

In The Matter Of:

Pledger v.

Janssen

(Jury Trial-AM Session)

XII

February 10, 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
3 CIVIL TRIAL DIVISION
4 -----
5 IN RE: RISPERDAL® LITIGATION :
6 March Term, 2010, No. 296 :
7 Phillip Pledger, et al., :
8 Plaintiffs, : APRIL TERM, 2012
9 v. : NO. 01997
10 Janssen Pharmaceuticals, Inc., :
11 Johnson & Johnson Company, :
12 and Janssen Pharmaceutical :
13 Research & Development, :
14 L.L.C. :
15 Defendants. :
16 -----
17
18 TUESDAY, FEBRUARY 10, 2015
19
20 COURTROOM 425
21 CITY HALL
22 PHILADELPHIA, PENNSYLVANIA
23
24
25 B E F O R E: THE HONORABLE RAMY I. DJERASSI, J.,
and a Jury

JURY TRIAL - VOLUME XII
- MORNING SESSION - (AMENDED)

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

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1 - I N D E X -
2 WITNESSES DIRECT CROSS
3 LODEWIJK IVO CAERS, Ph.D.
4 By Ms. Sullivan 9 --
5 By Mr. Kline -- --
6
7
8
9 E X H I B I T S
10 NO. PAGE NO.
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1 (The following transpired in open
 2 court outside the presence of the jury:)
 3 **COURT CRIER:** All rise.
 4 (Call to order at 9:37 a.m.)
 5 **THE COURT:** Good morning, everybody.
 6 **MR. KLINE:** Good morning.
 7 **THE COURT:** Virtually bright and
 8 early.
 9 Okay. Yes, sir.
 10 You can be seated, everybody.
 11 **MR. MURPHY:** Your Honor, I just have
 12 a brief motion before we begin as to
 13 defendant Johnson & Johnson.
 14 **THE COURT:** Yes.
 15 **MR. MURPHY:** We move for a compulsory
 16 nonsuit as to Johnson & Johnson. The
 17 evidence presented by the plaintiff did not
 18 in any way implicate Johnson & Johnson as a
 19 manufacturer, distributor, or a marketer of
 20 the drug in question, Risperdal. It's beyond
 21 question that Johnson & Johnson is but a
 22 holding company. There's no evidence that's
 23 been presented by plaintiff that would allow
 24 them to pierce the corporate veil, as it
 25 were.

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1 We're not granting a nonsuit on that basis.
 2 **MR. MURPHY:** Understood. I
 3 understand your ruling, Your Honor.
 4 **THE COURT:** All right. Let's get the
 5 jury in here.
 6 All right. I don't know whether you
 7 have the memorandum ready now or sometime
 8 later in the day.
 9 There were two issues that were held
 10 under advisement on the directed verdict
 11 motion. I don't plan on reading it on the
 12 fly today, but if it's available sometime
 13 today, I would be happy to read it.
 14 **MR. KLINE:** I don't believe I've seen
 15 it yet; is that correct?
 16 **MS. SULLIVAN:** It's on its way, Your
 17 Honor.
 18 **THE COURT:** Okay. No rush. Take the
 19 pressure off.
 20 - - -
 21 (Pause.)
 22 - - -
 23 **COURT CRIER:** All rise.
 24 (Whereupon the jury entered the
 25 courtroom at 9:42 a.m.)

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1 The only evidence regarding Johnson &
 2 Johnson that was provided to this Court was a
 3 LinkedIn page by the sales representative,
 4 Mr. Gilbreath, who in fact was employed by
 5 Janssen. There being no evidence as to
 6 Johnson & Johnson, we would move that --
 7 **THE COURT:** Well, is Johnson &
 8 Johnson a different party from any of the
 9 other parties, or are they the same? I'm
 10 talking about Johnson & Johnson versus
 11 Janssen Pharmaceutica.
 12 **MR. MURPHY:** A different company
 13 totally. It is a mere holding company.
 14 **THE COURT:** Ah, I see.
 15 Well, you know what, that's denied.
 16 We will cross that bridge when we get to it
 17 as far as the -- I mean, it's been pretty
 18 clear that the label involved in this case
 19 and the company that manufactured this was
 20 either Johnson & Johnson and/or Janssen
 21 Pharmaceutica. That was testified to by
 22 multiple witnesses in this case, ranging from
 23 Dr. Gilbreath to Dr. Mathisen to Dr.
 24 Kessler.
 25 So the record will speak for itself.

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1 (The following transpired in open
 2 court in the presence of the jury:)
 3 - - -
 4 **THE COURT:** All right. Good morning.
 5 Please be seated.
 6 **JURY PANEL:** Good morning.
 7 **THE COURT:** Good morning, everybody.
 8 All right. Now, members of the jury,
 9 as I told you yesterday, the plaintiff's side
 10 has rested and so now we are going to begin
 11 the testimony and evidence of the defense in
 12 this case, and for that purpose, I ask
 13 Ms. Sullivan to call your first witness when
 14 you're ready.
 15 **MS. SULLIVAN:** Thank you, Your Honor.
 16 Good morning.
 17 **THE COURT:** Good morning.
 18 **MS. SULLIVAN:** The defense calls as
 19 their first witness Dr. Ivo Caers.
 20 Dr. Caers, if you could take the
 21 witness stand.
 22 (Witness took the stand.)
 23 **COURT CRIER:** Just remain standing.
 24 Please state your name for the record and
 25 spell it.

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1 **THE WITNESS:** My name is Lodewijk Ivo
2 Caers, but my call name is "Ivo."
3 **COURT CRIER:** Can you spell that,
4 please.
5 **THE WITNESS:** L-O-D-E-W-I-J-K, I-V-O,
6 C-A-E-R-S. I'm a Ph.D.
7 **COURT CRIER:** And raising your right
8 hand.
9 - - -
10 ... LODEWIJK IVO CAERS, Ph.D., after
11 having been first duly sworn, was examined
12 and testified as follows:
13 - - -
14 DEFENDANT'S EVIDENCE
15 - - -
16 **DIRECT EXAMINATION**
17 - - -
18 **BY MS. SULLIVAN:**
19 **Q. Good morning, Dr. Caers.**
20 A. Good morning.
21 **Q. Good morning, everyone.**
22 **Dr. Caers, could you introduce**
23 **yourself to our jurors; tell them who you are and**
24 **where you work.**
25 A. Well, as I told, I'm Ivo Caers. I'm a

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1 scientist working with Janssen Research and
2 Development. I'm actually living -- I was born in
3 Belgium. I'm actually living in Belgium with my
4 family in a small town, Beerse, somewhere in the
5 north of Belgium, in Europe, middle Europe. And I'm
6 still working there daily, on a daily basis.
7 **Q. I think our jurors could tell it wasn't a**
8 **Philadelphia accent.**
9 A. I'm afraid not, no. But I'll improve on that
10 during the day.
11 **Q. And, Dr. Caers, for how long have you been at**
12 **Janssen Pharmaceuticals?**
13 A. More than 35 years. I've been working for
14 Janssen R & D for more than 35 years now.
15 **Q. And can you tell us a little bit about your**
16 **educational background.**
17 A. I studied -- I have a Master degree in
18 biology, which I did at the University of Leuven in
19 central Belgium. And the after that I did doctoral
20 work, Ph.D., as we call it, in biochemistry, which
21 I've terminated and completed in, I think,
22 April 1979.
23 **Q. And can you just walk us briefly through your**
24 **career experience at Janssen. What did you do when**
25 **you started back in 1979? And take our way through**

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1 **your career there, briefly.**
2 A. Sure.
3 In May 1979, I actually started in a
4 local operating company, Janssen the Netherlands.
5 So the Netherlands are just north of Belgium. And I
6 was there in a product development position and
7 product management position for three years, up to
8 1982.
9 In 1982 -- always based in Beerse,
10 Belgium. And in 1982, I switched to the clinical
11 research group and did clinical studies in various
12 domains: neurology, oncology, cardiovascular. I did
13 that for five years about. Then later in 1987,
14 about, I switched to what we called at that moment
15 global studies in marketing, which is a commercial
16 position, but more on strategic directions for drug
17 development and line extension, so additional
18 formulation development.
19 And during that time I also became
20 available for the psychiatry products, including
21 Risperdal. So me and my team, we did the global
22 launch of Risperdal back in 1992, '93. And we are
23 driving strategic directions for the compound up
24 to -- and I've been doing that for up to 1999, when
25 I switched again to the Janssen R & D organization.

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1 **Q. And R & D, Dr. Caers -- I'm sorry to**
2 **interrupt -- is research and development?**
3 A. Yes. Janssen R & D, yes, Research and
4 Development.
5 So back in mid-1999, I was asked to
6 become the team leader for Janssen R & D for
7 Risperdal. And I have been doing that from 1999 up
8 to 2009. After which, since then, I'm doing all the
9 developments within Janssen R & D in other
10 psychiatry products.
11 **Q. And, Dr. Caers, we're going to talk about**
12 **Risperdal and its development by Janssen. But**
13 **first, can you give our jurors some background about**
14 **your experience in drug development, in the**
15 **discovery and development of medicines.**
16 A. Well, you will understand in 35 years I've
17 gone several times through the whole life cycle of
18 the product. I've most -- I'm most familiar with
19 Risperdal from the early days on up to 2009, as I
20 said earlier. But I also been involved in
21 developments in psychiatry, in the compounds for
22 attention deficit hyperactivity disorders. I've
23 been dealing with compounds in depression. I'm
24 actually now still a compound development team
25 leader for the depression compound. But as I said

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1 earlier as well, I've started up new compounds that
 2 first we didn't make it because of efficacy or
 3 safety issues. So I'm pretty familiar with the
 4 first step, up to launch and beyond.
 5 **Q. And, Dr. Caers, Janssen Pharmaceuticals, when**
 6 **did that company become part of the Johnson &**
 7 **Johnson family of companies?**
 8 A. It was back in 1962, even before my time, that
 9 the company which was at that time also already
 10 based in Beerse, so it was north of Belgium where it
 11 still is, where that company was bought by Johnson &
 12 Johnson. And since then, Janssen Pharmaceutica is a
 13 member of the companies of Johnson & Johnson.
 14 **Q. And is Janssen named after somebody?**
 15 A. Yes, indeed. The company, the Janssen company
 16 was founded by Dr. Paul Janssen. Dr. Paul Janssen
 17 was a scientist in Belgium, grew up in Belgium, is
 18 from the region. And back in the early '50s, 1953,
 19 I guess, he started up his own lab looking and
 20 trying to invent new and better medicines; and he
 21 had been very successful, by the way. He has -- all
 22 of his career, he is the inventor of up to 80,
 23 eight-zero, new drugs for different areas of
 24 medicine. And that's why obviously, as I told
 25 earlier, back in 1962, that this company came under

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1 the attention of Johnson & Johnson as a very
 2 productive laboratory and very successful laboratory
 3 and as an interesting company to join Johnson &
 4 Johnson.
 5 **Q. And, Dr. Caers, did you personally have the**
 6 **opportunity to work with Dr. Paul Janssen?**
 7 A. Oh, yes, very, very closely. I was actually
 8 sitting on the same floor when I was in clinical
 9 research; and my boss reported directly to Dr. Paul
 10 Janssen.
 11 **Q. And, Dr. Caers, we're going to talk a little**
 12 **bit about how to develop a medicine and then talk**
 13 **about Risperdal. And you've been involved in**
 14 **discovery and development of medicines including**
 15 **Risperdal?**
 16 A. Yes, indeed, yeah.
 17 **Q. And we have just as a demonstrative Defense**
 18 **Exhibit -- Ms. Brown, can tell me?**
 19 **MS. BROWN:** Yes; 54.
 20 **MS. SULLIVAN:** And, Lamia, it's
 21 DG10.3.
 22 **MR. KLINE:** I'll need to see it.
 23 **THE COURT:** What is this now?
 24 **COURT CRIER:** This would be D-54,
 25 Your Honor.

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1 **THE COURT:** D-54.
 2 (Whereupon Exhibit D-54 was marked
 3 for identification.)
 4 **MR. KLINE:** I haven't seen this.
 5 (Handing document to the witness.)
 6 **THE COURT:** Counsel, I still -- I am
 7 going to ask that we follow the --
 8 **MS. SULLIVAN:** Oh, you can take it
 9 down.
 10 Yeah. I'm sorry. I didn't realize
 11 that they put it up, Judge.
 12 **THE COURT:** D-54.
 13 **MR. KLINE:** I've never seen it, Your
 14 Honor. And it was not produced.
 15 **THE COURT:** Okay.
 16 **MS. SULLIVAN:** It's a demonstrative.
 17 It's a timeline. I don't think it's
 18 controversial.
 19 **MR. KLINE:** I have to see it first.
 20 **MS. SULLIVAN:** I'll give them
 21 Dr. Caers' copy.
 22 **COURT CRIER:** Let me run that off.
 23 **MS. SULLIVAN:** That's okay.
 24 **COURT CRIER:** The Judge needs one and
 25 counsel. Thank you.

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1 **MR. KLINE:** Whether controversial or
 2 not, Your Honor, I object to the procedure.
 3 **THE COURT:** All right. Mr. Kline,
 4 I'm going to ask you to speak into the
 5 microphone.
 6 **MR. KLINE:** Yes. I object to the
 7 procedure. I'll look at the document, but we
 8 had an agreement to exchange all documents.
 9 Now it's, quote, just a
 10 demonstrative.
 11 **THE COURT:** Well, right now we're on
 12 court time here.
 13 **MR. KLINE:** I understand.
 14 **THE COURT:** We're going to proceed
 15 with this document one at a time.
 16 **MR. KLINE:** I understand. I need to
 17 see it. I still haven't seen it.
 18 **THE COURT:** Any objection?
 19 **MR. KLINE:** Other than the one I
 20 raised, no, Your Honor.
 21 **THE COURT:** No. It's all right.
 22 This is a demonstrative piece -- something to
 23 help explain something to the jury. It's
 24 okay.
 25 Go ahead.

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1 MS. SULLIVAN: Thank you, Your Honor.
 2 COURT CRIER: D-54 to the witness.
 3 MS. SULLIVAN: Ken, can we put it up?
 4 (Document D-54 displayed.)
 5 BY MS. SULLIVAN:
 6 Q. And, Dr. Caers, can you walk our jurors
 7 through the process of discovery and developing a
 8 medicine in accordance with the FDA -- by the way,
 9 Dr. Caers, are you familiar with the FDA regulatory
 10 scheme as it relates to the development and labeling
 11 of medicines?
 12 A. Yes, very much so, yeah.
 13 Q. And is that something you deal with regularly
 14 in your job?
 15 THE COURT: You know what, before we
 16 proceed, are we proceeding as an expert
 17 witness here or a fact witness? What is
 18 this?
 19 MS. SULLIVAN: He's a fact witness,
 20 Your Honor, but he certainly has expertise in
 21 these areas.
 22 THE COURT: Well, is he going to be
 23 offering an opinion of some sort?
 24 MS. SULLIVAN: He's -- no. Factual
 25 testimony, Your Honor.

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1 THE COURT: All right. Go ahead.
 2 BY MS. SULLIVAN:
 3 Q. And, Dr. Caers, can you walk us through --
 4 just to back up.
 5 Dr. Caers, how hard is it to get a
 6 medicine approved by the FDA?
 7 A. Well, in all fairness, it's pretty hard, and I
 8 will explain to you why.
 9 The whole process starts on the
 10 left-hand side. So the start is, you need to have
 11 an ID. So you have an ID that if you have a
 12 molecule that acts --
 13 Q. Is that "idea"?
 14 A. Say again.
 15 Q. Did you say you need an "idea"?
 16 A. You need an "ID," a hypothesis. And that
 17 tells you if I would have a molecule that has a
 18 certain activity, that may well be active in a
 19 certain disease area. So what you need on the
 20 left-hand side is a test and you need molecules.
 21 And we start making hundreds of molecules and we
 22 test them all in the lab to see whether this
 23 molecule may have had some activity that we want and
 24 that it is sufficiently powerful, this activity.
 25 Out of a couple hundred, you may

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1 select a couple, 10, 15, and you test them, and the
 2 next step is in animal models. You have a model
 3 where you can check whether indeed in living animals
 4 this molecule does what we hope to do; and,
 5 secondly, you check whether the safety, at least in
 6 animals, is good enough to go to the next step.
 7 Q. And so, Dr. Caers, so that test tube, that
 8 relates to just trying to test and discover
 9 molecules in the laboratory?
 10 A. That is correct.
 11 Q. And is it true that most medicines never get
 12 approved by the FDA?
 13 A. Well, as you can see, we start with a couple
 14 of hundreds. We selected a few tens, maximum, if
 15 not less, for testing in animals. Very few make it
 16 to the next step. And the next step is what we call
 17 Phase I studies. And that's the first time we give
 18 the molecule to a human subject.
 19 Q. And do you need FDA approval before you can
 20 start testing a medicine in people?
 21 A. If you want to do this in the US, you need to
 22 have an FDA approval. If you want to do it in other
 23 countries, you need to have other regulatory
 24 agencies' approval. Not an approval, an agreement.
 25 We talked -- well, don't mix it up with the final

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1 approval at the end of the whole development.
 2 Q. Yes. In other words, you need permission from
 3 the FDA before you can even test it?
 4 MR. KLINE: No. Objection. That is
 5 not what he said. Objection; and she's
 6 leading.
 7 THE COURT: All right. Sustained.
 8 BY MS. SULLIVAN:
 9 Q. Dr. Caers, do you need permission from the FDA
 10 before you can test in patients?
 11 MR. KLINE: Objection; asked and
 12 answered.
 13 THE COURT: All right. That has been
 14 answered.
 15 So in the interest of time, you know,
 16 if you got your answer, let's get another new
 17 subject or new -- you know. We don't have to
 18 repeat everything.
 19 BY MS. SULLIVAN:
 20 Q. Dr. Caers, can you walk us through what the
 21 company looks for -- and, by the way, when companies
 22 test their medicines in patients, how is that done?
 23 Is that done by outside doctors?
 24 A. Yes. So once we are beyond the human
 25 volunteers in Phase I and we still have a molecule

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1 that shows safety and is pretty well-tolerated in
 2 non-ill subjects, you go to the next phase, which we
 3 call Phase II, where you do your first evaluation of
 4 efficacy. And here you use -- you need patients and
 5 you need investigators, clinical centers that have
 6 those patients, because we don't have patients.
 7 Patients don't come to us. They come to doctors.
 8 And we ask the doctors to do a certain study. And
 9 in this case we are in Phase II. The objective of
 10 that study is how is that efficacy as we hope that
 11 to be and is it pretty well-tolerated in the limited
 12 number of patients that we include in Phase II
 13 studies.
 14 **Q. And do these outside doctors and the company**
 15 **need informed consent from patients to participate**
 16 **in these studies?**
 17 A. Yes, absolutely. There is -- first of all,
 18 there's a protocol and the protocol describes from A
 19 to Z what the study is, what is the objective of the
 20 study, how it will be done, what type of patients
 21 you need, what type of patients you should not
 22 include, what should you assess for efficacy and
 23 safety. And there's always an informed consent.
 24 And what is an informed consent?
 25 That is a short description in language that every

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1 patient can understand that explains what the study
 2 is all about; what are the potential risks; what is
 3 known about the product. And only once the patient
 4 has signed and agreed that he has understood it and
 5 he agrees to enter the study, the physician and the
 6 investigator can enter that patient in the study.
 7 **Q. And what sort -- and so in these clinical**
 8 **trials -- and is that what they call clinical trials**
 9 **when you're testing it in patients?**
 10 A. That is correct.
 11 **Q. And in these clinical trials, what are the**
 12 **kinds of things the company and these outside**
 13 **doctors are looking for in terms of safety issues in**
 14 **patients?**
 15 A. Oh, always in clinical studies you have a
 16 range of safety assessments. You have blood level
 17 assessments. You have EKGs to test the safety on
 18 the heart. You also collect adverse events. Every
 19 adverse event reported or noticed with the patient
 20 is written down by the investigator. You may also
 21 have certain assessment skills that you follow a
 22 certain structured interview to assess certain
 23 particular elements for safety. And that is all
 24 written down per the individual patient in a patient
 25 record form.

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1 **Q. And, Dr. Caers, this testing in patients, do**
 2 **you look at the impact the medicine has on various**
 3 **systems in the body, blood, heart, lungs?**
 4 A. Yes, indeed, yes.
 5 **Q. And, in other words, are you examining, as**
 6 **you're doing these clinical trials, how the medicine**
 7 **affects the body?**
 8 A. To a certain extent, to a certain extent that
 9 it is possible to do so, yeah.
 10 **Q. And as you're going through these clinical**
 11 **trials, Dr. Caers, is the company collecting data,**
 12 **collecting information about side effects?**
 13 A. Collecting -- we are collecting information on
 14 all adverse events, side effects, safety assessment
 15 and efficacy assessments, yes.
 16 **Q. And is that side effect information that's**
 17 **being collected by the company from these outside**
 18 **doctors, does the company report that information to**
 19 **the FDA?**
 20 **MR. KLINE:** Your Honor, objection;
 21 leading. He's just saying "yes" or "no."
 22 And this isn't testimony.
 23 **THE COURT:** Yes. I'll sustain that.
 24 Also, you know, again, unless it's a
 25 very important aspect of this entire case,

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1 these things can be summarized in a few
 2 minutes.
 3 **MS. SULLIVAN:** Yeah.
 4 **BY MS. SULLIVAN:**
 5 **Q. And, Dr. Caers, why don't you talk to our**
 6 **jurors about what information the FDA has given**
 7 **along the way in terms of the clinical trials.**
 8 A. Okay. Of every single study, once the study
 9 is complete, the last patient has completed the
 10 study, then all the data are collected and brought
 11 together in one single database. And at a certain
 12 moment when we have all the information available,
 13 then we close the database. That means all of the
 14 information as provided by the investigators is
 15 brought together. We analyze the study so that we
 16 know that whether the study shows efficacy and/or
 17 safety. This is written down in an extensive
 18 report.
 19 Initially we go to a topline result
 20 report, but that's only 10, 20 pages for internal
 21 use. But the eventual result of every study is what
 22 we call a Clinical Study Report. And that's a 100-
 23 to 150-page document, plus an additional couple of
 24 thousand pages of tables and individual data. That
 25 is basically what we call the Clinical Study Report.

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1 **Q. And what kind of side effect information is**
2 **the FDA provided by the companies as a result of**
3 **these clinical trials?**
4 A. Everything related to safety and efficacy is
5 written down by the investigators and is included in
6 the database and eventually described in the
7 Clinical Study Report. And it's a full Clinical
8 Study Report that is eventually shared with the FDA.
9 **Q. And so, Dr. Caers, as it relates to Risperdal,**
10 **for example, did the company conduct clinical trials**
11 **as part of the FDA approval process for Risperdal?**
12 A. Yes, of course.
13 **Q. And as part of that process, did the company**
14 **report side effect information to the FDA?**
15 A. Yes, indeed.
16 **Q. Including all the information about any**
17 **patients that might have developed gynecomastia?**
18 **MR. KLINE:** Objection; leading. It's
19 all leading, including the information about
20 the things. And he just has to say "yes" or
21 "no." This is a direct witness, Your Honor.
22 I object.
23 **MS. SULLIVAN:** I'll rephrase it, Your
24 Honor.
25 **MR. KLINE:** I object to the

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1 continuation of it.
2 **THE COURT:** That's sustained.
3 Sustained. I mean --
4 **BY MS. SULLIVAN:**
5 **Q. Dr. Caers, did the company provide side effect**
6 **information to the FDA as it related to Risperdal as**
7 **part of the clinical trials?**
8 A. Yes.
9 **Q. And what kind of side effect information was**
10 **the FDA provided?**
11 A. Well, all the side effects, all adverse events
12 reported during the studies were summarized and
13 described in the Clinical Study Report. But
14 obviously, an NDA, a New Drug Application, there's
15 more than one study. There might be 20 to 30
16 studies in such NDA. And every study has its own
17 Clinical Study Report and with all the efficacy and
18 safety information, including all adverse events, in
19 your New Drug Application. That is the total
20 package that you send to the FDA. You also have a
21 summary on efficacy which summarizes the results of
22 all the studies combined. And you do the same for
23 safety information. All the adverse events reported
24 and all the different study reports and studies done
25 with the compound are summarized in an overview

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1 report. And that's all part of what we call the New
2 Drug Application.
3 **Q. And, Dr. Caers, would that include any side**
4 **effects the company saw about gynecomastia?**
5 **MR. KLINE:** Objection; leading.
6 **BY MS. SULLIVAN:**
7 **Q. Would that have been reported?**
8 **THE COURT:** Sustained.
9 **BY MS. SULLIVAN:**
10 **Q. Did the company report side effects including**
11 **any prolactin-related side effects?**
12 A. Yes, indeed.
13 **Q. And what were some of those?**
14 A. Well, there were cases of gynecomastia,
15 galactorrhea and amenorrhea, so disturbance of the
16 menstrual cycle in females, that was part of the
17 adverse events that were in the data package
18 submitted for the New Drug Application back in 1992.
19 **Q. And was the FDA provided all of that**
20 **information about those side effects?**
21 A. Yes.
22 **MR. KLINE:** Objection, Your Honor.
23 **THE COURT:** Yes. Yes. Sustained.
24 **MR. KLINE:** The whole --
25 **THE COURT:** Was the FDA provided

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1 with something, that's a leading question.
2 Maybe we can just do this: Kind of
3 ask him what the story is or whatever.
4 **MS. SULLIVAN:** I was trying to move
5 it along, Judge; but okay.
6 **BY MS. SULLIVAN:**
7 **Q. The --**
8 **MR. KLINE:** Your Honor, my other
9 objection is that none of this that relates
10 to the approval in 1992 has anything to do
11 with children. And this drug was off-label
12 from '02 to '06.
13 **MS. SULLIVAN:** Your Honor, this is
14 not proper.
15 **THE COURT:** All right. Mr. Kline, I
16 appreciate that.
17 **MR. KLINE:** That's my objection.
18 **THE COURT:** But, you know, this is a
19 defense, and they're permitted to approach it
20 any way they see fit, as long as it's
21 admissible.
22 **BY MS. SULLIVAN:**
23 **Q. And, Dr. Caers, can you talk about -- how**
24 **long, Dr. Caers, for the first -- when was the first**
25 **FDA approval for Risperdal?**

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1 A. The first approval for Risperdal was back in
 2 December 1993, and it was for the manifestations of
 3 psychotic disorders.
 4 **Q. And that was in adults, correct?**
 5 A. That was based on data collected in adults,
 6 including elderly.
 7 **Q. And, Dr. Caers, how long did Janssen study**
 8 **Risperdal and conduct animal testing, clinical**
 9 **trials, et cetera, before the FDA approved it?**
 10 A. Well, the molecule was synthesized first,
 11 invented basically in 1984, and we got our approval
 12 late 1993. So that's nine years of research.
 13 **Q. Nine years of study before FDA approved it?**
 14 A. Yes, indeed.
 15 **Q. And I'm going to mark Defense Exhibit...**
 16 **MS. BROWN:** 55.
 17 **MS. SULLIVAN:** And this is DG6-1, a
 18 demonstrative.
 19 **MR. KLINE:** Your Honor, again, we had
 20 an agreement to produce documents that are
 21 going to be used with the witness; and I
 22 object.
 23 **THE COURT:** Let me see the document.
 24 **MR. KLINE:** Before I even see it, we
 25 had a specific agreement.

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1 **THE COURT:** Well, it may be. But
 2 right now I'm going to go one by one and then
 3 we'll look at it at another time.
 4 **MR. KLINE:** At a break, may I have
 5 whatever is being used?
 6 **THE COURT:** Pardon me?
 7 **MS. SULLIVAN:** Your Honor --
 8 **MR. KLINE:** All I ask is to be
 9 provided the documents ahead of time.
 10 **THE COURT:** Well, nothing's going up
 11 on the screen or anywhere until you've seen
 12 it, until it's reviewed, until it's either
 13 objected to or not; and if it is, then I'll
 14 rule on it.
 15 Do you have, actually, copies of
 16 these documents?
 17 **MS. SULLIVAN:** We thought we did,
 18 Your Honor. I'm not sure what happened.
 19 Your Honor, Mr. Kline provided us a
 20 whole bunch of documents the day his
 21 witnesses --
 22 **THE COURT:** Well, I'm not really
 23 interested in a --
 24 **MR. KLINE:** That's also not true.
 25 **THE COURT:** -- back-and-forth between

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1 counsel, I really am not. I don't think the
 2 jury is either.
 3 Well, you know what, I'll permit you
 4 to use this after you've gone through these,
 5 you know, after all of these different points
 6 have been either stipulated to or testified
 7 to by your client. You may certainly use
 8 this as a summary of the points that you're
 9 making. But it is in the fashion of leading
 10 to put this particular document up there and
 11 then just have your witness kind of reply
 12 what's already in the document.
 13 **MS. SULLIVAN:** Okay.
 14 - - -
 15 (Whereupon Exhibit D-55 was marked
 16 for identification.)
 17 - - -
 18 **BY MS. SULLIVAN:**
 19 **Q. Dr. Caers, has Risperdal been approved by the**
 20 **FDA for many different indications?**
 21 A. Yes, indeed.
 22 After the first approval in 1993,
 23 there were additional approvals for Risperdal with
 24 different formulations, so with different ways of
 25 administration, such as a liquid, an oral liquid, or

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1 a fast dissolving tablet which makes it easier for
 2 patients to take the pill; or in other indications
 3 such as bipolar mania, which is another psychiatric
 4 disease in which antipsychotics can be very
 5 effective.
 6 It was also approved later, somewhere
 7 in 2006, I think, in irritability associated with
 8 autism, which is a primarily child psychiatric
 9 disorder. It was later then also approved for
 10 adolescents with schizophrenia and for children and
 11 adolescents with bipolar mania. Again, this is
 12 another age group as it was approved for in adults.
 13 **Q. And, Dr. Caers, when the company submits its**
 14 **New Drug Application for approval to the FDA after**
 15 **all of this years of testing, how long typically**
 16 **does it take the FDA to review all of the data and**
 17 **decide whether the medicine gets approved?**
 18 A. At that time it took about 12 to 15 months for
 19 the FDA to review all your data that you provided.
 20 And be aware, we not only give the paper document,
 21 they also get the database electronically. So they
 22 can check the analysis we do in the studies, whether
 23 they are appropriate and do justify, indeed, the
 24 conclusions.
 25 After that review by the FDA, and the

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1 whole file is distributed to different reviewers,
 2 different specialists within the FDA, they all make
 3 their assessment, bring it all together, and that
 4 eventually leads to a reply, first reply, which is
 5 usually an approvable letter that says, yes, okay,
 6 it looks good, but this and this and this we still
 7 want you to explore and justify.
 8 And eventually then when you give
 9 your complete response and because you reply then,
 10 then they review that once more and then they can
 11 approve. And as part of the approval, they provide
 12 you the final label which is what they want to be
 13 said about this compound in the label to inform
 14 physicians how to use and prescribe this compound.
 15 **Q. And, Dr. Caers, when a medicine is approved by**
 16 **the FDA, do you get from the FDA an approval**
 17 **package?**
 18 A. Yes, indeed.
 19 **Q. And have you seen the FDA review memos that**
 20 **are part of that approval package?**
 21 A. Yeah. As I said earlier, so every -- the
 22 different parts of the file of the New Drug
 23 Application is reviewed by different specialists
 24 within the FDA. You have chemical; you have
 25 clinical; you have safety physicians; you have

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1 pharmacokinetics; so they are experts on how the
 2 drug behaves in a body, et cetera, et cetera. So
 3 they all make their review, bring it all together in
 4 assessment reports, and those are, shortly after
 5 approval, available in the public domain on the FDA
 6 website. So we do have access to these assessment
 7 reports.
 8 **Q. And, Doctor, so you -- does the company see**
 9 **then the various review memos from the different**
 10 **doctors at the FDA on the medicine?**
 11 A. That is correct.
 12 **Q. And, Dr. Caers, I am going to mark as Defense**
 13 **Exhibit 56, DX207, the approval letter from the FDA**
 14 **for Risperdal in 1993.**
 15 **MR. KLINE:** Objection to FDA
 16 document.
 17 **THE COURT:** Overruled.
 18 **MS. SULLIVAN:** Do we have a copy for
 19 the Judge and for --
 20 **MS. BROWN:** We do, yes.
 21 **THE COURT:** Well, let me see you at
 22 sidebar.
 23 Take that down, please.
 24 (The following discussion transpired
 25 at sidebar out of the hearing of the jury:)

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1 **THE COURT:** I don't mind the
 2 admission of this, but the contents of this
 3 are problematic, especially such that you
 4 highlighted that has the phrase, "safe and
 5 effective," which I did rule on in motion in
 6 limine. I don't want to get into the issue
 7 of safety and effectiveness as approved by
 8 the FDA.
 9 **MS. SULLIVAN:** Well, Your Honor, I'll
 10 block it out here. I will not --
 11 **THE COURT:** I don't know why you need
 12 all this. You have an approval. It's in the
 13 document, and that's it. The contents of
 14 this are problematic.
 15 **MS. SULLIVAN:** Your Honor,
 16 Dr. Kessler said the drug's unsafe. That
 17 opens the door to this. It goes to
 18 negligence, Your Honor. This is the FDA
 19 standard. We've met it. It's evidentiary.
 20 **THE COURT:** But it was unsafe perhaps
 21 for children. His point is well taken. This
 22 was an approval for adults. It's actually
 23 irrelevant. But beyond that, I'm telling
 24 you, we had a motion in limine ruling that
 25 specifically --

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1 **MS. SULLIVAN:** I'll block out the
 2 safe and effective, then.
 3 **THE COURT:** And I don't think the
 4 contents of this are admissible. They're not
 5 necessary.
 6 **MS. SULLIVAN:** Well, this is the
 7 label, Judge.
 8 **THE COURT:** Well, you have some
 9 testimony about the effectiveness and safety.
 10 You have testimony about it, or an opinion.
 11 **MS. SULLIVAN:** I'll block it out.
 12 **THE COURT:** But we're not doing it
 13 this way through the FDA.
 14 **MS. SULLIVAN:** Okay.
 15 **THE COURT:** We've ruled it out
 16 before.
 17 **MS. SULLIVAN:** Okay. I'll block out
 18 the "safe and effective."
 19 **MR. KLINE:** Well, no.
 20 Your Honor, Your Honor, as I
 21 understood, the Court just told her not to
 22 display it; and her answer back on the way
 23 out was "I will block it out."
 24 There's no good reason why this has
 25 to be displayed.

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1 **THE COURT:** No. No. This document
2 is not going up because the contents cannot
3 be -- I can't -- I cannot --
4 **MS. SULLIVAN:** Your Honor, this is
5 the label. And the FDA is saying this is the
6 label you have to use.
7 **THE COURT:** I'm telling you, you have
8 the approval. It's in the record, and it's
9 admitted. But the fact of the matter is the
10 contents of that document is not admissible.
11 It's not subject to cross-examination. It's
12 using a phrase that I had forbidden, and it's
13 putting the FDA imprimatur of safe and
14 effectiveness on this drug when in fact the
15 issue has to do with children. And this
16 particular label didn't have anything to do
17 with children.
18 **MS. SULLIVAN:** And, Your Honor,
19 just --
20 **THE COURT:** That's my ruling.
21 **MS. SULLIVAN:** I understand. But for
22 the record, Judge, you initially ruled that
23 the FDA defense is part of the case. This is
24 the approval from the FDA.
25 **THE COURT:** Well, it has to be

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1 according to --
2 **MS. SULLIVAN:** This is a business
3 record and a public record.
4 **THE COURT:** It is not -- the contents
5 of that document are not admissible in this
6 case --
7 **MS. SULLIVAN:** This is the labeling.
8 **THE COURT:** -- for the purposes that
9 you are presenting it. This is not a
10 business record for whom the contents are
11 admissible.
12 **MR. KLINE:** I have no objection to
13 the label as a document being used.
14 **THE COURT:** That's already in
15 evidence.
16 **MR. KLINE:** I have an objection to --
17 **MS. SULLIVAN:** But how about --
18 **COURT REPORTER:** One at a time.
19 **MS. SULLIVAN:** How about the
20 statement from the FDA: This is the label
21 you have to use?
22 **THE COURT:** I don't think you really
23 need that.
24 **MS. SULLIVAN:** Well, Judge, that's
25 our defense.

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1 **THE COURT:** Your defense is that in
2 1993 the thing was approved. You have an
3 official document to prove it.
4 **MS. SULLIVAN:** And the FDA says say
5 this. The FDA says you have to say this
6 verbatim.
7 **THE COURT:** You can use that.
8 **MS. SULLIVAN:** Thank you.
9 **MR. KLINE:** That would actually be
10 misleading because --
11 **MS. SULLIVAN:** That's what it says.
12 **MR. KLINE:** Of course that's what it
13 says, after a negotiation with them and
14 having nothing to do with children.
15 **MS. SULLIVAN:** That's cross-exam.
16 **MR. MURPHY:** Your Honor, if I might.
17 **THE COURT:** The objection is
18 sustained. I'm not going down that route.
19 **MS. SULLIVAN:** I can't show that the
20 FDA says use this verbatim?
21 **THE COURT:** No, no. You can get that
22 from your witness.
23 **MR. MURPHY:** Your Honor, just so --
24 **THE COURT:** Or get a stipulation.
25 It's a can of worms that injects the FDA's

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1 approval process as a -- without the FDA
2 people being here or an expert witness
3 testifying about these documents, just like
4 Kessler did. You cannot use this document to
5 speak for itself. You have to get an expert
6 in here to testify about these documents.
7 And that's my ruling.
8 **MR. MURPHY:** Your Honor --
9 **THE COURT:** That's it.
10 - - -
11 (Sidebar discussion concluded.)
12 - - -
13 (The following transpired in open
14 court in the presence of the jury:)
15 - - -
16 **THE COURT:** All right. The objection
17 is sustained, ladies and gentlemen. The
18 objection is sustained.
19 This particular document here can be
20 used for a particular purpose; namely, that
21 an approval of the FDA took place in 1993, as
22 we already know. That's it.
23 **BY MS. SULLIVAN:**
24 **Q. And, Dr. Caers, as part of the FDA approval**
25 **process, did the FDA also review the labels?**

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1 A. Well, part of the approval -- well, approval
 2 is the label. And the label is -- this is the
 3 document -- the FDA says this is the document that
 4 will be the label for this compound which is part --
 5 an intrinsic part of the approval letter and
 6 document.
 7 **Q. And, Dr. Caers, can you talk about your**
 8 **experience with the FDA in terms of labeling for**
 9 **medicines including Risperdal.**
 10 A. Well, with every NDA, New Drug Application,
 11 you propose a certain label, but you write this
 12 label in line with the guidelines. There are FDA
 13 guidelines on how to structure a label and what
 14 should be in a label and what should not be in a
 15 label, and that's a proposal. Part of the review
 16 process by the FDA is reviewing that label and
 17 always they will make recommended changes and
 18 adaptations. They may delete certain things. They
 19 may add certain things. And at the end, with the
 20 approval, they say this is in our opinion what
 21 should be in your label and this is part of your
 22 formal approval, which means that basically this
 23 product is safe and effective for the use as
 24 described in that label and for the patients as
 25 described in that label. That's a very strict

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1 process that is followed in that respect.
 2 **Q. And who, Dr. Caers, at the approval stage for**
 3 **a medicine, has the final say as to what goes in the**
 4 **label? The FDA or the company?**
 5 A. That's the FDA.
 6 **Q. And will the FDA permit you to market your**
 7 **medicine if you don't say what they tell you to say?**
 8 **MR. KLINE:** Objection.
 9 **THE COURT:** All right. Sustained.
 10 Is this an expert witness on
 11 pharmaceutical regulation, Counsel?
 12 **MS. SULLIVAN:** Your Honor --
 13 **THE COURT:** I'm going to ask you at
 14 this point to get into what this witness can
 15 testify as a fact witness about his
 16 involvement with the Risperdal approval
 17 process.
 18 **BY MS. SULLIVAN:**
 19 **Q. And, Dr. Caers, do you have a significant**
 20 **amount of experience dealing with the FDA on**
 21 **labeling issues?**
 22 A. Yes, I do.
 23 **Q. And can you tell us whether a company can say**
 24 **something different from what the FDA dictates --**
 25 **MR. KLINE:** Objection.

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1 **BY MS. SULLIVAN:**
 2 **Q. -- in the label?**
 3 **THE COURT:** Sustained. Sustained.
 4 What we're looking for as admissible
 5 as a fact witness is about this individual's
 6 own experience with the Risperdal approval
 7 process.
 8 **BY MS. SULLIVAN:**
 9 **Q. And, Dr. Caers --**
 10 **MR. KLINE:** I move to strike.
 11 **THE COURT:** And we are going to
 12 strike anything that this witness has to say
 13 that has been objected to, any answers that's
 14 been -- please do not consider that.
 15 He is not qualified here as an expert
 16 on pharmaceutical regulations.
 17 If he were, I'd let you know.
 18 **BY MS. SULLIVAN:**
 19 **Q. And, Dr. Caers, based on your experience with**
 20 **the FDA, do they have final say in what goes in your**
 21 **label?**
 22 **MR. KLINE:** Objection.
 23 **THE COURT:** That's sustained.
 24 Sustained.
 25 **BY MS. SULLIVAN:**

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1 **Q. When you get an approval letter from the FDA,**
 2 **what does it say about the label?**
 3 A. It has the label as it is approved by the FDA
 4 and as it will be used for the marketing of the
 5 product in this country.
 6 **Q. And what does that mean?**
 7 A. It means that the approved label as approved
 8 by the FDA describes, in the opinion of the FDA, all
 9 the relevant information that the physician needs to
 10 know in order to appropriately prescribe this
 11 medicine for his or her patients.
 12 **Q. And let's show our jurors the initial FDA**
 13 **approved label for Risperdal. Defense Exhibit 24,**
 14 **please.**
 15 **COURT CRIER:** D-57.
 16 **MR. KLINE:** Your Honor, may we look
 17 at it first?
 18 **THE COURT:** Of course.
 19 **MR. KLINE:** Rather than to display,
 20 as per the Court's --
 21 **THE COURT:** I thought I had made
 22 myself clear about that.
 23 **MS. SULLIVAN:** Your Honor, this has
 24 already been admitted.
 25 **THE COURT:** I don't care.

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1 MS. SULLIVAN: Okay.
 2 COURT CRIER: Previously marked as
 3 D-24, Your Honor.
 4 THE COURT: Isn't that the same
 5 document as some other document we've had,
 6 plaintiff something?
 7 MR. KLINE: No. It's the same as
 8 D-24. Now it's marked D-57.
 9 MS. SULLIVAN: No. It's D-24.
 10 THE COURT: D-24. Fine.
 11 All right. That's been previously
 12 marked.
 13 Go ahead.
 14 BY MS. SULLIVAN:
 15 Q. Dr. Caers, let's take a look at the initial
 16 FDA approved label back in 1993 for Risperdal.
 17 And if we could go to the Precautions
 18 section, Ken.
 19 (Technician complied.)
 20 BY MS. SULLIVAN:
 21 Q. And, Dr. Caers, can you talk about what was in
 22 the initial FDA approved label in terms of
 23 information about hyperprolactinemia or elevated
 24 prolactin and gynecomastia?
 25 MR. KLINE: Objection; misleading. I

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1 will not object if the word "adult" is used.
 2 MS. SULLIVAN: Your Honor, I just
 3 asked him what was in the label. This is,
 4 you know --
 5 THE COURT: Well --
 6 MS. SULLIVAN: Everybody knows --
 7 THE COURT: -- I'm not sure why we're
 8 going through this exercise.
 9 I mean, the jury can read it for
 10 themselves or what. I mean, is there a
 11 question based on this label?
 12 MS. SULLIVAN: Yeah.
 13 THE COURT: All right. Then ask the
 14 question.
 15 BY MS. SULLIVAN:
 16 Q. And, Dr. Caers, in the FDA approved label, was
 17 there information for physicians about the fact that
 18 Risperdal could increase prolactin levels?
 19 A. Yes, indeed. As you can see here, under the
 20 title "hyperprolactinemia," it says that as other
 21 products interfering with dopamine, and those are
 22 receptors, somewhere in the brain, also risperidone
 23 elevates prolactin in the blood, and that products
 24 that can increase prolactin in the blood; that
 25 certain adverse events such as galactorrhea,

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1 amenorrhea, gynecomastia, have been reported with
 2 this type of drugs.
 3 Q. And, Doctor, our jurors have heard the term
 4 "association" and "causation." Is there a
 5 difference between association --
 6 MR. KLINE: Objection.
 7 BY MS. SULLIVAN:
 8 Q. -- and causation?
 9 MR. KLINE: Objection.
 10 THE COURT: Overruled.
 11 THE WITNESS: Well, association means
 12 that these type of observations have been
 13 made while patients were treated with
 14 risperidone.
 15 A causation means that the
 16 observations have been induced and caused by
 17 risperidone. And there is indeed a major
 18 differentiation, because it's not because
 19 it's associated that it is caused by it.
 20 BY MS. SULLIVAN:
 21 Q. And can you explain why something associated
 22 with something doesn't necessarily mean caused by
 23 it, based on your experience?
 24 MR. KLINE: Same objection; expert
 25 testimony.

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1 THE COURT: Sustained. Sustained.
 2 You're -- again, this is like expert
 3 testimony. If you want to qualify him as an
 4 expert, I mean, I don't understand what --
 5 let me see -- what are we trying to -- he's a
 6 fact witness about what?
 7 MS. SULLIVAN: He's a fact witness
 8 who's a Ph.D., and has significant expertise
 9 in drug development and drug labeling and is
 10 familiar with these concepts for over 30
 11 years, Your Honor.
 12 THE COURT: That's an expert.
 13 MS. SULLIVAN: He's both.
 14 THE COURT: Well, then, qualify him
 15 as an expert.
 16 BY MS. SULLIVAN:
 17 Q. Dr. Caers --
 18 MR. KLINE: There's no report, Your
 19 Honor.
 20 THE COURT: That's right. You can't
 21 qualify him as an expert, I guess, because we
 22 don't have an expert report.
 23 MS. SULLIVAN: Your Honor --
 24 THE COURT: So then the objection is
 25 sustained. This is not the right witness for

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1 that.

2 **MS. SULLIVAN:** Your Honor, they've

3 had extensive depositions of this witness.

4 **THE COURT:** Not the right witness.

5 There's no expert report.

6 There are some Rules of Civil

7 Procedure involved in Pennsylvania, and so,

8 therefore, we're going to follow them.

9 I'm sure you have some other expert

10 witnesses who are going to testify and they

11 may do so properly. But this is a fact

12 witness, I presume, about his own experience

13 with this particular medication.

14 **MS. SULLIVAN:** And, yes, Your Honor,

15 the concept of association and causation is

16 in this label.

17 **THE COURT:** Well, ask him as relates

18 to Risperdal.

19 **MS. SULLIVAN:** Okay. Fair enough.

20 **BY MS. SULLIVAN:**

21 **Q. Dr. Caers, can you talk to our jurors about**

22 **this label and Risperdal as it relates to these**

23 **concepts "association and causation"?**

24 A. Well, what this label reads is that the use of

25 risperidone can be associated with the occurrence of

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1 certain adverse events, such as galactorrhea,

2 amenorrhea, gynecomastia.

3 **Q. And, Dr. Caers, in your experience, if the FDA**

4 **concluded Risperdal caused gynecomastia, have you**

5 **seen labeling where they say the word "caused"?**

6 **MR. KLINE:** Objection, Your Honor.

7 **THE COURT:** Sustained.

8 **MR. KLINE:** For many reasons.

9 **THE COURT:** Sustained.

10 **BY MS. SULLIVAN:**

11 **Q. Has the FDA, Dr. Caers, in your experience**

12 **with Risperdal, ever concluded that Risperdal causes**

13 **gynecomastia?**

14 **MR. KLINE:** Objection.

15 **THE COURT:** Sustained. Just not --

16 he's not qualified.

17 **MS. SULLIVAN:** That's not an expert.

18 I said has the FDA ever concluded that.

19 **THE COURT:** I don't have a basis for

20 his testimony on that from this witness.

21 **MR. KLINE:** That would be hearsay.

22 **THE COURT:** I mean, the labels speak

23 for themselves. We don't need this witness

24 to read the label to the jury. This jury has

25 seen this label about three times already.

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1 **BY MS. SULLIVAN:**

2 **Q. Dr. Caers, because gynecomastia is listed in**

3 **the label as a potential side effect, does that mean**

4 **it causes it?**

5 A. No.

6 **Q. And can you explain that.**

7 A. It is that it is observed in patients who are

8 being treated with risperidone, but that does not

9 necessarily mean that it is caused by it.

10 **MR. KLINE:** Your Honor, move to

11 strike.

12 **THE COURT:** Well, it's --

13 **MR. KLINE:** I just couldn't be on my

14 toes like on every question.

15 It's just every question.

16 **THE COURT:** That is stricken. That

17 is as an expert -- that is the testimony of

18 an expert.

19 He may be an expert, but you didn't

20 follow the rules, so I can't help you on

21 that. You have other experts, I'm sure, to

22 get that particular testimony in if you have

23 it.

24 Sustained.

25 Excuse me. Members of the jury, that

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1 last question and that last answer is

2 stricken. Just not the right person for

3 that.

4 **MS. SULLIVAN:** And --

5 **THE COURT:** About the causation of --

6 this particular causation issue as to whether

7 or not Risperdal causes this. He's not the

8 right guy for that.

9 **MS. SULLIVAN:** And, Your Honor, the

10 question related to labeling and what the

11 FDA --

12 **THE COURT:** I'm sorry, Ms. Sullivan,

13 sustained. You're going to have to play by

14 the rules.

15 **MS. SULLIVAN:** Just trying to get a

16 fair trial, Judge.

17 **THE COURT:** Well, you have to play by

18 the rules to get a fair trial.

19 **MS. SULLIVAN:** The --

20 **THE COURT:** There are two sides to

21 the coin. That's why we have Rules of Civil

22 Procedure.

23 **BY MS. SULLIVAN:**

24 **Q. And, Dr. Caers --**

25 **MS. SULLIVAN:** Can we look, Jed, at

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1 the safe and effective for children section?
 2 **BY MS. SULLIVAN:**
 3 **Q. And, Dr. Caers, in the adult label from 1993,**
 4 **is there a section that tells doctors about safety**
 5 **for children?**
 6 A. The only reference to children in the label of
 7 '93 is a statement that the efficacy and safety of
 8 Risperdal in children has not been established.
 9 **Q. Okay. And that was in the adult label from**
 10 **the beginning?**
 11 A. That is correct. Well, it's in the Risperdal
 12 label, full stop.
 13 **Q. Yeah. Okay.**
 14 **And, Dr. Caers, when the company got**
 15 **the FDA approval for Risperdal, was there review**
 16 **memos from the FDA as part of the approval package?**
 17 A. There are review memos, obviously, yes, we
 18 discussed earlier. Because the FDA experts
 19 summarize their findings in a review document, and
 20 those documents are available to the companies once
 21 your product is approved.
 22 **Q. And, Dr. Caers, is that information kept by**
 23 **the company as part of their regular and ordinary**
 24 **course of business?**
 25 A. Yes. Obviously we keep all the documents from

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1 the FDA after we receive --
 2 **Q. And have you seen the review memos from the**
 3 **FDA for the 1993 approval?**
 4 A. Back in the early '90s, yes, yes.
 5 **Q. And I'm going to show you what's been marked**
 6 **for identification as Defense Exhibit 213.**
 7 **MS. BROWN:** It will be 57.
 8 **MS. SULLIVAN:** 213A.
 9 **MR. KLINE:** The same thing we went to
 10 sidebar on, Your Honor. I object.
 11 **THE COURT:** I can't hear you.
 12 **MR. KLINE:** This would be the same
 13 thing we went to sidebar on already. I would
 14 object. It's just another version of it, of
 15 an FDA document.
 16 **THE COURT:** Is this an FDA document?
 17 **MR. KLINE:** Yes.
 18 **MS. SULLIVAN:** And also a business
 19 record.
 20 **THE COURT:** We had a motion in limine
 21 about this entire subject. That is
 22 sustained, at least through this witness in
 23 this manner.
 24 **BY MS. SULLIVAN:**
 25 **Q. Dr. Caers, are you -- are you -- do you know**

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1 **whether the FDA noted that Risperdal could elevate**
 2 **prolactin in their review memos?**
 3 **MR. KLINE:** Objection, Your Honor.
 4 **THE COURT:** Sustained as to what the
 5 FDA noted. This is -- you got a witness from
 6 Janssen. What did he know?
 7 **MS. SULLIVAN:** Well, Your Honor, he
 8 just testified that this is part of what the
 9 company keeps as their business --
 10 **THE COURT:** But you have other
 11 witnesses who are properly permitted to
 12 testify to these kind of things. This is not
 13 the right one. You didn't qualify him. He's
 14 not an expert on FDA pharmaceutical
 15 regulations or any of those kind of issues,
 16 Ms. Sullivan.
 17 I really -- I feel that in the end,
 18 we have to enforce at some point the Rules of
 19 Civil Procedure.
 20 **MS. SULLIVAN:** And, Your Honor, I'm
 21 just asking what FDA told Janssen.
 22 **THE COURT:** What FDA told Janssen,
 23 why is that relevant to this man's testimony?
 24 **MS. SULLIVAN:** Because he's Janssen.
 25 **THE COURT:** I don't understand that.

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1 **MS. SULLIVAN:** He's the doctor at
 2 Janssen that got this information.
 3 **THE COURT:** If you establish some
 4 foundation for something, yeah.
 5 **MS. SULLIVAN:** Yes.
 6 **THE COURT:** But if you're just
 7 throwing documents out there for him to read
 8 them for the jury, that's not permitted.
 9 **MS. SULLIVAN:** Well --
 10 **THE COURT:** We went through that
 11 before the trial.
 12 **BY MS. SULLIVAN:**
 13 **Q. Dr. Caers, you received the FDA review memos**
 14 **on Risperdal?**
 15 A. Yes, indeed.
 16 **Q. And --**
 17 **THE COURT:** When did he receive them?
 18 **THE WITNESS:** Well, they were
 19 available from shortly after the --
 20 **THE COURT:** Well, were you involved
 21 in this 1993 application?
 22 **THE WITNESS:** I was involved in
 23 Risperdal -- in all Risperdal issues from
 24 1991 on, yeah.
 25 **THE COURT:** Well, if you establish

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1 the foundation...

2 **MS. SULLIVAN:** May I show the

3 document to the jury?

4 **THE COURT:** No. You have to

5 establish a foundation as to how this witness

6 can share something about this document

7 that's meaningful for us.

8 **MS. SULLIVAN:** Okay.

9 **BY MS. SULLIVAN:**

10 **Q. And, Dr. Caers, as part of the FDA review, did**

11 **the FDA advise the company in the review memos that**

12 **they knew that Risperdal could elevate prolactin?**

13 **MR. KLINE:** Objection; leading.

14 **THE COURT:** Sustained. Sustained.

15 Sustained.

16 **MS. SULLIVAN:** Sustained as to what

17 the FDA told Janssen?

18 **THE COURT:** Absolutely. I don't

19 understand in what respect this is relevant

20 testimony here for this witness.

21 **BY MS. SULLIVAN:**

22 **Q. Did the FDA also, Dr. Caers, have comparative**

23 **data looking at Risperdal versus other medicines**

24 **like Haldol?**

25 **MR. KLINE:** Objection; repeated

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1 violation.

2 **THE COURT:** Sustained. Sustained.

3 Unless you lay a foundation as to this

4 doctor's personal knowledge of the issues in

5 play here and you set that up for us, we're

6 not going to just be flinging documents out

7 there. We've been here two and a half weeks.

8 We cannot just fling documents.

9 **MS. SULLIVAN:** I wasn't flinging,

10 Your Honor.

11 **THE COURT:** I think you are.

12 **BY MS. SULLIVAN:**

13 **Q. Dr. Caers, did the company provide the FDA --**

14 **and you were involved in the approval process for**

15 **Risperdal, right?**

16 A. Yes.

17 **Q. And did the company provide the FDA with**

18 **information on comparative trials, Risperdal**

19 **compared to other medicines?**

20 A. Yes.

21 **Q. And did the FDA -- and in those comparative**

22 **trials that you gave to the FDA, did it show that**

23 **Risperdal could elevate prolactin more than a first**

24 **generation antipsychotic?**

25 **MR. KLINE:** Objection. This is all

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1 leading.

2 **THE COURT:** Yeah. Sustained.

3 **MR. KLINE:** She's just asking for a

4 "yes" or "no."

5 **THE COURT:** Sustained.

6 I'd take a break right now except for

7 the fact that I do have this meeting, and

8 it's scheduled for 11 o'clock. I was trying

9 to use our court time.

10 But these questions, as you're

11 phrasing them, are impermissible.

12 **MS. SULLIVAN:** I understand the

13 Court's position, Your Honor.

14 **THE COURT:** It is my position. And I

15 hope you follow my position.

16 **BY MS. SULLIVAN:**

17 **Q. Dr. Caers, did the FDA -- you already told our**

18 **jurors you provide a comparative data as part of the**

19 **initial approval process showing how Risperdal**

20 **faired against other medicines on the issue of**

21 **prolactin, right?**

22 A. That is correct.

23 **Q. And so, Dr. Caers, are you aware as to whether**

24 **the FDA commented back in 1993 that they knew that**

25 **Risperdal could elevate prolactin more than other**

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1 **medicines?**

2 **MR. KLINE:** Objection.

3 **THE COURT:** All right. That's

4 another -- that's sustained.

5 That's, ladies and gentlemen,

6 hearsay. That's a statement that's made

7 outside of this courtroom not subject to

8 cross-examination. It's forbidden by our

9 rules of evidence except for certain

10 exceptions. I'm finding that there are no

11 exceptions at the moment. We cannot have

12 testimony about from the FDA through this

13 witness when that witness is not either here

14 or some exception. That's what's going on

15 here. And, you know, I just gave you an

16 education on hearsay.

17 **BY MS. SULLIVAN:**

18 **Q. Dr. Caers, did you provide the FDA with**

19 **information that showed that Risperdal elevated**

20 **prolactin more than Haldol?**

21 **MR. KLINE:** Objection.

22 **THE COURT:** No. As to what he

23 provided the FDA, absolutely permissible.

24 **MR. KLINE:** Why can't the question

25 be: What did you show to the FDA, rather

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1 than her giving him the answer?
 2 **THE COURT:** I agree with that. But
 3 anything that he provided to the FDA or he
 4 knows the company provided to the FDA, that's
 5 fair game, absolutely.
 6 **THE WITNESS:** Well, in our studies,
 7 we had Risperdal patients and we had patients
 8 on a reference compound, for example,
 9 haloperidol, also other first generation
 10 antipsychotics; and we had efficacy, safety,
 11 including prolactin levels, in all these
 12 different patients treated with different
 13 agents, including Risperdal and Haldol, yes.
 14 **BY MS. SULLIVAN:**
 15 **Q. And did you review the FDA memos back when**
 16 **they were provided?**
 17 A. Well, we obviously had to look at them after
 18 the approval. But as I said earlier, we only had
 19 them available after the approval, so not during the
 20 approval.
 21 **Q. Yes. Did you review the FDA memos after the**
 22 **approval?**
 23 A. I did some of them, yes.
 24 **Q. For what purpose, Dr. Caers, would you look at**
 25 **the FDA approval?**

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1 A. Well, it's always interesting to see what the
 2 opinion of the FDA expert is after they have seen
 3 our full data set so that you understand their
 4 position and how they came to the label text.
 5 **Q. And what did you learn, Dr. Caers, about the**
 6 **FDA findings in the review memos on prolactin**
 7 **elevation and how Risperdal compared and what the**
 8 **FDA knew about that?**
 9 **MR. KLINE:** Objection, based on the
 10 Court's prior rulings.
 11 **THE COURT:** Well, that's -- now we're
 12 getting closer to a permissible exception.
 13 You know, if you ask him what did he know
 14 that he then did on another test or
 15 something, fine.
 16 **THE WITNESS:** Well, our data showed
 17 that the effective doses of Risperdal, there
 18 was prolactin increase in the Risperdal
 19 patients, but also in the haloperidol
 20 patients. So if you just compared one versus
 21 the other, it was not too much of a
 22 difference in the degree of prolactin
 23 increase compared to first generation
 24 antipsychotics such as haloperidol.
 25 **BY MS. SULLIVAN:**

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1 **Q. And, Doctor -- and did you note that, based on**
 2 **your review of the FDA memos, that the FDA was aware**
 3 **of that?**
 4 A. Yeah, sure.
 5 **MR. KLINE:** Object.
 6 **BY MS. SULLIVAN:**
 7 **Q. And, Dr. Caers --**
 8 **THE COURT:** Overruled.
 9 **BY MS. SULLIVAN:**
 10 **Q. And, Dr. Caers, did you -- did the company,**
 11 **after FDA approved Risperdal in 1993, continue to**
 12 **study the medicine?**
 13 A. Yes, very much so. We did additional studies
 14 on schizophrenia but also in other psychiatric
 15 disorders in order to further have approvals later
 16 on, as we already reviewed.
 17 **Q. And, Dr. Caers, once the FDA approved**
 18 **Risperdal, can you talk to our jury about the kinds**
 19 **of other studies the company did and the kinds of**
 20 **other indications the company saw, from the FDA?**
 21 A. From the early to mid-'90s we started
 22 exploring Risperdal also in children with conduct
 23 disorders or disruptive behavioral disorders. We
 24 studied Risperdal in patients with bipolar mania,
 25 again, another psychotic disorder where

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1 antipsychotics can be very effective in. We started
 2 studying psychosis in the elderly with Risperdal.
 3 We started also studying Risperdal in adolescents
 4 with schizophrenia because schizophrenia can start
 5 up at the age of 12, 14, 16.
 6 We also studied Risperdal in children
 7 and adolescents with bipolar mania. As I said
 8 earlier, we did additional studies in schizophrenia.
 9 And we also studied different types of
 10 administration in different psychotic disorders.
 11 **MS. SULLIVAN:** And, Your Honor, I'm
 12 sorry, what time does the Court want to
 13 break?
 14 **THE COURT:** In about five minutes.
 15 **BY MS. SULLIVAN:**
 16 **Q. And, Dr. Caers, as Janssen continued to study**
 17 **the medicine -- and Risperdal is still on the market**
 18 **today, sir?**
 19 A. Yes, it is.
 20 **Q. Still being prescribed today?**
 21 A. Yes. Yes.
 22 **Q. And so it's been on the market for how many**
 23 **years, Dr. Caers?**
 24 A. It's about 20 -- 21, 22 years now, about.
 25 **Q. And can you give our jurors a sense of how**

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1 much safety data there is on Risperdal as of today?
 2 A. Well, then you need to differentiate it in two
 3 databases. When I stopped working for Risperdal
 4 back in 2009, we had more than 16,000 patients
 5 documented in clinical studies with Risperdal. But
 6 apart from that, there's also another database that
 7 is based on spontaneous reporting. Physicians when
 8 they see an adverse event that is a particular
 9 concern of interest, they report it to the
 10 authorities. And that's another type of very huge
 11 database with thousands and thousands, even hundred
 12 thousands of patients of whom some are reported to
 13 have a certain adverse event on Risperdal, for
 14 example.
 15 So that's a very -- thousands and
 16 thousands of patients safety database, apart from
 17 the clinical studies we had in our 16,000 patients.
 18 **Q. And, Dr. Caers, are you familiar, as part of**
 19 **your work in medicine development, with the FDA**
 20 **standards in terms of how many studies and how many**
 21 **patients you have to have to get FDA approval?**
 22 A. Yes. The minimum for an approval, but that's
 23 the absolute minimum, is you need to have 1,500
 24 patients exposed to the product, different subjects
 25 exposed to the products. You need at least 3- to

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1 600 patients exposed for six months. And you need
 2 at least 100 patients exposed for one year or more
 3 in order to have an approval package for one single
 4 indication.
 5 **Q. And, Dr. Caers, as it stands, how does what**
 6 **Janssen did in terms of safety testing on Risperdal**
 7 **compare with the FDA standards?**
 8 **MR. KLINE:** I have an objection, Your
 9 Honor.
 10 **THE COURT:** That's sustained. That's
 11 sustained.
 12 **BY MS. SULLIVAN:**
 13 **Q. Dr. Caers, did Janssen meet or exceed the FDA**
 14 **standards?**
 15 **MR. KLINE:** Objection. It's just a
 16 back door. Same question.
 17 **THE COURT:** You're asking his
 18 opinion?
 19 **MS. SULLIVAN:** Well, he's a fact
 20 witness, Your Honor. He knows.
 21 **THE COURT:** All right. That's
 22 sustained.
 23 **MR. KLINE:** That's an opinion
 24 question.
 25 **BY MS. SULLIVAN:**

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1 **Q. Dr. Caers, do you know by how much Janssen**
 2 **exceeded the FDA standards?**
 3 **MR. KLINE:** Your Honor, objection.
 4 **THE COURT:** Sustained. You are
 5 asking for some kind of evaluation,
 6 quantitative evaluation that only an expert
 7 can make. You know, you can ask him what he
 8 did, what he didn't do. But that's a fact
 9 witness. But to ask him for his opinion on
 10 whether he did enough, that's what the
 11 subject of this trial is about. Sustained.
 12 We're going to take a recess right
 13 here till about 11:30, all right? I do have
 14 a meeting that I'm going to attend very
 15 briefly and then come back. So we're going
 16 to take a recess here till 10:30.
 17 No. Then what's going to happen is
 18 we're going to return -- I mean 11:30. And
 19 then what we're going to do, we will return
 20 for another hour and then we'll take a recess
 21 for lunch is what we're going to do. I
 22 apologize at my end. But that way we didn't
 23 lose a whole morning for this meeting for us,
 24 all right? So we'll see you in about, I
 25 guess, at 11:30 I'll be here.

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1 **COURT CRIER:** All rise.
 2 **THE COURT:** You may go outside, of
 3 course, if you want to. You know, you don't
 4 have to stay here. Same rules apply.
 5 - - -
 6 (Whereupon the jury exited the
 7 courtroom at 10:42 a.m.)
 8 - - -
 9 **THE COURT:** Sir, you are excused till
 10 11:30. But please do not discuss your
 11 testimony now with your lawyers.
 12 **THE WITNESS:** I understand, Judge.
 13 **THE COURT:** Yes, sir.
 14 **MR. KLINE:** May I have whatever
 15 demonstratives are going to be used with this
 16 witness?
 17 **MS. SULLIVAN:** Sure.
 18 **THE COURT:** I guess that would be
 19 efficient for everybody.
 20 **MS. SULLIVAN:** Yeah.
 21 **MS. BROWN:** Yeah.
 22 **THE COURT:** I do urge counsel to
 23 review the motions in limine. We spent a lot
 24 of time on them. And I hope that they're a
 25 guide to what this Court's rulings will be

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1 here in court in front of the jury.
 2 **MS. SULLIVAN:** And, Your Honor, other
 3 than safe and effective, Your Honor, I
 4 thought that Judge New ruled that the FDA
 5 issues could come into this case.
 6 **THE COURT:** Well, the safe and
 7 effective, that particular language was
 8 forbidden. But I'm not, you know, going to
 9 jump over heels on it, because it was used
 10 just now by a witness and there was no
 11 objection.
 12 But the reality of the matter is that
 13 the FDA documents were precluded for reasons
 14 that were stated on the record before. These
 15 are documents that fundamentally can be used
 16 if they are introduced through a proper
 17 foundation the proper way. But not in order
 18 to -- we went through the same thing with
 19 Mr. Kline when he had Dr. Kessler here, and
 20 we did not permit all of these documents to
 21 be admissible. Only certain ones came in.
 22 If you want to run them by us ahead
 23 of time before the trial or before a witness,
 24 by all means. But it's at your peril if
 25 you're going to go against rulings that have

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1 already been made on these subjects.
 2 All right. We're at recess till
 3 11:30.
 4 - - -
 5 (Whereupon a recess was taken.)
 6 - - -
 7 **COURT CRIER:** Come to order, please.
 8 **THE COURT:** All right. Please be
 9 seated.
 10 - - -
 11 (Time noted: 11:36 a.m.)
 12 - - -
 13 (Witness resumed the stand.)
 14 - - -
 15 **COURT CRIER:** All rise as the jury
 16 enters the courtroom.
 17 - - -
 18 (Whereupon the jury entered the
 19 courtroom at 11:38 a.m.)
 20 - - -
 21 **THE COURT:** All right. Please be
 22 seated, everybody.
 23 All right. Thank you for your
 24 indulgence, everybody. It was good. Thank
 25 you.

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1 You may proceed when you're ready.
 2 **MS. SULLIVAN:** Thank you, Your Honor.
 3 Welcome back, everyone.
 4 - - -
 5 E X A M I N A T I O N
 6 - - -
 7 **BY MS. SULLIVAN:**
 8 **Q. Welcome back, Dr. Caers. Let me just get**
 9 **moving here.**
 10 **Dr. Caers, I wanted to talk some more**
 11 **about Janssen's study of Risperdal on children and**
 12 **adolescents; and you were involved with that,**
 13 **Dr. Caers?**
 14 A. Yes, I was.
 15 **Q. Can you tell our jury the nature of your**
 16 **involvement in Janssen's studying the medicine on**
 17 **children and adolescents?**
 18 A. Well, my team actually developed the study,
 19 the study protocols and actually run it by
 20 investigators, and also managed the analysis and the
 21 reporting of the study in the Clinical Study
 22 Reports, and eventually also managed and dealt with
 23 the composition of the New Drug Application -- in
 24 this case a Supplemental New Drug Application, which
 25 concluded -- which had all the information we have

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1 collected in the different studies in a big file,
 2 which was eventually submitted to the FDA at
 3 different occasions.
 4 **Q. And, Dr. Caers, after the medicine was**
 5 **approved in 1993, did the company become aware that**
 6 **it was being prescribed off-label by physicians to**
 7 **children and adolescents?**
 8 A. Well, we had information, indeed, that in this
 9 country there were physicians that prescribed
 10 Risperdal for children or adolescents at that time.
 11 **Q. And so if the company was already selling the**
 12 **medicine for off-label prescriptions, can you tell**
 13 **us what the reason was the company continued to**
 14 **study the medicine in children and get towards**
 15 **getting additional approvals?**
 16 A. Well, for the company it's very important that
 17 there's appropriate information on appropriate use
 18 of this medicine in different populations, such as
 19 in this case pediatric population, such as children
 20 and adolescents. And although it was used in the
 21 marketplace, which we call off-label, it is
 22 important to document efficacy and safety, have that
 23 reviewed by the FDA, so that you have appropriate
 24 guidance in the label on how to use this medicine in
 25 this population and for which type of population

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1 within this pediatric population.
 2 **Q. And, Dr. Caers, are there issues or challenges**
 3 **when companies try to study medicines in children?**
 4 **A.** Well, yeah. If you can understand, patients
 5 are requested and expected to give informed consent,
 6 as we discussed before the break, and particularly
 7 for children, this is not easy. I have three
 8 children as well. I have seven grandchildren. So
 9 you would think twice before you would conclude that
 10 you would allow your child or your grandchild to
 11 enter a study. Nevertheless, without the goodwill
 12 and the preparedness of these parents and children,
 13 we wouldn't be able to do these in clinical studies,
 14 and we would never be able to advise physicians on
 15 how to appropriately use this medicine in this
 16 population.
 17 **Q. And, Dr. Caers, while you were supervising**
 18 **some of these clinical trials on children and**
 19 **adolescents, can you tell us whether the FDA had any**
 20 **involvement in encouraging companies to study**
 21 **medicines?**
 22 **MR. KLINE:** Objection.
 23 **THE COURT:** Overruled.
 24 **THE WITNESS:** There are two ways that
 25 the FDA is involved. First of all, as we

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1 said earlier, for every study you want to do
 2 in this country, you need to have at least
 3 permission by the FDA to run the study. But
 4 there is a particular legislation as well
 5 that came into effect by the late '90s, and
 6 that has to do with pediatric exclusivity.
 7 What does pediatric exclusivity mean?
 8 Congress has voted legislation back
 9 in the late 1990s that said and that wanted
 10 to stimulate clinical research in children,
 11 because before actually we started in this
 12 area, there was no -- there was no research
 13 ongoing, not at all.
 14 So Congress and the FDA wanted to
 15 stimulate the companies to study drugs more
 16 in children and adolescents. And that's how
 17 the legislation of pediatric exclusivity came
 18 into account.
 19 And that legislation allowed and gave
 20 even the mandate to the FDA to tell companies
 21 this is the type of studies in this type of
 22 population that we want you to do. And if --
 23 on the other hand, there's a benefit for
 24 companies as well in the same legislation by
 25 Congress. If you actually do them, these

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1 studies, the way the FDA asked you to do it
 2 and you complete the studies, you make the
 3 Clinical Study Report and you submit this
 4 information to the FDA, and if this is, along
 5 with the written request, what the FDA asked
 6 you to do, then companies get an additional
 7 six months exclusivity, which basically means
 8 that you have six months more exclusivity on
 9 your product than without these pediatric
 10 studies. So that genetic companies can only
 11 come six months later on the market with a
 12 genetic compound. That's basically the
 13 benefit for companies first that they ask you
 14 to do.
 15 **BY MS. SULLIVAN:**
 16 **Q. So the FDA and government provided incentives**
 17 **for companies to study the medicine in children?**
 18 **A.** Within the --
 19 **MR. KLINE:** Objection. Objection.
 20 **THE COURT:** All right. That's
 21 sustained. Sustained.
 22 **BY MS. SULLIVAN:**
 23 **Q. And did you have meetings with the FDA,**
 24 **Dr. Caers, to get permission to study the medicine**
 25 **in children and adolescents?**

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1 **A.** We had meetings with the FDA on how to run
 2 these studies and how these studies would need to
 3 look like and what type of patients, et cetera, yes,
 4 we had several meetings of this kind.
 5 **Q. And, Dr. Caers, I'm going to put up an exhibit**
 6 **that has been up before. And this is DG6-3. And**
 7 **Ms. Brown can tell me what is the --**
 8 **MS. BROWN:** Yes. 58.
 9 **MS. SULLIVAN:** Defense Exhibit 58.
 10 (Exhibit D-58 marked for
 11 identification.)
 12 **COURT CRIER:** Counsel have it?
 13 **MS. BROWN:** Yeah, they have it.
 14 **MR. KLINE:** This is the
 15 demonstrative. I have no objection.
 16 **BY MS. SULLIVAN:**
 17 **Q. And, Dr. Caers, we're looking at Defense**
 18 **Exhibit 58. And can you tell the jury how many**
 19 **clinical trials Janssen did to support the approval**
 20 **of Risperdal in children and adolescents?**
 21 **A.** Well, in total, we did at least 18 studies in
 22 different populations of children and adolescents
 23 ranging from autism, disruptive behavior disorders,
 24 adolescent schizophrenia, children and adolescent
 25 bipolar mania. And they're, more or less, a little

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1 bit listed here on this list.
 2 And just for your information, on the
 3 left-hand side, Clinical Trial, the NED-9 is a study
 4 done in the Netherlands. The BEL is a study done in
 5 Belgium. International is an international study in
 6 different countries. USA is a USA study, and so on,
 7 Canada, Canada, and so on.
 8 **Q. Dr. Caers, what kind of safety information did**
 9 **Janssen collect in the course of these clinical**
 10 **trials in children and adolescents?**
 11 A. Well, similar to the adults, you collect
 12 basically all safety information. You do regular
 13 blood analysis. You also systematically measure
 14 prolactin in this population. We collected adverse
 15 events as reported by patients and by the
 16 investigator, which are written down by the
 17 investigators in the file. And all this
 18 information, apart from obviously the efficacy
 19 assessments, was all collected together in the
 20 database and eventually in the Clinical Study
 21 Report, just similar to what we discussed before the
 22 break on adult patients.
 23 **Q. And did Janssen provide all of the side effect**
 24 **information from these clinical trials to the FDA?**
 25 A. Yes, indeed.

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1 **Q. And, Dr. Caers, did Janssen also publish these**
 2 **studies for the world to see?**
 3 A. Yes. The different studies were, indeed,
 4 published in medical journals so that also the
 5 medical community and doctors could read about the
 6 experience and the findings in particular studies,
 7 both on efficacy and safety.
 8 **Q. And, Doctor, at this time was there any**
 9 **requirement for Janssen to publish their studies?**
 10 A. At that moment I don't think there was a
 11 requirement to publish the studies, but that was
 12 usually done.
 13 **Q. And, Dr. Caers, can you describe -- so there's**
 14 **been some discussion about the time lag between when**
 15 **a study is done and when it's published. Can you**
 16 **talk about the peer-review process?**
 17 A. Yeah. It's a -- there are different steps,
 18 obviously. Once you have your database closed and
 19 your analysis, the first thing you do is making sure
 20 you have the Clinical Study Report. And that's a
 21 hell of a job, as I said earlier. That's a 100- to
 22 150-page document with thousands of pages of tables.
 23 And then the next step is you consider to publish
 24 the findings of the study in a peer-review journal.
 25 So you develop a manuscript, have it reviewed by

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1 authors up and down and different versions. Then at
 2 the end you have a final manuscript which is
 3 submitted to a medical journal with requested
 4 publishes.
 5 Peer review means that experts in the
 6 field review your paper, very often have comments,
 7 recommendations to -- can you say this differently,
 8 we don't think this is an appropriate phrase. Can
 9 you do that additional analysis? So the next step
 10 is you do, again, your additional things. You adapt
 11 your manuscript. You resubmit it and then very
 12 often it is either accepted for publication and it
 13 goes in the waiting list for the final publication,
 14 which may take another six to nine months. So
 15 overall, this period can take a few years even,
 16 usually.
 17 **Q. And, Dr. Caers, how did the company decide**
 18 **what kind of indications or reasons the company**
 19 **should study Risperdal for as far as children and**
 20 **adolescents?**
 21 A. Well, there are two sources to make that
 22 decisions. First of all, we had experts in the
 23 field and we did advisory panels because we knew --
 24 **Q. Is that advisory panels?**
 25 A. Yeah, advisory panels, yes. So that's a group

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1 of experts in the field that you bring together and
 2 that you raise questions and you hear on their
 3 opinion. And they said -- because we knew there was
 4 widespread use in pediatrics of Risperdal -- and
 5 they said, well, where is this used most prominent?
 6 And consequently, that is where you have the most
 7 prominent, pronounced medical need.
 8 On the other hand -- and also the
 9 FDA -- and remember the pediatric exclusivity law --
 10 there, the FDA said we want you to do clinical
 11 studies in pediatrics in this indication, which was,
 12 in our case, schizophrenia and bipolar mania,
 13 because those are the two indications for which the
 14 product was approved in adults. And they said once
 15 this indication can also occur in pediatrics, we
 16 want you to study that field. So there are two
 17 different sources in making that selection.
 18 **Q. So outside experts, outside doctors would**
 19 **suggest ways that Risperdal may be helpful and then**
 20 **the FDA also gave you some information about what**
 21 **they wanted?**
 22 **MR. KLINE:** Objection; asked and
 23 answered; and simply repeating his testimony
 24 as she's inclined to do, so I object.
 25 **THE COURT:** How about leading?

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1 MR. KLINE: And leading, too.
 2 THE COURT: Sustained. Sustained.
 3 BY MS. SULLIVAN:
 4 Q. And, Dr. Caers, I want to show you a document
 5 that was marked by the plaintiffs. It was
 6 Plaintiff's Exhibit 16, if I may.
 7 MS. SULLIVAN: Okay. Is there any
 8 objection?
 9 THE COURT: I don't know. What is
 10 this document?
 11 MR. KLINE: I need to get the
 12 document in front of me.
 13 MS. SULLIVAN: It's your Exhibit
 14 Plaintiff's 16.
 15 MR. KLINE: I understand that. And
 16 there was a pile this high.
 17 THE COURT: Okay. This is D-16?
 18 MS. SULLIVAN: Plaintiff's 16.
 19 MS. BROWN: P-16.
 20 COURT CRIER: It was a plaintiff's
 21 exhibit.
 22 THE COURT: P-16.
 23 MR. KLINE: Your Honor, it's an FDA
 24 contact document, and it's a Janssen
 25 document. I just need to know what the

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1 question is before the display.
 2 THE COURT: Yeah, I agree.
 3 MR. KLINE: Certainly every document
 4 doesn't need to be displayed.
 5 THE COURT: All right. Why don't you
 6 ask your questions and see how you're going
 7 to use this document.
 8 MS. SULLIVAN: Sure.
 9 BY MS. SULLIVAN:
 10 Q. Dr. Caers, were you involved with interactions
 11 with FDA and interactions with people in your group
 12 who interacted with FDA about what indications
 13 Janssen should seek approval for?
 14 A. Yes, I was.
 15 Q. And there are also meetings with the FDA on
 16 that issue?
 17 A. Yes, there were.
 18 Q. And, Dr. Caers, you're familiar with -- well,
 19 tell us about the conduct disorder issue.
 20 A. Well, conduct disorder, that was back in the
 21 mid-'90s when the advisors, as I referred to
 22 earlier, advisors that this was one of the areas in
 23 pediatrics where there was a major medical need and
 24 where there was a substantial use already at that
 25 moment. And that's why in the mid-'90s we started

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1 the whole development program to study Risperdal in,
 2 the umbrella term, "conduct disorder," or with other
 3 words also, disruptive behavioral disorders. And we
 4 did several double-blind studies.
 5 First, there's placebo. That means
 6 you give one group the active compound and the other
 7 group you give a sugar pill, but that looks the same
 8 and you don't know which one of the two has the
 9 active and which one has the placebo, the sugar
 10 pill. And then you see whether you find a
 11 difference between the active and the placebo, which
 12 is the documentation of your efficacy, and obviously
 13 also document all safety. So this is the efficacy
 14 study.
 15 On top of that, we did long-term
 16 safety studies where you have patients exposed to
 17 the compound over a long period and you document all
 18 safety aspects related to the product.
 19 Q. And, Dr. Caers, you said it was already being
 20 used in conduct disorder. What do you mean, sir?
 21 A. Well, as was mentioned earlier today, there
 22 was also in the '90s, there was a certain off-label
 23 use in the US of Risperdal in pediatrics. And based
 24 on the feedback we got from these experts, this was
 25 one of the areas where there was substantial

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1 off-label use; but also that in their experience,
 2 there was a very substantial benefit. But obviously
 3 that had to be documented in well-designed studies.
 4 Q. And, Dr. Caers, did the FDA have any concerns
 5 about Janssen seeking approval for the indication
 6 conduct disorder for children and adolescents?
 7 A. Well, yeah. We consulted with the FDA to
 8 which extent the FDA thought that this would be a
 9 valid indication for Risperdal and they raised their
 10 concerns. They thought that this product, and
 11 particularly its use would be targeted towards
 12 aggression and agitation in conduct disorders'
 13 patients, and they didn't feel that aggression on
 14 itself was an appropriate indication for label --
 15 MR. KLINE: Your Honor, please.
 16 THE COURT: I'm going to permit him
 17 to finish his answer.
 18 MR. KLINE: Yes.
 19 THE WITNESS: They did not say it
 20 didn't exist, because there's a big book -- a
 21 thick book, the DSM-IV, which lists all the
 22 psychiatry disorders by the American
 23 Psychiatry Association. They said, yes, we
 24 recognize it's in that thick book, but,
 25 nevertheless, we don't think this is an

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1 appropriate indication for label.
 2 **MR. KLINE:** Move --
 3 **MS. SULLIVAN:** And --
 4 **MR. KLINE:** May I, please?
 5 Move to strike. It's all hearsay
 6 based on what he says the FDA says.
 7 **THE COURT:** Well, I am going to deny
 8 that motion at this time. I'm going to deny
 9 it.
 10 But, again --
 11 **MS. SULLIVAN:** May I use the
 12 document, Your Honor?
 13 **THE COURT:** I don't know. You have
 14 to use that for a legitimate purpose. I
 15 mean, to refresh memory, some kind of
 16 reference, you know, something that has to be
 17 legitimate as far as being flashed up on
 18 evidence.
 19 **MS. SULLIVAN:** Well, they've put it
 20 up. This is their document. They put it up.
 21 **THE COURT:** It doesn't matter whether
 22 it's their document. They used it for a
 23 particular purpose.
 24 **BY MS. SULLIVAN:**
 25 **Q. And, Dr. Caers, are you familiar -- the jury**

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1 **has seen the term -- and Mr. Kline showed**
 2 **Dr. Kessler -- the term as it related to conduct**
 3 **disorder, the FDA's concern about, quote-unquote, a**
 4 **"chemical straitjacket." Are you familiar with that**
 5 **document?**
 6 A. Well, yes. Because that was in the minutes, I
 7 think, of that actual meeting.
 8 **Q. Yeah.**
 9 A. And that has exactly to do with the treatment
 10 of aggression. That's -- that's a delicate issue.
 11 Why do you treat aggression? Is it in order to help
 12 the patient or is it in order to help the
 13 environment?
 14 **Q. And, Doctor --**
 15 **MR. KLINE:** Your Honor, move to
 16 strike. He's not a physician. He's not even
 17 a physician.
 18 **THE COURT:** Well, no. Overruled.
 19 Overruled.
 20 It's still unclear to me, Counsel,
 21 exactly what role this witness had in all of
 22 this.
 23 **MS. SULLIVAN:** Fair enough, Judge.
 24 **BY MS. SULLIVAN:**
 25 **Q. Dr. Caers, can you describe -- can you tell**

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1 **our jurors what role you had in the overall**
 2 **Risperdal approval process?**
 3 A. Well, not only in the approval process, my
 4 team, as I said earlier, which was managed by me, so
 5 headed by me, was dealing with all clinical studies
 6 done with Risperdal worldwide. We were dealing with
 7 all submissions. We were dealing with all the
 8 consultations with regulatory bodies, including the
 9 FDA, but not limited to the FDA. My team was
 10 dealing with all the studies with it, reporting
 11 them, putting the files together, submitting the
 12 files, negotiating and having meetings with the FDA
 13 before submission, if necessary after submission,
 14 and eventually dealing with the final label as
 15 approved by the FDA.
 16 **Q. And, Dr. Caers, as part of that process, would**
 17 **you review minutes of meetings with the FDA?**
 18 A. Yes.
 19 **THE COURT:** And also, Counsel, would
 20 you ask him what the timetable of his
 21 involvement in this -- what he just
 22 described, what are we talking about? So I
 23 can understand for relevancy sake, once and
 24 for all --
 25 **MS. SULLIVAN:** Sure.

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1 **THE COURT:** -- what we're talking
 2 about.
 3 **THE WITNESS:** If I may.
 4 **THE COURT:** Yeah. Go ahead.
 5 **THE WITNESS:** I played this role as a
 6 team development leader since 1999, mid-1999,
 7 but also before I was involved in the
 8 Risperdal strategy, but less so in dealing
 9 with the FDA meetings. But from 1999 up to
 10 2009, I was involved with basically all these
 11 meetings.
 12 **MS. SULLIVAN:** And so can I now
 13 display Plaintiff's Exhibit 16?
 14 **MR. KLINE:** No. It's just full of
 15 FDA stuff, Your Honor.
 16 I don't object to the "chemical
 17 straitjacket" part.
 18 **THE COURT:** Pardon me?
 19 Well, as far as I'm concerned, is
 20 this a document he's familiar with?
 21 **MS. SULLIVAN:** Yes.
 22 **THE COURT:** Why don't you just
 23 authenticate it in the usual way.
 24 **MS. SULLIVAN:** Yeah.
 25 **THE COURT:** And then we'll go for it.

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1 **BY MS. SULLIVAN:**
2 **Q. And, Dr. Caers, is this a document that you're**
3 **familiar with; that you've seen?**
4 A. Yeah, sure. Because Al Derivan is one of the
5 gentlemen -- he was my clinical leader on my team as
6 a child psychiatrist; Goedele DeSmedt. So, yes, all
7 these people were a member of my team. And
8 obviously I was involved from A to Z in preparing
9 for this meeting. I was not actually at that
10 meeting, but I was also involved in reviewing the
11 minutes and the next steps.
12 **MS. SULLIVAN:** And, Your Honor, may I
13 display the --
14 **THE COURT:** For what purpose?
15 **MS. SULLIVAN:** I wanted to talk about
16 their -- in response to Mr. Kline's argument
17 about chemical straitjacket, what was really
18 going on here.
19 **THE COURT:** Well, why don't you have
20 him review this document, look at the bullet
21 point and ask him. You don't need to put the
22 whole document up there because I don't
23 believe this whole document was admitted
24 before in its entirety, unless there's a
25 reason for it.

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1 **MS. SULLIVAN:** They had it up with
2 Dr. Kessler, Your Honor.
3 **THE COURT:** Again, whatever -- I have
4 to go through my notes as to what the reason
5 was.
6 For the purpose that you're telling
7 me now, you can have him comment on what was
8 going on with that chemical straitjacket
9 bullet point by refreshing his memory about
10 that point without putting the whole document
11 in there.
12 **BY MS. SULLIVAN:**
13 **Q. So, Dr. Caers, can you talk about the FDA's**
14 **concern on this chemical straitjacket statement that**
15 **Mr. Kline referred to in his case and what the**
16 **company's response was?**
17 **MR. KLINE:** Object to the hearsay.
18 No objection to the company --
19 **THE COURT:** No. As to his concern,
20 FDA, or Janssen's response to that whole
21 issue, absolutely.
22 You may proceed.
23 **THE WITNESS:** So as I said earlier,
24 the FDA had concerns about treating
25 aggression as a target, and they didn't say

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1 no, because they don't -- they just raised a
2 concern and referred to the term
3 "straitjacket." But they also said, look,
4 before we decide on this, you can go ahead,
5 but we will bring it before a public advisory
6 board. And a public advisory board is part
7 of the review process with the FDA in which
8 they ask, again, experts in the field,
9 whether the experts support an approval, yes
10 or no. So it's not you can't do it, but they
11 said we are not convinced.
12 **BY MS. SULLIVAN:**
13 **Q. And so what did Janssen do in response to**
14 **that?**
15 A. Well, we did two things, because, again, this
16 is within the pediatric exclusivity legislation.
17 Part of this meeting was as well. Our question to
18 the FDA, this is the studies we have already done in
19 pediatrics. Can this be used for submitting for the
20 pediatric exclusivity?
21 And there, the FDA said, no, we don't
22 think so because we -- we -- and this legislation
23 was very new at that moment. The position by the
24 FDA was we want you, first of all, to study,
25 according to the pediatric exclusivity legislation,

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1 we want you to study Risperdal in this case in
2 schizophrenia and bipolar mania, because those are
3 the two indications the product was also approved
4 for in adults. And this indication, this disease
5 can occur in children and adolescents, at least for
6 schizophrenia in adolescents.
7 **Q. And, Dr. Caers, did Janssen pursue those**
8 **indications in children, schizophrenia and bipolar?**
9 A. So as a consequence of this meeting, we
10 definitely pursued and did studies in both
11 adolescents with schizophrenia and in children and
12 adolescents with bipolar mania, and we eventually
13 got pediatric exclusivity approved.
14 **Q. And was Risperdal approved for children with**
15 **schizophrenia?**
16 A. Not for children, but for only adolescents.
17 **Q. Adolescents.**
18 A. Schizophrenia doesn't occur before the age of
19 adolescents. So it was adolescents with
20 schizophrenia and children of 10 years and older and
21 adolescents in bipolar mania.
22 **Q. And can you talk to our jurors about how**
23 **Janssen's decision to pursue FDA approval for kids**
24 **with autism came about?**
25 A. That's a whole different story.

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1 It all started with a study and a
 2 consortium of US academic centers. And there they
 3 had to combine themselves -- organize themselves under
 4 what they call the RUPP consortium. And RUPP stands
 5 for Research Unit for Pediatric Psychotherapy, or
 6 Psychopharmacology. And they concluded, with the
 7 sponsorship of the National Institute of Mental
 8 Health, which is a government organization that
 9 sponsors and that stimulates research in mental
 10 health, this consortium run what is called the RUPP
 11 study, or the USA-150, totally without really
 12 contacts and input from our side in the study design
 13 and the study conduct.

14 **Q. And, Dr. Caers, you were familiar with the**
 15 **RUPP study?**

16 A. Yes, I am.

17 **Q. And can we -- and did Janssen -- well, can we**
 18 **mark -- I think it's already been used. Defense**
 19 **Exhibit...**

20 **MS. BROWN:** It would be -- we're
 21 going to mark the flip chart as 59. So it
 22 would be 60, if we have not already used it.
 23 (Exhibits D-59 and D-60 marked for
 24 identification.)

25 **MS. SULLIVAN:** Any objection?

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1 **MR. KLINE:** Yes. Your Honor, the
 2 learned -- if it's learned treatise, it falls
 3 under Aldridge. And to the extent he
 4 testifies he knows it and the like, that's
 5 fine. To the extent it's going to be read,
 6 displayed, parroted, then I object, under
 7 Aldridge, specifically under the Aldridge
 8 case, which doesn't allow that.

9 **MR. MURPHY:** He's not an expert.

10 **MR. KLINE:** With an expert or a
 11 nonexpert.

12 **THE COURT:** Yes. Sustained.

13 **BY MS. SULLIVAN:**

14 **Q. Dr. Caers, the study that you talked about,**
 15 **who funded that study, the RUPP study?**

16 A. The RUPP study was funded by the National
 17 Institute of Mental Health.

18 **Q. And that's the government?**

19 A. That's a government-sponsored institute to
 20 stimulate research in mental health in the United
 21 States of America.

22 **Q. And can you tell me -- and so Janssen -- did**
 23 **Janssen have anything to do with the RUPP study?**

24 A. No. We were not involved in the design and
 25 the execution of the study.

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1 **Q. And what did this government-funded study find**
 2 **on the issue of Risperdal and whether it worked for**
 3 **kids with autism?**

4 A. Well, the results which were published in
 5 2002, I think, they showed that there was clear
 6 efficacy of Risperdal in the children compared to
 7 placebo. Remember, the sugar pill. It was a
 8 double-blind study. And there was very robust
 9 efficacy, particularly on what they call the
 10 irritability associated with autism, which are
 11 symptoms of agitation, aggression, restlessness and
 12 things like that. And they also obviously
 13 documented the safety in this study as described in
 14 the paper.

15 **Q. And can you tell us whether the RUPP study got**
 16 **any press?**

17 **MR. KLINE:** Objection, Your Honor.
 18 Whether it got press is irrelevant.

19 **THE COURT:** Whether it got press,
 20 sustained.

21 **BY MS. SULLIVAN:**

22 **Q. How, Dr. Caers, if at all, did the findings of**
 23 **the RUPP study impact Janssen in terms of their**
 24 **research?**

25 A. Well, the data were published in the New

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1 England Journal of Medicine, by the way, which is
 2 one of the most famous medical journals here in this
 3 country and worldwide, by the way. But also we were
 4 contacted actually by the RUPP investigators, and
 5 they said look --

6 **MR. KLINE:** Objection to the hearsay.

7 **THE COURT:** Well, I'm really more
 8 interested --

9 **MR. KLINE:** "They said."

10 **THE COURT:** -- in what this witness
 11 did. So if you can -- you know, if it was in
 12 response to something --

13 **MS. SULLIVAN:** Yeah. It's offered
 14 for a non-hearsay purpose, Your Honor.

15 **BY MS. SULLIVAN:**

16 **Q. So did the RUPP investigators communicate to**
 17 **you information that led Janssen to research this**
 18 **medicine in children with autism?**

19 A. Well, as I was trying to say, the RUPP
 20 investigators contacted us and actually said, hey,
 21 you should really look at those data because we
 22 really think these are unique findings.

23 **MR. KLINE:** Objection to the hearsay,
 24 Your Honor. I can't cross-examine them.

25 **THE COURT:** You know what, so we're

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1 really clear, what is easy to tell the jury
 2 about from a legal point of view is what you
 3 did in response to what you were told by the
 4 FDA. But you're really not allowed under the
 5 general rules to tell us what the FDA told
 6 you. So what you need to do is to say, I
 7 heard from the FDA and I did this.
 8 **THE WITNESS:** I'm not referring to
 9 what the FDA told us.
 10 **MS. SULLIVAN:** These are the --
 11 **THE WITNESS:** I'm referring to what
 12 the RUPP investigators told us.
 13 **MS. SULLIVAN:** These are the folks on
 14 the government study.
 15 **THE COURT:** But that's still the same
 16 thing from a hearsay. That's still somebody
 17 else. That somebody else is not here to
 18 testify.
 19 **THE WITNESS:** Bottom line is: Those
 20 RUPP investigators suggested to us to talk to
 21 the FDA regarding this data, and they
 22 suggested us to see what the FDA -- whether
 23 this data might be suitable for including
 24 this information in the label because they
 25 were convinced that this was very important

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1 and relevant for the medical field.
 2 **BY MS. SULLIVAN:**
 3 **Q. And the RUPP investigators, can you, Dr.**
 4 **Caers, based on your experience with them, describe**
 5 **for our jurors who they were and what RUPP was**
 6 **about.**
 7 A. Well, RUPP was, as I said, a consortium of
 8 academic child psychiatric centers all over the
 9 country, and so these investigators were prominent
 10 child psychiatrists linked to different universities
 11 in this country.
 12 **Q. And, Dr. Caers, can you tell us what the**
 13 **company did next as a result of this RUPP study and**
 14 **your communications with these outside**
 15 **investigators.**
 16 A. Well, then we had a consultancy meeting with
 17 the FDA on the database, on the data from the RUPP
 18 study, but also because, as I had told earlier, we
 19 had done substantial research already in disruptive
 20 behavior disturbance in children and adolescents.
 21 So we went to the FDA and said, look, this is valid
 22 data on the use of Risperdal in children with autism
 23 and beyond that. We have very substantial and large
 24 database on Risperdal in children and adolescents,
 25 more particularly in conduct disorder.

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1 And the outcome of that meeting was
 2 that the FDA was prepared to accept such an SNDA, a
 3 Supplemental New Drug Application, for use of
 4 Risperdal in children and adolescents with
 5 irritability associated with autism. And that's
 6 important from the safety point of view with the
 7 much larger database we had collected in children
 8 and adolescents with conduct disorder.
 9 **Q. And, Dr. Caers, as part of the approval**
 10 **process for Risperdal for autistic kids, did the**
 11 **company do some of their own studies?**
 12 A. We had -- apart from the RUPP study, we had
 13 also a Canadian study which was company organized,
 14 which was also a double-blind study with active and
 15 the sugar pill, which the results of which were very
 16 much in line with the findings of the RUPP study.
 17 And that obviously was added to the weight of
 18 evidence in the SNDA. And, by the way, it was all
 19 information we had on the safety of Risperdal in
 20 children and adolescents.
 21 **Q. So, Dr. Caers, the safety data -- did the**
 22 **safety data that supported the autism approval with**
 23 **FDA include the safety data from this**
 24 **government-funded study, the RUPP study?**
 25 A. That is correct.

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1 **Q. And also some studies done by Janssen?**
 2 A. Yes.
 3 **Q. And, Dr. Caers, the plaintiffs in their case**
 4 **allege that the autism approval was pushed**
 5 **through --**
 6 **MR. KLINE:** Objection to the form.
 7 **THE COURT:** The plaintiff's claim?
 8 **MR. KLINE:** Yeah.
 9 **THE COURT:** No; sustained.
 10 **BY MS. SULLIVAN:**
 11 **Q. Dr. Caers, was the autism approval pushed**
 12 **through by Janssen or the FDA?**
 13 A. I'm afraid it's very difficult to push
 14 something through to the FDA. They are a fully
 15 autonomous body and they make up their own mind
 16 based on their own assessment by experts in the
 17 field within the FDA.
 18 **Q. How long, Dr. Caers, did it take between the**
 19 **time Janssen submitted the new drug approval package**
 20 **for autism to the FDA to the time the FDA ultimately**
 21 **approved the medicine for kids with autism?**
 22 **MR. KLINE:** Your Honor, objection.
 23 **THE COURT:** Basis?
 24 **MR. KLINE:** Basis is that the entire
 25 case here is '02 to '06. This is all about

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1 getting approval in '06.
 2 **THE COURT:** All right. I realize
 3 that.
 4 **MR. KLINE:** We admit that, and
 5 everyone in the case agrees --
 6 **THE COURT:** All right. I realize
 7 that. That's overruled.
 8 I mean, in case we forgot, why don't
 9 you have him answer. just in case we forgot.
 10 **THE WITNESS:** No. I think, to be
 11 honest with you, we submitted somewhere the
 12 SNDA for autism mid-2003 and eventually got
 13 an approval late 2006. So that is nearly two
 14 years and a half.
 15 **BY MS. SULLIVAN:**
 16 **Q. So it took a couple years?**
 17 A. Yes.
 18 **Q. And the FDA -- and, Dr. Caers, was there**
 19 **interaction between the company and the FDA over**
 20 **those years?**
 21 A. Yes; several.
 22 So first, that is, you submit your
 23 SNDA, and then the FDA reviews and they come back
 24 with the first feedback, after 10, 12, 15 months,
 25 which in this case was an approvable letter. That

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1 means it looks okay, guys, but you need to provide
 2 more information. Do you have more safety
 3 information? Do you have more dose information?
 4 Because that was a critical issue in this
 5 submission.
 6 We consequently brought additional
 7 data together and submitted them in what we call a
 8 complete response. Then the FDA once more reviews
 9 this additional information and then comes back with
 10 the next feedback and judgment, and that was an
 11 unapprovable letter. They said we still have decent
 12 questions about your dose recommendation, and
 13 that's -- that has technical reasons. I can
 14 elaborate upon, if you wish.
 15 Then we had a meeting with the FDA, a
 16 face-to-face meeting on what we could do next in
 17 order to come up to their concerns, and particularly
 18 the dosing recommendations. And eventually they
 19 accepted that with some additional specific analysis
 20 of the data and the existing data. They accepted an
 21 approval with what we call a Phase IV commitment;
 22 that the FDA said, yes, we approve, but that means
 23 that you're going to need one additional study after
 24 we approve, which is a Phase IV commitment, on
 25 studying the lowest effective dose in children and

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1 adolescents with autism.
 2 **Q. Did the --**
 3 **MR. KLINE:** Your Honor, we weren't
 4 told the year.
 5 **THE COURT:** Well, again, there's an
 6 objection?
 7 **MR. KLINE:** Yes. There's no
 8 objection if we're told the year of this.
 9 **THE COURT:** I mean, if you want to,
 10 we can go back through all of that and give
 11 the relevant time periods, if you want.
 12 **THE WITNESS:** Well, as I said, the
 13 first submission was in mid --
 14 **MR. KLINE:** My objection was only to
 15 the year that it was approved.
 16 **THE WITNESS:** The approval was in --
 17 **THE COURT:** No. Counsel, that's
 18 overruled. Otherwise I would permit just
 19 putting the document up there that
 20 Ms. Sullivan wanted at the very beginning.
 21 We need to get through this.
 22 **THE WITNESS:** Yeah. Once again, we
 23 did submit the SNDA in mid-2003, about, and
 24 then the different steps, which I don't know
 25 by heart the actual dates, but I do know I

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1 think we had the final approval in
 2 October 2006.
 3 **BY MS. SULLIVAN:**
 4 **Q. So, Dr. Caers, can you tell us whether the**
 5 **company satisfied the FDA's request for additional**
 6 **safety data, additional information, as part of the**
 7 **approval process?**
 8 A. Yes. Of course we did, because otherwise the
 9 FDA would not have approved the indication back in
 10 October 2006.
 11 **Q. And, Dr. Caers, I want to show you, and with**
 12 **permission from the Court, I want to show the jury**
 13 **the FDA October 23, 2006 approval letter for the**
 14 **autism indication.**
 15 **MR. KLINE:** Objection, based on the
 16 Court's rulings.
 17 **THE COURT:** That's sustained. That's
 18 the same thing.
 19 **MR. KLINE:** And she knows it.
 20 **THE COURT:** We have a label in
 21 evidence. And we know that this document
 22 exists. The letter is -- you can mark it,
 23 put it into the record. But there's no
 24 reason to -- there is just no reason to put
 25 that up on the board. We know that.

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1 MS. SULLIVAN: Well, Your Honor, at
 2 sidebar you said I could show the children
 3 and adolescent label.
 4 THE COURT: I didn't say anything of
 5 the sort.
 6 MS. SULLIVAN: I mean the approval
 7 letter.
 8 THE COURT: I didn't say anything of
 9 the sort. We have the 2006 label. That's in
 10 evidence.
 11 MS. SULLIVAN: I can't show that
 12 there was the approval letter from the FDA?
 13 THE COURT: Was your application for
 14 autism in children approved by the FDA?
 15 THE WITNESS: Yes.
 16 THE COURT: All right. So much so.
 17 BY MS. SULLIVAN:
 18 Q. And, Dr. Caers, as part of the approval
 19 process, does the FDA send you an approval letter?
 20 A. Yes, of course.
 21 Q. And does the FDA communicate -- did the FDA
 22 communicate to Janssen what they could say on the
 23 FDA approved label?
 24 MR. KLINE: Objection; violative of
 25 the Court's direction.

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1 THE COURT: No. I mean, again,
 2 you're permitted to ask that, sure.
 3 THE WITNESS: Well, as every approval
 4 letter, that gives you the label that the FDA
 5 wants us to use from the day one, which is
 6 obviously an updated label, because now it
 7 covers all the relevant information that is
 8 relevant for the appropriate use of Risperdal
 9 in children and adolescents with irritability
 10 and autism.
 11 BY MS. SULLIVAN:
 12 Q. And let's show -- and, Dr. Caers, were you
 13 involved in the 2006 autism approval process with
 14 the FDA?
 15 A. Yes, I was.
 16 Q. And can you tell the jury who made the final
 17 decision on what should be said in the label?
 18 A. Well, that's obviously the FDA, as we alluded
 19 to earlier.
 20 Q. And, Dr. Caers, I'm going to put up the FDA
 21 approved label for autism in 2006. It's attached to
 22 the approval letter, which I won't show per the
 23 Court's instruction.
 24 Defense Exhibit...
 25 MS. BROWN: 61.

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1 MS. SULLIVAN: 61.
 2 MS. BROWN: You're showing the label
 3 from the approval, right?
 4 MS. SULLIVAN: Just the label.
 5 It's DX210. Now it's 61.
 6 MS. BROWN: From the approval letter,
 7 the 2006 approval letter.
 8 - - -
 9 (Whereupon Exhibit D-61 was marked
 10 for identification.)
 11 - - -
 12 BY MS. SULLIVAN:
 13 Q. And, Dr. Caers, in order to get FDA approval
 14 for children with autism, what did you have to
 15 establish with the FDA?
 16 A. In order to get the approval, you need to
 17 submit your complete data set, obviously, as we did
 18 in different steps.
 19 Q. And the FDA concluded it was appropriate for
 20 children?
 21 A. Well, the FDA back in October 2006 concluded
 22 that Risperdal is safe and effective in the
 23 management of irritability associated with autism,
 24 which is basically the meaning of an approval.
 25 Q. And if we look at the 2006 label, Dr. Caers,

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1 you have it on your screen?
 2 A. Yes, I do.
 3 Q. Okay. And this --
 4 MR. KLINE: Your Honor, this is --
 5 oh. It's the label. Okay. No objection.
 6 THE COURT: Okay.
 7 BY MS. SULLIVAN:
 8 Q. And, Dr. Caers, if we look at Page 11, it
 9 talks about the fact that it's now approved for
 10 irritability associated with autism, right?
 11 A. That is correct.
 12 Q. And it describes the symptoms. And if you
 13 could just read them for the jurors.
 14 A. Yes.
 15 As you can see here, these basically
 16 include symptoms of aggression towards others,
 17 deliberate self-injuriousness, temper tantrums, and
 18 quickly changing moods.
 19 Q. And so the FDA specifically at this juncture
 20 approved Risperdal for this purpose --
 21 A. That is correct.
 22 Q. -- in children and adolescents?
 23 A. That is correct.
 24 Q. And is this the same -- so there's been
 25 discussion -- and you mentioned there was off-label

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1 prescribing of Risperdal before it was approved in
 2 autism, right?
 3 A. Yes.
 4 Q. Is this the same compound, in other words, did
 5 the medicine change in terms of its compound or
 6 chemical make-up in 2006 as compared to what was
 7 being prescribed in '93, '94, 2002?
 8 A. It's the same compound.
 9 Q. So the same compound that was being prescribed
 10 off-label now had on-label?
 11 MR. KLINE: Objection; asked and
 12 answered. She just repeated.
 13 THE COURT: Yes. Sustained. That is
 14 sustained.
 15 BY MS. SULLIVAN:
 16 Q. And, Dr. Caers, if we look further in the
 17 label, there was a Precautions section in the label.
 18 A. Yes.
 19 Q. And you're familiar, Dr. Caers, with -- does
 20 the FDA have a format that Janssen has to follow in
 21 terms of how things are laid out in medicine labels?
 22 A. Yes. The full format of the label is fully
 23 described in FDA guidelines and has its own fixed
 24 format and chapters.
 25 Q. And does the FDA dictate the sections and the

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1 type and things like that?
 2 A. Yes.
 3 MR. KLINE: Your Honor, this goes --
 4 this goes to whether he's an FDA expert or
 5 not. And I just can't be on my toes all the
 6 time.
 7 THE COURT: Again, that's true.
 8 Sustained.
 9 You're going to have experts on this,
 10 aren't you?
 11 MS. SULLIVAN: Well, Your Honor, this
 12 gentleman --
 13 THE COURT: He doesn't know. He's
 14 not a member of the FDA, nor has been
 15 qualified as an expert. He knows from his
 16 own experience what he did and what kind of,
 17 you know, things that he had to do to get
 18 this thing approved for children.
 19 BY MS. SULLIVAN:
 20 Q. And, Dr. Caers, going further in the
 21 Precautions section, there's a section about
 22 elevated prolactin.
 23 A. Yes, indeed.
 24 Q. And can you talk to our jurors about what's in
 25 that section and why.

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1 A. Well, as has been in the label since 1993,
 2 reference is made to the occurrence of
 3 hyperprolactinemia in drugs such as Risperdal who
 4 interact, as I said earlier, with the receptors in
 5 the brain, the dopamine 2 receptors, and that in
 6 patients treated with drugs, that can increase
 7 prolactin; that certain adverse events, such as
 8 galactorrhea, amenorrhea, gynecomastia, and
 9 impotence, have been reported.
 10 Q. And, Dr. Caers, in the label there's also a
 11 pediatric section?
 12 A. Yes, there is, yes.
 13 Q. And there is separate information about the
 14 data in children and adolescents in the 2006 label,
 15 right?

16 Q. And can you talk to our jurors a little bit
 17 about what was in the October 2006 label on children
 18 and adolescents and elevated prolactin and
 19 gynecomastia.
 20 A. First of all, it is repeated in this section
 21 that risperidone increases prolactin. And this was
 22 also the case in the studies we provided. And that
 23 in the clinical trials we provided up to 1,885
 24 children and adolescents treated with Risperdal,
 25 there were, indeed, adverse events reported, such as
 galactorrhea in .8 percent of patients, and
 gynecomastia in 2.3 percent of the patients in our
 database.
 Q. And, Doctor, to get the 2.3 percent, did you
 look at all of the data in children and adolescents?
 A. Yes. It takes --
 Q. Go ahead.
 A. It takes all the studies that were done with
 risperidone, Risperdal in children and adolescents
 together, and then you come to the overall incidence
 of, in this case, gynecomastia, in this total
 population of 1,885 patients.
 Q. And, Doctor, there's been some criticism in
 this case about --
 MR. KLINE: Objection. I don't
 object to straight questions.
 THE COURT: Sustained. Sustained. I
 don't know what you're referring to. By
 whom?
 BY MS. SULLIVAN:
 Q. Dr. Caers, the jury has heard Dr. Kessler
 criticize --
 MR. KLINE: Objection. It's not a
 proper way to start a question.

1 **THE COURT:** Why don't you rephrase
2 it, Counsel.
3 **BY MS. SULLIVAN:**
4 **Q. Dr. Caers, whose idea was it to pool, to**
5 **include data on all of the children to get the**
6 **2.3 percent?**
7 **A.** That comes from the FDA. That's common
8 practice. That's the only way they systematically
9 document incidences in labels, incidences of adverse
10 events. They take all of the patients exposed for a
11 couple of days, up to a couple of years, take all
12 together and take one single database in which they
13 calculate the incidences. And that's how it is
14 reflected in the label.
15 **Q. And, Dr. Caers, I want to show you what's been**
16 **marked -- what will be marked as Defense Exhibit...**
17 **MS. BROWN:** 62.
18 **MS. SULLIVAN:** 62.
19 **BY MS. SULLIVAN:**
20 **Q. And it's a mark-up from the FDA of this 2006**
21 **label. And I'm going to ask you about it, if the**
22 **Court permits.**
23 **It's D234.1.**
24 **MS. SULLIVAN:** Do you have a copy,
25 Dr. Caers?

1 the mark-up of the label?
2 **MR. KLINE:** I have no objection to
3 what I believe is the mark-up of the label.
4 **MS. SULLIVAN:** And how about the
5 e-mail from the FDA?
6 **THE COURT:** Who's this made out to,
7 by the way?
8 **MS. SULLIVAN:** This is to -- this is
9 from the FDA to Janssen.
10 **MR. KLINE:** Yes; that I do. It
11 just -- it doesn't say anything. But I don't
12 believe they come in under the rules.
13 But I don't object to the document
14 you want to show.
15 **THE COURT:** The front page?
16 **MR. KLINE:** I do for the front page
17 because it's the FDA document. But the going
18 back and forth, which I think is what she
19 wants to show, I don't object to.
20 **MS. SULLIVAN:** It's to Janssen, Your
21 Honor. It's in their files. It's a business
22 record, from their regulator.
23 **THE COURT:** Let me see counsel here
24 at sidebar quickly.
25 - - -

1 **THE WITNESS:** I don't think so.
2 **COURT CRIER:** Not yet.
3 Mr. Kline.
4 **THE COURT:** It's been marked?
5 **COURT CRIER:** 62.
6 **MS. BROWN:** 62.
7 (Exhibit D-62 marked for
8 identification.)
9 **MR. KLINE:** This is just the FDA
10 track labeling?
11 **MS. SULLIVAN:** It's an e-mail from
12 FDA to Janssen about the label.
13 **MR. KLINE:** I have no objection to
14 the document.
15 **THE COURT:** It's now marked as P-62.
16 **COURT CRIER:** D-62.
17 **THE COURT:** D-62.
18 **MR. KLINE:** The document itself, not
19 the e-mail. I have no objection to the
20 mark-up of the label.
21 **MS. SULLIVAN:** I'm sorry, I didn't
22 hear you.
23 **MR. KLINE:** I have no objection to
24 the --
25 **THE COURT:** He has an objection to

1 (The following discussion transpired
2 at sidebar out of the hearing of the jury:)
3 - - -
4 **THE COURT:** First of all, this is now
5 going to be marked as what? D something?
6 **MS. SULLIVAN:** 62.
7 **THE COURT:** This discovery has been
8 provided. There's no discovery issue here,
9 correct?
10 **MR. KLINE:** No.
11 **MS. SULLIVAN:** No. We provided it.
12 **THE COURT:** Okay. So where is the
13 section on gynecomastia?
14 **MS. SULLIVAN:** The section I want to
15 show him is marked up by the FDA.
16 **THE COURT:** What page is that?
17 **MS. SULLIVAN:** It's Bates No. 752;
18 and Page 24 of the document.
19 **MR. KLINE:** 752. Bear with me.
20 **THE COURT:** I don't have the mark-up.
21 There's a mark-up there or something?
22 **MS. SULLIVAN:** It's 752, Your Honor.
23 **THE COURT:** So who's in the marking
24 up here?
25 **MS. SULLIVAN:** This is from the FDA;

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1 and he can talk about how they marked it up
 2 and what they told him to do. That's part of
 3 the discussions with the FDA.
 4 **MR. KLINE:** My understanding from --
 5 **MS. SULLIVAN:** And he can say he saw
 6 it; he knew it.
 7 **THE COURT:** All right. Well, this
 8 is --
 9 **MR. KLINE:** Well, he might have seen
 10 it, but he wasn't involved at all in this
 11 mark-up.
 12 **THE COURT:** Yeah.
 13 **MS. SULLIVAN:** Sure, he was.
 14 **MR. KLINE:** He may have been the
 15 boss, but he wasn't involved in this mark-up,
 16 as I understand it.
 17 **THE COURT:** The problem here is, is
 18 that unless this individual was the person
 19 who's involved in the FDA -- from Janssen in
 20 this correspondence, there's nothing to
 21 cross-examine this fella on.
 22 **MS. SULLIVAN:** He was -- he was
 23 provided it at the time, Your Honor. He was
 24 the boss.
 25 **THE COURT:** No. No. If he was the

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1 one -- okay. If you lay the foundation that
 2 he was personally involved in it --
 3 **MS. SULLIVAN:** Okay. Yeah. I'll do
 4 that.
 5 **THE COURT:** And then he's subject to
 6 Mr. Kline's cross-examination, I'm fine with
 7 it.
 8 **MS. SULLIVAN:** I'll do that, Judge.
 9 - - -
 10 (Sidebar discussion concluded.)
 11 - - -
 12 (The following transpired in open
 13 court in the presence of the jury:)
 14 - - -
 15 **BY MS. SULLIVAN:**
 16 **Q. Last point, Dr. Caers, before I think the**
 17 **Court wants to take a lunch break.**
 18 **THE COURT:** First of all, we're now
 19 on the record as to P-62.
 20 **COURT CRIER:** "D."
 21 **MR. MURPHY:** "D."
 22 **COURT CRIER:** Defense Exhibit 62.
 23 **THE COURT:** All right. This document
 24 is admitted for the purposes of its
 25 existence, and I think we are perhaps going

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1 to be able to refer to two pages of this
 2 document, if the proper foundation has been
 3 laid.
 4 **BY MS. SULLIVAN:**
 5 **Q. And, Dr. Caers, are you familiar with this**
 6 **document?**
 7 A. Yes.
 8 **Q. And were you involved at the time in the**
 9 **labeling decisions and discussions with the FDA?**
 10 A. Yes, I was.
 11 **Q. And I want to just show our jurors what's been**
 12 **marked as D-62.**
 13 **And, Dr. Caers, this is an e-mail**
 14 **from the FDA, right?**
 15 A. Yes, indeed.
 16 **MR. KLINE:** Your Honor, that's the
 17 exact document we didn't agree to at sidebar.
 18 But as long as I don't waive an inconsistency
 19 objection, she can show it.
 20 **THE COURT:** Well, this appears -- no.
 21 I don't really have a problem. This is an
 22 e-mail to Janssen saying that we are
 23 negotiating and discussing this label; is
 24 that right?
 25 **MR. KLINE:** It's a transmittal.

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1 **MS. SULLIVAN:** This is a --
 2 **THE COURT:** So we can now go to the
 3 actual points in question.
 4 **MS. SULLIVAN:** Sure.
 5 **THE COURT:** This witness was not on
 6 this e-mail, correct?
 7 **BY MS. SULLIVAN:**
 8 **Q. But, Dr. Caers, you would have seen this**
 9 **document?**
 10 A. Yes.
 11 **THE COURT:** So I'm interested in
 12 laying a foundation for the other questions
 13 involving the contents that are part of this
 14 document.
 15 **MS. SULLIVAN:** Sure.
 16 **THE COURT:** Of the attachment. And I
 17 don't need this particular document on the
 18 screen.
 19 **BY MS. SULLIVAN:**
 20 **Q. Dr. Caers, did the FDA provide a mark-up to**
 21 **Janssen before approval -- this is a month before --**
 22 **the September 28th date is a month before the FDA**
 23 **approves the medicine for autism?**
 24 A. Yes, indeed.
 25 **MR. KLINE:** Objection; leading;

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1 simply leading. It's asking to confirm.
 2 **THE COURT:** All right. Well, she's
 3 attempting to lay a foundation, so that's
 4 permitted.
 5 Overruled.
 6 **BY MS. SULLIVAN:**
 7 **Q. And, Dr. Caers, did the FDA actually mark up**
 8 **the label and tell Janssen what it wanted?**
 9 A. Yes.
 10 So what this is, is they identify
 11 track changes. So you can see what they delete.
 12 You can see what they add by underlining the
 13 letters. So you can see what changes the FDA
 14 proposes to the label in order to come to a final
 15 approved label for Risperdal in irritability
 16 associated with autism.
 17 **Q. And as part of the proposed label that the FDA**
 18 **marked up, did they make -- did the FDA comment on**
 19 **how Janssen should disclose the data about**
 20 **gynecomastia in the 2006 label, as it related to**
 21 **children?**
 22 A. Well, here it refers to, indeed, to the latest
 23 number of patients that we eventually had in the
 24 total file and consequently through the total
 25 incidence, in these 1,923, about patients that have

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1 been documented with Risperdal.
 2 **Q. And did the FDA ask Janssen to pool all the**
 3 **data?**
 4 A. Oh, yes. That's common practice.
 5 **MS. SULLIVAN:** Okay. It's a good
 6 time, Your Honor, if that makes sense for the
 7 Court.
 8 **THE COURT:** Sure.
 9 Pages 24 and 25; is that what we're
 10 talking about? Well, actually --
 11 **MS. SULLIVAN:** That was Page 24, Your
 12 Honor, and also the first -- the document,
 13 the e-mail from the FDA.
 14 **THE COURT:** All right. For the
 15 record, this is at JJRP00824751 and 4752.
 16 You want to take a break now,
 17 Ms. Sullivan?
 18 **MS. SULLIVAN:** Oh, I'm sorry, I
 19 thought we were.
 20 **THE COURT:** No. We can take a break
 21 anytime.
 22 **MS. SULLIVAN:** Okay. I thought it
 23 was a good spot, Your Honor.
 24 Thank you.
 25 **THE COURT:** You want to take a break

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1 here?
 2 **MS. SULLIVAN:** Yeah. That's good.
 3 **THE COURT:** All right. Members of
 4 the jury, we are going to recess for lunch
 5 right here. Please come back around 1:30,
 6 and we will continue.
 7 To our juror from McDonald's, all I
 8 can tell you is that I'm working on it, and
 9 I'm very surprised by the reaction of
 10 McDonald's, okay? We're working on it.
 11 We will take a break here. Please do
 12 not discuss this matter with each other, and
 13 wear your yellow badges. And please do not
 14 refer to any outside source for any
 15 information about this case, all right?
 16 Thank you.
 17 See you at 1:30.
 18 **COURT CRIER:** All rise as the jury
 19 exits.
 20 - - -
 21 (Whereupon the jury exited the
 22 courtroom at 12:36 p.m.)
 23 - - -
 24 **THE COURT:** All right. Then we're in
 25 recess till 1:30.

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1 (Morning Session concluded.)
 2 - - -
 3 (Whereupon the Afternoon Session was
 4 reported and transcribed by Judith Ann
 5 Romano, CRR, Official Court Reporter.)
 6 - - -
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1 CERTIFICATION

2
3 I hereby certify that the proceedings
4 and evidence are contained fully and
5 accurately in the notes taken by me on the
6 trial of the above cause, and that this copy
7 is a correct transcript of the same.

8 I further certify that I am not a
9 relative or employee of any attorney or
10 counsel employed in this case.

11
12
13
14
15 _____
16 John J. Kurz, RMR, CRR
17 Registered Merit Reporter
18 Certified Realtime Reporter
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