

EXHIBIT 47

08-I-99343 sh

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation
MDL DOCKET NO. 1769

This document relates to all Group One Trial Cases:

- Janice Burns v. AstraZeneca LP, et al. Case No. 6:07-cv-15959
- Sandra Carter v. AstraZeneca LP, et al. Case No. 6:07-cv-13234
- Connie Curley v. AstraZeneca LP, et al. Case No. 6:07-cv-15701
- Linda Guinn v. AstraZeneca LP, et al. Case No. 6:07-cv-10291
- David Haller v. AstraZeneca LP, et al. Case No. 6:07-cv-15733
- Hope Lorditch v. AstraZeneca LP, et al. Case No. 6:07-cv-12657
- Eileen McAlexander v. AstraZeneca LP, et al. Case No. 6:07-cv-10360
- Clemmie Middleton v. AstraZeneca LP, et al. Case No. 6:07-cv-10949
- Charles Ray v. AstraZeneca LP, et al. Case No. 6:07-cv-11102
- William Sarmiento v. AstraZeneca LP, et al. Case No. 6:07-cv-10425
- Richard Unger v. AstraZeneca LP, et al. Case No. 6:07-cv-15812
- Linda Whittington v. AstraZeneca LP, et al. Case No. 6:07-cv-10475

ORAL DEPOSITION OF
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Volume 1

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1 looked at some of the Clozapine data because they were
 2 head-to-head data. I also looked at -- now, you're talking
 3 about just first generation?
 4 **Q. Yeah.**
 5 A. Oh, okay. Then haloperidol was the main drug, and
 6 then there are a few trials that looked at perphenazine.
 7 **Q. Okay. Do you think haloperidol is an effective**
 8 **medication in treating mental illness?**
 9 A. Yes.
 10 **Q. Would you agree with me that first-generation**
 11 **antipsychotic drugs, as a group, are associated with certain**
 12 **movement disorders?**
 13 A. Some of them, yes. And some are worse than others,
 14 but, yes. In fact, that's how -- if you read my report, I try
 15 to start out with sort of a primer on pharmacology. And
 16 Goodman & Gilman teaches that there are -- the reasons the
 17 second-generations were developed was to try to improve on that
 18 safety profile.
 19 **Q. So --**
 20 MR. ALLEN: Hold on. Take a little break.
 21 (Recess from 12:26 p.m. to 12:27 p.m.)
 22 **Q. (BY MR. BROWN) The -- so, as a group,**
 23 **second-generations were studied and ultimately marketed because**
 24 **they had better side effect profiles with respect to movement**
 25 **disorders, correct?**

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1 A. I don't know they were ultimately marketed. But that
 2 was one of the impetus, looking for drugs that had less of a
 3 propensity to produce some of these movement disorders. But
 4 what was interesting is if you look at the labeling for the
 5 drugs, that statement is not allowed to be put into the
 6 labeling. In other words, I don't believe that the evidence
 7 has shown head to head, at least to the sufficiency of the FDA,
 8 that any one drug has a specific percent advantage over
 9 another.
 10 I would agree with you as a class, in general,
 11 when you look at first generation versus second, that as a
 12 general rule, you expect the second-generations to have less
 13 propensity, but that doesn't mean they have no propensity.
 14 **Q. Let me ask this question: Have you -- do you have an**
 15 **opinion with respect to whether haloperidol has a better EPS**
 16 **profile than Seroquel?**
 17 A. I haven't formed that opinion. I believe that
 18 haloperidol has a propensity to produce it and I believe
 19 Seroquel does as well.
 20 **Q. In doing a risk-benefit analysis, you have to**
 21 **consider side effects, correct?**
 22 A. Yes.
 23 **Q. Wouldn't you need to know whether one caused EPS more**
 24 **frequently than the other to actually make that assessment?**
 25 A. It depends. If you're doing -- it depends what

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1 you're doing with the risk-benefit assessment. My issue -- and
 2 maybe this will help you: When I did the risk-benefit
 3 assessment here for Seroquel, I was looking for what were the
 4 general -- what were the types of risks that had been
 5 associated routinely with Seroquel and what were the benefits
 6 that were shown? And then when I'm looking at that drug, I
 7 make an assessment based upon whether I think the risks
 8 outweigh the benefits.
 9 Now, I'm not saying that the risks outweigh the
 10 benefits for this drug such that it should be removed from the
 11 market. That's not what I'm saying. I'm saying that when I --
 12 and if you look at what my statement is, I believe there are
 13 safer alternatives. I believe that if you look at Seroquel, it
 14 should not be a first-line agent necessarily because the
 15 metabolic risks of this drug are different from some of the
 16 other drugs, and that is above and beyond the neuromuscular
 17 risks.
 18 That's not to say that there isn't a patient
 19 that Seroquel could be given to safely, and it's possible that
 20 it is, but I don't think it should be a first-line treatment.
 21 **Q. So, it must be so, based on what you just told me,**
 22 **that you have an understanding of the side effect profile of**
 23 **first-generation antipsychotics, correct?**
 24 A. Yes.
 25 **Q. And you've researched it in forming your opinions**

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1 **here today, correct?**
 2 A. Yes. In general terms, yes.
 3 **Q. And do any of the materials you have brought to the**
 4 **dep today or identified in your report discuss the side effect**
 5 **profiles of first-generation antipsychotics?**
 6 A. Many of the published articles talk about that. My
 7 textbook talks about that. And then you also even have
 8 head-to-head clinical data on Seroquel versus some of these
 9 other first-generations that talk about side effect profile.
 10 So, absolutely, yes.
 11 **Q. And you mentioned that there are safer alternatives**
 12 **to Seroquel, correct?**
 13 A. I believe there are, yes.
 14 **Q. And what are the safer alternatives to Seroquel?**
 15 A. I believe that haloperidol would be a safer
 16 alternative to Seroquel. I believe that ziprasidone would be a
 17 safer alternative to Seroquel, and possibly -- I can't think of
 18 the generic name, but Abilify.
 19 **Q. And have you carefully reviewed the side effect**
 20 **profiles for haloperidol?**
 21 A. I have reviewed the -- I don't know what you mean by
 22 "carefully." I certainly, for my perspective in forming my
 23 opinions, have reviewed the side effect profile for
 24 haloperidol. And in addition to that -- I'm basing my opinions
 25 in part on some of the head-to-head studies that I've provided

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1 here for you in my literature and on those disks.

2 **Q. Okay. Do you know what head-to-head studies you**

3 **looked at that compared haloperidol to Seroquel?**

4 A. I'd have to go through my pile to tell you. I mean,

5 there -- but it's certainly ones -- some of them are cited in

6 my report and then there's others that are on the PDF files

7 that I've given you. But they wouldn't necessarily be cited as

8 a head-to-head study. I'm just telling you that there are

9 studies that -- I know some of the ones in there have

10 haloperidol versus -- usually versus quetiapine and something

11 else as well.

12 **Q. Does haloperidol cause diabetes?**

13 A. I believe that haloperidol has been shown to have

14 some patients that have shown up with metabolic effects

15 certainly because it can produce some weight gain and some of

16 those things. However, I have not formed an opinion in the

17 same way as I have with Seroquel. I have formed the opinion

18 that I think that Seroquel, Zyprexa, and Risperdal -- and I've

19 been very clear on this in my presentation in the New Jersey

20 Education Day -- appear to have a greater and unique risk over

21 a drug like haloperidol and even over, like, ziprasidone and

22 some of the other second-generation drugs.

23 **Q. Did some of the epi literature you rely on quantify**

24 **the increased risk of diabetes with haloperidol?**

25 A. I'm sure they did because that was a comparative drug

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1 in some of the epi literature.

2 **Q. Would you agree with me that there are a number of**

3 **studies that show the risk of diabetes is greater for**

4 **haloperidol versus Seroquel?**

5 A. I'd have to look at the individual studies to answer

6 that, so I don't want to agree with you or disagree with you.

7 If you want to talk about specific numbers like that, I would

8 want to pull the studies out. And if you want to --

9 **Q. We'll do it today.**

10 A. -- show me one, we can look at it.

11 **Q. Would that surprise you? Based on your opinion,**

12 **would that surprise you that haloperidol had a greater risk, at**

13 **least in some epi studies, than Seroquel?**

14 A. Not necessarily surprise me. I'd have to look at the

15 individual study though to interpret the data.

16 **Q. And ziprasidone and Abilify are the other two**

17 **products you think are safer alternatives?**

18 A. I think they could be. Again, it's a

19 patient-specific decision. But I think that based upon the

20 profile I see, they could be safer alternatives.

21 **Q. And as a non-medical doctor, you're never asked for a**

22 **particular patient what the best medication is, correct?**

23 A. I'm answering this as a pharmacologist. So, if you

24 ask me as a pharmacologist, based upon the information I see,

25 that's how I answer the question, right. I'm not a physician,

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1 so I don't -- I would not make that decision for an individual

2 patient.

3 **Q. Would you agree with me that all drugs have some**

4 **risk?**

5 A. Yes. I would say that that's a common -- common

6 thing for anything I can think of. Even water has a risk.

7 **Q. So, no drug's a hundred percent safe, correct?**

8 A. That's right.

9 **Q. All drugs have some level of side effects to varying**

10 **degrees?**

11 A. Yes, some levels, and they differ in severity and

12 occurrence rates.

13 **Q. Medical doctors consider the risks of a medication**

14 **when they prescribe it, correct?**

15 A. I assume they do and I would hope they do, and I

16 certainly taught my medical students in pharmacology that they

17 should do that.

18 **Q. So, a medical doctor in his or her office today here**

19 **in Houston, if they're making a determination about what**

20 **medication's appropriate -- Seroquel, haloperidol,**

21 **ziprasidone -- they should be doing -- looking at the side**

22 **effects and the possible benefits and making a determination**

23 **based on that with that particular patient?**

24 A. Well, again, I think you'd have to ask a doctor what

25 they do. But I certainly would expect my doctor to be familiar

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1 with the side effect profile, as well as the efficacy profile,

2 for any drug that he was to prescribe or attempt to prescribe

3 for me.

4 **Q. Would you agree with me based on your review of all**

5 **this literature that mentally ill patients are difficult to**

6 **treat?**

7 A. What do you mean by "difficult to treat"?

8 **Q. That often doctors -- would you agree with me that**

9 **doctors often need to try a number of different medications in**

10 **the schizophrenic population -- let's talk about those folks**

11 **for one minute -- before they can find one that will work?**

12 A. I'm, again, not a physician. I can only speak from

13 what I have read. And certainly from what I have read, I see

14 that doctors often switch patients from one to another. In

15 other words, there's a discontinuation. Doesn't work, you try

16 a different drug, yeah.

17 **Q. Okay. Turn to Paragraph 16 in your report.**

18 A. 16?

19 **Q. Yeah.**

20 MR. ALLEN: Okay. I didn't understand you. Did

21 you say --

22 MR. LASKER: 16.

23 MR. ALLEN: 16? I thought -- I thought somebody

24 said "60." I didn't remember there being that many.

25 **Q. (BY MR. BROWN) Dr. Plunkett, I wanted to look at**