

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 : APRIL TERM 2012
PLEDGER, as Guardian of his :
Person and Conservator of his :
Estate, :
Plaintiffs, :
:
v. :
:
JANSSEN PHARMACEUTICALS, INC., :
JOHNSON & JOHNSON COMPANY, :
and Janssen Pharmaceutical :
Research and Development, :
L.L.C. :
Defendants : NO. 01997

WEDNESDAY, FEBRUARY 4, 2015

**VOLUME VIII
MORNING SESSION**

COURTROOM 425
CITY HALL
PHILADELPHIA, PENNSYLVANIA

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

REPORTED BY:
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CERTIFIED REALTIME REPORTER
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I N D E X

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(Hearing is reconvened at 9:52 a.m. with all parties present.)

THE COURT: Good morning, everybody. We do have the jury now and we are ready to proceed.

Where are we, by the way? We are in the middle of the direct examination as if on cross of Mr. Gilbreath?

MR. KLINE: Yes, Your Honor.

THE COURT: Do you have the witness here?

MR. KLINE: I believe Janssen has him here.

THE COURT: Before we start, Marianne has reminded me to mark the --

MR. KLINE: Are you talking about these charts up here? I have them marked. Shall we do them?

THE COURT: It would be best to do it before the jury comes in.

THE COURT CRIER: So this chart will be Plaintiff's Exhibit 63.

(P-63 is marked for identification.)

MR. KLINE: That's the chart that has

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exhibits.

THE COURT: Whatever is satisfactory to the court reporter.

MR. KLINE: I think that would work for them.

THE COURT CRIER: Your Honor, Plaintiff's Exhibit 63 is an easel chart with the heading 3-11-03, and it has a division problem on it.

(P-64(A) through (D) are marked for identification.)

THE COURT CRIER: Plaintiff's Exhibit 64(A), (B), (C) and (D) are sales calls of Mr. Gilbreath to Dr. Mathisen's office.

(P-65 is marked for identification.)

THE COURT CRIER: Plaintiff's Exhibit 65 is the easel chart with milliliter math on it.

THE COURT: I want to be clear now on the record that should any of these documents be used during closing argument they must be the original documents, no photographs. Okay?

MR. KLINE: Sure. I just meant photos for the --

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365 into 1205 equaling 3.3 years.

THE COURT: Why don't you organize it and come up here.

(Pause.)

THE COURT: Just take the notes down and as soon as these individual things are marked, we will review them at the lunch hour. I don't want to keep the jury waiting.

MR. KLINE: Your Honor, what I would simply suggest is that when the jury comes in, since they are the ones who also need to see these, I will identify them right in front of the jury.

THE COURT: Why don't we have them marked ahead of time so we are not going back and forth between Marianne and you.

MR. KLINE: I think she has them.

THE COURT: By the way, these particular documents, where are they now, the ones that have been marked now by both counsel? They should be part of our court reporter's records.

MR. KLINE: We plan to take a snapshot of them and make them part of the book of

(Pledger v Janssen, et al.)

THE COURT: For our court reporter.

But the reason we are taking note of these now is so there is no objection later to the use of these things, because they have been marked and they are part of the evidence and they have been seen by the jury, and we don't want a hassle during closing arguments. And so that means we need the originals. So I am just wondering, where are the originals?

THE COURT CRIER: I am going to take them.

THE COURT: And Ms. Sullivan had a couple, too.

THE COURT CRIER: Yes.

THE COURT: All right, let's go.

(JASON GILBREATH, having and previously sworn, resumes the witness stand.)

(The jury enters the courtroom at 10:01 a.m.)

THE COURT: All right, be seated. Good morning, everybody. We are now going to resume the direct examination as if on cross of Mr. Gilbreath by the Plaintiffs.

What that means is that this is a

(Gilbreath - As on Cross)

witness who is on the Plaintiff's case, all right, this is a witness on the Plaintiff's case so it should be evaluated according to the Plaintiff's proof.

So, Mr. Kline, you may proceed now with your direct examination.

- - -

AS ON CROSS-EXAMINATION

- - -

BY MR. KLINE:

Q Your Honor, good morning. Members of the jury, good morning all, and good morning, sir. Second night in our city.

A It's a great city.

Q I couldn't agree with you more. We left off with your sales calls, and I have been preparing a chart listing them all and I would like to continue.

My first goal is to go back and cover a few visits. Having the benefit of last night, I picked up a few more samples that you dropped off that were not previously found by you and me, so I might want to go there for starters, that's my goal.

A Okay.

Q And then my hope is to go through those and

(Gilbreath - As on Cross)

For example, 80 .5s would be --

MR. MURPHY: Objection, Your Honor, is this a question? This is just testimony.

MR. KLINE: I am getting back to where we were.

THE COURT: That's overruled. You may generally lay a foundation, but I am aware of time issues involved in this trial.

MR. KLINE: I know, Your Honor, I just want to put it back where we are: And the 160 .25s equal 80 .5s, and that's where we are. That's all I was trying to do.

BY MR. KLINE:

Q Now I want to go back and pick some things up as efficiently as we can. I would like to display 62(J), which takes us back to 9-12-03. I simply want to go to the samples. This would be for 9-12-03. Do you have it?

A Yes.

MR. KLINE: All right, we are allowed to display. I would -- do you need the Bates number? Okay, it was a switching issue.

Q For 9-12-03, we had picked up the 30 milliliter solution, the 300 milligrams equivalent

(Gilbreath - As on Cross)

ask you some other questions.

A Of course.

Q Thank you, sir. We were in the middle of a number of exhibits. We talked about milligrams, math, milligrams with milliliters, and I marked that 65 for the jury's benefit. And I had marked a chart of sales calls under the 64 exhibit number, now bearing 64(A), the visits 5-3-02, 8-8-02, 9-9-02, 11-19-02, and 3-11-03. And we are going to go back to just a few of them. New stuff, not old stuff.

And then 64(B) now has a sticker and I marked that as the chart of 8-5-03, 8-26-03, 9-12-03 and 10-14-03, 11-17-03.

And then 64(C) I marked the visits of 12-9-03, 1-13-04, 2-12-04, 3-2-04, 4-5-04, 5-18-04. And we were currently working on 62(D), which is 6-1-04 and 6-3-04, and we had left off with a discussion of you dropping off 20 M-tabs, and we were consistently doing it, as a recollection here, to put it in perspective, when we had .25 milligrams we were counting up the number of tablets in the packet, and then if they were .5 milligrams we were breaking down the .25 equivalent, which are the numbers out in the right-hand column.

(Gilbreath - As on Cross)

of the drug, and we did not pick up that you also dropped off ten .25 packs. Do you see it?

A I do see that.

Q I think we just collectively missed it maybe. But ten .25 milligrams, 1X7. So that would be 70 more .25s dropped off to Dr. Mathisen for when we do a final total here. Would you agree?

A Yes.

Q Moving right along, also, if I can pull up P-62(L), which was the visit of 11-17, also on our display chart 64(B).

On 11-17, you and I had picked up that you had dropped off five .5 milligrams doses, 1X7 packs, and we did not pick up that there was an additional group of samples you dropped off that day. Do you see them there, sir?

A I do.

Q And you dropped off some M-Tabs, correct?

A Yes, that's indicated in the record.

Q And those are .5 milligrams, half milligrams, correct?

A That is correct.

Q And let's see what you dropped off. You dropped off five 4x20s?

(Gilbreath - As on Cross)

1
2 A Yes.
3 Q So that would be 20 times five. That would be
4 a hundred .50s, correct?
5 A One hundred .5s, yes.
6 Q When I put on this chart 50, 50s are
7 .5 milligrams?
8 A I apologize, yes.
9 Q I just want to make sure we all know the lingo
10 I adopted here.
11 So in .25s, that would be the
12 equivalent of a hundred more .25 doses, if they were
13 broken into .25 doses, correct? Quarter doses,
14 correct?
15 A Yeah.
16 Q Okay. So we picked up that one which I missed
17 yesterday. So for 2-12-04, which is?
18 THE COURT: P-62(O).
19 Q Yes, P-62(O), the calculation is in my hand
20 chart in front of me, 64(C), and bear with me, this
21 is 2-12-04, and we have -- we picked up five
22 4x1x20s, if we can highlight that quickly, what we
23 picked up. Those appear to be M-Tabs, correct, sir?
24 A Yes.
25 Q The dissolvable tablet in the mouth?

(Gilbreath - As on Cross)

1
2 .25 milligrams, if it were broken down into that
3 dose. Correct, sir?
4 A Repeat that one more time, please.
5 Q Yes, it would be 70 .25s in that packet, 30
6 .50s equaling 70 .25s -- I am sorry, oh, no, I am
7 wrong.
8 Seven times ten is 70. They are 1X7s,
9 so they are ten packs of seven, it's 70 .50 tablets,
10 if you broke them in half equaling 140 .25s,
11 correct?
12 A Yes.
13 Q And 62(S), which is 6-1-04. I don't think we
14 got to 6-1-04 yet yesterday. Correct, Mr. Gomez?
15 MR. GOMEZ: We did.
16 THE COURT: 62(S).
17 Q 62(S) is displayed to the jury, and I am
18 working on my chart 64(D), having previously made
19 the entry on 64(C).
20 So 64(D) on 6-1-04, we had picked up
21 that you dropped off ten .5 milligrams, 1X7s, which
22 would be 70 of .50s, broken in half would be 140 of
23 .25s. We also did not pick up yesterday on 6-1-04,
24 Exhibit 62(S), that there were also five
25 .25 milligrams in an 1X7 pack, correct?

(Gilbreath - As on Cross)

1
2 A Yes.
3 Q But we missed a bunch more. Do you see that?
4 A I do see two additional entries.
5 Q And we are going to add for 2-12, ten of
6 .25-milligram 1X7s, so that's an additional 70 .25s,
7 correct?
8 A Yes.
9 Q And by the way, in .25-milligram dosages,
10 correct?
11 A In .25-milligram dosages, yes.
12 Q Right. And we also missed five M-Tabs in
13 .5 milligrams, and those were 4x1x20s. So that
14 would be 20 times five equals a hundred of .5s, or
15 in .25s, that would be 200 more .25s, correct? If
16 they were broken in half.
17 A Yes.
18 Q Okay. 62(Q). 62(Q) is 4-5-04. We had picked
19 up five 1X7s unscored. And we had our discussion
20 about unscored, just to put it in context?
21 A Yes.
22 Q And you also dropped off that day, ten .50s in
23 1X7. Correct?
24 A Yes.
25 Q So that's 35 .50s, equaling 70 of

(Gilbreath - As on Cross)

1
2 A Yes.
3 Q So that would be an additional 35 of .25s that
4 you dropped off that day, correct?
5 A Yes.
6 Q And on 6-30, that would be P-62(T) -- correct,
7 Mr. Gomez?
8 MR. GOMEZ: Correct.
9 MR. KLINE: Is this now a new display?
10 The jury, I do not believe, has seen this one
11 before, correct?
12 THE COURT: 62(T) was shown.
13 MR. KLINE: Okay, I lost track.
14 THE COURT: 6-30-04.
15 MR. KLINE: Yes, thank you.
16 Q 6-30-04, we picked up the 20 M-Tabs, you also
17 in addition to the 20 M-Tabs dropped off five .25s
18 in a 1X7 pack. So that's an additional thirty-five
19 .25s, correct?
20 A Yes.
21 Q Okay, now, we are moving forward to 7-27-04.
22 You were back again within a month, correct?
23 A Yes, about a month.
24 Q 62(U), we are marking as 62(U), the sales call
25 of 6-30-04.

(Gilbreath - As on Cross)

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

MR. MURPHY: I thought (T) was 6-30.

MR. GOMEZ: 62(U) should be 7-27-04.

MR. MURPHY: Thank you.

Q 62(U) is 7-27-04. We are back again that you did a presentation, correct?

A Yes.

Q And you had Risperdal, let's see what you dropped off that day.

We have 7-27-04, which was Risperdal -- you dropped off five .5 milligrams?

A Yes.

Q In a 1X7. That would be 35 .50s or 70 .25s, correct?

A Yes.

Q And you also dropped off 1 milligrams, you dropped off five 1 milligrams, 1X7s.

So that would be thirty-five 1 milligram tablets. You divide them in four it would be 35 times four, 140 of .25 equivalence. Correct?

A Yes.

Q Then you saw Dr. Mathisen on 8-17-04, correct?

A Yes.

MR. KLINE: And that will be marked as

(Gilbreath - As on Cross)

We actually had been doing that, as I mentioned many times, up to that point, but this was a way to formally capture it and have it recorded, if you will.

Q Yes, sir, the formal policy changed because there were lots of sales reps going into lots of offices with lots of these medication --

MR. MURPHY: Objection.

MR. KLINE: I am finishing the question. Let me take it one at a time.

Q There were lots of sales reps who were dropping off medication to doctors, correct, of Risperdal? Can we go that far?

MR. MURPHY: Objection.

MR. KLINE: Let me start again.

THE COURT: What is the basis of the objection?

MR. MURPHY: It's irrelevant, Your Honor.

THE COURT: Sustained. We are concerned about this case.

MR. KLINE: I am about this case.

There was a change in the policy because they were dropping the stuff off like water --

(Gilbreath - As on Cross)

62(V) as in Victor.

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

Q You did a presentation or not?

A Yes.

Q And there, you have some writing. And by the way, sir, in 2004 -- I like to use an expression, I think it's actually a southern expression, there was a big hullabaloo in the company about qualifying doctors, about not going into the offices and giving all of this medication out off-label. Do you recall that?

MR. MURPHY: Objection to form, Your Honor. It's argumentative.

MR. KLINE: I will rephrase it.

Q Do you recall there being big discussion in 2004 about making sure that you absolutely qualified doctors who were really qualified to get all these samples, rather than doctors who were seeing children? Do you recall that hullabaloo, sir?

MR. MURPHY: Same objection.

THE COURT: That's overruled.

Hullabaloo is a known word. Go ahead.

A I do recall that we had a formal way of capturing the qualifying the customer initiative.

(Gilbreath - As on Cross)

MR. MURPHY: Objection.

THE COURT: Again, only if he knows what the policy is.

MR. KLINE: He told me he knew the policy change.

THE COURT: Ask him about that policy.

Q The policy changed, correct?

A There was a policy that we would formally capture it, yes.

Q It was a new policy --

MR. MURPHY: Your Honor, the witness ought to be allowed to finish answering the question.

BY THE COURT:

Q Please, that was a new policy, that's my question?

THE COURT: He may answer.

A It was a new policy, but we had informally captured that all along. Due to the requirements of the label, we had to ensure all along that they were appropriate to receive samples and discussion. So this was a time when we actually formally captured that to have it on record.

Q Yes, "we" formally captured it. Now as a

(Gilbreath - As on Cross)

matter of fact, what we have seen here today, or yesterday, is how the policy of -- in these exhibits which are 64(A), (B), (C) and (D), we show how you meticulously followed the policy of not giving drugs to an unqualified pediatrician, correct, sir?

MR. MURPHY: Objection, argumentative.

THE COURT: Sustained.

Q So when the policy changed, sir, it was about the middle of 2004, correct, about?

A I don't recall the exact date, but that sounds appropriate.

Q And there was discussion in the company, of which you were aware as a sales representative, that it was important to actually follow the rules.

Correct, sir?

A Yes. We always --

Q That's not my question. My question is -- we will judge whether the rules were followed.

A Okay.

Q The question, sir, is was there a policy put into effect, a new policy put into effect in 2004, that's all I need to know, about actually following the rules? Yes or no?

MR. MURPHY: Objection, asked and

(Gilbreath - As on Cross)

A It was pre-populated, meaning there were a menu of options to select what was discussed with the physician.

Q Okay, and so what was discussed was the "flexible dosing for easy titration including oral disintegrating formulation," correct?

A Yes, that's what was selected.

Q And that was the discussion that you had with Child Neurologist Mathisen that day, correct?

A Yes, it's indicated in the record.

Q And then you saw him again on 9-8-04. And you didn't drop off any samples, correct?

A Correct.

Q By the way, at this point did you know, sir, that it was in the works by Janssen to try to get approval for an indication for children with autism? Did you know that was in the works?

A I don't know if I knew at this time. I mean we became aware of it at some time, but I don't know if it was at this juncture or not.

Q Well, when the company was trying to get a new indication, would you as a salesperson back then, generally know what the company was up to and what indications were coming next?

(Gilbreath - As on Cross)

answered.

THE COURT: I don't understand the answer. Go ahead and ask it again.

MR. KLINE: I will withdraw it. If it was asked and answered I withdraw it. Let's go to 8-17-04.

Q 8-17-04, which is Exhibit 62(V), it's up there, it's listed as another professional call. With a presentation only, correct?

A Yes.

Q And, sir, there is a message that you actually typed in this time, correct?

A Actually, as I recall, I did not physically type that in. There was a time where drop-down menus were actually included to capture the majority of the discussion, you know, what was the item presented.

So this was not typed in at this time. It was free text up until a period of time, but this one was not free-handed in there, it was a drop-down.

Q Did you call it pretext?

A I am sorry?

Q I didn't hear the word you said?

(Gilbreath - As on Cross)

A No, generally only when it was near term, like 12 months or less, would we know about it. But I don't recall exactly what time we became aware of the pursuit of an indication for this.

Q Well, this is within 12 months of the company going to the FDA. Do you know if you knew or you didn't know?

A I don't think I knew. I mean at some point I did, I just don't know when it was right now. I really don't know.

MR. KLINE: Okay, 62(W). Is that 9-8-04?

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

Q No samples again, correct, sir?

A That's correct.

Q Right. Because by this time, sir, by this time, you knew that you weren't supposed to drop off samples to a doctor like Dr. Mathisen, correct, sir?

MR. MURPHY: Objection, Your Honor, argumentative.

THE COURT: Overruled.

Q Is that correct, sir? That's why this changed all of a sudden?

A That's not correct. It was appropriate to

(Gilbreath - As on Cross)

drop samples off with Dr. Mathisen at his request all along because he told me initially and all along that he saw adults with schizophrenia.

Q I didn't ask you all along, I didn't ask you at his request. I said, now you knew, sir, we have been watching you drop off samples in the hundreds of doses, at one point over a thousand doses. Now all of a sudden there were no samples being dropped off. What changed?

A I only suggest that he didn't request them, because I would have provided them had he requested them as I always had.

Q I am going to suggest something different to you. I am going to suggest that the company admonished people and told them there was a new policy here?

MR. MURPHY: Objection, Your Honor, it's not a question.

THE COURT: As far as the term "admonish", I am going to sustain that. Ask him another way, get an answer and let's move on.

Q The company cracked down, correct, sir?

A Not in my opinion it was a crack down, we had

(Gilbreath - As on Cross)

Q No samples again, correct?

A That is correct.

Q Fifteen times previously you had given samples, and now three times in a row you don't. Correct?

A Three times at the end, that is correct.

Q Would you agree with me, sir, that something changed other than Dr. Mathisen all of a sudden not wanting the medicine?

A No, not in my recollection anything changed. I don't know -- the only thing I can read into this is that he simply didn't request them.

Q You don't have any -- go ahead, finish?

A If I had samples at the time and he had requested them, I would have provided them as I had all along.

Q But you have no recollection, correct?

A Correct.

Q No note, correct?

A Correct.

Q No record, correct?

A Correct. Not from these records but --

Q Just an explanation, correct?

A I don't know if I understand an explanation.

(Gilbreath - As on Cross)

had the policy in place all along, it was just a formal way to capture it at this point.

Q And the company knew they were in trouble, correct?

MR. MURPHY: Objection, Your Honor.

THE COURT: Sustained.

Q And you saw him one more time, 62(X).

(62(X) is marked for identification.)

Q Did you read the newspapers at that time, sir? Were you reading the newspapers?

MR. MURPHY: Objection.

THE COURT: I am going to caution counsel here.

MR. KLINE: Okay.

Q The last one, I think, and then we are going -- and he handed him over to another -- I think to Ginger. This is 10-18-04. And if I can go back to the other two previous ones. (Pause.)

MR. KLINE: Chris, he doesn't have (X).

It may be out of order. Bear with us. Thank you all for being patient.

Q For (X) it's a presentation only, on 10-18-04, correct?

A Yes.

(Gilbreath - As on Cross)

What do you mean by that?

Q So let's now look at this last one that you did, and you say that, your message drop-down on your presentation, this is about the presentation, correct?

A Yes.

Q It says, "Risperdal flexible dosing for easy titration including orally disintegrating formulation (Risperdal M-Tab)." Correct?

A Yes.

Q Now I would like to do a call out of 62(V), (W) and (X), for these three dates.

Sir, three times in a row, on this date, this date, and this date, being 8-17-04, 9-18-04, and 10-18-04, you, in addition to dropping off no samples, claim to have given the same exact presentation. Correct?

A The same record was selected, yes.

Q When you say the same record was selected, this says what you would have talked to him about, correct?

A Yes. It's one of the things, yes.

Q This is a serious question: do you think Dr. Mathisen had a learning disability and he didn't

(Gilbreath - As on Cross)

pick it up the first time?

A I am not aware of Dr. Mathisen having a learning disability, no.

Q You didn't talk to him three different times about Risperdal's flexible dosing for easy titration, did you, sir? That doesn't make any sense. Can we agree?

A No, that would have been one of the things that we spoke about. In every interaction we used the guidance included in the FDA-approved label as well as the approved materials that were supplied. So this was probably not the entire balance of the discussion but it was on the select menu.

Q In two days, sir, how many times have you said the FDA's approved label and the FDA's-whatever you keep saying? How many times have you said that, do you think?

MR. MURPHY: Objection, Your Honor, it's argumentative.

MR. KLINE: It's a question.

THE COURT: That's a question, I will permit that.

Q How many times do you think you have in front of this jury recited those same words that you

(Gilbreath - As on Cross)

eventually was established December 13, 2004. Does that sound familiar to you?

A I don't know exactly the date that it was established but --

Q Does it sound it would have been around December, sir?

A I really don't know.

Q And did you know that beginning immediately at that point you needed to ask the current or perspective customers a qualifying question? Do you remember that, sir?

A Yes, the Qualifying Customer Initiative was where we asked a physician what we had asked all along, do you see patients that meet the qualifications of the label.

Q But you see, sir, you don't usually need a policy to enforce if that's what was happening all along, usually in a company and including one that you have now made your way up the ranks, correct?

MR. MURPHY: Objection, Your Honor.

THE COURT: That's sustained as to what the company usually does.

Q Sir, after the qualifying customer policy went into effect, and you do agree with me that a

(Gilbreath - As on Cross)

recited in your last answer? How many times?

A I really haven't kept count.

Q Would it surprise you if it was more than ten when we go back to the transcript before closings?

A No, it's common --

Q Common parlance? That's how you talk?

A Yes.

Q Okay. I get it. Now, let's finish a couple of things here. Bear with me.

Now, sir, I am going to suggest something to you, maybe we can do it without a lot of exhibits and things. On December 13 of 2004, there was a memo. Did you go over it prior to your testimony here today, sir, in preparation? I would just like to know, then I will know if you are familiar with it.

A I don't have a specific recollection of that, no. It's possible during the deposition preparation and this, but I don't have a recollection of it as I sit here right now. If I see it I may recognize it.

Q You know there was a thing called Qualifying Customers Initiative, correct?

A Yes.

Q And this is what was the formal policy that

(Gilbreath - As on Cross)

qualifying customer policy went into effect, do you agree with me on that?

A Yes.

Q And can we agree it was in December of 2004?

A We had asked the question all along.

Q I heard you say that over and over, sir. You asked it over and over again to Dr. Mathisen, you said, Dr. Mathisen, on the day that you handed him 1592 doses of the drug, you asked him that question. I have heard you say that.

A I don't know if I asked him the question that day, but I asked him periodically, yes.

Q You did. And everyday you went there, sir, the sign didn't change on his office door, did it?

A I don't really recall his sign on his door.

Q Pediatric Neurologist. If you don't recall.

A Okay.

Q And, sir, this qualifying the customer policy that you say was just something you did anyway, the fact of the matter is that after that policy went into effect, you stopped seeing Dr. Mathisen. Correct?

MR. MURPHY: Objection, Your Honor.

THE COURT: Overruled.

(Gilbreath - As on Cross)

- 1
2 Q Correct?
- 3 A Yes, but at the same time, it was towards the
4 end of the year and as best as I can recall, we had
5 a change in focus with our group where we had
6 multiple other medications, and so our Alzheimer's
7 product was particularly important, so we had to
8 allocate our time accordingly.
- 9 Q So all of a sudden you became too busy to see
10 poor Dr. Mathisen; is that correct?
- 11 A I don't recall it being too busy, I think it
12 was more of a business decision.
- 13 Q You decided you were going to sell your
14 Alzheimer's drug instead of supplying him the
15 samples that he needed; is that correct? For his
16 schizophrenia patients, by the way. He had all
17 these schizophrenia patients that needed the drug.
- 18 MR. MURPHY: Objection, Your Honor,
19 argumentative.
- 20 THE COURT: Overruled.
- 21 A Would you repeat the question?
- 22 Q Yeah. Dr. Mathisen had all these adult
23 schizophrenia patients using all these drugs, you
24 abandoned him. Why?
- 25 A I didn't abandon him.

(Gilbreath - As on Cross)

- 1
2 talk about the drug, correct?
- 3 MR. MURPHY: Objection, Your Honor,
4 that's argument. It always was legal.
- 5 THE COURT: Sustained as phrased. You
6 might want to rephrase that.
- 7 MR. KLINE: Yes, I will.
- 8 Q Janssen sales reps started to go back after it
9 became legal to talk to a child neurologist about
10 the indications for autism, correct?
- 11 A I do not agree with that. In fact, it was
12 legal all along, due to the items I have mentioned
13 previously.
- 14 Q No, I think we will agree it was illegal if
15 you said one word to that doctor or knew anything
16 that he was using this drug for children. Correct?
- 17 MR. MURPHY: Objection, Your Honor.
18 THE COURT: Overruled.
- 19 Q These samples, these samples. Correct, sir?
- 20 A I did not discuss children with Dr. Mathisen,
21 as I have mentioned many times. When I was there I
22 asked him the nature of his request, I let him know
23 what the label supported when I began seeing him and
24 revisited that during the process, and then when we
25 had the discussion it was in the context of the

(Gilbreath - As on Cross)

- 1
2 Q Sure. You are laughing because you know it's
3 silly.
- 4 MR. MURPHY: Objection, Your Honor.
5 THE COURT: That's sustained.
- 6 Q You left Dr. Mathisen because the policy
7 changed and they said you couldn't hustle the drug
8 anymore, that's what happened?
- 9 MR. MURPHY: Objection, Your Honor.
10 THE COURT: Sustained, sustained,
11 sustained.
- 12 Q And you didn't see him, you didn't see him
13 from 10-04 -- no Janssen representative saw him all
14 of 2005, correct? You know this?
- 15 A Yes, I do recall that through some of the
16 notes.
- 17 Q And nobody saw him until they got the autism
18 approval, correct?
- 19 A I don't know exactly when they resumed seeing
20 him.
- 21 Q Well, you have a memo that says you handed him
22 over to Ginger. Do you remember that?
- 23 A I don't remember a memo of handing over.
- 24 Q When the autism label changed, when it became
25 legal to go into a child neurologist's office and

(Gilbreath - As on Cross)

- 1
2 label.
- 3 Q It was illegal if you knew you were giving him
4 those drugs for use for children. Correct, sir?
- 5 MR. MURPHY: Objection.
- 6 Q Yes or no?
- 7 MR. MURPHY: Objection, asked and
8 answered.
- 9 THE COURT: Overruled.
- 10 Q As you understood it, sir, you knew it was
11 illegal to give this child neurologist drugs that
12 would end up in the hands of children; correct, sir?
- 13 MR. MURPHY: Objection. That is not
14 the law. And that has not been the testimony.
- 15 MR. KLINE: I am asking his
16 understanding.
- 17 THE COURT: Overruled. I need his
18 answer one way or the other and we have to
19 move on very shortly.
- 20 A I don't know the legality of things. I know
21 that we had a policy in place that if the customer
22 requested a visit, we asked if they had the
23 opportunity to use our products for patients that
24 the label supported. If the answer was yes, we
25 would continue to see them in that context.

(Gilbreath - As on Cross)

Now what he actually, after he had custody of those samples, who he provided those to were explicitly his --

Q His business. His business?

A Yes.

Q Right. I get it.

And to follow up on that question, sir, so on this day when you gave him 13 bottles containing --

THE COURT: What day was that, counsel?

MR. KLINE: 12-9-03.

Q When you gave him 13 bottles of 592 .25-milligram doses, what he did with them was his business, correct, sir? Yes or no?

A Yes, it was the discretion of every prescriber. Once samples left our custody they were in the custody of the prescriber to do with in their professional medical judgment.

Q And could you agree with the statement I made, once you handed him those 30 bottles, what he did with them was his business; correct, sir?

MR. MURPHY: Objection. Asked and answered.

Q Is that a correct statement?

(Gilbreath - As on Cross)

A I cannot dispute that, no. I don't have them in front of me, but I know there was a gap.

Q And by the way, sir, the term that you used for these were "sales calls," correct?

A They were used interchangeably. Physician visit, sales call, that's the same thing.

MR. KLINE: I want to mark this as the next exhibit number. P-66, no sales calls time period.

(P-66 is marked for identification.)

Q By the way, sir, I believe we have learned from another witness that approval for autism was 10-6-06, approval, with the new label. And you became familiar with that new label, didn't you?

A I did.

Q And you knew that that new label had a pediatric indication. Correct?

A It was for treatment of irritability associated with autism disorder, yes.

Q And you also knew it contained different warnings than were previously on the package insert, correct?

A Yes. There was an updated label with the -- supportive of the newly approved use.

(Gilbreath - As on Cross)

THE COURT: I believe that question is related to the previous question.

A Would you repeat the question?

Q I will, the fourth time.

MR. MURPHY: Exactly.

Q Once the 1592 doses got in the hands of the child neurologist, what he did with them was his business; can you agree, yes or no?

A It was his business, yes, and --

Q That's what I needed to know.

A And I would also submit, though, every physician had the responsibility of that because I have no bearing on what a physician -- how they use sample medication after it leaves my custody because we can't weigh in on individual patient cases of any kind or of any age.

Q Yes, I have the answer, sir.

Now, no visits, according to the records, and tell me if you have any evidence to contradict this, sir. By the way, you went through the call notes, you sat down, I think you told me with three lawyers, went through the call notes. You saw no call notes from 11-18-04, no visits, from 11-18-04 through 10-30-06. Correct?

(Gilbreath - As on Cross)

Q I know it was an updated label, I know it was supportive of the new use. My question was a completely different one. It had new warnings on it, correct, sir?

A It had new safety information which included warnings and precautions and any other clinical trial data as well.

Q I didn't ask about clinical trial data or any other stuff. I asked you if it had new warnings on it?

MR. MURPHY: Objection, Your Honor, he answered the question.

THE COURT: I am going to direct the witness to answer just the question. Otherwise we will be here for a little.

Q It contained new warnings?

A Yes. I don't have the label in front of me, but, yes.

Q You darn well know that it contained 2.3 incidence of gynecomastia, correct?

MR. MURPHY: Objection, Your Honor. That's argumentative.

THE COURT: That's sustained as asked.

MR. KLINE: What can't I ask?

(Gilbreath - As on Cross)

THE COURT: "Darn well".

MR. KLINE: I am sorry. I was trying to make him feel at home. Okay.

Q Let's go to 10-30-02, and I think I have an E-mail.

I think you were about to get promoted in 2006, correct, up the company chain?

A I took the district manager job in February of 2006.

Q Now the sales reps are working for you?

A Yes, I had supervision responsibility over them.

Q How many?

A Ten, I think.

Q That's pretty good. And you had earned your stripes, correct, in the company?

A I don't know in there were stripes associated, but it was a good opportunity.

Q Well, my word, would you agree that part of earning your stripes was the good job you did with many different doctors, correct?

A Yes.

Q And that would include Dr. Mathisen. That would have been included in your evaluation as to

(Gilbreath - As on Cross)

him.

THE COURT: Whatever you do, we are going to take a break shortly.

MR. KLINE: But you want to take a break in ten minutes?

THE COURT: Yes. Whatever you do, bear in mind the issues involving timing in this entire case.

MR. KLINE: I understand well. Let's take a break, I will reorganize and try to finish him up.

THE COURT: Ladies and gentlemen, we will take a recess right here, and just keep the same rules in effect, please do not discuss the trial with each other right now, and we will come back in ten minutes.

(The following transpired in open court out of the hearing of the jury:)

MR. MURPHY: In the course of his questioning --

THE COURT: Wait a minute, I am going to excuse our witness at the moment. Why don't you step outside, Mr. Gilbreath.

(The witness exits the courtroom.)

(Gilbreath - As on Cross)

whether you got this promotion, correct?

A He was one of many that I visited with.

Q He was. He was one of many child psychiatrists and child neurologists who you saw regarding Risperdal, correct?

A I wouldn't say "many", but there were others.

Q And here you are in 2006 and you now have a promotion. So now Dr. Mathisen, who we now know prescribes a lot of Risperdal, this would be someone who you would tell the sales rep, who he hadn't seen in two years, to get back into his office. Correct?

MR. MURPHY: Objection. No foundation.

THE COURT: Overruled. Unless you don't understand the question.

A I do understand the question. Actually, that was not the geography within my responsibilities as district manager. I only had Tennessee at the time.

Q Had you moved to Tennessee by this time?

A I had.

Q Just one second.

THE COURT: Counsel, in about ten minutes we are going to take a break.

MR. KLINE: I will do something different and then take a break and finish

(Gilbreath - As on Cross)

MR. MURPHY: In the course of questioning Mr. Gilbreath, Mr. Kline violated the Court's order regarding the in limine motion related to other matters regarding Risperdal, including plea agreements, investigations, and things of that nature. Blatantly and knowingly, he made reference to, Were you reading the newspaper at that time, the company was in trouble, asking him about violations of the law, and gave the jury the impression that that, in fact, was occurring.

It wasn't a turn of phrase, it wasn't inadvertent, it was blatant, and he knows it. The jury ought to be instructed to disregard those comments.

THE COURT: My belief is that all that's on the record is a question, and I cautioned Mr. Kline and he did not pursue it. If you want me to call attention to it, I will be happy to. I will be happy to call attention to the issue, saying, ladies and gentlemen, there has been a reference to newspapers, you know that you are not supposed to read the newspapers about this case or

(Gilbreath - As on Cross)

anything having to do with Risperdal. Do you want me to do that now? There was no answer to the question.

MS. SULLIVAN: The better instruction is to disregard all comments by counsel. It's not evidence.

THE COURT: That goes for you as well. I will do that any time.

MS. SULLIVAN: This was a blatant and knowing violation --

THE COURT: I will do that any time.

MS. SULLIVAN: Did you read the newspaper about violations of the law --

THE COURT: I know you have been very quiet so far, Mrs. Sullivan, but I will do that at any time for both counsel to disregard all the side comments that were made as part of your compounded questions for both counsel.

MR. MURPHY: That would satisfy me, Your Honor.

THE COURT: I will do it right now.

MR. MURPHY: I appreciate it.

THE COURT: We will take a recess for ten minutes.

(Gilbreath - As on Cross)

MR. KLINE: Your Honor, thank you.

BY MR. KLINE:

Q Home stretch, at least for me, sir.

A Okay.

Q During the break I did some math, and hopefully, we won't have to stand here with a pencil, we can check it at some point, but I am marking it as the next exhibit, P-67.

(P-67 is marked for identification.)

Q Sir, when we go through all of your exhibits, all of your sales calls, which were in the 64 Exhibit series, your sales calls to Dr. Mathisen in that period of time from 2002 through 2004, you visited him 21 times, correct, sir?

A Yes.

Q And if you were to break it down in .25-milligram categories, you provided 16,505 .25 doses to this child neurologist. Does that sound about right, without having to run through all the math? Would you trust me on it?

A I have not done the math, but I understood how you got there so I am in no position to dispute that.

Q Okay, sir, even if you looked at it in 1

(Gilbreath - As on Cross)

(A brief recess is taken.)

(The jury enters the courtroom at 11:14 a.m.)

THE COURT: All right, members of the jury, a couple of things I want to point out, actually tell you. We have a juror here who is a teacher at a charter school, I want to let you know some good news, that the board of trustees has voted to change its policy, and all persons who are on a jury shall be paid beyond the five days.

So our juror who is serving on the jury who is a teacher at the charter school in question has no worries. So that's nice to know.

The other thing is a reminder that questions by any attorney who is asking any questions at any time, that is not evidence. Just remember that. That is not evidence. Only testimony from the witness stand or other things that have been admitted pursuant to these rules over here, the Rules of Evidence, that's evidence. Questions are not. Okay?

All right, you may proceed.

(Gilbreath - As on Cross)

milligram, and we had a discussion about whether they were scored or unscored tablets, whether you could break the ones or not, whether you could bite the ones or not down, even if you look at this in 1 milligram tablets, you provided 4,126. That would be if some schizophrenic patient was taking four of the .25s rather than a child taking .25 out of the 1s. Even at that, you have 4,126 milligrams of this drug which you dropped off. Correct?

A I see how you got the math, yes.

Q Now, at the time, sir, and I am happy to show you a document or happy to just have an agreement on this, at the time, Janssen, on Risperdal prescriptions for individuals under the age of 18, you sales reps, sir, were being incentivized, on those prescriptions. Correct, sir?

A I do not know. I know there was a time when those were carved out. I don't recall exactly when that time was.

Q Yeah, that's the point. In December 13, 2004, and I am referring to -- I will mark Plaintiff's Exhibit No. 68.

(P-68 is marked for identification.)

MR. KLINE: I marked the chart

(Gilbreath - As on Cross)

Marianne, marked Gilbreath-Mathisen's Sales Calls as P-67. And if I hadn't said it, my apologies to you.

THE COURT: No, she did. Any objection to this document?

MR. MURPHY: Objection, Your Honor, beyond the scope. Beyond the time period in question, Your Honor. He stopped detailing this doctor in October. This is a December 17 --

THE COURT: On that basis, overruled. Go ahead.

BY MR. KLINE:

Q Sir, I am referring to an exhibit which we have marked as Plaintiff Exhibit 67. I have a copy for the Court --

THE COURT: I have it.

Q -- 68. Do you have a copy for the witness as well?

THE COURT CRIER: P-68 is handed to the witness.

Q This is a sales communication document and it's to all Janssen Elder Care CNS Sales Reps. Who are CNS sales reps? Central nervous system sales

(Gilbreath - As on Cross)

A Yes.

Q And it says in the sixth paragraph, which we will display, Exhibit JJ RE 00748285.

"In addition to qualifying each of your customers" -- can you see it? Let's look at this.

"In addition to qualifying each of your customers, Janssen will be employing the use of new IMS database that will enable all Risperdal prescriptions for all individuals under the age of 18 to be removed from incentive measurements."

Highlight "removed from incentive measurements."

Sir, if something is being removed from incentives, it means that it previously was incentivized, correct?

A It was my understanding that they had no way of breaking it out, so I assume that it probably was.

Q Yes, it probably was. So when you were selling to Dr. Mathisen as a salesman, your bonus system is on an incentive system, correct, so far?

A It's performance related, yes.

Q It's performance related. It's how much the doctor then actually prescribes to patients,

(Gilbreath - As on Cross)

reps?

A Yes.

Q And ROCs. Who are ROCs?

A I think that stands for Region Office Coordinator.

Q And Field Sales Management. And the subject is "Qualifying Customers Initiative." Do you see that?

A I see Qualifying Customer Initiative, yes.

Q And of course, you were -- when did you get your promotion, sir, when in 2004?

A I was actually promoted in February of 2006.

Q Oh, okay. So as of 2004, were you still a Janssen elder care sales rep?

A I was.

Q Oh, okay. Then you got this E-mail? This E-mail was addressed to all Janssen Elder Care Reps, correct?

A I cannot see that, actually -- okay, second page, I apologize.

Q Second page, do you see it? To all Janssen Elder Care Sales Reps?

A Yes, I see that.

Q That's you?

(Gilbreath - As on Cross)

correct?

A Yes.

Q Prior to this December 13, 2004 directive, you were incentivized on all of the Risperdal that was prescribed by Dr. Mathisen. Correct?

A I don't have any reason to dispute that so, to my knowledge.

Q Yes, right, and then what happened was in December of -- and you knew that at the time, correct? Of course, you knew how you were being bonused?

A Yes, the bonus included multiple layers, we had an institutional setting, an office base setting, with three or four different products.

Q Right. So as a salesman, you had good reason to be in Dr. Mathisen's office, because you knew when he would prescribe the medication it would then count towards your book, if you will, correct?

MR. MURPHY: Objection, Judge. It's argumentative.

THE COURT: Overruled.

Q Correct?

A Yes.

Q Now, transitioning the doctor, Dr. Mathisen,

(Gilbreath - As on Cross)

we know that you left off on 10-18-04. That was your last sales call, right?

A Yes.

Q And, sir, you remained an elder care sales rep in this region until how long?

A I think it was January or February of 2006.

Q So I am going to mark in here on Exhibit 66, the label change was 10-30-06, and Gilbreath promotion -- what date?

A I think officially, February of 2006.

Q 2006. So we now know that from 10-18-04 through 2/06, you remained as a sales rep in that region yet never went near Dr. Mathisen, correct?

A I did not see him after 10-18-04.

Q In any capacity, correct?

A Not to my recollection, no.

Q Do you have any notes or records that you tried?

A No.

Q And then what happened was in March of 2006, your having gotten your promotion 2/06, I am writing on P-66, "2/06 Gilbreath promotion."

On March 6, 2006, I have an E-mail -- I

(Gilbreath - As on Cross)

BY MR. KLINE:

Q Sir, let me show you an exhibit, before displaying it I will put it in your hands, P-69.

This comes March and it's an E-mail from you to Marc Marano. Who is Marc Marano?

A In March of 2006, he would have been my boss.

Q And this is, you are now leaving, and of course, in leaving there needs to be a smooth transition and get everybody put in the right places. That's what this is about, correct?

A I will have to read it, but it sounds reasonable.

Q Yeah. It says "Attached is a work-with letter for our session last Thursday and Friday. Hard copy to follow. You are off to a great start"?

A Yes.

Q Nice to hear.

A Yes.

Q "And I look forward to catching up with you soon. If you have any questions, don't hesitate to call." Marc Marano, and that's to you.

And then attached to this there is an E-mail from your boss to you dated 3-5-06?

A Yes.

(Gilbreath - As on Cross)

don't have a JJ RE number on this. And I will mark it as an exhibit, JJ RE-15727492.

Exhibit P-69. It is an E-mail with attachments, being handed to the Court. I will wait before I discuss it with the witness.

THE COURT: Any objection?

MR. MURPHY: We don't have it.

MR. KLINE: It's coming.

(P-69 is marked for identification.)

Q And by the way, while we are marking it and they are examining it, let me ask you a few questions. The pills themselves, have you ever had them in your hands, Risperdal pills?

A I don't recall having anything besides the sample packages in my hands.

Q You are well aware of the fact, whether scored or unscored, they could simply be either broken or just bitten. You are aware of that fact?

A Yes.

MR. MURPHY: Your Honor, with regard to what's been marked as P-69, it is again irrelevant, beyond the time period. That's my objection to it for the record.

THE COURT: Overruled.

(Gilbreath - As on Cross)

Q Do you see it?

A Yes.

Q And it is marked as part of P-69. For the technician's benefit it is JJ RE-15727493.

And it says, Rep Responsibilities?

A Yes.

Q "For the most part territory activity is complete. You have transitioned" -- and it's called a key appointment -- "key appointments, samples and programs to Ginger Owen in late February."

Do you see that?

A Yes.

Q So when you left in late February of 2006, Ginger Owen is now in this position of key appointments, samples and programs, correct?

A Yes.

Q And then I have marked as 62(Y), the appointment of -- well, I will show it to counsel, 62(Y). It's a call note, 10-30-2006.

MR. MURPHY: 10-30, counsel?

MR. KLINE: Yes.

MR. MURPHY: No objection.

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

MR. KLINE: I would request to display

(Gilbreath - As on Cross)

1 it as per our usual custom.

2 Q This is 62(Y). We are now in October of 2006.
3 10-30-06. I am marking my hand tablet as 64(E),
4 which is a continuation of sales calls.

5 And what is Ginger's last name?

6 A Owen. O-W-E-N.

7 Q And we can look at it and see that there was a
8 presentation. By the way, on 10-30-06 -- do you see
9 it?

10 A I do.

11 Q The day the drug got an autism approval, the
12 saleslady was in Dr. Mathisen's office. Correct?

13 MR. MURPHY: Objection, Your Honor.

14 THE COURT: Basis?

15 MR. MURPHY: It's not what the prior
16 testimony has been.

17 THE COURT: No, that's overruled. I
18 think it was during that month.

19 MR. KLINE: Oh, it was 10-6. Brain
20 rewind.

21 Q 10-6 to 10-30. New Question: It took the
22 Janssen sales force 24 days to get into Dr.
23 Mathisen's office after the autism approval,
24 correct?
25

(Gilbreath - As on Cross)

1 A It looks like she provided .25.

2 Q .25. Based on the new autism label, correct?

3 A I don't know what it was based upon. I know
4 it looks like she spoke about the autism label.

5 Q Well, the new autism label applied to
6 children, correct?

7 A Yes.

8 Q She gave him new autism information. Autism
9 information is about children now, it's the new
10 indication. There is no autism -- that's what it's
11 for, correct?

12 A No, it still had indication for schizophrenia,
13 it had indication for bipolar mania, and now autism.

14 Q But it says here that she talked to him about
15 autism. It says it right up there, sir. Do you see
16 it?

17 A Yes.

18 Q And talking about autism -- it says "the new
19 autism information", the new autism information is
20 for pediatrics, correct?

21 A The autism indication was in children and
22 adolescents.

23 Q Children and adolescents, right?

24 A Yes.
25

(Gilbreath - As on Cross)

1 A Yes.

2 Q Not having seen him in the time period we have
3 already discussed from 10-18-04 through 10-3-06.
4 Correct?

5 A Yes.

6 Q Do you know Ginger personally?

7 A I do.

8 Q Had she been an elder care rep?

9 A No, she was a CNS, Ginger was CNS.

10 Q But not pediatric?

11 A No. None of them were pediatric. We were all
12 adults.

13 Q And Dr. Mathisen, there is a little note there
14 about, that he was "so very happy" -- not just
15 happy, very happy -- "to see a Risperdal rep again.
16 He says he writes more Risperdal than anyone in the
17 state. Thanked him, gave him new autism
18 information." And of course, what else did she give
19 him?
20

21 A (No response.)

22 Q Samples? It says presentation and samples?

23 A Yes, I see that. I just didn't see the
24 specific sample. I apologize.

25 Q And what samples are given?

(Gilbreath - As on Cross)

1 Q And when she prescribed the medication, let's
2 compare with what she gave -- it doesn't say
3 anything about having any discussion with him about
4 schizophrenia, does it?

5 A No, it's not indicated in that box.

6 Q Right. So she is not there, you would agree,
7 talking about schizophrenia, she is there on the new
8 autism information?

9 A It says she provided it.

10 Q And if we go back to 64(A) -- let's see here
11 for a minute. On 5-30-02, do you see how she gave
12 .25 milligrams, 1x7, child dose, as described in the
13 label? Do you see that?

14 A It says she provided .25, yes.

15 Q Well, .25 was the new dosing suggestion for
16 starting children in that label. We don't have to
17 take it out again, do we, sir, can we agree?

18 A On the new label, yes.

19 Q Right. She is giving a .25 child dose 1x7
20 starter pack, correct?

21 A Yes.

22 Q Looking back at 64(A), just like Scott Hansen
23 did, when he gave ten starter packs of
24 .25 milligrams back in 2002, correct?
25

(Gilbreath - As on Cross)

1
2 A I don't recall exactly what Scott provided.
3 Q It says it right here, right here in front of
4 your eyes, ten .25s. We spent sometime doing it.
5 A I am sorry, I didn't know you were referencing
6 Scott Hansen's call.
7 Q Can we agree?
8 A Yes.
9 Q And when you first showed up, you gave ten
10 .25s, .25 1x7s, correct?
11 A Yes.
12 Q And the second time you showed up, you gave
13 five 1x7s, correct?
14 A Yes.
15 Q Of .25 milligrams, correct?
16 A Yes.
17 Q Just like she did when it's now approved with
18 new warnings on the label. Correct?
19 A Yes. I don't have the label in front of me,
20 but, yes.
21 Q A kid's dose, correct? A kid's starter dose?
22 A The .25 dose was in the label all along. It
23 was -- it's a provided strength is what I am saying.
24 Q Do we have to go back and see that the
25 indicating starting dose where we were way yesterday

(Gilbreath - As on Cross)

1
2 here until, you know, tomorrow, Mr. Gilbreath.
3 We just need the answers and then we can move
4 on.
5 THE WITNESS: Of course.
6 Q Do you remember where you were?
7 A Actually, I don't, I apologize.
8 Q What I was trying to --
9 A Oh, special population.
10 Q I was trying to see if you would agree with
11 me, okay?
12 A I don't know the actual scope of a special
13 population, but I do know it's referenced in the
14 label.
15 Q Sir, when a bottle of this medicine was
16 provided, like one of those 30 milliliter bottles?
17 A The oral solution?
18 Q Yeah.
19 A Yes.
20 Q What was that worth?
21 A Financially?
22 Q What would it cost at the pharmacy, yeah.
23 150 bucks?
24 A I don't know the cost at the time.
25 Q No idea?

(Gilbreath - As on Cross)

1
2 for adult schizophrenics was 1 milligram, four times
3 .25, and the starting dose for bipolar was
4 2 milligrams, eight times of .25. Do you recall
5 talking about that yesterday?
6 A Yes, I recall it from yesterday.
7 Q The company was making it in .25s, at that
8 time, correct?
9 A Yes, FDA had approved it in .25s.
10 Q But there was no indication as a starting dose
11 for any adult at .25?
12 A There were special populations in the label,
13 and once again, they used it in titration and things
14 like that.
15 Q I get it. Special populations are that narrow
16 band of people that may need some special
17 consideration, correct?
18 A Yeah, I don't know the definition of special
19 population per se but I --
20 Q You would expect it to be small, that's my
21 point.
22 MR. MURPHY: Objection, Your Honor, the
23 witness should be allowed to answer the
24 question.
25 THE COURT: Sustained. But we will be

(Gilbreath - As on Cross)

1
2 A Probably 100, \$200. I really don't know.
3 Q In terms of the value of what you were
4 dropping off, the value of these pills on some of
5 these days was literally a few thousand dollars;
6 correct?
7 A I would have to look at the pricing sheets
8 but --
9 Q That wouldn't surprise you?
10 A Yeah, if it was bought at a retail pharmacy,
11 it would be several dollars.
12 Q Sir, you actually weren't the first -- Scott
13 Hansen and you weren't the first sales reps in
14 Mathisen's office. You are aware of the fact that
15 back in 1997, when we have already heard in this
16 courtroom there was meager safety data, there was a
17 Janssen -- I am going to rephrase the question.
18 In 1997 to 1998, there was a sales
19 representative in the office of Dr. Mathisen of
20 Janssen dropping off samples, correct?
21 MR. MURPHY: Objection, Your Honor.
22 THE COURT: If you know. Do you know?
23 THE WITNESS: I don't. That was before
24 I even joined the company.
25 Q I know it was before you joined the company,

(Gilbreath - As on Cross)

1 sir, but you are telling me that you haven't
2 reviewed the documents of the prior sales rep even
3 to the point of sitting in this witness stand today?

4 A I can tell you I knew that Scott Hansen was in
5 there previously, but I am aware of no one else.

6 Q Really?

7 A Yes, really.

8 Q Let me see if I can refresh your recollection.
9 I need the full 62 exhibit in front of me, quickly.

10 Okay, I am going to move on.

11 Sir, there are a couple of things I
12 want to pin down. Am I correct that you as a sales
13 rep back then were not allowed to share any
14 information about Risperdal, whether safety or
15 efficacy, if not approved by Janssen?

16 A That's correct. Or the FDA-approved label.

17 Q Nothing to do with the FDA-approved label. I
18 want to know, I am asking you the same exact
19 question you said yes to in your deposition, sir.

20 You are not allowed to share any
21 information about Risperdal, whether safety or
22 efficacy, if not approved by Janssen. You said yes
23 to that question without any explanation. Would you
24 agree you said yes to that?
25

(Gilbreath - As on Cross)

1 THE COURT: Overruled. Again, this has
2 to do with just answer the question. Answer
3 the question so we can move forward.

4 A His was a busy office.

5 Q Yes. And when you waited in there in that
6 office, I want you to search your memory. The
7 office waiting room was full of parents and
8 children, almost all the time?

9 A I really don't remember the waiting room. I
10 don't even know if I went through the waiting room
11 to see him.

12 Q Do you know?

13 A I don't, actually.

14 Q Do you have any memory?

15 A No, not really.

16 Q So maybe you were in the waiting room,
17 correct?

18 A It's possible, but I don't have recollection
19 of that.

20 Q Sir, maybe I can save some time on redirect --

21 THE COURT: If there is going to be
22 any. I am not sure. I am not sure.

23 MR. KLINE: This is my cross, I mean on
24 redirect.
25

(Gilbreath - As on Cross)

1 MR. MURPHY: Objection, Your Honor,
2 it's argumentative.

3 THE COURT: I know you are trying to
4 save time, but if that's not going to work,
5 ask him the old-fashioned way.

6 Q Simple straight up, sir: You were not allowed
7 to share any information about Risperdal, whether
8 safety or efficacy, if not approved by Janssen,
9 correct?

10 A Correct.

11 Q When you would go to Dr. Mathisen's office,
12 sir, you would not always get to see him right away,
13 you would have to wait, correct?

14 A Yes. It's common that we would have to wait
15 sometimes and I am sure that was the case with Dr.
16 Mathisen.

17 Q And his office was a busy office, correct,
18 sir?

19 A Yes. I recall him being busy, but virtually
20 all doctors' offices are busy.

21 Q I didn't ask you that. Some doctors' offices
22 are not busy, you know that. Maybe only the ones
23 you go to were busy.

24 MR. MURPHY: Objection, Your Honor.
25

(Gilbreath - As on Cross)

1 THE COURT: This has to end sometime
2 before the summer.

3 MR. KLINE: I hope so. I am trying
4 hard with a lot of information.

5 THE COURT: There will be cross
6 examination, and if there is redirect it will
7 be in the format we did with the other
8 witness, ten or 15 minutes.

9 MR. KLINE: Right. I get it.

10 THE COURT: So you have the witness
11 here, ask whatever you wish. I have been very
12 indulgent that way, but after cross
13 examination is over, that's it. Except for
14 about a 15-minute period. So wrap it up.

15 MR. KLINE: When I was referring to
16 direct I was thinking of me being on cross and
17 them being on direct.

18 THE COURT: I understand that. You are
19 on direct examination as if on cross, I think
20 is how we call it.

21 MR. KLINE: That, too, I agree.

22 BY MR. KLINE:

23 Q What else do you want to tell us, sir? What
24 did I miss?
25

(Gilbreath - As on Cross)

MR. MURPHY: Objection, Your Honor.

THE COURT: That's sustained.

Q No, I would like to know if in answer to any of my questions, in case I want some follow-up on it, there is anything else that you would add to the jury that they haven't seen about your visits to Dr. Mathisen?

A No.

MR. MURPHY: Objection, Your Honor, for the record.

THE COURT: Overruled. You have the answer.

A No, I have nothing else to add.

Q Do you believe that we have covered it fully, the way you have seen our discussions?

MR. MURPHY: Objection, Your Honor, these are counsel's questions, its not for the witness to determine whether there has been a full discussion.

MR. KLINE: I want to know what he believes.

THE COURT: That's sustained.

MR. KLINE: Okay, thank you, sir.

THE WITNESS: Thank you, Mr. Kline.

(Gilbreath - Redirect)

Dr. Mathisen. Do you recall that?

A Yes.

Q And during the course of his questioning, Mr. Kline suggested to you that toward the end of the time that you were calling upon Dr. Mathisen, those last three times, that those were the only times that you had made presentations. Do you recall that?

A I recall him pointing those three out.

Q But that wasn't true, was it? That is to say, you made a presentation only to Dr. Mathisen on prior occasions, hadn't you?

A Yes, I had.

Q So the suggestion that those last three times were the only three times that you made presentations only would not be correct?

A Correct.

Q One other thing I wanted to clear up is something that you were confronted with regarding the 1 milligram denomination, and whether it was unscored?

A Yes, right.

Q And Mr. Kline's question to you was along the lines that when you made a call in April of 2004,

(Gilbreath - Redirect)

MR. KLINE: Thank you. I wish you safe travel, sir.

THE WITNESS: Thank you very much.

THE COURT: You may proceed with cross examination. Counsel, we will be going until about 12:30, 12:45.

MR. MURPHY: May I proceed, Your Honor?

THE COURT: Yes, sir.

MR. MURPHY: Thank you. Good morning, everyone.

- - -

REDIRECT EXAMINATION

- - -

BY MR. MURPHY:

Q Mr. Gilbreath, I want to ask you a few questions, clarify a few things, and march through some questions that I had for you initially.

A Sure.

Q And I am going to ask you and the jury to indulge me a little bit because I will probably have to use the elmo as well as the screen to make sure that everyone can see.

One thing I want to clear up, you were asked questions about presentations that you made to

(Gilbreath - Redirect)

that was the first time that you had provided to Dr. Mathisen unscored Risperdal in the denomination of 1 milligram. Do you recall that?

A I do recall that discussion.

Q But it is a fact that every time you dropped off a 1 milligram denomination, it was unscored because all 1 milligram denominations are unscored. Right?

A To my knowledge, we only had one denomination. I don't recall at what point it was scored or not scored, but I do know it was called out like that.

Q Well, let's be fair to you, the record and to the jury, all right?

A Yeah.

Q I am going to use the elmo at this point, and using Mr. Kline's nomenclature, we are looking at 62(F).

MR. KLINE: Ken, would you kindly give me the date?

Q So can you see, Mr. Gilbreath, the reference two from the bottom that says, "Risperdal, 1 milligram, 1X7, unscored"?

A I do.

Q And just to zoom out, this is what we have

(Gilbreath - Redirect)

1
2 been talking about at 62(F), right?
3 A Yes.
4 Q And if you see the top, we see a date of
5 3-11-03?
6 A Yes.
7 Q Okay. And now we are going to look at the
8 call note from 8-5-03. Do you see that?
9 A I do.
10 Q Bear with me one second because that's not the
11 one I want. Let's look at the call note from
12 5-18-04. Do you see that?
13 A I do.
14 Q And now if we look at the bottom, the sample
15 that was left behind, 1 milligram, 1X7, unscored,
16 correct?
17 A Yes.
18 Q Okay. That was 62(R). And if we look at
19 what's been marked as 62(Q), which is a call note
20 from April 5th, 2004, do you see that at the top,
21 Mr. Gilbreath?
22 A I do.
23 Q And if we look at what was left behind, the
24 bottom, the last description of a sample that you
25 provided, we see 1 milligram, 1X7, unscored.

(Gilbreath - Redirect)

1
2 MR. MURPHY: I am happy to do so, Your
3 Honor.
4 MR. KLINE: If he needs to take the
5 transcript out, I object.
6 THE COURT: What's your question first?
7 MR. MURPHY: The question is whether he
8 knows that Dr. Mathisen told the jury, in
9 fact --
10 THE COURT: That's sustained then.
11 What difference does it make whether he knows?
12 MR. MURPHY: What is relevant --
13 THE COURT: It's not relevant. Move on
14 to another question.
15 MR. MURPHY: Not a problem.
16 THE COURT: He is not supposed to know.
17 That's why we have sequestration.
18 MR. MURPHY: I understand.
19 THE COURT: All right, so let's move on
20 to a different angle.
21 BY MR. MURPHY:
22 Q The samples that we went through, Mr. Kline
23 went through with you for the two years or so?
24 A Yes.
25 Q That you left with Dr. Mathisen, am I correct

(Gilbreath - Redirect)

1
2 Correct?
3 A That's correct.
4 Q So again, this is showing that the 1 milligram
5 denominations all were unscored?
6 A Yes.
7 Q We are clear on that?
8 A Yes.
9 Q Okay. Now, one of the things Mr. Kline
10 suggested to you was that Dr. Mathisen treated
11 children almost exclusively. Do you recall that?
12 A He did.
13 Q But you testified that Dr. Mathisen told you
14 that he also had adult patients?
15 A He did.
16 Q You were not here when Dr. Mathisen testified
17 in court, were you?
18 A I was not, no.
19 Q And do you know that Dr. Mathisen told the
20 jury the same thing you told them --
21 MR. KLINE: Objection.
22 THE COURT: That's sustained. It's the
23 jury's recollection as to what Dr. Mathisen
24 said. Unless you want to take the transcript
25 out.

(Gilbreath - Redirect)

1
2 that you left those samples because Dr. Mathisen
3 requested those samples?
4 A Yes. All samples were left at physician
5 requests.
6 Q At one point Mr. Kline confronted you with the
7 2002 Risperdal label, I believe that is D-1, and --
8 A I am sorry, what did you say, the label?
9 Q Yes, the label. And before we go further,
10 there has been use of the term "label" and the term
11 "package insert" and PI?
12 A Yes.
13 Q For the jury's edification, package insert and
14 label is the same thing?
15 A Yes, it's what the Food and Drug
16 Administration allows for, I would call it
17 officially prescribing information. There is a
18 Physicians' Desk Reference that contains a big
19 appendix of all the medications that are available.
20 But label, PI, prescribing information,
21 package insert, same thing, it's all used
22 synonymously.
23 Q Mr. Kline showed you the 2002 label and
24 suggested to you that the recommended dose for
25 Risperdal in schizophrenia was 1 milligram. Do you

(Gilbreath - Redirect)

recall him having that exchange with you?

A Yes, I do.

Q And you in fact informed him that there are special populations where the initial dose in fact is less than, recommended dose is less than 1 milligram, correct?

A Yes.

Q Mr. Kline did not invite your attention to the special --

MR. KLINE: Your Honor, objection. Can we have questions that have to go with what he asks, not what I call or didn't call to his attention.

THE COURT: Counsel, I haven't heard the question so it's a little premature. I just don't know what the question is.

MR. KLINE: The question was not a direct question. It's all about me. It's all about me.

MR. MURPHY: Trust me, it's not all about you, my friend.

THE COURT: There was some leeway during your examination on this witness and I am going to permit the same thing here. We

(Gilbreath - Redirect)

section addressing Special Populations?

A Yes. I believe it's actually present in both labels.

MR. MURPHY: Any objection to me showing that, Mr. Kline?

MR. KLINE: Are you talking about the elderly section?

MR. MURPHY: No, I am talking about the Special Populations, sir.

MR. KLINE: I don't have any objection if you just point it out to me.

THE COURT: Has this been previously marked?

MR. MURPHY: Indeed it has. This is D-1 for the record, Your Honor, and I believe we are talking about Bates numbers ending in 176.

MR. KLINE: It's the 2002 label I understand.

MR. MURPHY: If I said 2006 I apologize. It's 2002.

MR. KLINE: Although I did not display 2002, I have no objection.

THE COURT: I think we have actually

(Gilbreath - Redirect)

don't even know what the question is.

MR. KLINE: It should be about them.

THE COURT: What is the question?

Q The question is, is there not a Special Population section in the 2002 Risperdal label setting forth doses for special population?

MR. KLINE: Your Honor, objection. I showed the 2006 label.

THE COURT: It's overruled.

MR. KLINE: But he has suggested to the jury that I showed the 2002 label. I showed the 2006.

THE COURT: Not in the question. I think the way we are going to get through this, Mr. Murphy, if you just ask the questions and let's not bring anything else other than the evidence into the question.

MR. MURPHY: That's all I am trying to do, Your Honor.

THE COURT: The question in the 2002 label there is a question about special population or something? Ask the question again and we will get an answer.

Q In the 2002 Risperdal label, is there not a

(Gilbreath - Redirect)

seen this document before. No?

MR. MURPHY: We have seen the label itself.

THE COURT: All right, you want to show the Special Populations, let's get there.

MR. MURPHY: Exactly that's what I asked for. Bates ending in 176, Special Populations. Dosage in special populations.

Q Mr. Gilbreath, do you see on your screen what this section provides?

A Yes, I do.

Q And it states, "The recommended initial dose is .5 milligrams BID." And just for the record and the jury's edification, BID means what?

A That's two times a day. BID would suggest once in the morning, once in the evening.

Q ".5 milligrams BID in patients who are elderly or debilitated, patients with severe renal or hepatic impairment." Right?

A Yes.

Q So in fact, in this 2002 label there is a section with a recommended dosage for special populations, less than 1 milligram, correct?

A Yes.

(Gilbreath - Redirect)

1
2 Q Okay. And you told the jury you began at
3 Janssen as a primary care rep?
4 A I did.
5 Q And then you became an elder care rep?
6 A Yes, that's correct.
7 Q During your tenure as a sales rep,
8 Mr. Gilbreath, did you become aware that doctors
9 prescribe oral solution of Risperdal to adult
10 patients?
11 A Yes. It was somewhat common.
12 Q Mr. Kline also engaged you in a --
13 MR. KLINE: Objection.
14 Q -- mathematical exercise on the dosage
15 associated with the samples you left; do you
16 remember that?
17 A Yes.
18 Q And he broke them down into .25-milligram
19 denominations. Do you recall?
20 A I do.
21 Q And what we are looking at right here, what
22 the jury can see as 64(A), in particular was your
23 call from 3-11-03. Can you see that as well?
24 A I can.
25 MR. KLINE: It's not on the screen.

(Gilbreath - Redirect)

1
2 P-65-what?
3 MR. MURPHY: Your Honor, this is simply
4 what's on the easel. I can go to the easel.
5 THE COURT: That's what I want you to
6 do.
7 MR. MURPHY: Okay, happy to do that.
8 THE COURT: As long as you don't write
9 on it. If you are going to write on it then
10 you create your own document.
11 MR. MURPHY: I am not going to write on
12 it.
13 BY MR. MURPHY:
14 Q Here we go. P-63?
15 A I see that.
16 Q P-63 is a calculation of the samples that you
17 delivered to Dr. Mathisen on 3-11-03?
18 A Yes.
19 Q Calculated into the number of .25-milligram
20 denominations, right?
21 A Yes.
22 Q The equation here is 365, number of days of
23 the year. Do you follow?
24 A Yes.
25 Q And that's divided into the number of

(Gilbreath - Redirect)

1
2 Q And the calculation?
3 A Yes.
4 Q What I want to ask you about this
5 calculation -- I am going to go to the elmo at this
6 point. For this document, Mr. Kline took your --
7 MR. KLINE: Your Honor, I thought we
8 were going to use the original exhibits.
9 THE COURT: Excuse me. What's the
10 issue?
11 MR. KLINE: Just so I have an
12 understanding, outside the presence of the
13 jury we were told we were going to use
14 exhibits in their original form. Now this
15 exhibit is up on the elmo.
16 THE COURT: I will sustain that. If
17 you have a document that we are using, it's
18 right there, Mr. Murphy. I am not really keen
19 on using the Power Points or the screens
20 unless they are formally admitted and with our
21 permission.
22 At this point you have a document in
23 front of us, you want to point something out,
24 do so, but let's not get into how you have a
25 footnote to an exhibit with -- what's this,

(Gilbreath - Redirect)

1
2 .25-milligram denominations?
3 A Yes.
4 Q And Mr. Kline, in using this, said that that
5 was 3.3 years for schizophrenic patients?
6 A He did, yes.
7 MR. KLINE: Objection to the question.
8 Based upon his testimony that they were using
9 .25s in those patients.
10 THE COURT: Overruled. This is
11 redirect.
12 Q Mr. Gilbreath, schizophrenic patients in the
13 2002 label, their recommended dosage was 1
14 milligram, was it the not?
15 A Yes, as a starting.
16 Q Not .25?
17 A Correct.
18 Q So if we wanted to be true to the math and
19 true to the label, we would need to divide this by
20 four?
21 A Yeah, for a 1 milligram equivalent versus a
22 .25 equivalent.
23 Q Bear with me now and I will ask you to indulge
24 me. If we divide 1205 by four, we get 300.75.
25 A That sounds accurate.

(Gilbreath - Redirect)

1
2 Q That's the number of doses that we have.
3 Correct?
4 A Yes, in 1 milligram equivalents.
5 Q And we saw in the 2002 label that the
6 recommended dosage for a schizophrenic is 1
7 milligram BID. Do you recall that?
8 A Yes.
9 Q And you just explained to the jury that BID
10 means twice daily?
11 A I did.
12 Q So we are now cutting that in half. So it's
13 300.75 divided by two?
14 A Yes.
15 Q That gives us 150 days, if my math is correct?
16 A Yes, approximately.
17 Q But we know that not all schizophrenics simply
18 are maintained on one BID, that is 1 milligram twice
19 a day, correct?
20 A That's correct.
21 Q If in fact there was 2 milligrams BID, we
22 would be with dividing that further in half, would
23 we not?
24 A Yes.
25 Q And so instead of having 150 days of dosage,

(Gilbreath - Redirect)

1
2 about starter dose and that was my only
3 objection.
4 THE COURT: We will have the question
5 rephrased.
6 MR. KLINE: Thank you, Your Honor.
7 Q When Mr. Kline visited with you on P-61, he
8 identified these populations, and he identified
9 starting doses associated with them, correct?
10 A Yes.
11 Q But you are able to tell the jury that adult
12 schizophrenics, A, start with 1 milligram BID
13 initially, correct?
14 MR. KLINE: Objection at this point to
15 leading. This is a direct witness, Your
16 Honor, and it's significant, it's on core
17 issues.
18 THE COURT: Overruled. I am asking
19 that you get the mathematics on the table and
20 then you can ask the question. So whatever
21 Mr. Kline went through as far as the
22 mathematics are concerned, if you repeat that,
23 Mr. Murphy, I will permit that, and then you
24 ask the question.
25 MR. MURPHY: Understood.

(Gilbreath - Redirect)

1
2 you would only have 75 days of dosage, right?
3 A Yes.
4 Q That's a far cry from 3.3 years, isn't it?
5 A It is a difference.
6 Q Thank you for indulging me.
7 A You're welcome.
8 Q I have to go back to the chart and I
9 apologize. There is one other exhibit here, I will
10 find it, it's 61. Mr. Kline visited with you a
11 little bit on P-61, and here he charted different
12 populations and their starting doses?
13 A Yes.
14 Q And that was part of what he used in making
15 this calculation using the .25 dose. Do you recall
16 that?
17 A Yes.
18 MR. KLINE: Objection to that question
19 because it's a starter dose.
20 MR. MURPHY: That's the term I used.
21 THE COURT: Wait a minute. Is there an
22 objection?
23 MR. KLINE: My objection was that I
24 didn't believe that I heard -- I thought I
25 heard the question as stated I was talking

(Gilbreath - Redirect)

1
2 Q My questions, Mr. Gilbreath, are simple.
3 Let's focus on adult schizophrenics.
4 A Yes.
5 Q Adult schizophrenics, are you aware whether
6 they start out with 1 milligram on the first day?
7 MR. KLINE: Your Honor, objection.
8 That's simply a leading question on a core
9 issue.
10 THE COURT: Again, that's sustained.
11 The problem here is it has to be according to
12 what the testimony was. In other words, what
13 you are talking about is a standard dose. I
14 mean we don't know what this doctor
15 prescribed. That's part of the difficulty of
16 this case.
17 MR. MURPHY: I agree with you.
18 THE COURT: All right, so right now
19 when you are talking about -- you have to
20 stick with what Mr. Kline, what his
21 hypothetical was or what his question was,
22 rather than to say, Oh, it was a .1 dose. We
23 don't know what the doses were that were
24 actually given by this doctor, do we?
25 MR. MURPHY: No, we don't. And that is

(Gilbreath - Redirect)

a fair point.

THE COURT: Stick to the questions that Mr. Kline presented which were based, I believe, on whatever point he was trying to make.

MR. MURPHY: I can move on.

THE COURT: All right, that's acceptable as well. In fact, why don't we just take a recess right here for lunch.

Members of the jury, we are going to recess until 1:30 for lunch. And we are going to make sure, please wear your yellow badges, that you make sure also that you do not discuss this matter with anybody, that you keep an open mind in the case, and any media reports, if any, about this case are to be ignored. All right? And have a good lunch and we will see you soon.

(The jury exits the courtroom.)

THE COURT: A reminder not to discuss with matter with any of the lawyers.

THE WITNESS: Yes, of course not. That means I eat alone.

(A luncheon recess is taken at 12:21 p.m.)

(Gilbreath - Redirect)

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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