 Okay. All right. Thank you,
2 everybody.

3 COURT CRIER: All rise as the jury
4 exits.

5 - - -

6 (Whereupon the jury exited the
7 courtroom at 4:29 p.m.)

8 - - -

9 THE COURT: All right. Let's close
10 the door.

11 - - -

12 (The following transpired in open
13 court outside the presence of the jury:)

14 - - -

15 THE COURT: And I just want to ask
16 counsel, when was your desire, Mr. Kline and
17 Mr. Gomez, to have Dr. Goldstein appear?

18 MR. KLINE: Tomorrow.

19 THE COURT: Okay. In that case,
20 we'll argue then the -- I'll hear argument.
21 I have reviewed the document, and I have
22 reviewed this situation involving this
23 defendant's motion to exclude testimony.
24 Well, what is the actual -- the new one is --
25 it's in the form of Defendants Janssen

1 Pharmaceuticals, Inc., Johnson & Johnson,
2 Janssen Research and Development, LLC, Bench
3 Memorandum Regarding the Inadmissibility of
4 Dr. Goldstein's Testimony.

5 So let me hear argument on this
6 briefly, and then we'll -- I'll see if I need
7 more time on this or not.

8 MR. MURPHY: Sure. Thank you, Your
9 Honor.

10 When we learned that there had been
11 an IME of the plaintiff, we then engaged an
12 endocrinologist to do the same. We engaged a
13 local endocrinologist, Dr. Vaughan.

14 THE COURT: Dr. Who?

15 MR. MURPHY: Dr. Vaughan. He is
16 someone who will be testifying in our case.

17 Dr. Vaughan is local, in Alabama. We
18 were aware of what the rules require in terms
19 of someone practicing in the locale. We have
20 an expert, Dr. Braunstein, from California
21 who has written both a general as well as a
22 specific causation report in this case. But
23 we knew we could not send Dr. Braunstein in
24 light of the rules that are in Alabama.
25 That's what we did.

1 Going forward --

2 THE COURT: Let me ask you a
3 question, Mr. Murphy.

4 MR. MURPHY: Yes. Sure.

5 THE COURT: I have reviewed the law
6 that was provided to me, and I've also
7 reviewed our own law, not to the extent about
8 admissions of licenses, but our own case
9 management system.

10 So, first of all, let me ask you
11 this: This seems to me to be in violation of
12 the case management order in this case. And
13 the question becomes for a court, trial
14 court, whether or not to enforce the case
15 management order that exists in these cases
16 or any case. And, you know, if you can tell
17 me how it is that this particular issue is
18 now raised for the first time on the eve,
19 when apparently this IME report was done --
20 the examination that's in question was done
21 on March 14th of 2014, and you did not
22 include this particular issue in a motion to
23 exclude that went before Judge New which was
24 filed on May 7th. And I want to know why you
25 did not include this issue at that time.

1 MR. MURPHY: Sure, Your Honor.

2 The issue that I raised with you this
3 morning, that is, the last-minute request to
4 have a de bene esse deposition of a causation
5 expert, the person who is saying that
6 Risperdal --

7 THE COURT: Is Dr. Goldstein coming
8 in live or --

9 MR. MURPHY: No, no, he is because in
10 light of your ruling.

11 THE COURT: Then, what does that have
12 to do with anything?

13 MR. MURPHY: What it has to do
14 with --

15 THE COURT: That was some kind of
16 effort, as I understood it, to conduct, at
17 your inconvenience, a videotape tonight. I
18 ruled against that. He's coming in.

19 MR. MURPHY: And I --

20 THE COURT: I'm asking you why this
21 issue, the so-called licensure issue, was not
22 included in the initial motion to exclude
23 expert testimony of Dr. Goldstein's decided
24 by Judge New before this trial -- it never
25 got to me -- when you knew at that time that

1 the alleged doctor, that Dr. Goldstein had
2 conducted his examination on March 4, 2014,
3 and the actual motion to exclude before Judge
4 New was not filed till after that, so you
5 knew about this issue.

6 MR. MURPHY: No, no. What I'm
7 telling you -- I'm answering your question as
8 to when it came to our attention and what
9 sparked it. It made absolutely no sense --

10 THE COURT: All right. All right.

11 MR. MURPHY: What I'm saying is, it
12 made absolutely no sense to say you want to
13 conduct a de bene esse. We then looked to
14 see, well, what could be the problem here?
15 Is there some issue?

16 We go. We say, is he in fact
17 admitted? Maybe he's not. Maybe that's the
18 issue. Are they going to provide us
19 anything?

20 THE COURT: I'm sorry. On those
21 grounds alone, I would deny this motion,
22 because, frankly, it's a violation of the
23 case management order. You knew of this
24 situation.

25 MR. MURPHY: No, I did not.

1 THE COURT: When was his document
2 actually provided?

3 MR. MURPHY: His report?

4 THE COURT: Yeah.

5 MR. MURPHY: He's got a report in --

6 MR. KLINE: And he was deposed. And
7 he was asked all about the exam at his
8 deposition.

9 MR. MURPHY: I'll give you the date.
10 His report is dated March 31st.

11 THE COURT: Of what year?

12 MR. MURPHY: 2014.

13 THE COURT: And your motion to
14 exclude in front of Judge New of the expert
15 testimony of David Goldstein was filed on
16 May 14, 2014. So you had this issue before
17 you filed it. You failed to include it, and
18 instead you wait till the eve of trial of a
19 witness. It is denied on those grounds.

20 But I will go to the merits also
21 because I have to say that I'm not an Alabama
22 judge, and therefore, we're going to follow
23 the rules of Pennsylvania in terms of this
24 evidence.

25 And the reality of the matter is if

1 Alabama wants to sanction Dr. Goldstein, they
2 may. All you have given to this Court is a
3 1998 informal opinion of a medical practice.
4 My prima facie reading of it is that this
5 particular doctor, in conducting this
6 independent medical examination, was not
7 practicing medicine even in Alabama; and if
8 he were, he was given up to ten days in
9 Alabama in order to be able to practice -- to
10 give this particular type of assistance to a
11 forensic situation as this.

12 So I'm not going to make any formal
13 ruling on Alabama law because it's not before
14 me. But I think this is a frivolous motion,
15 untimely, and I am not going to let this one
16 go if these type of motions keep on coming to
17 me right before testimony when it should have
18 been brought in front of Judge New who in
19 fact denied the motion to exclude
20 Dr. Goldstein's testimony.

21 MR. MURPHY: May I be heard?

22 THE COURT: Very briefly, Mr. Murphy.
23 You should know better. We're not going to
24 be intimidated, essentially, by having these
25 motions pop up on the eve of a trial of

1 cross-examination when there is a violation
2 of the case management order. There's a
3 violation of evidence. And on top of that,
4 on the merits it would appear to be a
5 frivolous motion.

6 MR. MURPHY: May I?

7 THE COURT: Yeah.

8 MR. MURPHY: Okay.

9 THE COURT: I mean, you can have
10 every right, by the way, to cross-examine
11 this witness as to where the examination took
12 place, under what circumstances, and all the
13 rest. That should be enough.

14 MR. MURPHY: I understand that, Your
15 Honor. The point of the matter is, I
16 explained to you what brought it to our
17 attention.

18 THE COURT: Okay.

19 MR. MURPHY: Okay. And this is not
20 the first time that there has been an
21 overlooking of a technical nicety. In this
22 case we've had a situation where the
23 guardianship and conservatorship was not in
24 place at the time it should have been. That
25 resulted -- that resulted in this trial being

1 adjourned for some period of time, okay?

2 What we looked --

3 MR. KLINE: That has nothing to do
4 with the --

5 MR. MURPHY: No. No.

6 THE COURT: Mr. Murphy, as I said, I
7 think I'm being very indulgent to you in even
8 considering this motion at this time. I do
9 have -- a motion in limine must be filed no
10 later than December 9th of 2014, signed by
11 Judge Arnold L. New, Jr., and that was dated
12 September 25th of 2014, well after you knew
13 that this particular Dr. Goldstein examined
14 this particular plaintiff in Alabama.

15 And with all due respect, I am
16 really, really not very pleased that this
17 Court is being subjected to these kinds of
18 last-minute motions in a trial of this nature
19 where you've all been working this case for
20 years and years and years.

21 Anything else?

22 MR. KLINE: Yes. Here's the problem
23 I have, Your Honor, and I have what I believe
24 is a significant problem which I'd like to
25 raise with the Court about Dr. Goldstein:

1 Dr. Goldstein was here last week, so the
2 Court knows. He hung around here all week.
3 He came a day early because he wanted to beat
4 the snow in. He didn't get on because
5 Dr. Kessler's testimony went on forever.

6 We had some discussions with him and
7 we said, you know what, we'll get you in and
8 out, and so we did -- we arranged for the de
9 bene esse. I understand the Court's point
10 and I get it. But that was what that was all
11 about. I knew nothing about this.

12 On the other hand, on the other hand,
13 and this goes to the chilling of testimony.
14 Hear me for just a moment, please. They
15 claim to have gotten Dr. Vaughan, and he
16 examined this patient on April the 25th of
17 2014, because they believe there were
18 "criminal ramifications" if he were
19 to examine -- if Dr. Braunstein, their
20 Hollywood, California expert, were to come to
21 Alabama and do it. They don't say anything
22 to us, okay? They don't say anything to
23 anybody. They take Dr. Goldstein's
24 deposition. They don't say anything there.

25 Long after they say that they believe

1 that a crime was committed.

2 Now -- and they do say, they do say
3 that it's a crime and that it could be
4 punishable in Alabama up to ten years in
5 jail.

6 Now, I have a witness coming in here
7 tomorrow, okay, totally chilled under these
8 circumstances. I have to tell him -- I have
9 to tell this man who, by the way, is a
10 50-year practicing endocrinologist. And I
11 might vouch for him in this way, not his
12 credentials: A nice and good, decent man.
13 I've spent a number of hours with him, okay?

14 Now, I have to go back and tell him
15 that these people from -- the good people
16 from Janssen, as they call themselves, the
17 good people from Janssen believed for a year
18 that you've committed a crime. Sir, I can
19 tell you, I'm not an Alabama practitioner; I
20 couldn't in a million years believe it. I
21 can't give you advice. I'm not a criminal
22 lawyer in Alabama, and --

23 THE COURT: I haven't read the
24 criminal statute, by the way.

25 MR. KLINE: Well, I've looked at it.

1 THE COURT: You talking about Alabama
2 code?

3 MR. KLINE: There's an Alabama code
4 and there's an informal opinion.

5 THE COURT: I've read that. I read
6 that, yes.

7 MR. KLINE: But the Alabama code has
8 a -- there's an issue which in order for this
9 man to get further involved, if I were him, I
10 would want counsel.

11 Now --

12 THE COURT: Well, you don't have to
13 put him on tomorrow. You can wait.

14 MR. KLINE: There's another solution
15 to it, by the way.

16 And that's why I wanted to get this
17 before Your Honor earlier. A solution -- a
18 solution to this since they think that
19 they're on to something which they -- by the
20 way, they were literally aiding and abetting
21 supposedly what they now call a crime because
22 they knew and I didn't. But what I suggest
23 is a potential solution.

24 First of all, I want to go and talk
25 to Dr. Goldstein. I have to. He's not my

1 client, so I can't give him legal advice. I
2 have a very serious problem here. And what
3 I'd like to do is try to figure it out. Try
4 to get him some -- try to get some advice.
5 And in the meantime, I have at least
6 considered getting somebody else, flying
7 Austin up here very quickly.

8 Oh, that gets them on their feet
9 quickly.

10 MS. SULLIVAN: No.

11 MR. KLINE: Having a report in a day
12 maybe, something like that. There are
13 experts locally who have cooperated with us
14 in the Risperdal litigation, and solving this
15 whole problem.

16 Your Honor, I don't want to put a man
17 who's devoted his life to practicing medicine
18 who's 71 or 72 years old to -- to being
19 chased around by the Alabama Attorney General
20 due to their malfeasance. And I really would
21 like to just try to work through the issue.

22 So one of the things that I'd like to
23 do -- and I don't have the answers yet, but I
24 certainly know, I believe, as a long-time
25 practicing lawyer, what some of the issues

1 are here. And what the issues are is I have
2 to go back and talk to a man who's not my
3 client and if I were him, I would tell him
4 you got to get counsel because I can't advise
5 you.

6 And one way through the whole thing
7 is, by the way, let this case go forward,
8 I'll fly Austin up here. By the way, I can
9 represent to you that Philip Pledger,
10 Austin's father, can get on a 6:30 plane
11 tonight. We can get -- they're literally on
12 standby. I'll get him up here. I'll get
13 them in the hands of a pediatric
14 endocrinologist up here or a pediatric -- or
15 a plastic surgeon.

16 By the way, both of whom they've
17 deposed because this litigation has a million
18 tentacles. That won't surprise you. There
19 will be no surprise. And we'll give you a
20 report and we'll go on.

21 This is simply -- this is on its face
22 a simple matter. This is somebody has to
23 come in and say Risperdal is a substantial
24 contributing factor in this boy's injury.
25 It's all in the, by the way, in my view

1 anyway, "duh" category. They themselves --
2 "duh" meaning it's obvious -- they themselves
3 have an expert witness.

4 THE COURT: You mean obvious that
5 this is not practicing medicine?

6 MR. KLINE: No, no, no, no, no. That
7 part I can't vouch for.

8 THE COURT: Right.

9 MR. KLINE: I'm not an Alabama
10 lawyer --

11 THE COURT: I'm not an Alabama judge
12 for sure.

13 MR. KLINE: -- let alone an Alabama
14 criminal lawyer.

15 THE COURT: You're right. You're
16 right.

17 MR. KLINE: But I can tell you one
18 thing, that that's one way through it.

19 What I can't tell the Court and the
20 bind that I'm in based on their conduct, not
21 mine --

22 THE COURT: All right.

23 MR. KLINE: -- they're holding this
24 for a year.

25 THE COURT: All right, Mr. Kline.

1 MR. KLINE: A year.

2 THE COURT: Well, I've already made
3 my point, which is that this is an untimely
4 motion. It is precisely the reason why these
5 particular case management orders are in
6 effect, is to prevent this kind of unfair
7 surprise at the moment of a witness's
8 appearance. I've already established --

9 MR. KLINE: I need a remedy.

10 THE COURT: Excuse me. I've already
11 established on the record that the conduct or
12 the alleged conduct of this particular
13 witness as regards to Alabama and Alabama law
14 was known to the witness -- to the
15 plaintiff -- defendant before the filing of a
16 motion. And so I see this as really a
17 tactical measure by the defense in order to
18 cause some kind of unfair surprise. And for
19 that reason I will in fact permit a new
20 report or a new IME. If we have a patient --
21 a live witness that can come up to
22 Philadelphia and show the jury in certain
23 types of in-camera situations what it is that
24 he has, that will be permitted. Or if we can
25 have a doctor conduct another investigation

1 over the next week or so, that will be
2 permitted.

3 I am not going to permit a defense
4 from this kind of misconduct.

5 MS. SULLIVAN: Here's the issue, Your
6 Honor: We knew -- we knew about this --
7 they're lawyers, too, Judge. There's a
8 statute in Alabama. We had to go out of our
9 way to get a local guy that we didn't want --

10 THE COURT: I don't know. You
11 haven't cited to me a single case on this
12 particular situation involving expert
13 testimony for a court.

14 MS. SULLIVAN: Your Honor --

15 THE COURT: If you had something to
16 work with since -- Mr. Kline is right. We
17 don't want his witness to be a guinea pig
18 necessarily for this kind of a litigation.

19 MS. SULLIVAN: But here's the
20 prejudice, Your Honor, because we followed
21 the law --

22 THE COURT: If you had filed this
23 back in April --

24 MS. SULLIVAN: Your Honor, we didn't
25 know -- we assume they had a letter from an

1 Alabama doctor.

2 THE COURT: The problem here,
3 Ms. Sullivan, is you had your own witness as
4 early as April of 2014.

5 MS. SULLIVAN: And we thought that
6 they complied with the statute. All that
7 required was that they had a consult with an
8 Alabama doctor. When they did the de bene
9 esse, we were like, oh, my God, maybe they
10 didn't.

11 THE COURT: Again, I don't see it --
12 I see it as unfair surprise that is being
13 launched here the night before.

14 MS. SULLIVAN: Your Honor, because
15 they violated the law, you're going to put
16 us --

17 THE COURT: I don't know whether they
18 violated the law. There's been no
19 adjudication about that.

20 I do know that you're violating this
21 Court's case management order, that much I do
22 know.

23 MS. SULLIVAN: Well, Your Honor, it
24 didn't come to our attention --

25 THE COURT: It may not have the force

1 of law, but it has the -- it actually is the
2 law in this case.

3 MS. SULLIVAN: But, Your Honor, it
4 didn't come to our attention until the de
5 bene esse.

6 THE COURT: All right. I understand
7 your position. That is denied as far as this
8 motion is concerned.

9 MS. SULLIVAN: But the defense has
10 framed their entire case --

11 THE COURT: Mr. Kline has raised a
12 good point. That has to do with
13 consideration of Dr. Goldstein's own legal
14 position, and therefore, if I'm told that he
15 may not or will not testify, I am going to
16 give Mr. Kline and the plaintiff a remedy.

17 MS. SULLIVAN: Your Honor, we have
18 framed our entire defense -- we opened based
19 on Dr. Goldstein's report and his opinions in
20 this case. To now change the case because
21 their expert violated the law is completely
22 prejudicial and unfair to us.

23 MR. MURPHY: And the suggestion --

24 THE COURT: Well, frankly, if you had
25 brought --

1 MS. SULLIVAN: We did nothing wrong.
2 We didn't know about it.

3 THE COURT: Frankly, if you had
4 brought this particular issue ahead of
5 time --

6 MS. SULLIVAN: We didn't know about
7 it.

8 THE COURT: You had known about it at
9 the time you filed the motions in limine
10 before trial so that you wouldn't have been
11 prejudiced with your opening arguments. You
12 just didn't play it that way, Ms. Sullivan,
13 or Mr. Murphy.

14 MS. SULLIVAN: No.

15 THE COURT: And I'm not going to
16 permit that kind of unfair surprise in any
17 case, let alone in this one in which we have
18 a doctor who apparently needs to be advised
19 about what his legal position is regarding
20 some conduct in Alabama.

21 MR. MURPHY: And, Your Honor, I hear
22 you. I hear you, and I understand you. But
23 I have to say on the record and make it
24 abundantly clear that we did not know. And
25 what you're saying --

1 THE COURT: You didn't know till
2 today?

3 MR. MURPHY: We did not know that --

4 THE COURT: What are you telling me?

5 MR. KLINE: They told me --

6 COURT REPORTER: One at a time.

7 MR. MURPHY: What I'm telling you is
8 I did not know, we did not know that they had
9 not crossed the box; that they had not in
10 fact either gotten a local physician to
11 comply with him -- to consult with him.

12 MR. KLINE: When was his deposition?

13 THE COURT: Frankly, unless you're
14 telling me that the testimony itself is
15 incompetent to be heard in this courtroom, I
16 don't really care.

17 In other words, that is a matter
18 between Mr. Kline and his witness. It's not
19 a matter for you. If you're telling me his
20 testimony is incompetent because he may have
21 violated some technical situation in Alabama,
22 that's something I care about.

23 MR. MURPHY: Well, that is the very
24 point.

25 THE COURT: Well, show me something

1 where that is an actual -- something that
2 binds this Court on whether or not to accept
3 an expert opinion from Dr. Goldstein because
4 of some kind of Alabama situation that none
5 of you have ever litigated or will litigate
6 apparently.

7 MR. MURPHY: Well, no. I've never
8 litigated it, but here's the point, and
9 please appreciate it: The very underpinning
10 of his opinion, okay, is based upon an
11 illegal and invalid --

12 THE COURT: If you tell me -- if you
13 show me or give to me some kind of legal
14 argument that is legal; in other words, that
15 is telling me that his testimony is
16 incompetent and must be stricken. Let's say
17 he testified now, are you telling me that
18 there's some kind of violation or some kind
19 of rule that hasn't been litigated before and
20 you're telling me that I must strike it, then
21 I would. But right now you're not giving me
22 anything other than something that it seems
23 like if there's a problem down in Alabama
24 that we didn't know about till the eve of
25 trial, then all of a sudden, it's not

1 admissible here, I don't know. Show me
2 something.

3 MR. MURPHY: If the very basis for
4 his opinion rests on an act that was invalid
5 and illegal, how can that be --

6 THE COURT: Well, you show me.

7 MR. MURPHY: Just hear me out.

8 THE COURT: Mr. Murphy --

9 MR. MURPHY: How can that be injected
10 in a civil proceeding?

11 THE COURT: You show me. You show
12 me.

13 MR. MURPHY: Okay. Understanding my
14 argument, if you choose to disagree with me,
15 fine. But I --

16 THE COURT: I don't choose to do
17 anything.

18 MR. MURPHY: But I need you to
19 understand --

20 THE COURT: I am ruling -- I am
21 ruling this particular motion denied on the
22 basis of untimeliness. That's it.

23 MR. MURPHY: Fair enough.

24 But I needed you to understand the
25 basis for the motion.

1 THE COURT: I understand your basis,
2 and we'll carry on.

3 My suggestion is that if Mr. Kline
4 believes through his witness that his witness
5 may have violated a statute that could put
6 him at some kind of risk down there, whatever
7 his situation is, I will give the plaintiff
8 the opportunity to have a new IME produced
9 because of the untimeliness of your motion.

10 MS. SULLIVAN: Then we move --

11 MR. KLINE: Okay. Thank you.

12 THE COURT: But that's it. We are
13 out of here.

14 MR. KLINE: Thank you.

15 MS. SULLIVAN: Then, Your Honor, we
16 would move for a mistrial, because that
17 changes the entire case. We defended based
18 on Dr. Goldstein's report. We learned that
19 he didn't consult with an Alabama expert when
20 they pulled this de bene esse thing.

21 THE COURT: No, no, no, no. You were
22 responding to Dr. Goldstein's report in your
23 opening without anything having to do with
24 Alabama, I think.

25 MS. SULLIVAN: I opened that he was

1 not licensed in Alabama, Your Honor. I
2 opened.

3 THE COURT: Fine, not licensed in
4 Alabama. That does not mean that, you know,
5 that his testimony in this Court is stricken.
6 If you're moving for a mistrial, say so.

7 MS. SULLIVAN: Only if you're
8 switching -- if you're going to permit them
9 to switch experts at this late date --

10 THE COURT: I don't know. At this
11 point, at this point that is premature
12 because Mr. Kline and his team have not --

13 MS. SULLIVAN: Okay. Then I'll
14 reserve my motion.

15 THE COURT: I personally don't
16 believe it's an issue for this gentleman
17 because I have reviewed the law myself, and I
18 don't believe he was practicing medicine in
19 Alabama. And then the other reason for that
20 belief is that if he were there, there is an
21 exception in the Alabama code that permits a
22 nonlicensed doctor to practice for up to ten
23 days.

24 So if his examination was less than
25 ten days, he should be comfortable in terms

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of his own legal position in Alabama.

MR. MURPHY: When consulting with a state licensed doctor.

THE COURT: I don't know about that.

MR. MURPHY: It's in the statute.

THE COURT: Again, you're leaping to conclusions, and therefore -- but my ruling at the moment solely is that this particular motion to exclude Dr. Goldstein's testimony is denied for untimeliness.

All right. So we will return tomorrow at 9:30.

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(Court adjourned at 4:52 p.m.)