

EXHIBIT 12

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

- - -

IN RE:

SEROQUEL LITIGATION : MDL NO. 1769

:

THIS DOCUMENT RELATES:

TO ALL ACTIONS :

- - -

June 18, 2008

- - -

C O N F I D E N T I A L

- - -

Videotape deposition of BARRY
DAVID CHARLES ARNOLD, held at the
Radisson Edwardian Manchester, Free Trade
Hall, Peter Street, Manchester, England
commencing at 9:14 a.m. before Linda L.
Golkow, Registered Diplomate Reporter,
Certified Shorthand Reporter.

- - -

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1 Q. Is that a common symptom in
2 people with diabetes?
3 A. It's actually a sign rather
4 than a symptom, but it may be a sign of
5 diabetes mellitus. But, of course, there
6 are many other causes of ketonuria as
7 well.
8 Q. Do you see where it says,
9 "Seroquel discontinued about 3 months
10 later. DM" or diabetes mellitus
11 "reported to have resolved that same
12 day." Do you see that?
13 A. Yes, I do.
14 Q. So, would that be an example
15 of a positive dechallenge?
16 A. I would regard that as an
17 example of a possible positive
18 dechallenge. The data that's presented
19 in front of me is not full. What we
20 don't know is what concomitant
21 medications the patient was on, we don't
22 know whether those medications were
23 stopped at the same time, and then,
24 equally, what we don't know is, was the

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1 patient subject to some sort of dietary
2 control at the same time as discontinuing
3 Seroquel. So, this is a case that lacks
4 complete data, and, therefore, it may
5 appear as a positive dechallenge, but
6 that has yet to be confirmed.
7 Q. Well, from the data that is
8 presented, does this appear to be a case
9 of positive dechallenge?
10 A. Well, the important thing is
11 when you are --
12 MR. BROWN: Objection.
13 THE WITNESS: The important
14 thing is when you're assessing
15 individual clinical cases like
16 this is that you assess them on
17 the basis of a complete dataset if
18 you're trying to categorize them
19 in the manner that you seem to be
20 attempting.
21 BY MR. BLIZZARD:
22 Q. Do you know what efforts
23 were made by the company to get a
24 complete dataset after analyzing this

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1 information here?
2 A. I do not know the specific
3 details of the followup of this
4 particular patient. I'm aware that the
5 company has a standard operating
6 procedure for followup. And to my
7 experience, the data handling teams and
8 the clinical teams who were managing
9 adverse event reports follow that SOP
10 very diligently.
11 Q. Would the fact that it
12 resolved on the same day give you a clue
13 that it might be a positive dechallenge?
14 MR. BROWN: Objection to the
15 form.
16 BY MR. BLIZZARD:
17 Q. Would that be a pretty
18 strong indication of a positive
19 dechallenge, resolving on the same day
20 that Seroquel was discontinued?
21 MR. BROWN: Objection.
22 THE WITNESS: The fact that
23 it resolved on the same day may be
24 taken as an indicator that it

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1 might be a positive dechallenge.
2 I would not characterize it as
3 being a clue, and I certainly
4 wouldn't characterize it as being
5 a strong indicator, as you
6 suggest, due to the lack of data.
7 BY MR. BLIZZARD:
8 Q. If you look at the one
9 that's second from the bottom of the
10 first page, which is 2004UW06024, it's
11 described as a nonserious event. Do you
12 see this involved an 11-year-old male?
13 A. Yes.
14 Q. The dose was unknown,
15 approximately six months, correct?
16 A. That's correct.
17 Q. And in the comments, does it
18 say the preferred term was "blood glucose
19 increased"?
20 A. So, that would be the
21 reported event, yes.
22 Q. Then it said, "Patient" has
23 arrow up or that would be increased
24 "blood sugar," right?

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1 A. That is correct.
2 Q. And then "TX" -- that's
3 treatment, isn't it?
4 A. That would stand for
5 treatment.
6 Q. It says, "equals oral
7 anti-diabetic med (unspecified).
8 Seroquel discontinued. BS normalized,"
9 "BS" being blood sugar, correct?
10 A. That's correct.
11 Q. So, again, after Seroquel
12 was discontinued, blood sugar normalized,
13 correct?
14 A. It states that blood sugar
15 was normalized. It implies that it was
16 after Seroquel was discontinued. It
17 doesn't state that factually, whereas the
18 first patient that you indicated to me
19 was very factual, reported to resolve
20 that same day.
21 Q. Well, it says "Seroquel
22 discontinued," and then the next sentence
23 says "BS" or blood sugar "normalized,"
24 right?

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1 A. Yes. I'm just being very
2 precise because you tried to use the word
3 "then." That's an assumption or an
4 implication.
5 Q. Okay.
6 So, when you're reading
7 this, the blood sugar did not normalize
8 after the Seroquel was discontinued?
9 A. No. I think it's an
10 assumption that it normalized after
11 discontinuation of Seroquel, but that's
12 not -- should not be stated as a matter
13 of fact, based upon the summary that's
14 provided in this comments column.
15 Q. Well, we could look at the
16 original adverse event report, couldn't
17 we?
18 A. Yes, we could, and that
19 perhaps might be more informative.
20 Q. And do you really think that
21 it was normalized before Seroquel was
22 discontinued?
23 A. I'm just dealing with facts
24 for the purpose of this jury. I think

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1 that you've made an assumption that it's
2 normalized afterwards. I'm not saying
3 that that's not a reasonable assumption.
4 I'm just saying it's an assumption,
5 rather than a statement of fact.
6 Q. Well, let's go to the next
7 one then. See, this is 2004UW08948.
8 This is a 7-year-old male, correct?
9 A. It appears that way, yes.
10 Q. This is a 7-year-old male
11 taking 300 milligrams daily, correct?
12 A. Yes.
13 Q. It says the PTs is
14 "Hypoglycemia, Hyperglycemia, Lipids
15 increased," right?
16 A. That's correct.
17 Q. It then says, "Patient had
18 decreased blood sugars and increased
19 blood sugars"?
20 A. Yes.
21 Q. "BS fluctuating from 42
22 (fasting) to 202 (1 hour after fruit),
23 HbA1c equals 4.9%, GTT equals 99 (2 hours
24 post glucose). Patient also had

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1 increased lipids (no lab data). Seroquel
2 discontinued within one week positive
3 blood sugars back to normal."
4 Do you see that?
5 A. Yes.
6 Q. Is that a case of a positive
7 dechallenge?
8 A. It's an apparent case of
9 positive dechallenge, but I'm not sure
10 what it's a positive dechallenge to,
11 because it says blood sugar back to
12 normal, but we don't know whether that's
13 referring to the decreased blood sugar,
14 hypoglycemia, or the increased blood
15 sugar, hyperglycemia.
16 I'd also remark that the
17 HbA1c of 4.9 percent, to my knowledge,
18 that does not equate with a HbA1c level
19 that matches hyperglycemia. Patients who
20 are hyperglycemic who may be tending
21 towards diabetes, you would expect a
22 higher HbA1c than that. So, yes, it
23 appears to be a positive dechallenge, but
24 I'm not sure what event is actually being