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

IN RE: RISPERDAL® LITIGATION : March Term, 2010, No. 296 :

PHILLIP PLEDGER, by BENITA PLEDGER, as Guardian of his Person and Conservator of his Estate, Plaintiffs,

٦7.

JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, and Janssen Pharmaceutical Research and Development, L.L.C. Defendants APRIL TERM 2012

: NO. 01997

TUESDAY, FEBRUARY 3, 2015

VOLUME VII MORNING SESSION

COURTROOM 425 CITY HALL PHILADELPHIA, PENNSYLVANIA

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

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(Pledger v Janssen, et al.)

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(Pledger v Janssen, et al.) (Hearing is reconvened at 9:43 a.m., and the following transpired in open court:)

MS. SULLIVAN: Your Honor, the Plaintiffs alerted us last night that they are dropping Dr. Goldstein, their causation expert, and would like to substitute an expert. I submit, Your Honor, that's a violation of Pennsylvania Rule of Civil Procedure 4003.5, which says that an expert whose identity is not disclosed in compliance with the discovery rule "shall not be permitted to testify on behalf of the defaulting party at trial. However, if the failure to disclose the identity of the witness is the result of extenuating circumstances beyond the control of the defaulting party, the court may grant a continuance or other appropriate relief."

I submit, Your Honor, that the Plaintiff sending an expert to Alabama when he was not licensed under applicable Alabama law is not extenuating circumstances. I request that Your Honor exclude the new expert. It would be dramatically an unprecedented

(Pledger v Janssen, et al.) evidence that he consulted with an Alabama doctor. They caused this problem. We should not be punished. We complied with the law, they did not. Unprecedented and dramatic prejudice to switch their major causation expert --

THE COURT: Ms. Sullivan, I haven't heard anything yet from the Plaintiff formally. Let's hear from the Plaintiff and then we will look at the situation in the context of what is planned other than causation testimony today.

> MR. KLINE: Good morning, Your Honor. THE COURT: Good morning.

MR. KLINE: Dr. Goldstein has gone home, he is no longer in Philadelphia. Per the Court's discussion with us yesterday, I had a discussion with him. There are just a series of complicating factors which are -which he cannot be exposed to. And so I put in the works, per the Court's directive that I could have another expert, that which will be done today.

The Plaintiff will be examined, I

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(Pledger v Janssen, et al.) prejudice to us. We have framed our whole case, our opening, our cross-examination is based on their causation theory of this expert. Our experts have been lined up for a year in response to their causation expert and his report. They have specifically referenced findings and material in their expert's report. This dramatically changes the face of the entire case, and so I request that Your Honor exclude the witness.

If Your Honor is inclined not to, the Defendants would request a mistrial in light of the circumstances and the significant prejudice. And also, Your Honor, we submit that no additional witnesses should be called in light of the fact that we don't even have any report, and so we are going to have witnesses testify when we are cross-examining witnesses without notice of the theory of the case. This is unprecedented.

Honor, it came to our attention when they tried to hide Dr. Goldstein behind this de

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(Pledger v Janssen, et al.) expect a report tomorrow, I expect to have the expert testify Thursday.

The surprise and prejudice which is mentioned here is down right silly. The theory of the case, Plaintiff's case has always been and will remain that this boy has gynecomastia as a result of this drug Risperdal, and the bases are also well-known. My word, we have been at this for years. And they knew about this issue, as the Court knows, a year ago and they are the ones who sat on it in ambush, and all I did last night was follow the Court's directive, and I am in the process, at my client's cost, prejudice, and inconvenience, to be examined and to have a new expert report.

The rule that Ms. Sullivan cites, right in that rule, the part she didn't emphasize, gives the Court considerable latitude, and indeed, the Court exercised that discretion.

THE COURT: Which rule are we discussing here?

MS. SULLIVAN: Your Honor, this is Pennsylvania Rule of Civil Procedure 4003.5.

We did not cause this situation, Your bene esse issue. They did not produce any

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anything, and we are going to hold it under advisement, but we are going to continue now. We have a jury waiting.

MS. SULLIVAN: Your Honor, we would object to that and move for a mistrial. THE COURT: Either they have the

causation evidence or they don't. If they don't, it will be a nonsuit. So therefore --MS. SULLIVAN: Your Honor, it's

significant prejudice --

THE COURT: Ms. Sullivan. Bring in the

(Pledger v Janssen, et al.) are now proceeding with Plaintiff's next witness.

MS. SULLIVAN: I object to that, Your Honor, and move --

THE COURT: Mistrial is denied. There is nothing on this record yet the Court has decided that has been prejudicial that I can see to the Defendant in this matter. The Plaintiff is entitled to bring witnesses in the order they see at this time.

MS. SULLIVAN: And I would move for a stay of that, Your Honor, because we don't have a causation expert anymore in this case.

THE COURT: Sit down.

MS. SULLIVAN: You are denying a stay, Your Honor?

> THE COURT: A stay of what? MS. SULLIVAN: A stay of --

THE COURT: I am denying a stay as to the order of the witnesses of the Plaintiff.

MS. SULLIVAN: Thank you, Your Honor.

THE COURT: I will also remind both parties that this particular matter is more complicated than it seems at first because of

(Pledger v Janssen, et al.) jury.

MS. SULLIVAN: It's significant prejudice, Your Honor, it goes to the timing and onset. The entire case was framed around this expert's opinion. We object to --

THE COURT: The order of admission of witnesses is up to the Plaintiff or the Court.

MS. SULLIVAN: But, Your Honor --

THE COURT: And I am permitting right now new testimony with the jury waiting at ten of 11 from whoever the Plaintiff wants to bring that's admissible. That's the ruling of the Court. Please sit down.

MS. SULLIVAN: Your Honor, the direct and cross examination would differ depending on the causation expert they have.

THE COURT: I am sorry, this is your motion.

MS. SULLIVAN: And, Your Honor, I move for mistrial and I move for a stay of Your Honor's ruling so we can take it up to the Superior Court.

THE COURT: I haven't made any ruling. I said I will hold it under advisement. We

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(Pledger v Janssen, et al.)

the late filing of the motion that defense filed yesterday on the eve of the testimony of Dr. Goldstein. It is more complicated; there are provisions for extraordinary circumstances in Rule 4003.5, and also, there are provisions there. "Upon cause shown, the court may further order discovery by other means, subject to such restrictions as to scope and such provisions concerning fees and expenses as the Court may deem appropriate." That is at 4003.5(2).

We will review the matter and hold it under advisement.

I will say this, though, if it's possible to prove causation through existing witnesses, that is also acceptable to this Court. From what I have seen, because I have read Dr. Goldstein's expert report, there are two aspects of his expert opinion, one has to do with the effect of Risperdal generally, and one specifically as to this client. You may be able to prove it by inferential evidence, circumstantial evidence, I just don't know.

(The jury enters the room at 9:53 a.m.)

15 1 (Gilbreath - As on Cross) 2 at either Janssen or Johnson & Johnson? 3 I have been with Johnson & Johnson for 15-plus 4 years. I was actually in the role of representative 5 from 1999 through 2005. So from 1999 to 2005, you were in sales, 6 7 correct? 8 Α 9 Q And you were compensated like a salesman, 10 correct? 11 Α Yes. 12 You were compensated on how much was sold that 0 13 you were out trying to sell, correct? 14 A small portion was in accordance with that 15 but, primarily, we had a salary and then there 16 were --17 Bonuses? 0 18 Α Ves 19 And the bonuses were linked to how much was 0 20 purchased through the customer, correct? 21 The customer didn't "purchase", but according 22 to their prescriptions, yes, and there was a smaller portion --23

Yes, and you tracked -- I am sorry, I was

talking over you, I apologize. You were finishing?

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14 (Gilbreath - As on Cross) 1 2 And part of sales is to promote, correct? 3 Yes. I would say promote for appropriate Α 4 uses. 5 Well, I am just talking about sales generally. 6 The definition of sales is to sell, having nothing 7 to do with appropriate or inappropriate use, 8 correct? 9 MR. MURPHY: Objection. Asked and 10 answered. THE COURT: Overruled. It's too early 11 12 in the morning for this fussiness. Go ahead. Correct, sir? 13 0 Repeat the question, please. 14 Α Yes. As a general proposition, the objective 15 16 of sales is to promote, correct? 17 Yes, we describe appropriate uses in 18 appropriate patients --19 I am not talking about patients or anything, sir, I am just talking about establishing a dialogue 20 here. Is the word "sell" meaning that you promote 21 22 something, yes or no? 23 Yes. 24 That's what I wanted to know. Now a specific 25 question: How long were you in a position of sales

16 (Gilbreath - As on Cross) I think I had nothing else. I am sorry. Α Okay. Let's try to pin some things down. So the way you define "customer" and I know he didn't buy it, but the customer was the physician, correct? Yes, they were the folks who we spoke to who prescribed our medications and made the decision whether or not the patient was appropriate for our medications. Yes, sir, when you say that was the person who you -- who prescribed, the physician, you in documents called the physician the customer, correct? Yes, I think that's in some cases true. Α And while the doctor did not actually buy the drug, he was in a position to direct the purchasing of the drug, correct? Α Yes. And so that's why in the Janssen documents you call him the customer, correct? MR. MURPHY: Objection, Your Honor, lack of foundation. MR. KLINE: I will rephrase. THE COURT: I thought we already had

the answer, though.

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1 (Gilbreath - As on Cross) 2 MR. KLINE: Okay.

3 Now, you would not only get a salary you would 4 get a bonus, correct?

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And the bonus was determined in part by the amount that the customers that you were seeing would have purchased through patients, correct?

Not entirely, but partially, yes.

And you were incentivized, sir, you were incentivized to see that the drug was sold, correct?

We were incentivized to see that the drug was represented appropriately, and for appropriate patients, if there were more than one medication that was appropriate, we would ask them to consider ours, if both were appropriate.

My question, sir, was you were incentivized by whether the drug was sold, correct, sir?

I don't know if I really agree with the way the question is framed, but in terms of if a physician prescribed our medication, was that a good

23 Yes, and then there were records kept of how 24 much the doctors who you saw actually prescribed, 25 correct?

(Gilbreath - As on Cross)

that as well.

There is IMS data on Dr. Mathisen, correct?

Yes. I don't have specific recollection of his data, just due to the timeframe it was, but I am sure if he was on the list he might have been included at some point.

Yes, I am going to later on today try to refresh your recollection on that very point.

0 By showing you the IMS data?

Α Okav.

> And how much he was prescribing and whether you knew it.

Now, let's have a discussion of your movement up the J&J line. First of all, back in 1999 through -- you came to Johnson & Johnson when?

I believe it was May of 1999.

19 May of 1999. That was a good day, correct, Q 20 sir?

Α Yes, it was.

22 And you have been with them ever since, Q 23

correct?

Α Yes, I have.

> And let's see. When you came to them in 1999 Q

18

(Gilbreath - As on Cross)

Yes. We had information on what a physician would use from time to time. It was not always available but in many cases it was.

And you looked at that data, correct?

Yes, when it was available. Α

Yes, and you would know if a doctor was -whether it was worth your while to go see a doctor and whether he was actually prescribing the drug, correct?

> MR. MURPHY: Objection, argumentative, Your Honor.

THE COURT: I think this has been established.

MR. KLINE: I don't think that was, but okav.

THE COURT: Sustained.

You knew if a doctor that you were going to see over and over again was using your drug, correct, sir?

Yes, but primarily because they stated that they were or were not.

And also you had access to data, which was called IMS data, correct?

Yes, when it was available we would refer to

(Gilbreath - As on Cross)

you had been to junior college at Snead State Community College, correct?

That is correct.

And I think your major there was in animals, something with animals?

Α Pre-veterinary animal science curriculum, yes.

Q And you did not go to veterinary school, correct?

I did not. Α

And I think your major was in aviary, I think Q in birds?

Α It was animal science, specifically avian or poultry, yes.

And then you finished there in 1991, and then you went to Auburn from 1995 to 1996, correct?

17 That is correct. Α

> What was your degree at Auburn in? Q

19 Α It was in avian science, avian and poultry 20 science.

> Any training there in epidemiology, sir? Q

Not specifically. It may have been contained in some of the biology, pharmacology, other courses like that, but not specifically epidemiology, no.

Okay. Now, what did you do after you got out

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(Gilbreath - As on Cross)

of college? Because I see a three-year gap?

My wife and I, we actually married shortly after high school, so I married my high school sweetheart, and we actually worked our way through college. So we actually purchased a farm of our own in 1990, February of 1990, and by operating that farm, I did that concurrently while I was at Snead State. I had the farm full time as well as Snead State. And so we ran the farm in order to pay for

So that's why the gap was there, we had the farm and to save up enough money to finish college, but that's what we were able to do.

- My question was after college. What did you 15 16 do, between 1996 and 1999 where did you work?
- 17 I apologize.

college.

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- That was my question. 18 0
- 19 I apologize. Α
- It sounds interesting on the farm, by the way. 20 21 We don't have many farms here in our parts.
- Well, there are some rather beautiful ones out 22
- 23 in Pennsylvania, it's a beautiful state. 24 I know, but in the City we have some vacant
 - lots, in the summer we do some gardening and that

(Gilbreath - As on Cross)

- Α T do.
 - Did you ever get a check? 0
- 4 I don't recall getting one. I think it's Α
- 5 always been direct. So I apologize.
- So sales rep from 1999 to 2006; is that 7 correct?
 - Α
 - Q And when you were in that job did you have a supervisor?
- 11 Yes. All the time. Α
- 12 And who did you report to? 0
 - Α In '99 or throughout?
- 14 No, from 1999 to 2006, what's the person's Q 15 title?
- 16 Α District manager, I reported to a district 17 manager.
 - All this time, and I am in particular interested in 2002 through 2006. What was your
- 21 In 2002 through 2006, it would have been elder 22 care representative.
 - Elder care representative. Did Dr. Mathisen treat any elder cares?
 - Not to my knowledge, no. I would say, he

22

(Gilbreath - As on Cross)

2 stuff.

- I apologize, I misinterpreted your question.
- Chickens are against the code but you know all of that stuff.

THE COURT: Only in Philadelphia County.

MR. KLINE: I know that, too. I have been to court on one of those.

- So after I completed college I went to work for an animal health company, an agricultural company, it was called Gold Kist, Incorporated, based out of Atlanta, Georgia.
- And then did you go to work for Janssen, or did you go to work for Johnson & Johnson?
- I went to work at Johnson & Johnson, but 16 specifically they are a subsidiary of Janssen, so my 17 18 actual employment was with Janssen Pharmaceutica.
 - That's an important thing. At all times when you got your paycheck, including your salary as well as your bonus for what the customers bought, that would be a Janssen Pharmaceuticals check, correct?
- 23 To my knowledge. I really don't recall exactly the way it would appear. 24
 - Do you have direct deposit?

(Gilbreath - As on Cross)

actually did say he treated adults. Now I didn't know the exact age of those adults --

- There is no question pending, sir. And we are going to talk about what you knew and didn't know. But as to what your title -- is that your title,
- 7 elder care representative?
 - Yes, it was.
- 9 And one of the drugs that you were handling 10 was this stuff Risperdal, correct?
- 11 Α
- 12 Q Were you handling other drugs, too, at the 13 time?
 - Yes, we had multiple other medications. Α
- 15 You. I am not talking about we as Janssen? 0
- 16 Yes, I had responsibility for other Α
- 17 medications.
 - How many others? Q
- 19 Two or three.
 - Two or three, okay, and Risperdal, was that a substantial part of your repertoire?
- I don't recall the specific breakout but 22 23 probably a third.
 - Okay, that's helpful. And were the other drugs for the elderly? Because I would assume if

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(Gilbreath - As on Cross)

you were an elder care representative, the drugs would all be marketed to doctors who were treating elderly patients; is that correct?

Not exclusively, but some of them were. One was a medication for Alzheimer's disease, and so that was one. The other one was for chronic pain,

and that was for all adult ages. And then

9 Risperdal, which was also for all adult ages at the 10 time.

And just to have a record, the Alzheimer's drug, that was what drug?

13 It was galanthamine was the chemical name, but Reminyl was the name when it was presented to the 14 market. 15

16 So you were doing Reminyl, which is an 17 Alzheimer's drug. Chronic pain drug was what?

Duragesic. 18

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19 And Duragesic is a drug that's used significantly in the elderly population, correct? 20

21 It's used significantly but not exclusively 22 there.

23 By question was whether it was used 24 significantly there. Is the answer yes, sir? 25

(Gilbreath - As on Cross)

correct?

Α Yes.

Now, at the time were there pediatric drug representatives?

With our company or with other companies?

7 Your company, that you knew of?

Yes. I think so. I know we had consumer Α healthcare with drugs like Tylenol and other medications like that.

Just to finish with your background -- by the way, do you work from home, largely, or do you go to an office?

Α No, my office is out of my home. But I am out and about a good bit.

Let's take that one at a time. When you were a sales rep between 2002 and 2006, did you report to an office daily or did you work out of your home?

No, I worked out of my home.

20 On the farm, correct?

21 No. This was not on the farm at this time. I Α 22 had --

Q No more farm?

Α No more farm. I still visit my parents there a good bit, but no, I did not live on a farm at that

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(Gilbreath - As on Cross)

And then you have Risperdal, which is also both indicated for and was used significantly in the elderly, correct?

5 Yes, there was some use there, at physician 6 discretion.

Nothing to do with physician discretion, sir, was it used significantly in the elderly population, yes or no?

I can't say to what extent it was used. I know it was used in adults and that included adults from 18 all the way through 80s, 90s, whatever they would be.

You went to doctors who treat geriatric patients, their practices specialized in geriatrics, correct?

Some of them, not all of them. 17 Α

18 Not all of them but some of them? Q

19 Α

20 And you would go to visit those doctors who were geriatric doctors, correct? 21

22 Α Yes.

23 For Risperdal? Q

24 Α Yes.

> 0 For Risperdal. And it was on-label there,

(Gilbreath - As on Cross)

time.

Okay, but you were working out of your home. It's like you get up in the morning, you go out and you go see doctors, correct?

Yes. Generally, we would see physicians on a daily basis unless we had another engagement, a company meeting or an internal meeting.

In fact, you were well familiar with the term targeting doctors, correct, you knew that term?

There was a physician list, people that we would see on a routine basis.

That's not my question. My question is you were familiar with the term used at the Janssen Pharmaceutical company called targeting doctors, correct? You knew that term, it's not something you heard from me for the first time?

I heard it before, but not everyone used that term. We used physician list, prescriber list, things like that.

My question is, you were well familiar with the term targeting physicians, can you agree with me?

> MR. MURPHY: Objection, Your Honor, asked and answered.

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1 (Gilbreath - As on Cross) 2 THE COURT: Overruled. 3 You were well familiar with the concept and 0 4 term targeting doctors, that's my only question? 5 I know what you mean by it, but it's not 6 vernacular we used all the time. 7 It's not vernacular you used all the time, it 8 was vernacular you used some of the time, correct? 9 I know what the term means, yes, but I did not 10 refer to it. I referred to it as a prescriber list 11 or a physician list. 12 Now, you then became a district manager. You 13 got a promotion in 2006, correct? I did move into a district manager role in 14 Α 2006. 15 16 And when you were a sales rep you were a sales Q 17 rep in the Birmingham, Alabama area, correct? That is correct. 18

19 And your home was in or around Birmingham; is 20 21 Yes, I lived in or around Birmingham for seven 22 years, I suppose, '99 to the end of 2005, early 23 2006.

And then you were a district manager in Tennessee and Mississippi. So did you move away? (Gilbreath - As on Cross)

providers, Medicare carriers, if you will. Like Medicare is administered through Medicare administration carriers, so both the medical benefit through Medicare as well as the pharmacy benefit through Medicare. I work with them as well as state medicare agencies and some of the commericial insurance carriers that folks may have through their employers, something like that.

I see. And I see here -- I happen to pull up your LinkedIn, page. I figured you and I would be linked in today, so last night we might as well get LinkedIn. And I see here everything you say here is Johnson & Johnson.

Okav.

It doesn't say a thing about Janssen. I just wondered about that. Are you working for Johnson & Johnson or Janssen?

I work for a subsidiary of Johnson & Johnson, specifically Janssen. They are multiple subsidiaries.

Used interchangeably, Johnson & Johnson and Janssen, you see it?

Α We primarily use the subsidiary. So my business card carried Janssen Pharmaceutica during

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(Gilbreath - As on Cross)

I did, I moved to Nashville. The Greater Nashville, Tennessee area is where I reside now.

On a farm?

I have 11 acres, so it's on the outskirts but it is $\operatorname{--}$ it's one where we are able to have cattle and, you know, some other livestock if needed.

Wow.

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We still maintain a presence with the farm. It's not everyday, but it is something our family has been very close to our whole life so I really enjoy that.

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13 That's great. On a salesman. Wow. Okay. Then you became a business development manager from 14 2010 to 2011? 15

Α Yes.

17 Covering Tennessee and Alabama. And now since 18 2011, you have made your way up the food chain, you 19 are the strategic market director, correct?

20 Yes, that's a role that I have held recently.

Yes, well, you have held it since 2011? Q

22 Α

23 And you deal with key commercial customers,

24 correct?

> Α Yes. I also have responsibility for Medicare

(Gilbreath - As on Cross)

the timeframe that we were speaking about.

How come on your LinkedIn everything is listed including back as being a sales representative -and I have this on my Ipad but it's photo screened so I will mark it as an exhibit and we will print it momentarily, Exhibit No. 60.

How come you list yourself as being a senior sales representative from 1999 to 2006 --THE COURT: Is this a profile?

MR. KLINE: Yes, his profile.

-- at Johnson & Johnson?

MR. MURPHY: Objection, Your Honor, irrelevant.

THE COURT: It's a little unorthodox evidentiary procedure, but we will permit P-60 being your presentation of this man's profile on LinkedIn.

(P-60 is marked for identification.)

I will walk up to you. Is this your profile on LinkedIn?

Α It looks like it.

And just tell me why do you say you worked for Johnson & Johnson from 1999 to 2006 when you really worked for Janssen?

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1 (Gilbreath - As on Cross) MR. MURPHY: Objection, Your Honor. 2 THE COURT: Sustained. 3 4 Sir, you have been aware for a couple of weeks 5 that I asked for you to testify in this case, 6 correct? 7 Yes, I became aware about two weeks ago, maybe 8 three. 9 Q And you met with various people in preparation 10 for your testimony, correct? Yes. I met with a couple of folks 11 12 representing our organization, yes. 13 Yes, lawyers, to be specific? Yes. Not all of them but some of them. 14 Α How many lawyers have you met with all told? 15 O Three. 16 Α 17 Before testifying. Three? Yes, I think primarily. I have been 18 19 introduced to others but I met three. 20 How many other lawyers were you introduced to? 21 MR. MURPHY: Objection, Your Honor. 22 THE COURT: Overruled. 23 Maybe two additional. Α 24 Q So five lawyers you have met, company lawyers, 25 correct?

(Gilbreath - As on Cross)

customer, you go back and you review their prior history to the extent you can find it, right?

- If it's available. It's not always available.
- There are computer records in the company and you would be able to look at the prior notes, of course?
- Not necessarily. It depends on if a physician Α is actually in the database, if you will. Not all of them are in there and sometimes you have to actually go through a process to have them added to make sure they are a licensed provider in that state and things like that.
- But if there are prior call notes, sir, if there are prior call notes, they are accessible, correct?
- Once the profile is in the system the prior call notes might be available, but not before then.
- And you were aware that there were prior call notes for Dr. Mathisen prior to your seeing this customer, correct?
- Actually, I don't recall. I don't recall them being available because he was not in the database until he requested to see me. And then when I did see him, that's when I requested to have him added

(Gilbreath - As on Cross)

Yes.

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Okay. And you sat down and went over what testimony you would be expected to be giving here? MR. MURPHY: Objection, Your Honor,

it's whole totally inappropriate.

THE COURT: Overruled as to that question, yes.

- Yes, we did review -- I gave a deposition about this time last year regarding this case, and so we did review that, the questions that were asked at that time, and also, what might be spoken about and discussed in the courtroom today.
- Okay, and by the way, sir, did you review your call notes? I just want to try to know what you are familiar with. Did you review your call notes?
- Yes, I saw those in the deposition. I don't think that I have reviewed them this year, but I do recall seeing them when we were preparing for the deposition.
- And by the way -- I am sorry, did I cut you Q off?
- Α No. I saw them during the deposition process.
- And by the way, when you first call on a new customer, in this case Dr. Mathisen, but on any

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(Gilbreath - As on Cross)

2 based on his feedback.

> You are well aware of the fact that there were call notes back in 1997-1998 of this doctor by a prior salesman, correct?

I have not seen those notes, but I am aware that another person visited him.

- I am going to show them to you and see if it refreshes your recollection?
- Α
- Okay, now, let's talk about some other things -- oh, by the way, did you -- I am going to use the term because the jury may hear it, "detailing". When you say you "detail" someone, that means you give them information about a drug and you answer questions, correct?
- Yes. When -- detailing is referring to the exchange of information with the physician maybe regarding efficacy information, how well a product works, safety information, things to be aware of when prescribing, as well as clinical studies and how to dose it. So that would be really what I would describe as detailing.
- And did you ever detail Dr. Mathisen on any Alzheimer's patients?

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(Gilbreath - As on Cross)

2 I did not.

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- And Risperdal, sir, was Risperdal approved for 0 4 use in elderly, use in dementia?
 - No, it was not in dementia. It was approved for use in schizophrenia in elderly but not for dementia.
- So as to going to see doctors about Risperdal 8 use in dementia, for Alzheimer's, that was 9 10 off-label, correct?
 - Yes. The label supported the use of Risperdal in schizophrenia at the time in adult patients.
- 13 You would go to see doctors who were using the drugs for dementia, correct? 14
 - I didn't know if they were using the drug for dementia, we discussed their use of Risperdal in adults with schizophrenia, because young patients with severe mental illness, they obviously grow old as well and need treatment.
 - Let's get something out on the table, sir. You are not allowed to promote a drug off-label when it's not an approved indication in the label, correct?
- 24 Correct. When we discuss the use of our 25 medication --

(Gilbreath - As on Cross)

- We actually asked the physician if they treated patients or had appropriate patients, adults with schizophrenia for discussion of our medication, and if the answer is yes, then we would move forward. We didn't ask them to quantify if it was a hundred or 50 or 30 or whatever it was, but we would ask them the question, Do you treat adult patients with schizophrenia. If the answer was yes, then we would discuss it with them.
- Yeah, and the really important question, sir, is whether they are treating all, or nearly all, children, not whether they are treating one adult, correct?

MR. MURPHY: Objection, Your Honor, argumentative.

THE COURT: Overruled.

Correct, sir?

No. In fact, we had multiple physicians that we would see sometimes that treated all ages. There were general psychiatrists, general neurologists, who treated patients of all ages, as well as children and adolescent psychiatrists who treated -they treated a lot of children, sure, like Dr. Mathisen, but they also had adults.

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(Gilbreath - As on Cross)

- 2 That's all I need to know right now. Is that 0 3 yes?
 - Yes, if it's in the label it's appropriate for us to discuss it. If it's not in the label, we do not discuss it.
 - It's not discussed?
 - Correct.
 - Right, so if you go to a doctor's office you only need to ask them one question, which is, as to Risperdal with children, are you using this drug in children? Correct?
 - No, actually, my question would be, are you using this product in adults, or do you treat adult patients with schizophrenia? That's actually the question.
 - And if you got the answer, yes, I treat one patient, then it's okay to get in there, right, with a wink, correct sir?

MR. MURPHY: Objection, Your Honor. THE COURT: Sustained.

Q Then you can get in there, correct, sir? MR. MURPHY: Objection, Your Honor, he asked the question again.

THE COURT: Overruled.

(Gilbreath - As on Cross)

Do you remember the question? Q

Α Yes.

Sir, you kept no records with Dr. Mathisen as to whether you ever asked him the question about whether he treated adults, correct?

We actually ask every physician the question Α if he treats adults.

- You have no record is my question, sir, you have no record that shows that you ever asked that question, correct?
- Not to my knowledge.
 - You have no box checked anywhere that says, Asked and established the doctor is treating adult patients. Correct?
 - Because it was implied. We asked --
 - I asked you if this is a correct statement? MR. MURPHY: Objection, Your Honor, he should let the witness answer the question.

THE COURT: May I hear the question again, Judy?

(The pending question is read by the court reporter.)

THE COURT: I am going to sustain that question. You need to tell us what that is

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1 (Gilbreath - As on Cross) 2 about. MR. KLINE: I will get there with the 3 4 documents. 5 Sir, what did you review prior to coming in 6 the courtroom, I would like to know? Your call 7 notes, I am sure. 8 MR. MURPHY: Objection, Your Honor, that calls for privileged information. 9 10 MR. KLINE: Not the documents he 10 reviewed, Your Honor, I don't want to know his 11 11 12 discussions with the lawyers. 12 13 THE COURT: You may ask him 13 specifically documents that you know exist and 14 14 ask if they have been reviewed. 15 15 16 MR. KLINE: I would like to know --16 17 THE COURT: No, sustained. 17 Did you review the call notes? 18 18 19 I reviewed call notes as part of the 19 deposition. I don't recall reviewing them over the 20 20 21 21 past couple of weeks. Now, let's talk about Dr. Mathisen. 22 22 23 Sure. 23 Α 24 Have you reviewed his testimony from the trial 24

(Gilbreath - As on Cross)

for any use, correct?

Correct, but it was approved for use in adults and he stated that he had adults, like many other physicians with a children and adolescent psychiatry specialty.

Do you remember the question, sir?

8 Α

> 0 What was the question?

Α You asked me if he actually was a child neurologist, and -- actually, I don't know if I do know the question verbatim, I apologize.

The question was a simple one. Do you have any knowledge that he was anything other than a child neurologist, yes or no?

No, I do not have any evidence that he was anything other than a child neurologist. But other physicians did, so I was thinking the possibility would exist.

The question wasn't to other physicians, sir, my question was to him, and whether he was a child neurologist.

And you knew, sir, at the time that it was illegal to promote a drug to a child neurologist that wasn't indicated in the label, correct, you

(Gilbreath - As on Cross)

Actually, I have not. Α

the other day?

Do you remember Dr. Mathisen? 0

4 I do remember Dr. Mathisen.

5 And do you remember visiting him in his 0 6 office?

7 Yes, I remember visiting with him. Α

Do you remember his specialty?

Yes. He was child neurology, as I understand, as a primary specialty, but I am not sure of his

secondary specialties. 11

12 Did he have a secondary specialty?

I don't recall at the moment. Α

If I told you, sir, that he came in here and he told us that he was a child neurologist, that was

his job, would you have any evidence to dispute 16

that? 17

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Α No.

19 So you were going to see a child neurologist.

20 Do you count 20 times or 21 times?

> I think it was 21 times, over a period of a Α

22 couple of years.

> Twenty-one times you went to see a child neurologist. During that entire period of time,

sir, the drug was not approved for use in children

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(Gilbreath - As on Cross)

2 knew that much?

> Α That's exactly why I didn't promote --

I didn't ask you that, I only asked you if you

5 knew that fact, sir, yes or no? 6

Α Yes. I would not have promoted, because from day one we only promoted from inside the FDA label.

We are going to see that you dropped off sample packets, correct?

Yes, at his request, like every other Α physician.

Not like any other physician, sir, not at his request. Did you or did you not, that's my only question, did you or did you not drop off samples, yes or no?

Yes, but it was at his request.

17 Well, did you tell him, sir, I can't drop you 18 off children samples, that would be promoting?

No, I could not describe where they can or cannot use their samples. Once it's in their custody it's their discretion where they use them.

Let me understand, sir, we are going to get into this. You got a lot of understanding about a lot of this from your training at Janssen, correct?

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1 (Gilbreath - As on Cross) 2 Q They told you what you could and couldn't do, 3 correct? 4 Α 5 You didn't make these decisions on your own, Q 6 correct? 7 No, we did not. 8 So when you had this idea that if a doctor who was a child neurologist asked you for samples, that 9 10 that was okay, according to what you knew, correct? 11 That was okay? 12 13

It was only okay if I asked him if he saw adult patients. If the answer was yes, then I could discuss it and provide samples. If the answer was no, then I would discontinue discussions.

Let me try this one on you, sir. Someone says, Hey, can I have some samples? You know he is a child neurologist. Are you with me so far?

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And you say, Doctor, do you treat adults? And he says, Oh, yeah, I treated an adult or two. Is it okay to give him samples now, yes or no?

MR. MURPHY: Objection, Your Honor.

THE COURT: Overruled.

It would really depend on the number of

(Gilbreath - As on Cross)

kinds of adult patients with special needs and special considerations, so the .25 was a starter dose, as well as the .5 and even 1 milligram.

.25 was the starter dose for children, correct, sir? And you know it.

> MR. MURPHY: Objection, Your Honor, argumentative.

THE COURT: I don't know whether he knows it or not. Overruled.

I do not actually know that to be a starter dose for children because the label supported adults, and I do know it was an appropriate starter dose for adults with considerations.

You knew that that was the most commonly used starter dose for children, correct, sir?

I did not know that to be true because we did not discuss children nor have we been trained on children because it was not on the label at the

You are in a child neurologist office and you weren't trained at all on the use of the drug in children? Is that your testimony?

Yes, it is my testimony. We were not trained on the use of Risperdal in children because we were

(Gilbreath - As on Cross) patients and samples and things like that he requested. So if he had one or two patients I would probably quantify that a little more. So are you considering starting Risperdal for this patient or two, and then I would leave an appropriate amount of samples, which would be the case then.

And, sir, would it be okay, would it be legal to drop off, and as you understood it back then, to drop off children's dosing of the medication? Would that be okay?

> MR. MURPHY: Objection, Your Honor, lack of foundation.

> > THE COURT: Overruled.

MR. KLINE: I am going to show

.25 milligrams.

THE COURT: Overruled. You can proceed with the question and the answer.

Would it be okay to drop off children's doses of the drugs, yes or no?

We actually did not have children doses of the drug at that time.

Sir, what's .25 milligrams of that drug?

It's a starter dose. Kind of terminology at the time was start low and go slow. We had all

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(Gilbreath - As on Cross) trained on the use of Risperdal in adults.

Q Let me ask you a question.

Α

Looking back at this today, and we have a long 0 way to go on your testimony?

Α

Q Just looking back on this today, looking back on it today, it was wrong to be in that child neurologist's office whose practice was almost exclusively for children. Can you agree with me?

12 Absolutely not. I would repeat the --

13 Q You would do the same thing again?

> I would, because he told me he had adult patients with schizophrenia that he managed, many of them he began treating as they were children and adolescents, but as they aged into adulthood he would continue to manage them. So that was the basis.

I just want to get it down right. You would do it again, right, same thing?

Yes, I have no regrets about seeing Dr. Mathisen.

Q How many --

MR. MURPHY: Objection. Let him answer

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1 (Gilbreath - As on Cross) 2 the question. 3 THE COURT: I thought we had the answer 4 to the question. Do you have another 5 question? 6 MR. KLINE: I do. 7 How many adult schizophrenia patients did Dr. 8 Mathisen have, sir, tell me? He never described the actual number to me, 9 10 but no one that we saw ever actually described the 11 actual number because I don't know if they actually 12 knew. 13 A doctor knows how many patients he has, doesn't he? 14 No, not all the time. 15 Α 16 All you got to do is say what percentage of 17 your practice is adults and what percentage is children, correct? 18 19 They can take an estimate, I presume. They may not have the actual number. 20 Do you have any estimates written down for Dr. 21 22 Mathisen? 23 I do not. Α 24 0 Do you know what he told this jury? 25 I do not. Α

51 1 (Gilbreath - As on Cross) 2 Q Did you count them up? 3 I did not. Α 4 Would 103 sound about right in the math? 103 5 samples that you dropped off to him, sir, does that 6 sound right? 7 Yes, but that's actually a small number 8 compared to --9 Q What you have done with others? 10 Α Yes, because it was their request. If we had 11 the samples we would make them available to start 12 patients that they deemed appropriate. 13 Right, because every sample that you give out, 14 sir, is a potential for a new customer, correct? 15 That's at the physician's discretion. 16 That's the idea, though, of the pharmaceutical 17 company and the representative. Every sample could 18 be a new customer, correct? 19 The idea of samples was to provide for 20 patients starting therapy, but it's up to them how 21 they used them. They may have used it in patients 22 that needed medication until they got it filled at 23 the pharmacy or something, I don't know, but 24 primarily it was used to start patients.

2 He told this juror it was exclusively children 3 except when they crossed over to adulthood. 4 MS. SULLIVAN: Objection, Your Honor, 5 that's not the testimony. 6 THE COURT: Overruled. The question is 7 just the question. I don't know whether he 8 knows the answer or not. 9 MR. KLINE: I will ask it in the form 10 of a question. Did you know, sir, that he was treating 11 12 children at the time, nearly exclusively? Did you know that? 13 14 I did not know nearly exclusively. He told me he had some he managed into adulthood, and 15 therefore, treated patients above 18 with 16 17 schizophrenia. 18 If you knew, sir, that he was nearly 19 exclusively treating children, would it have been proper for you to be dropping off large numbers of 20 21 samples to him? Yes or no? Describe large numbers of samples. 22

How many sample packs did you drop off in

I would have to look at the records.

those two years, sir, do you know?

(Gilbreath - As on Cross)

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(A brief recess is taken.)

(The jury enters the courtroom at 11:03 a.m., and the following transpired in open court:)

THE COURT: You may be seated everyone.

Sir, you said before the break that .25 was an adult dose. Do you remember saying that?

Α

Now, sir, I want to see if this might refresh your recollection. I would like to show P-9, display page, previously marked and admitted and has been previously displayed, a different portion of it, I would like to look at Bates JJRP 00838263.

As you know, the drug was approved in 2006 for autism, correct?

Yes. Α

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(Gilbreath - As on Cross)

MR. KLINE: It's a good time for a

break.

THE COURT: We are going to take a break here, ladies and gentlemen. For about ten minutes. Please do not discuss this matter with each other or anyone at this time, keep an open mind, and we will be back in a few minutes.

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(Gilbreath - As on Cross)

And there is dosing information. I want to look at the dosing information for adult schizophrenia, sir.

So the label says as to adult schizophrenia, says right here, "Risperdal is generally administered". Do you see "generally administered"?

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10 "At 1 milligram BID," and BID is twice a day, correct? 11

12 Α

13 And then highlight the word "Initially." Do you see that? 14

T do. 15 Α

The initial dose for adult schizophrenics,

17 sir, is, Adult, 1 milligram initially. Not .25.

.25 is a quarter of the dose, correct, sir?

Yes. 19 Α

> 0 So .25 wasn't an adult dose, was it?

21 Actually, it was. There were, you know, it

22 says generally. And there were situations where

someone might have a renal or hepatic impairment,

something that might require a lower dose. 24

Sir, the general adult dose as stated in the

(Gilbreath - As on Cross)

can you first show that it's Pediatric Use.

Pediatric Use, and what does it say? "Drug should be initiated at .25." Correct?

Yes, that's what it states. Α

So when you told the jury before our break, sir, that when you were dropping off .25s, that was the starting dose for adults, that's not correct. Can we agree?

It was one of the starting doses for adults. They could use that at their discretion in patients who might need a lower dose.

The prescribing information, sir, in the label says that 1 to 2 milligrams, depending on if it's schizophrenia or bipolar, is the usual starting dose. Can we agree?

17 Yes, generally.

> And .25 is the usual starting dose for children, correct?

With the label in 2006, I think that's what it was referred to. I don't know if it referred to that prior to 2006.

So, sir, if we see you dropping off .25 milligrams, a person could conclude that that was intended for children when handed off from your

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(Gilbreath - As on Cross)

label is 1 milligram. Not a quarter of a milligram. Correct, sir? The general dose?

Yes. That's what it states.

Not for the off, odd person who has a renal problem or something like that.

By the way, if you go to bipolar mania -- that's for schizophrenia. Bipolar mania adults, where did they start that, sir? You should know this from your days selling the drug. Where did they start that as a dosage?

12 I don't recall exactly, but it was generally 1 13 milligram as well, I believe.

Yeah, well, let's look.

Bipolar: Bipolar adults was 2 to 3 milligrams. Do you see that?

Yes, I do. 17

18 Starting. Meaning that's what you generally 19 start a patient with that on. Correct?

20

So, sir, if you are in an office and you are dropping off quarter doses, .25 milligrams, let's see if that corresponds to what eventually got in the label.

Can we see the Pediatric section, and

(Gilbreath - As on Cross)

hands to a pediatric child neurologist. Correct? MR. MURPHY: Objection. Argumentative, Your Honor.

THE COURT: Overruled.

Correct, sir? Q

No, actually, that's what the physician requested, like many others, because beyond the starting dose they would also use the lower doses in titration, sometimes.

You don't remember that happening, you don't remember any conversation like that, do you?

Α No, I don't specifically with Dr. Mathisen, no.

The fact of the matter is that you knew that a child neurologist was asking you for child doses, correct?

Dr. Mathisen asked for all doses, and I think we provided multiple strengths, as well as other physicians, too.

The tablets, when the tablets are started with children you know that they move up in doses, correct?

I don't always know that. That's the physician's response.

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(Gilbreath - As on Cross)

- You know as a general fact, having detailed the drug for how many years?
- Six or seven. Α

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For six years. You know that generally speaking, they start out at a lower dose, .25, and generally speaking, children then move up, correct?

MR. MURPHY: Objection to form.

THE COURT: Overruled.

- Correct?
- I don't actually know what they move to on the dose. It really is the physician discretion. They will oftentimes start low and go slow on titration. So we don't have information on what exactly that looks like because we are not privy to that.
- In six years you didn't have any conversation with any doctor as to whether they started low and then went higher? Yes or no, sir?
- 19 Yes, it was common. They would start lower 20 and go higher.
- 21 Q That's my question.
- 22 Yes.
 - Now, how did you get involved with Dr.
- 24 Mathisen? How did you learn that he was acceptable 25
 - to a sales call from you?

(Gilbreath - As on Cross)

- You literally had to walk over toys and small people furniture to get in to see him, correct?
- Actually, that's not correct. I don't recall Α walking over toys or small people to see him.
- I didn't ask you -- let me ask you this: Did you see toys?
- I don't recall seeing toys. It's possible Α they were there but I don't recall seeing them.
- Do you recall seeing small people furniture?
- 11 I do not. Α
- 12 Is there any doubt in your mind that you were 0 13 in a children's office, sir?
 - No, I knew he treated children, but once Α again, I also asked him if he had adults. He said yes, I manage them into adulthood, I would like to discuss Risperdal with you.
 - Yes, you knew that the adult patients he had were the ones he happen to carry over into adulthood, correct?
 - I don't know that specifically to be true.
- 22 That's what you just said. Q
 - He told me he managed children and then he did Α not dismiss them when they turned 18, and then I don't know at what point he would initiate

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(Gilbreath - As on Cross)

- Actually, I responded to the request from another colleague that worked for another operating company, a sister company of ours that was in there and stating that he had requested to see a Risperdal representative, and he actually was on the same campus as some other physicians that I saw, so I went, investigated subsequent to that request.
- You investigated, you meant you found out if that was true, if this was a potential customer, correct?
- 12 Yes, I found out if it would be appropriate to 13 meet his request. He requested discussion and samples, and I wanted to make sure that it was 14 appropriate to see him and provide samples. 15
 - Did you look him up?
- 17 I don't know what you mean by look him up.
- 18 On the Internet, did you look him up and see
- 19 what kind of doctor he was?
- No, he was in the building that I was already 20 in so I just went by. 21
- You knew he was a child neurologist, correct? 22 0
 - Yes, I am sure there was --Α
- You were in his office 21 times, correct? 24 Q
 - Α Yes.

(Gilbreath - As on Cross)

Risperdal. It might have been before, it might have been after.

- Do you think, sir, that he was telling you that he treated all of these children and then, oh, when they turn 18 he decided he was going to put them on Risperdal, is that what you thought?
- No, I would not have thought that.
- You would have thought he was a child neurologist giving Risperdal to children. Can we admit that?
- No, I did not presume that he was a child neurologist giving Risperdal to children.
- Would you admit to me, sir, that you knew that a man who substantially treated children, he told you that was his practice, that was on his door, that was what was evidenced in his waiting room, are you telling me that you believe he was not giving this Risperdal to children? Is that your testimony?
- Well, my testimony is I did not know specifically if he was providing Risperdal to certain children patients. I do know it was widely known in the community at the time that it was being studied, I know that Risperdal was being used in children, but bear in mind, we were under strict

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1 (Gilbreath - As on Cross) 2 quidance not to promote outside the FDA-approved label and that's why I had the discussion that I 3 4 did. 5 You were under strict quidance because it was 6 illegal to do it, correct? 7 It was against company policy, for sure. I 8 don't know the legality of that. You were told that it was illegal? 9 10 I was told that we were restricted to speaking with inside the scope of the label. 11 12 And sir, did you have an idea that so long as 13 you didn't find out, that that would be okay? MR. MURPHY: Objection, Your Honor. 14 THE COURT: Sustained. 15 16 MR. KLINE: I will take the question 17 back, I will go back, I will start again. Sir, when you gave samples to this doctor, who 18 19 was a child neurologist, you had a very good idea that these pills and these liquid formulations were 20 21 going to end up in the bodies of children, correct? 22 MR. MURPHY: Objection, asked and 23 answered. 24 THE COURT: That's sustained. 25 Q All right, now, you see the patient --

(Gilbreath - As on Cross)

was in the building, I went by to inquire. Okay, now, Dr. Mathisen had a -- I am going to

the 1997 stuff -- Dr. Mathisen had a history of prescribing the drug, correct?

I don't know that at the time. I would not have known that at the time.

Well, are you sure you wouldn't have known it at the time?

Α I did not know that.

There were call notes, sir. Let me see if it 0 refreshes your recollection.

Sure.

MR. KLINE: I am marking what was marked as a whole packet of call notes, all the call notes to Dr. Mathisen, as Exhibit P-62. And there are Bates numbers within them.

(P-62 is marked for identification.) MR. MURPHY: Your Honor, I have an objection at this point. We have a stipulation regarding what call notes were appropriate as to the time period.

THE COURT: I don't know, let me see what the stipulation is. Is there a

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(Gilbreath - As on Cross)

MR. KLINE: Oh, let's quickly mark my adult thing as P-61. We are going to mark the LinkedIn page as -- we already marked it? P-61 is the dosing, child versus adult

dosing.

(P-61 is marked for identification.)

Now, we were talking, you and I, we're having a discussion.

Α Okav.

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About the dosing or -- how you found out. So 11 12 who was the colleague who told you that Dr. Mathisen 13 might be amenable to a visit?

You know, I don't recall the exact colleague. It was either one of our consumer folks like, you know, Tylenol and Motrin and things like that, or one of the others in, like, McNeil pediatrics.

And so how did you contact Dr. Mathisen?

19 I just dropped by the office.

Just stopped by?

Yes. I was in that building and campus for other purposes.

23 Q Cold call?

> Yes, I went in as requested, they said he would like to see a Risperdal representative, so I

(Gilbreath - As on Cross)

stipulation here?

MR. KLINE: No, there was a discovery stipulation as to what documents needed or not needed to be produced. The 1997 ones were produced and I want to ask him whether he had knowledge of all of this prior detailing of this doctor and refresh his recollection as to what he knows or what he doesn't know.

THE COURT: About this doctor?

MR. KLINE: Yeah, they are documents they produced.

THE COURT: I don't understand what the objection is about.

MR. MURPHY: The agreement between counsel, myself and Mr. Gomez is --

THE COURT: You know what, let me see these documents before we get into some kind of an agreement that I know nothing about in front of this jury. Let me see these documents.

Is there a specific one that you want to show?

MR. KLINE: I will tell you what I want to do, Your Honor, there were 98 samples

MR. KLINE: We did mark, Your Honor, as P-62 all the call notes which were produced which include 1997 as well as through 2006?

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THE COURT: I understand that, but again --

MR. KLINE: I am only going to refer now to 2002.

THE COURT: What I am going to ask you to do to help the Court is when you have a specific document that we marked in some kind of notation as part of P-62, so P-62(A) or (B) (Gilbreath - As on Cross)

document and see what these are all about. I don't think any of us really know what a call note is.

MR. KLINE: I think if I am hand him a packet he will be familiar with them, Your Honor.

THE COURT: Give him one document to refresh his memory about what these things

MR. KLINE: I will start while Mr. Gomez does that.

What's a call note, sir?

A call note is a record of a discussion or Α visit with a physician.

You are required to do one every time that you Q visit a physician?

Yes. If we have an in-person interaction with a physician, we usually record that in the form of a

And is that done on a computer screen?

Α Yes, generally.

And that information is in the computer, correct?

Yes. Α

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(Gilbreath - As on Cross)

or whatever you want to do, so that these individual documents are reflected in the record and understood by us as to what it's about.

MR. KLINE: Will do. I will give them A, B, C numbers and --

THE COURT: If it's something about 1997, we will examine that when we have a chance.

MR. MURPHY: That is a violation of the rule on the in limine motion regarding call notes. We will take it up later.

THE COURT: Are you saying you object to any use of call notes?

MR. MURPHY: No.

THE COURT: Do you concede as to what is admissible under any previous rulings by this Court?

MR. KLINE: Yes, Your Honor, I am going to focus on 2002 through 2004 with this man.

I am first of all looking at the call note -and let's get a packet up in front of him if we can. THE COURT: Why don't we just take one

(Gilbreath - As on Cross)

And you could go to the computer and punch up your call notes, correct?

Α

0 You could also punch up call notes by physicians who were detailed previously, correct?

If it was someone that we had overlap with.

Not only overlap, sir, you could go to Dr. Mathisen and look in his call notes and see what was entered by prior individuals who saw him, correct?

Only after I got him "into the system." So the initial visit -- so we had a list that was generated, if you will, and then if someone like Dr. Mathisen, or another example would be if a resident came out of residency and went into practice, then we would add them. They would not be there. or if it's someone like, in this case Dr. Mathisen who was not in my existing system, we would have to add them, and then the records would follow at a later time.

Let me try to ask it simply, sir. Q

22 Α

> Q Ginger took over from you, correct?

24 Yes, that's my understanding. Α

> What's Ginger's last name? 0

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(Gilbreath - As on Cross)

Ginger Owens.

And all she would need to do to know how you were detailing Dr. Mathisen was punch up Jan Mathisen, and what you entered in the Janssen

6 computer would come up as to his prior history,

7 correct?

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You know, I don't know that to be true. It's possible, it's certainly possible, but I don't know that to be true. It really depended on what was made available through the system at that time. So I don't know what information about Dr. Mathisen was available.

What's your title again? 14 0

My title? 15 Α

16 Yeah, at Johnson and Johnson. Q

17 Currently?

Yeah. 18 0

19 Strategic marketing director. Α

> As the strategic marketing director you can't tell this jury, as somebody who has been with this company since 1996, you can't tell this jury whether the call notes which are entered in the computer can be pulled up by the next individual who comes along?

Is that what you are telling us, you can't tell us?

(Gilbreath - As on Cross)

And you can put in there, there is room in the call note we are going to see, for information that you want to put in there, correct?

Yes. I believe there is a space where you can type something extra if needed.

You can type something called "details", correct?

Yes, I think that's probably correct. Α

Okay, and let's take a look at the one I am ready to display -- I will give it a number.

MR. MURPHY: May I have it.

THE COURT: We will get there, Mr. Murphy and Mr. Kline. P-62-something. Let Ms. Sullivan and Ms. Brown look at it, and then if there is no objection we will show it on the screen. If there is an objection, I will rule on it.

MR. KLINE: I have marked the packet of call notes as P-62. I am marking as 62(A) the call note from May 30, 2002.

(P-62(A) is marked for identification.) THE COURT: Do you have a copy of that, counsel?

MR. KLINE: I am sorry, he was there

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(Gilbreath - As on Cross)

I cannot tell you that it was available immediately. At some point, after you got them, it was a process we called them certified or verified. If there wasn't a clear record we had to make sure internally that they were a licensed provider in the state where they were practicing, and then at that point they were, I think it was called certified or something in our system, and then the information would follow.

Sir, I don't want to belabor this, but a long-time prescriber has a history of call notes that are punched into the computer sequentially by the sales reps who come along. Can we agree on that?

Yes. I am sure there is a record. I am just telling you it's not immediately available to us in terms of who was there previously.

19 So you go to see Dr. Mathisen on 5-30-02, 20 correct?

Α Yes.

You have gone over these call notes, and a call note details the information about the visit, correct?

Α Generally, yes.

(Gilbreath - As on Cross)

May the 3rd of 2002. I want to show him 5-30-02 as an exhibit.

THE COURT: Is it 5-3 or 5-30?

MR. KLINE: It's 5-3-02. This is Exhibit 62(A), it's on Bates numbers, Ken,

THE COURT: At the top left, Mr. Murphy, if says 5/3/2002.

MR. MURPHY: I have it.

THE COURT: Is there any objection to showing this to the witness?

MR. MURPHY: There is none.

THE COURT: Let's get it on the screen and the witness can look at a hard copy or on the screen. Marianne, why don't you give him the hard copy so he has that himself.

Q Now this is a call note, correct?

Α Yes, it looks like that.

The first question I would like to ask you, sir, is this -- when is this information entered? Is it entered after you get home from notes and then you enter it in the computer when you do your paperwork for the day?

Generally, within 24 hours.

(Gilbreath - As on Cross)

Q But you don't enter this like on the spot?

3 A Same do. I wouldn't say it's routine, but 4 same do.

Q I don't care about some. How about you?

A Sometimes it was entered on the spot. Other times it was entered later that night or at the

8 convenient time.

correct?

9 Q When you entered it on the spot, did you do it on a computer, a laptop, an Ipad?

A I believe at this time it was probably on a laptop computer.

Q And by the way, sir, we are going to see a lot about samples. How did you get the samples? How did you get the samples?

16 A The samples were provided by our sample
17 supplier, our home office sample supply department,
18 if you will.

19 Q And were you responsible to keep track of the 20 samples?

A Absolutely. We had to maintain custody of them, and if they were lost or damaged or stolen or anything like that, we would have to report that accordingly. So, yes, we had custody of those samples until they were requested by the physician

(Gilbreath - As on Cross)

A Actually, we did not review these in depth. I knew some call notes existed. I did not review this specific one.

Q Let's put this one out in front of you, and let's also put -- this is 62(A). I actually want to do 62(B), which is the call note from 8-8-02?

MR. MURPHY: Your Honor, for the record, $62(\mbox{A})$ is not a call note of the witness.

THE COURT: It's already been admitted.
MR. MURPHY: Understood.

(P-62(B) is marked for identification.)

MR. KLINE: And 62(B) -- your Honor, do
you want them or do you just want to follow
these up there?

THE COURT: I need to hear there is no objection to the showing of --

MR. KLINE: 62(B) is the call note from 8-8-02.

MR. MURPHY: There is no objection. $\mbox{THE COURT:} \quad 8-8 \mbox{ may be shown.} \quad \mbox{This is}$ 62(B).

Q I have (A) and (B) up. Let's start with (A).

(A) is a call note, and a call note from a

(Gilbreath - As on Cross)

and we provided them.

Q And when you kept track of them, would you eventually have a record separate from this call note where you would give the company back the disposition of the samples, that is to say, these went to Dr. Mathisen, these went to Dr. Kline, these went to Dr. Djerassi, these went to Dr. Murphy?

A There was a record in a call note like this. That would be the method.

Q Would there be a separate list that you would account for all of your samples, for example, before you got new samples?

A We would do annually like a sample audit to make sure our inventory was correct, and I don't think that would be specific to physician, though.

Q Okay, now, what I would like to do is, you are familiar with these call notes from 2002, correct?

19 A The one that we are looking at right now?

Q Well, generally you are. You met with the lawyers, you have gone over these call notes,

MR. MURPHY: Objection, Your Honor.

THE COURT: Objection is overruled. Go ahead.

(Gilbreath - As on Cross)

representative whose name is Scott Hansen, correct?

A Yes.

Q And I am going to do a chart as we go along. A call note shows whether there was a presentation, correct?

A Yes. Presentation really indicates that an in-person discussion took place.

Q Okay, and there is information as to whether samples were provided, correct?

A Yes. That would be presentation with sample.

12 Q And if samples are provided, the number of 13 samples that are provided, correct?

A Yes, that is correct.

Q Now, as for 2002, 5-3-02, do you see that? Do you see that document, sir?

A Yes, I do, on the screen.

Q Okay, now, do you see, also, that samples were given of Risperdal?

A I do.

Q And how much samples were given? What does it say there?

A A quantity of ten of one strength, a quantity of ten of another strength.

Q Quantity of ten of one strength and ten of

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(Gilbreath - As on Cross)

another strength?

- Yes.
- So that's 20, correct?
- And when you say ten of one strength and ten
- of another strength, ten of .5 milligrams, correct?
- Ten of .5 milligrams, and it says there one by
- seven. What does one by seven mean? We can
- highlight that.
- Sure, one by seven means a blister pack of
- seven pills.
- What pack?
- A blister pack.
- One of those packs that you pop the pills out
- of?

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- Yes. So that's what that suggests is a
- blister pack containing seven of those pills.
- A starter pack?
- Yes.
- And so here, Dr. Mathisen was given ten .5s,
- and ten .25 milligrams, or if we are going to do a
- little math, that would be -- when it's one times
- seven, the one means one pack times seven pills?

(Gilbreath - As on Cross)

- Q To a child neurologist?
- Yes, who stated he also treated adults. Α
- 0 You don't know what he stated to Mr. Hansen,
- do you?
- Α I don't.
- 7 You weren't there?
 - I know what he stated to me, though.
 - You don't know what he stated to Mr. Hansen at all. You don't even know if the question was asked, do you?

MR. MURPHY: Objection, asked and answered.

THE COURT: That's sustained.

- That's Mr. Hansen. I thought you told us awhile ago that you learned from somebody else that Dr. Mathisen wanted to see a representative. Do you remember telling us that?
- I do, that's correct. Α
- And that would have been sometime around the time that you visited him. Do you know when that conversation took place?
- I am thinking it was probably in the middle of 2002. I don't recall the exact date of that conversation.

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(Gilbreath - As on Cross)

- 2 That's correct. Α
- 3 So he was given on this day -- and we are
- 4 going to put an asterisk here, I am going to put it
- 5 out in the column, this is Mr. Hansen. Do you know
- 6 Mr. Hansen? What is his first name?
- 7 I do know Mr. Hansen. His first name is Α 8 Scott.
- 9 Mr. Scott Hansen. Does he still work for J&J? 0
- 10 Yes, it's my understanding that he does. Α
- And what was his title at the time, sir? 11
- 12 I think he was CNS representative.
- What does CNS stand for? 13 O
- Central nervous system. 14 Α
- Was he a specialist in pediatrics? 15
- 16 Α No, he was not.
- He was a specialist in adults, wasn't he? 17 0
- 18 Yes. We all were. Α
- 19 None of you were pediatric salesmen, neither
- you nor Mr. Hansen, correct? 20
- No, that's correct. 21 Α
- 22 So on 5-3-02, correct me if I am wrong,
- 23 Mr. Hansen dropped off to this doctor 140 pills of
- 24 Risperdal, 140 pills, correct?
- 25 Yes, that seems to be indicated.

(Gilbreath - As on Cross)

- Well, by the middle of 2002, sir, Dr. Mathisen had been detailed and had been supplied literally 140 pills. Correct?
- It looks like that was left at this visit, Α yes.
- Now, that takes us to -- and by the way, I am just going to keep a running tab of pills.

By the way, sir, did you have kind of limits on the amount of samples that you would be giving out, like maybe it was a general rule, maybe five packs, maybe three? Was there any rule, any limit?

Not a specific limit, no. We would have guidance, I mean we got a finite supply, it wasn't unlimited. And certainly when physicians like Dr. Mathisen, they would oftentimes tell us that they wanted to maintain a certain number on hand, and whether their nurse was the one that managed that for them or a staff person, or they would ask us to check it sometimes, but that's why I think you will probably see the quantity of five or ten. It was multiples of five that we could leave, as I recall. So that would be the rationale.

There was another rationale, too, wasn't

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(Gilbreath - As on Cross)

there, sir, which was the bigger the user the bigger the samples they might get?

Not necessarily.

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- But not -- not necessarily. Not necessarily in my parts means maybe yes, maybe no. Does it mean the same in yours?
- Repeat that, please? I am sorry.
- Now we go to 8-8-02. By the way, sir, if I may go back to -- if we can just look at the call note generally. The way a call note sets up, so we all are familiar with it, let's look at the left box and the middle box and the right box. So let's start with the left top box.

Left top box gives an indication, there is an event date, a promotional event ID -- what is that, sir?

- I don't recall what that means. There was a -- I really don't know.
- There is plenty of room for comment, correct? 20
- 21 Yes, there are boxes for comment.
- And in a comment section, if one truly had 22
- 23 said, had asked the question or had verified the
- doctor was treating mostly adults or partly adults 24 25
 - or even some adults, you could put it in the

(Gilbreath - As on Cross)

- I did not quantify the number of adults, but the way I asked the question was do you have adults, patients over 18 with schizophrenia. If the answer was yes, we proceeded.
- And you never asked the question, what percentage of your patients are adults, correct? You never asked that question?
- Α
- Now let's go to the next section, I just want to establish what these sections are.

Here, you have got the name of the doctor, the city, the state, the zip code, the print name. The person ID, sir, what was the person ID? Dr. Mathisen looks like he has got a number, 1408197.

- I do not know what that number represents, actually.
- And a DDD number. What is a DDD number, sir? Q
- The best of my recollection, it's like drug Α distribution data. I don't know what all that actually constitutes, though.
- A legal entity ID, what is that? 0
- Α I don't know.
 - And physician seen, do you know what that box

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(Gilbreath - As on Cross)

comments section, you could?

out of the ordinary.

- We could, but we really -- at least let me speak for myself. I did not use the comment section for things that were really common and understood. I used the comment section for something that was
- Sir, it was out of the ordinary to be in a children's neurologist office with an adult drug, wasn't it?
- No, actually, there were a number of child psychiatrists, there were a number of general
- 13 psychiatrists and general neurologists who actually 14 saw all ages.
 - Yeah, you went to see other child neurologists and other child psychologists in Birmingham and its environs as well, correct?
 - Yes, because they also saw adults, just like Α Dr. Mathisen.
- 20 Right, one adult and you get in the door, correct? 21
- 22 MR. MURPHY: Objection, Your Honor. 23 Argumentative.
 - THE COURT: Overruled.
 - One adult and you get in the door? 0

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(Gilbreath - As on Cross)

2 is for? It's blank here.

> Α I do not.

Let's look at the next section. The next section of one of these documents is the name of the person, and you see it's Scott Hansen, 6043, Division JAN. Is that Janssen?

8 Yes, I would assume so.

- EMPL ID is employee ID, correct?
- 10 I would think so, yes. Α
- 11 And the territory is J2400701. It's almost as 12 long as one of our Bates numbers. Did you divide 13 the country -- did Janssen divide the country by 14 territories?
 - Yes. With all our representatives we had certain geography that we had responsibility for. It was generally by zip code, and so those were certain zip codes that would have been included in the territory.
 - Help me on this, sir. How did Hansen have him in May and you had Dr. Mathisen as a customer in
 - Well, responsibilities change from time to time and there are changes in territories and changes in geographies as well as responsibilities

1 (Gilbreath - As on Cross) 2 on certain products and settings. So I don't know 3 exactly what the case was in the middle of 2002, 4 it's been a little while, obviously, but those were 5 frequently the case.

Q Let's look together at the next section just so we know what these are. There is Details, so there is Professional ID -- I assume that's a doctor number. Was that a Janssen number, his license number, what is it?

A You know, I don't know.

12 Q You filled out these forms for six years, sir?

A We did not fill out this portion.

14 Q Who filled out that portion?

A Once we submitted a physician's name and information to the visit with them and the verification, that's where the company had an internal process where they would actually take a look at the physician's information, there is a state database of license numbers, there is also —

there is ways that they can verify that the physician is valid and licensed to practice

23 medicine.

Q Right, and using the drug. They verify that, too, you know that? (Gilbreath - As on Cross)

 ${\tt Q}$ — And it says Sample Description Risperdal, .5, one times seven, and then sample number, and sample product C D. Is that sample product code?

A I don't know for certain, but that's a fair assumption, I think.

7 Q Do you know?

8 A I do not know.

9 Q This is a form that you used everyday for six years, sir, correct?

A I don't know if it was everyday, but yes, we used it.

 ${\tt Q}$ And when you told me there were two different samples, the ten and ten, the ten is on a different place, I think it is.

Sample quantity is ten of each. I believe it's in front of the jury.

Now, where does it say whether a presentation was made or not?

A (No response.)

MR. KLINE: We can take that part down, please, and in fact, would you simply pull out the sample description in a full pullout? I just want to do a snapshot of it, real quickly.

(Gilbreath - As on Cross)

A I don't know that to be true.

Q You don't know that one way or the other?

A I don't, no.

Q Okay. We see here the next section as Details -- I am sorry, did we finish that, Details? Yes. And then underneath that it's Samples. I am looking for the portion, sir, here is Samples, and let's go across it. An it has the Professional ID again --

THE COURT: Excuse $\operatorname{me.}$ Can we have that zoomed in or something?

MR. KLINE: So everyone knows, the problem is you can only enlarge it so far.

THE COURT: Some members of the jury cannot see it, otherwise we would have to publish the document.

MR. KLINE: No, we will get it. When it stretches this way you can't get it bigger so we have to take a piece of it. So we will do exactly that.

Can that be seen now? Yes? No? $\label{eq:Q} \text{$Q$} \qquad \text{There is a portion of it that is specifically for samples, correct?}$

A Yes.

(Gilbreath - As on Cross)

I am doing a snapshot, what's the next exhibit number with a full number, please?

THE COURT: P-62(C)? Is that what you want?

MR. KLINE: 62(C). It's a call out of the May 3, 2002.

(P-62(C) is marked for identification.)

Q Now, let's move to 62(B), which is the 8-8-02 call out.

Sir, this format is somewhat different than the format we just saw, correct?

A Yes.

Q And why is that?

A We had different IT systems that supported, you know, the way we captured activity with physicians. So I am assuming that there was a change about this time is the reason.

Q And so we now need to look at this call note which is marked as 62(B). And 62(B) is your call note, correct?

22 A Yes.

Q 8-8-02?

24 A Yes.

Q This, sir, let's look at the left column --

(Gilbreath - As on Cross)

let's look at these boxes right across sequentially, bing, bing, bing. You type in Jan Mathisen, MD with his address, correct?

A I don't believe we type them in. We make the request and we select the physician from a menu, if you will. If they are not in there we would have to type it in.

Q That's what I was talking about earlier. It wouldn't be typed in because the guy is already in the system, correct?

A In this case I am not sure. I don't think he was in the system at the time, so I probably would have had to have searched and select.

Q Sir, you just told us just a second ago it would have been typed in for you. Which is it?

A If he was existing in the database, then we would select it. But if he was not, I would have had to type it in.

Q Sir, when you say if he was in the database, you are there 8-8, my word, three months earlier he had been given 140 pills. Of course, he is in the database, correct?

A Let me describe, there is --

Q Correct, sir? That's my question.

(Gilbreath - As on Cross)

MR. MURPHY: Objection, argumentative. There is no foundation for that.

THE COURT: That's sustained as to the way it's phrased, "you should have."

Q That's information which you would have searched for to determine whether this doctor had been seen and detailed and had been given samples before you showed up in his office. Can we agree?

MR. MURPHY: Objection, no foundation.

THE COURT: Overruled.

12 A I had to request the information --

Q Can we agree, sir, to that proposition?

A Would you repeat it one more time, please?

Q Let's move on. 8-8-02, Presentation. Now,

sir, if I look in here at the next column, briefly, the next column, that provides other information, correct?

19 A Yes

Q What does that tell us, briefly?

21 A It tells us IMS number, professional ID, J&J

22 ID.

 ${\tt Q} \quad \quad {\tt Let's} \mbox{ get the IMS number. Where does it say that?}$

A The first column to the right.

(Gilbreath - As on Cross)

MR. MURPHY: Objection, Your Honor.

THE COURT: Overruled. There is a question, was he in the database or not?

Q That's the question. Would a doctor who had just been detailed three months earlier, having been given 140 pills, been in the database, yes or no?

A He would not have been in my database. He would have been in the company's database.

Q And you worked for the company?

A I did, but I didn't have access to all of the records.

Q All you have to do is get the record of this particular doctor. You were a supervisor, correct?

A No, I was not at that time, no.

Q Are you telling us that when you went to see this doctor you didn't know that three months

earlier he had been dropped off 140 pills, 20

19 packets?

A Yes, I did not know that.

Q You were just clueless to that, seriously?

A I did not know that information when I saw him.

23 him.

Q You should have, correct? It should have been information that you knew, correct? (Gilbreath - As on Cross)

Q Now the IMS number, tell the members of the jury what the IMS number is?

A To the best of my knowledge, the IMS is a separate company that they actually work with physicians and collect information and they in turn make that available to industry partners.

Q Industry partners. That would be pharmaceutical companies, so that they can track how much drugs the doctors are actually prescribing, correct?

A I don't know exactly what all they track, but I do know the prescription information is generally available. But the physician also has the option of blinding that information, so if they don't want to provide that they don't have to.

Q And in this case Dr. Mathisen provided it, correct?

19 A I do not know, actually.

Q I am going to show you to see if it refreshes your recollection.

22 A Sure

Q Now, sir, who typed in IMS number, would that be you?

A I don't know. I normally did not have IMS

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1 (Gilbreath - As on Cross) numbers.

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- Do you know? 0
- I do not. Α
- 5 Let's look at the next column. Here you 6 Listed it as a professional call, and you say there

7 is a presentation only. When there is a

- presentation I am going to put a check mark here, okay?
- Yes.
- On my sheet. We see there is no presentation 12 mentioned in this one, on 5-3-02.

Now, sir, on that day you made a professional call, on 8-8-02, and did a presentation only, correct?

- 16 Yes. Α
- 17 You did not provide any samples, correct?
 - I did not.
- 19 0 Well, he didn't need any samples, he had 20 packs already from May, correct? 20
 - No, actually, as I recall, the reason I did not provide samples is because I had to verify that it was appropriate for me to provide samples, both with the question as well as making sure he was a licensed provider in the state in which he was

(Gilbreath - As on Cross)

- Q Every time?
- Yes, before we provided samples. Α
- And every time, would you take that same care to make sure absolutely and write it down that he wasn't treating almost all children? Would you take that care?
- No, I did not write down who all he was treating.
- Did you ever, sir, in any of these 21 visits write down on anyone of these sales calls or anywhere else that you asked this doctor if he was treating adults? Did you ever write it down?
- No, because it was implied. We asked most every physician if they saw appropriate patients.
- You did not write it down, correct? Q
- No, because it was standard practice.
- 18 You did not write it down, correct?
 - No, I did not. It was standard practice. Α
 - Standard practice not to write down the most important question, as to whether what you are doing would be legal or illegal? Do I have that right, too?
 - MR. MURPHY: Objection, Your Honor, argumentative.

(Gilbreath - As on Cross)

2 practicing.

- Sir, you keep saying that, I had to verify whether he was a licensed provider. That takes about a second to find out for a pharma rep if a doctor is licensed, doesn't it?
- True, but it's not my words. It's actually is it on record at the home office that this physician is appropriate, and it takes a little time.
 - Did you really think that was an issue here, that Dr. Mathisen was a licensed doctor? Can we get through that issue?
- It was. 13 Α
- Did you do it every time? 14 0
- Before we provided samples, absolutely. 15
- So you would go back every time -- let me 16 understand this. You would take the time to check 17
- 18 whether the doctor still had his medical license
- 19 every time you gave him samples; is that correct?
- We would absolutely look and see if they were 20
- 21 still --
- 22 My question is, sir, every time that you saw a 23 doctor, would you go back and check to see if he was 24 still licensed, yes or no?
 - I would check our system, yes.

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(Gilbreath - As on Cross)

THE COURT: Sustained.

Now, you provided no samples on that day, but it does say you gave a presentation.

Now, Dr. Mathisen told us -- what was the presentation, sir?

- The presentation --
- The man was a child neurologist, what did you have to say to him?
- It would have contained essential information, such as package insert, we would have used the package insert, the one that was approved at the time, we would have discussed that, the efficacy of how the product works, is it safe, and probably before any of that we would have asked -- I would have asked because I routinely asked, did he see adult patients.
- And if he saw one he got the green light, correct?

MR. MURPHY: Objection, Your Honor, same basis.

THE COURT: Sustained. We have been over that, counsel.

MR. KLINE: I know, but I don't ask the same question, I just hear the same thing

(Gilbreath - As on Cross)

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THE COURT: It's the same point, though.

Q Now presentation, sir, you couldn't tell him anything about use in children, correct?

7 A Correct.

Q First of all, sitting here today, can you tellus what you said to him?

A Verbatim, no.

Q Do you have any notes as to what you said to

12 him?

13 A No, but I do recollect what we said to 14 virtually everyone at that time.

14 Virtually everyone at that time.
15 Q Were you allowed to talk to him about the use

of it in children?

A No. And if it came up, if he brought it up to

me, then there was a process that I would, you know,

triage that and provide it to the appropriate parties so they can respond.

21 Q Why were you not, sir?

22 A Because it was not contained in the FDA label.

Q It was not something you could even mention,

24 was it, children?

A No, we were not able to speak to children at

(Gilbreath - As on Cross)

A Yes, the label was adult schizophrenia.

Q How many schizophrenia patients did Dr.

Mathisen have?

A I don't know. He never quantified that.

Q Did you ever ask him to quantify that?

A $\,\,$ No, I didn't ask to quantify. I asked him, as I stated earlier, do you have patients.

Q My question is a different one. Did you ever ask him to quantify the number of adults he had with schizophrenia in his practice, yes or no?

 $\mbox{MR. MURPHY:}\mbox{ Objection, Your Honor,}$ it's the third time he has asked the same question.

Q Yes or no?

THE COURT: You are directed to answer the question.

A Repeat the question one more time.

Q Did you ever ask Dr. Mathisen to quantify, that is to say, state the number of adult patients who have schizophrenia, which was the only use legal use for this drug? Did you ever ask him? I heard your explanation, sir, my question is yes or no?

A $\,\,$ No. It was not routine that we asked the exact quantity.

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(Gilbreath - As on Cross)

that time because the label supported use in adults, those 18 and above who had schizophrenia.

Q Right, and by the way, sir, do you have any documents -- it was only approved for adults and only approved for adults with schizophrenia,

7 correct? 8 A Yes.

Q Do you have anything in any document of any kind that he actually treated not just adults, but

an adult with schizophrenia? Do you have any

12 evidence of that?

13 A No, but he said he did.

14 Q No, I am asking you do you have anything

15 written down?
16 A No.

17 Q Do you have anything -- you couldn't detail

18 him even as to adults that didn't have

19 schizophrenia, correct?

20 A Correct. I --

Q The only thing that this drug was approved

22 for, the only thing this drug was approved for when

you were in a child neurologist's office 21 times,

24 the only thing it was approved for was adults with

schizophrenia, correct?

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(Gilbreath - As on Cross)

Q Now, you gave him a presentation, so I assume, sir, the only presentation you could give him would be on adults who had schizophrenia, correct?

A Yes, that's correct.

Q So you would be -- let me get the picture. You would be -- you were in a child neurologist's office on August 8, 2002, talking to him about adult usage for schizophrenia, which was the only legal thing that you could talk to him about. Do I have it correct?

12 A Yes, that's correct, and it was at his 13 request.

Q Now, let's go forward. I think we can do it much quicker. 9-9-02.

 $\label{eq:You are back. It's not even a month later and you are back, correct?}$

A Yes.

MR. KLINE: 62(D).

(P-62(D) is marked for identification.)

Q 62(D), let's get it right up. You saw him on 9-9-02?

A Yes.

Q And it says here you gave a presentation, correct?

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(Gilbreath - As on Cross)

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- Is that really truthful, sir, that you gave a 3 0 4 presentation again?
 - Yes. The presentation would have indicated a discussion with Dr. Mathisen. Now exactly the verbiage on that discussion, I am not sure.
- 8 Okay, but again, the presentation could only 9 legally have been about adult schizophrenics, 10 correct?
 - Α Yes, correct, it would be within the scope of the FDA-approved label.
- 13 It would go something like this: Hi, Dr. Mathisen, how are you, I am here today to see you, I 14 know your practice is child neurologist, do you 15 16 treat an adult patient, and by the way, let me talk 17 to you now about adult schizophrenia.
 - Do I have it about right what you were saying?
 - Yes. We described clinical studies supportive in the use of Risperdal in adults, we would describe the efficacy, how well the drug worked, safety to be aware of, and also dosing.
 - Tell me about all your schizophrenic adults you were treating, that would be your basic input

(Gilbreath - As on Cross)

- Did you ever go to anyone at the company, Janssen, you have big resources at this company, don't you?
- We have resources, I don't know whether they Α would be considered big or enough.
- You have heard big pharma, you heard that term, haven't you?

MR. MURPHY: Objection, Your Honor. THE COURT: Sustained.

- The fact of the matter is if you wanted to find out about a doctor's practice you had resources to find out, correct? You had people to say, Hey I want to find out about this doctor and who he really treats?
- Yes, and that's exactly what we did through Α the process.
- Do you know if anybody gave you a report back to show you that 90-some percent of his patients were children?
- No --Α
- Did you ever get that kind of report? Q
 - We would not have that information available. Α
 - If you knew, sir, that 99 percent of his patients were children, would you still have gone in

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(Gilbreath - As on Cross)

you would want back from him, correct?

- We didn't discuss specific patients that he was treating due to confidentiality and so forth, so we would talk about available data supported by the label.
- 7 Of course, that discussion would be about 8 adult schizophrenics, correct?
- 9
- Okay, and you gave him no pills at the time, 10 0 11 none, correct?
- 12 Yes, and I do recall that he was not verified 13 in the system to provide samples. So I don't know 14 if this was exactly the case but --
- Tell me how you remember that. Is that why 15 you didn't give him samples these two days, he 16 wasn't verified in the system yet to get them? 17
 - Perhaps, yes.
- 19 Okay. By the way, was there anybody back --
- when you say "verify", did you have like an 20
- 21 assistant or somebody working with you or people
- back in the home office back up here in Pennsylvania 22
- 23 and New Jersey?
 - Yeah, we had home office personnel. I did not have someone working with me personally.

1 (Gilbreath - As on Cross)

there and given him these samples, yes or no?

3 If I knew that 99 percent --

> 99 percent were children and 1 percent was adults, would you still have given him these samples, yes or no?

- If he requested them and he had appropriate patients, 99 percent of what? It could have been a big number, depending on how large his practice was.
- So you would have done it?
- Depending on the context, yes.
- Now, that's 9-9 and we don't know if he is in the system yet. Let's go to the next time you go to see him, 11-19. 62(E).

(P-62(E) is marked for identification.)

- Now we are at 11-19-02. Are all of these calls generally, sir, cold calls, or do you make an appointment at some point?
- It really depends on the individual and the office. Sometimes they will want you to establish a set appointment, sometimes they will say come by on this day during this window.
- How about this doctor, do you have any recollection?
- My best recollection, I don't remember

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1 (Gilbreath - As on Cross) 2 exactly, but my best recollection was, come by 3 during this window of time during a certain day, and 4 I don't remember what days those were. 5 11-19 you go, and it says here, let's look at

11-19, it says -- 11-19, Presentation and Samples. Okay, I will check off Presentation, and Samples. This is the first time you are giving him samples,

8 correct? 9

Yes.

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10 11 Did he tell you he needed a resupply from

12 Mr. Hansen's 140 pills?

> I don't know specifically, but every time we provided samples it was at the physician's request. It's not something where we would go and simply drop

16 them. They had to sign saying they requested them. 17 You get kind of into a routine with these

things, don't you? You know when a particular physician is going to ask you for samples, don't

Α Not all the time, but yes, there is some predictability to it.

23 You have a good idea who the askers are, don't 24 you?

> Α In general. Some folks asked for general

(Gilbreath - As on Cross)

MR. MURPHY: Objection, Your Honor, we have been down this road.

THE COURT: Yes. Sustained. "Did you pay attention to."

MR. KLINE: I will can it a different way.

Is it of any consequence to you what the 0 office door says?

Not necessarily, no, because we would, as mentioned before, we would have general psychiatrists, general neurologists, child and adolescent psychiatrists, and in this case a child neurologist, who also treated adults.

Would you tread more carefully if it said child neurologist or child psychiatrist? Would you tread more carefully, yes or no?

> MR. MURPHY: Objection, Your Honor, basis. There is no foundation here. THE COURT: Overruled.

It's simply a yes or no question, sir. Would you tread more carefully if the front door said child neurologist or child psychiatrist when you knew it was illegal to promote to them, yes or no? Yes, it would be logical to ask the question,

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(Gilbreath - As on Cross)

samples routinely. Others not as often.

And as this went on, you knew he was a doctor who asked for samples, correct?

He had requested samples, yes.

My question is a different one. My question is you knew that he was one of those physicians who routinely wanted samples. He wanted to see you so he could get them samples, correct?

I did not know him to be a physician who routinely asked because I was really just getting to know him at this point.

How about as it went on? As it went on there was a pattern here. You were showing up and he was taking samples, correct?

He was requesting samples and I was providing them, but that was the case with virtually, I would say the majority of the physicians that we saw.

I forgot to ask you this. What did the door of his office say was his specialty?

You know, I don't recall the door of his Α office.

Did you pay attention to what the door of an office of a doctor said, whether it said child neurologist?

(Gilbreath - As on Cross)

look, you are a child neurologist but this medication is approved for adults, do you have adults that you actually treat, what was your basis for requesting the visit. If the answer is yes, I saw him, if the answer was no, I would not.

I can understand that. By the way, sir --

8 Yes. Α

> By the way, sir, child psychiatrists and child neurologists, sir, you recognize are treating probably the most vulnerable people in our society. Would you agree?

> > MR. MURPHY: Objection, relevance.

Would you agree that you knew that? THE COURT: Sustained as to any characterization for him to decide.

So 11-19, Professional call, Samples. Let's get to your samples, sir. The samples are on the bottom of each page.

Oh, by the way, let's look in the place up above, where it says Next Call? Where there is room for notes? Do you see that section, that long box there, sir? That's long field where you can type in whatever notes you want, and on some of them you did type in notes, correct?

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1 (Gilbreath - As on Cross)

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3 0 There is plenty of time to type in things

- 4 like -- whatever you want, correct?
 - Yes, it's a free text box. Α
- 6 And it's on every one of these call notes,
- 7 correct?

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- 8 Α Yes.
- 9 0 Let's go down to the bottom, Samples?
- 10 Quantity, how many, sir?
- Ten, ten, and five. 11
- 12 Hold on, let's get there. Ten, ten and five.
- 13 So let's see what we have.

14 We have ten at -- maybe we can

highlight -- we have ten .25, one times seven, and 15

16 what do we also have? Ten 50s, one by seven. And

- 17 five 30 milliliter solution, correct?
- 18 Yes.
- 19 Now, the five 30 milliliter solution, that's a
- 20 bottle, correct?
- 21 Α Yes.
- About how big? 22
- 23 A bottle about that big. Α
- 24 And it contains how many 25-milligram doses
- 25 does it contain in it, approximately?

(Gilbreath - As on Cross)

other.

You can split up the oral -- I want to go back here. We have a 30 milliliter bottle. After the lunch hour I will show you a bottle and see if we agree if that's the bottle.

THE COURT: Lunch hour, by the way, counsel, is about 15 minutes.

MR. KLINE: I am not going to get through this section but I will get to the 15-minute mark, Your Honor. Much appreciated for the heads up.

Q So it's 1 milligram per milliliter.

> MR. KLINE: Now we are in chemistry, Your Honor.

THE COURT: I haven't had it since tenth grade.

MR. KLINE: We had it in my high school in 12th. I don't know how good I did.

So it was 1 milligram, so when we divide it by 30 and it would be times four if we want to get it to -- there are 120 .25-milligram doses in this bottle. Correct? It's 30, 30 times one would be 30, but I divide it by four, so I got 120 kids' doses at .25 milligrams. Correct?

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(Gilbreath - As on Cross)

- I do not know the answer to that question. My best recollection is 1 milligram per one milliliter.
- 1 milligram per milliliter. And, sir, you are well aware of the fact that the oral dosage was used in children, correct?
- 7 I am not aware of that. It was used in 8 multiple patients with multiple ages.
 - Were you aware at the time that doctors were using this off-label orally in children? My
- question is simply were you aware at the time that 11
- 12 it was being used by doctors for children, yes or 13
- no?

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- 14 They certainly had the opportunity to if they Α wanted. 15
- 16 Q My question is whether you knew. That's the 17 question?
- 18 No, I did not have specific knowledge that 19 they were using this specific sample in children.
- 20 No, that's not my question about the specific sample. Were you aware that the oral solution was
- being used by doctors in children, yes or no? 22
- 23 There was a general knowledge that Risperdal 24 as a whole. I don't have knowledge as to which dose
 - might have been inclined more or less than the

(Gilbreath - As on Cross)

- I don't agree that they were kids' doses per se but I agree that the math there were 120 .25 milligrams.
- You don't agree they were kids' doses, but you would agree that's the kids dose in the 2006 label,
- Α That's what the label stated in 2006, but this was not 2006.
- I know, yeah, we do know that. And so if we were going to, just keeping track of doses that were dropped off, this would be five of 30 milliliter bottles, that would be 120 25-milligram doses.

So what you dropped off that day would be, in 25-milligram doses -- well, you dropped off ten 7-packs, so that would be 70 doses, correct?

- Yeah, 70 pills.
- You dropped off ten 50s, which would be 170 Q doses, if you doubled it to 25, we won't even do that. Then you dropped off the equivalent of 120 more doses in the bottles, correct?
- 22 Yes, I provided all three doses.
 - So I count up here, in terms of 25-milligram doses, if I times two for the 50s, I have 140 and 120, and 70. So I have 140 and 120 is 260, and 70,

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113
1
                    (Gilbreath - As on Cross)
2
     330 .25-milligram doses, correct?
3
                   330 doses were dropped off at this
4
     doctor's office that day. That would be a seven
5
     pack of 25s, a seven pack of 50s, so we would have
6
     to times it by two to get it to 25, and we know that
7
     the 30 milliliter bottles are 120 .25 milliliter
8
                   330 of 25 milliliter doses. Can we
9
10
     agree? .25. Can we agree?
            Are you asking me, sir?
11
12
     0
13
            Yes, of course, I can agree to that.
            Wow, 130. One more Question: Those 50s could
14
     0
     be broken in half, correct?
15
16
            It's actually .5, but yes.
     Α
17
            .5, they can be broken in half and made into
      .25s, correct?
18
19
            I don't know. Some tablets were scored, I
     can't recall if they were or not.
20
21
            Sir, you detailed this drug for six years and
22
     you can't tell us whether you could break it in
23
     half?
24
            Some of them were scored for that purpose, but
25
     I don't recall if the .5 was not. In fact --
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115
 1
                    (Gilbreath - As on Cross)
 2
            If you are looking at increments of .25,
 3
      that's correct.
 4
            I am. I am.
 5
                   MR. KLINE: Let's try to get one more
            in. The next visit is marked as P 62(F).
 6
 7
                   (P-62(F) is marked for identification.)
 8
            We are at 3-11-03. So once again I think we
      0
 9
      have it up there, and our trusted friend Corey can
10
      show us whether there is a presentation. Was there
11
      a presentation?
12
      Α
13
            Same old about adult schizophrenia, you had a
14
      discussion?
15
            Yes, it was the context of every presentation
16
      at that time.
17
            And let's see. Did you drop off samples?
18
            Yes, it looks like I did.
      Α
19
            Let's go to work on samples. You dropped off
      Q
20
      five .25s, one by seven, correct?
21
      Α
22
            So you dropped off there 35 .25-milligram
      Q
23
      doses, correct?
24
      Α
```

114 (Gilbreath - As on Cross) 1 2 Even if a tablet is not scored, you are 3 familiar with this tablet, aren't you? 4 5 0 All you do is (indicating) and you got half, 6 correct? 7 Some were splitting them, yes. Α 8 People split pills all the time, right? 9 MR. MURPHY: Objection. 10 THE COURT: Sustained. Indicating for the record by counsel 11 12 that he made a biting motion on a pill. MR. KLINE: I did, and I broke my 13 14 tooth. THE COURT: The objection is sustained, 15 16 though, why don't we move on. 17 MR. KLINE: I think I got it. Let's 18 try to do one more. I am going to put on my 19 chart 330 of .25s. 20 By the way, if I can go back, sir, to when my 21 math was 140, actually, ten 50 milligrams is 70 doses at 50, but it's really times two as a .25. So 22 23 it would be 140 and 140 is 280, in terms of 24 25-milligram doses that Mr. Hansen dropped off, 25 correct?

(Gilbreath - As on Cross)

And then you dropped off, what's next, five

.5s.

Q

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And by the way, sir, you may or may not know this, that with a label that said that the adults schizophrenic dose was 1 milligram, and the bipolar dose was 2 milligrams, can you tell us as someone who was selling this drug why it was being made in .25-milligram pills?

Special populations, special considerations, once again, liver or kidney conditions, special populations in general, as well as for titration.

So I know sometimes if one was moving from a 1-milligram to 2-milligram, that's an entire doubling of the dose. They might use the .25 or .5 in increments to maybe not go as high that fast.

Maybe you can help us with this, sir. Yesterday at the end of the day we saw 1.26 million doses were being used for children. Do you know whether the .25 milligrams had anything to do with the 1.25 million children's use doses?

I don't know that, actually.

Sitting here today as a Janssen/Johnson & Johnson representative?

Yes. Α

0 Is that the first time that you found that

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1 (Gilbreath - As on Cross) 2 out, that 1.26 million children's doses were being used in 2002? 3 4 That is the first time I have heard the 5 1.26 million, but I mean, I have known that

It was common knowledge it was being used in children. And let's see if we can agree on something that is almost a blinding flash of the obvious, that these 2.5s were being used in children by a child neurologist. Can you agree?

Risperdal was used in children. I mean it was

No. I mean, I had to --

Can you? 14 0

common knowledge.

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24 25 THE COURT: Let him finish, please.

If I were to question Dr. Mathisen, I quess I Α could have asked him specifically. But we didn't ask about specific patients, did you use this dose for these particular patients or this dose for these

Sir, on 3-11-03, you dropped off 35 pills in the .25-milligram dose. And you never asked him a question about it? You never said to him, sir, you are a child neurologist, are you using them in children? You never asked that question?

(Gilbreath - As on Cross)

doses, did you ask him, Sir, you are a child neurologist, are these going to be used for kiddies? Did you ask him that question?

Of course, not. We did not make it a routine to ask how they would use a specific sample. They would request samples and we would provide them per their request, as per our discussion.

Did you ever hear of Nancy Reagan?

10 Α Yes, of course.

> Do you recall the saying -- I want to see if this applies to this day -- do you recall the saying, Don't ask don't tell?

> > MR. GOMEZ: Objection.

MS. SULLIVAN: That's Bill Clinton. THE COURT: Sustained.

Let's finish this out, hopefully, in three minutes. You drop offed five of .50s one by seven? Α Yes.

So that's 35, of course, we have to have it times two. That would be the equivalent of 70 .25 milligrams, and then you had continuing on, five of 1 milligrams. And that would be one times seven. So that would be 35 times four, would be 140 at .25 milligrams.

118

(Gilbreath - As on Cross)

MR. MURPHY: Objection. Asked and answered, Your Honor.

Q On this day. On this day --THE COURT: Sustained.

0 On this day --

> THE COURT: Well, then get the day right. March 17, not March 11.

Okay, my mistake. On March 11, on that day, when you handed off -- this was, by the way, hand to hand, wasn't it? He would take the pills from you? You to him, correct?

No, I don't recall hand-to-hand transaction.

Who would you give the pills to? Who would be the recipient?

I don't recall if it was a staff person, many offices had a staff person. I don't recall Dr. Mathisen's exact setup. But they would usually have a closet or some kind of locked cabinet that they would keep medications just for security.

Do you know if this doctor's office did, do Q you know?

Α I don't really recall.

Let's talk about this office. On that day when you handed him thirty-five .25 milligrams

(Gilbreath - As on Cross) 1

> And by the way, sir, you were aware -let me ask you this. Have you become aware that children who are started on Risperdal, in fact, like Austin Pledger, start at a low dose like .25 and then are moved up to .5 and sometimes as much as one? Are you aware of that fact?

No, I am not. I am not aware of the specific dosing with any patient, much less Mr. Pledger.

You handled the drug for six years, sir, were you not aware at any time how these pediatricians and pediatric psychiatrists and pediatric neurologists were using and dosing the drug when they were using it off-label?

No, because we did not ask them nor speak to off-label usage. We really spoke to the context what the label did support. If they brought it up we would inform them that it was outside the scope of the label. If they had a question we would submit it and get the answer from the appropriate department.

And then you dropped off eight bottles of 30 milliliter solution. And that, of course, would be, eight times three is 240 grams, and if you broke it out into four, it's 964 of .25 milliliter doses. Do

1:45. Mr. Gilbreath, you are under

do not discuss your testimony or your

instruction at this point not to talk to any

lawyers. If you have lunch, whatever, please

(Gilbreath - As on Cross)

I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF THE SAME.

JUDITH ANN ROMANO, RPR-CM-CRR OFFICIAL COURT REPORTER COURT OF COMMON PLEAS PHILADELPHIA COUNTY

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(Gilbreath - As on Cross) involvement with any lawyers at this time. All right, thank you. All right, we are in recess, everybody until about 1:30. (A luncheon recess is taken.)

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