

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

IN THE MATTER OF:)
)
Plaintiff,)
)
vs.)
)
WB: WILLIAM BIGLEY)
)
Defendant.)
_____)
Case No. 3AN-08-00493 PR CI



VOLUME II

TRANSCRIPT OF MOTION HEARING

BEFORE THE HONORABLE SHARON GLEASON
Superior Court Judge

Anchorage, Alaska
May 14, 2008
10:17 A.M.

APPEARANCES:

FOR THE STATE: Timothy M. Twomey, Esq.
Assistant Attorney General
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501

FOR THE DEFENDANT: James B. Gottstein, Esq.
Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501

1 3AN6308-79

2 10:17:01

3 THE COURT: Okay. We are back on record in a
4 case involving Mr. Bigley, who is present here in the
5 courtroom. And we have Mr. Twomey and Mr. Gottstein.

6 And I received paperwork from you,
7 Mr. Gottstein, yesterday. And in it, it indicated you
8 had not yet received the chart. Has that been
9 remedied, or what is the status there?

10 MR. GOTTSTEIN: Your Honor, I received -- it
11 was there when I got back from my supreme court oral
12 argument, so yesterday.

13 THE COURT: All right. And I see a rather
14 lengthy witness list. And I am concerned about the
15 timeframe. So -- and it looks like three are simply
16 to have available for cross examination of the
17 materials you submitted, which I have reviewed; is
18 that correct?

19 MR. GOTTSTEIN: Yes, Your Honor. I really
20 only have three witnesses I plan to call.

21 THE COURT: Dr. Jackson, Dr. Hopson, and
22 Camry Altaffer (phonetic)?

23 MR. GOTTSTEIN: Altaffer.

24 THE COURT: Altaffer. All right.

25 Mr. Twomey, are you ready to proceed?

1 MR. TWOMEY: Yes, Your Honor.

2 THE COURT: All right. And who would you
3 seek to call first, Mr. Gottstein?

4 MR. GOTTSTEIN: Dr. Jackson. And her number
5 is area code 910/208-3278.

6 THE COURT: All right. Thank you.

7 So did I indicate until noon today we could
8 go, or did I -- is that what I had indicated? Or did
9 I make any indication?

10 I have to go to an event at noon or there
11 about. So we'll see where we are time-wise. I know
12 it's an important issue for your client,
13 Mr. Gottstein. If we need to find more time in the
14 next couple of days, we can do so. So let's see what
15 progress we can make up until noon.

16 MR. GOTTSTEIN: You indicated noon.

17 THE COURT: I did. All right. That was my
18 recollection, but I didn't see it in the log notes.
19 All right.

20 We are a little late getting started, which
21 was not really my fault, but my reality, anyway.

22 MR. GOTTSTEIN: Your Honor, I gave the clerk
23 exhibits for this morning.

24 THE COURT: I have them right here. A
25 through F; is that correct?

1 MR. GOTTSTEIN: Yes, ma'am. And I gave them
2 to Mr. Twomey.

3 THE COURT: Mr. Twomey, you have a copy, as
4 well?

5 MR. TWOMEY: Yes. I received them this
6 morning, Your Honor.

7 THE COURT: Do I have Grace Jackson on the
8 phone?

9 THE WITNESS: Yes.

10 THE COURT: All right. Good morning,
11 Ms. Jackson. My name is Judge Gleason. We have you
12 on a speakerphone here in a courtroom in Anchorage,
13 Alaska.

14 You have been called as a witness on behalf
15 of the respondent, William Bigley. It is a matter
16 here where I have the lawyer from the state and
17 Mr. Gottstein present.

18 I am going to be recording your testimony
19 here in just a moment. I will administer an oath to
20 you. But any questions first?

21 THE WITNESS: No.

22 THE COURT: All right. If you'd raise your
23 right hand, please.

24 (Oath administered.)

25 THE COURT: If you would then please state

1 and spell your full name.

2 THE WITNESS: Grace Elizabeth Jackson.
3 That's G-R-A-C-E, Elizabeth, E-L-I-Z-A-B-E-T-H,
4 Jackson, J-A-C-K-S-O-N.

5 THE COURT: All right. Thank you.
6 Go ahead, please, Mr. Gottstein.

7 **DR. GRACE JACKSON**
8 called on behalf of the respondent, testified
9 telephonically as follows on:

10 DIRECT EXAMINATION

11 BY MR. GOTTSTEIN

12 Q Thank you, Dr. Jackson. First off, did you
13 send me a copy of **your curriculum vitae?**

14 A Yes, I did.

15 Q And it's 11 pages?

16 A I believe that is correct, yes.

17 MR. GOTTSTEIN: I'd move to -- it's
18 Exhibit A. I would move to admit.

19 THE COURT: Any objection there?

20 MR. TWOMEY: No, Your Honor.

21 THE COURT: All right. A will be admitted.
22 (Exhibit A admitted.)

23 MR. GOTTSTEIN: Should I give this to the
24 clerk at this point?

25 THE COURT: That's fine. You can hold on to

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1 it, and we'll get it later, if that's easier for you.
2 BY MR. GOTTSTEIN
3 Q Okay. And if I might just take care of the
4 other part of it, too. Did you also send me
5 essentially an analysis of the neuroleptics,
6 neurotoxicity of -- oops, I didn't number it -- 19
7 pages.
8 A Yes, that's correct.
9 Q And is that your work?
10 A Yes, that is my work.
11 Q And this analysis is true to the best of your
12 knowledge?
13 A That's correct.
14 MR. GOTTSTEIN: I would move to admit that,
15 Your Honor.
16 THE COURT: That is Exhibit E?
17 MR. GOTTSTEIN: E.
18 THE COURT: All right. Any objection to E,
19 Mr. Twomey?
20 MR. TWOMEY: No, Your Honor.
21 THE COURT: All right. E will be admitted.
22 (Exhibit E admitted.)
23 BY MR. GOTTSTEIN
24 Q Thank you, Dr. Jackson. Could you briefly
25 describe to the court your experience, training --

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1 training, education and experience?
2 A Certainly. I attended medical school at the
3 University of Colorado between 1992 and 1996.
4 Following that, I entered and successfully
5 completed residency in psychiatry, which was performed
6 actually within the U.S. Navy. And that residency was
7 performed -- well, the internship was in 1996 through
8 '97, the residency 1997 through 2000.
9 Subsequent to completing that residency
10 program, I served as an active duty psychiatrist in
11 the U.S. military. I actually transitioned out of the
12 military in the spring of 2002, and I have been
13 actually in self-employed status since 2002 working at
14 a variety of different positions in order to have some
15 flexibility for research, lecturing, writing, and
16 clinical work, and also forensic consultation.
17 Q Could you describe -- so have you published
18 papers?
19 A Yes. I have published papers in peer-review
20 journals. I have contributed chapters to other books
21 which have been edited by other mental health
22 professionals, both in this country and overseas.
23 And I am also the author of my own book,
24 which I published in the year 2005.
25 Q And what was the name of that book?

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1 A That book is called Rethinking Psychiatric
2 Drugs, a Guide for Informed Consent.
3 Q And have you testified as an expert --
4 testified or consulted as an expert in
5 psychopharmacology cases?
6 A Yes. I have served as a consultant in a
7 number of cases involving psychiatric rights similar
8 to this case.
9 Also involving disputes over the use of
10 medications versus alternative treatments in regards
11 to child treatments. I've served as a consultant to
12 families or their doctors in other states in order to
13 assist in the preparation of different treatment
14 plans.
15 And I've also been involved as an expert
16 witness in consulting on product liability cases.
17 Q Were you qualified as an expert in
18 psychiatric and psychopharmacology in what's known as
19 the Myers case in Alaska here in 2003?
20 A Yes, I was.
21 Q And did Dr. Moser testify I think something
22 like that you -- that you knew more about the actions
23 of these drugs on the brain than any clinician he knew
24 in the United States?
25 MR. TWOMEY: Objection, hearsay, Your Honor.

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1 THE WITNESS: I'm sorry. I'm getting a lot
2 of beeps on my phone. Can you hear me all right?
3 THE COURT: Yes.
4 But, Mr. Gottstein, your response to the
5 hearsay objection?
6 MR. GOTTSTEIN: It's actually in the
7 testimony that was filed, I believe.
8 THE COURT: Well, then the testimony speaks
9 for itself.
10 MR. GOTTSTEIN: Okay.
11 THE COURT: So you can go forward.
12 MR. GOTTSTEIN: I would move Dr. Jackson as
13 an expert in psychiatry and psychopharmacology.
14 THE COURT: Any objection there, Mr. Twomey,
15 or voir dire?
16 MR. TWOMEY: No, Your Honor.
17 THE COURT: All right. Then I will find the
18 doctor so qualified in those two fields.
19 Go ahead, please, Mr. Gottstein.
20 BY MR. GOTTSTEIN
21 Q Dr. Jackson, in preparation for this case,
22 have you reviewed the -- what's known as the -- well,
23 the affidavit of Robert Whitaker?
24 A Yes, I have.
25 Q And what is your opinion on that affidavit?

1 A I believed it was very truthful. I thought
 2 it was a very accurate presentation of the history of
 3 this specific class of medications which we are
 4 discussing in this case, the antipsychotic
 5 medications.
 6 And also a very succinct but accurate
 7 description of some of the problems that have emerged,
 8 not only in the conduct of the research, but also in
 9 terms of the actual lived experience of patients. So
 10 I felt it was a very accurate and very clear
 11 presentation of the information as I understand it
 12 myself.

13 Q Now, would it be fair to say that this
 14 information is not generally shared by most clinicians
 15 in the United States?

16 A Oh, I think that would be a very fair -- very
 17 fair statement.

18 Q And why would you say that is?

19 A Well, I think we have a short time here.
 20 It's really a broad subject. But quite succinctly
 21 what has happened is that the educational process
 22 throughout medicine, not just psychiatry, and also the
 23 continuing medical education process, even when
 24 physicians have completed the first steps of their
 25 training, have actually presented a very biased

1 begin to have an exposure to a different perspective.
 2 But the most -- probably the most important
 3 thing for me was the lived reality of my patients,
 4 just opening my eyes and really paying attention to
 5 see whether or not people were improving.

6 Q I'm sorry; I missed that a little bit. Could
 7 you go into that a little bit further, what you found?

8 A Sure. Well, what really happened is that
 9 internship -- I should probably just back up and say
 10 that I regard -- in retrospect, I look at the
 11 educational process as really an indoctrination.

12 And I think it's rather unique or heroic when
 13 people can begin to examine things more critically.
 14 And I was just lucky enough to have an exposure to
 15 some individuals who allowed me to do that.

16 But more specifically, I began to see that in
 17 clinic after clinic, whatever setting I was moving
 18 through, I was seeing the patients were in fact not
 19 improving, that in most cases, in fact, patients were
 20 getting sicker and sicker.

21 And there are two ways to react to that. One
 22 could either blame that on the underlying illness and
 23 say that we just don't have treatments yet that are
 24 effective, or one could even begin to pay attention
 25 and ask a broader question or more pointed question,

1 depiction of the history, or actually omitting the
 2 history of many medications.

3 So a lot of this is a reflection of the
 4 educational process, both in the first stages of
 5 medical school and residency, and then what is
 6 occurring in the medical literature even now.

7 Q Let me stop you right there just for a
 8 minute. So were you trained in this way?

9 A Yeah. I was -- absolutely. I was trained in
 10 the traditional sense that basically serious --
 11 especially severe -- quote, severe mental illness or
 12 mental illnesses are diseases of the brain which
 13 require chemical treatments, i.e., medication
 14 treatments, and that in most cases, these medications
 15 must be used on a very chronic or even permanent
 16 basis.

17 Q And did something happen to cause you to
 18 change your mind or question that information?

19 A Lots of things happened. Probably one of the
 20 most important things is that I was fortunate enough
 21 to be trained -- or be training in a location that
 22 exposed me to some additional information.

23 In other words, some of the history, and also
 24 some of the alternative work which could be done that
 25 might be effective. So that was one part, is I did

1 gee, is it possible that there's something about the
 2 way we are approaching these phenomena that is in fact
 3 getting in the way of recovery?

4 And once I began to ask that question, I
 5 basically had a 180-degree turnabout in terms of how I
 6 had to practice ethically and according to science.

7 Q And did that result in a -- I think you kind
 8 of testified to this -- in a change in direction more
 9 towards researching this issue?

10 A Oh, absolutely. Well, basically, it resulted
 11 in two things. It resulted in a great deal of
 12 conflict between myself and most conventional
 13 settings. It's why I'm an independent practitioner
 14 and not a person enjoying an academic appointment or
 15 an appointment in a facility.

16 So it really made -- I had to make a firm
 17 decision, was I going to be truthful to science or was
 18 I going to go after a \$200,000 a year job with nice
 19 perks and the respect of my colleagues?

20 So it was very clear to me that in order to
 21 honor the dictum first do no harm, I had to really
 22 stay truthful to the science. And that's really what
 23 necessitated my breakaway. So that's why I'm really
 24 an independent person who does my own research and
 25 tried to just help where -- you know, where the help

1 is actually needed or asked for.
 2 Q Thank you. And so then, just to kind of fill
 3 in then this, it's Exhibit C, your neurotoxicity
 4 analysis, that would be some of your, you know, more
 5 recent work, is that correct, or current state of your
 6 research into this issue?

7 A Yeah. Fairly current.
 8 I am trying to finish a second book this
 9 year. And what has really happened over the past two
 10 years is that I try to do clinical work to keep myself
 11 current with that.

12 But I also step aside. And probably every
 13 single day, I am working on the most current research
 14 in the field in order to, you know, lecture and to
 15 also write this second book.

16 What really happened about four years ago is
 17 I began to appreciate the fact that most physicians --
 18 and this isn't just a criticism of psychiatry, by any
 19 means. But most of us ignore something which is
 20 called target organ toxicity. We don't pay attention
 21 to how the treatments we're using might actually be
 22 adversely affecting the very target we are trying to
 23 fix or help improve or repair.

24 So in my case, about two years ago, I started
 25 to just begin focusing on the most current research

1 phenomena as brain diseases.
 2 The second thing that happened was the birth
 3 of something called evidence-based medicine. This
 4 was -- actually sort of became official through the
 5 Journal of the American Medical Association and other
 6 major journals to really elevate an importance, not
 7 the actual day-to-day observations that a doctor would
 8 be making and not the actual science of what causes
 9 illness, but clinical trials that are aimed at just
 10 improving or changing symptoms.

11 The third thing that happened was something
 12 that is called direct consumer advertising in 1997,
 13 which again was trying to market these drugs and make
 14 them more popular or appealing to the public.

15 And the fourth big thing that has really
 16 changed is something called the preemption doctrine.
 17 And also, the Daubert litigation.

18 Daubert was a supreme court decision in 1993
 19 that has really made it quite difficult for toxic tort
 20 litigation to occur, so that the implications of that
 21 for doctors -- and they don't realize this. It's very
 22 much behind the scenes -- is that the pharmaceutical
 23 industry began publishing as many papers that they
 24 could as fast as possible in the journals in order to
 25 meet the Daubert standard of something called weight

1 that looked at the brain-damaging effects of different
 2 kinds of interventions. And that is really what I've
 3 been focusing on.

4 So the document that you have there is a
 5 reflection of some of that research. I should say
 6 that it's not completely up to date, because some of
 7 the research I've been doing more recently even
 8 demonstrates that these drugs are more toxic than what
 9 I have written in this report.

10 Q Okay. Thank you. I want to get to that --
 11 get to that also a little bit more. But I'm also --
 12 are there other reasons why clinicians are not really
 13 understanding this -- this state of affairs?

14 A Sure. Well, I think there are so many things
 15 that happened.

16 I'll just take my example. I went to medical
 17 school in 1992, graduated in '96, and did my residency
 18 until 2000. This was a very pivotal time in what was
 19 occurring within the mental health field and also
 20 within the United States culturally. And if I just
 21 picked, like, maybe four key things.

22 One is the government decided to name this
 23 decade the decade of the brain. In doing so, it sort
 24 of attached a governmental license or the
 25 (indiscernible) of sanctioning regarding these

1 of evidence or preponderance of the evidence.
 2 So essentially what happened in the 1990s is
 3 that the journals, more than ever before in history,
 4 became a tool of marketing, a marketing arm for the
 5 drug companies. And drug companies shifted in terms
 6 of previous research in the United States.

7 Most of the research had previously been
 8 funded by the government and conducted in academic
 9 centers. In the 1990s, that was pretty much over, and
 10 most of the funding is now coming from the
 11 pharmaceutical industry. So that's really in a
 12 nutshell what happened in the 1990s when I was
 13 training.

14 Now, where are we now? What that means is
 15 that the journals that most doctors are relying upon
 16 for their continuing information continued to be
 17 dominated by pharmaceutical industry funded studies
 18 and by papers which are being written, if not entirely
 19 by the drug companies, then by authors who have part
 20 of their finances paid for by the drug companies.

21 And while I don't believe that it's
 22 necessarily going to buy us the information in an
 23 article, I think trials have to be funded by someone.
 24 Unfortunately what has happened is that there have
 25 been too many episodes of the suppressed information,

1 so that doctors cannot get the whole truth.

2 Q Well, I want to follow up on that. What do
3 you mean by suppressed information?

4 A Well, one of the things that has happened
5 repeatedly, and again, most doctors don't realize
6 this, is that the pharmaceutical industry has not been
7 forthcoming in terms of surrendering all of the
8 information to the Food and Drug Administration that
9 they were by law I believe, or at least under ethics,
10 required to do.

11 For instance, in January of this year, the
12 New England Journal of Medicine published a very
13 important article that had been done. Actually, one
14 of the key authors was a former reviewer at the Food
15 and Drug Administration, who is now back in private
16 practice, or somewhere.

17 And he and his co-authors had actually had
18 access and reviewed the clinical trial database on the
19 antidepressant medications. And they found that
20 31 percent of the trials were never published. So
21 31 percent of that information was never reported in
22 the journals so that doctors could see it.

23 Okay. Well, you might say who cares. The
24 point of it is that within that 31 percent, had they
25 been published, the overall risk benefit understanding

1 Administration still may not have seen all of the
2 actual data that has been generated in the actual
3 trials. So it is a continuing problem and a
4 continuing concern.

5 And yes, I believe that most people -- I'll
6 give you an example. When I was working in the VA
7 clinic a couple summers ago in Oregon, I attended a
8 dinner lecture where a speaker for a specific
9 antipsychotic medication slipped out some information
10 that I thought was extremely important. He said that
11 the FDA and the public still has not seen information
12 on Abilify, Aripiprazole, another antipsychotic.

13 And he alluded to the fact that there was a
14 severe problem with cardiac toxicity, but he would not
15 go any further. He was speaking on behalf of another
16 company. But he said that it would be possible to
17 contact him and perhaps he could share that
18 information.

19 Well, my point is, why are the rest of the
20 doctors not getting this information that Abilify is
21 eight times more toxic to the heart than the other
22 antipsychotics? I sort of filed that away in the
23 background of my head and said, boy, you know, I'd
24 like to have this information.

25 But the point is, doctors are not getting the

1 of this category of medications would have been
2 changed. Instead of favoring these drug treatments,
3 it would have altered the whole face of the journals,
4 and potentially the use of these medications would
5 have become more limited.

6 Because that 31 percent of the information
7 was showing that the medications were, A, not terribly
8 effective or not more effective than placebo at all,
9 and, B, it really began to reveal the full scope of
10 the hazard. So by not publishing all this
11 information, there is a false view of efficacy and
12 safety.

13 I should say the same thing has happened with
14 Vioxx. The same thing has happened with the
15 cholesterol-lowering drugs. This is an epidemic right
16 now, which is a real crisis in the integrity of
17 medicine. It's not just psychiatry.

18 Q Does the same thing happen with respect to
19 the neuroleptics?

20 A Absolutely, the same thing has happened with
21 respect to the neuroleptics. I think you're a perfect
22 example of someone who has tried to work to bring some
23 of this hidden material to the forefront, because I
24 still think there are concerns among professionals,
25 and I hope among the public, that the Food and Drug

1 information. And that's a real problem both for them
2 and it's a problem for their patients.

3 Q Is it fair to say that you've really devoted
4 your life to -- or your work at this point to
5 ferreting out this sort of information and making it
6 available?

7 A Right. As best I can. And you know, it's --
8 it's really sort of a Catch 22. I would love to have
9 the respect of my peers. I would love to be at
10 Harvard teaching. You know, I would love to be an
11 academic able to teach medical students.

12 But unfortunately, the system is so skewed
13 still in the direction of the pharmaceutical companies
14 and their products that I can't, you know, even get a
15 foot in the door.

16 So yes, I am full-time researcher trying to
17 do my best to understand this material accurately, and
18 fairly, and objectively, and then to actually act
19 responsibly in response to that knowledge.

20 Q So in reviewing this information, is it
21 important to carefully look at the data and analyze
22 what's actually presented?

23 A It's extremely important to look at the
24 methodology. I don't think -- unless a person is
25 actually working at the Food and Drug Administration

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1 or one of the actual clinical trial researchers, you
 2 know, actually producing the data that you would
 3 actually -- that a person like myself would have
 4 access to the raw data.

5 But what I can analyze and ask questions
 6 about is to go to people who have either performed
 7 these studies, or when I read the published studies,
 8 which is usually what I have access to, to really use
 9 good critical thinking in terms of analyzing the
 10 methods that have been used.

11 And you might -- I'm not sure if we're going
 12 to have time to discuss methodology, but this is one
 13 of the key things that any physician really has to pay
 14 attention to.

15 It's not just the fact that there might be 10
 16 or 20 studies that say a particular medication is
 17 either good, bad, or indifferent. It's actually
 18 important to -- you know, before even looking at that
 19 conclusion, to address how the study was performed so
 20 that one can make a well-informed and an appropriate
 21 judgment as to whether or not the conclusion should
 22 even be considered.

23 Q And so without going too much into it, could
 24 you describe a couple of methodological concerns that
 25 you have with respect to the second generation of

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1 neuroleptic studies of which Risperdal is a member?
 2 A Certainly. One of the things that has
 3 happened is that the database or the research
 4 (indiscernible), which is actually used to approve
 5 medications in this country, psychiatric medications,
 6 and then used to continue to argue in their favor,
 7 especially in product liability litigation or in a lot
 8 of cases. That data set is very limited in terms of
 9 generalizability.

10 What most people don't realize is that when a
 11 drug is being approved, the people performing the
 12 research want to pick the healthiest or the least sick
 13 or the least damaged patients, so that they can try
 14 and produce good outcomes. So that is one of the main
 15 concerns that all of us doctors have about clinical
 16 trials is that we recognize the fact that the
 17 generalizability is limited.

18 What do I mean by that? Well, they usually
 19 want to pick people who don't have additional
 20 illnesses, such as diabetes, heart disease, lung
 21 problems, liver disease.

22 Well, that's going to rule out a large number
 23 of people who are actually existing in the real world,
 24 because once they've been on many of these
 25 medications, they are guaranteed to have some of these

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1 problems.

2 Number two is they eliminate the use of
 3 additional drugs, meaning additional medication.
 4 Well, that eliminates another huge portion of the
 5 United States population, because most of the people
 6 who are being seen in mental health settings are
 7 actually receiving more than one, and in some cases,
 8 you know, as many as 10 or even 20 medications for
 9 various conditions.

10 So it makes it very difficult to extrapolate
 11 to the real-world setting the information that they
 12 get or they find in a clinical trial.

13 Another problem is the length of a clinical
 14 trial. A clinical trial usually is cut off at six
 15 weeks. That's it. And the drug companies understand
 16 and actually choose the six-week cut off for a very
 17 good reason. They know that generally speaking, they
 18 can't continue to produce favorable results after six
 19 weeks.

20 And then another big problem with these
 21 methodologies is the fact that they really are
 22 enrolling people who have previously been receiving
 23 medications.

24 So what does that mean and why does that
 25 alter or bias the results? Well, one of the problems

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1 in the antipsychotic medication literature, as in the
 2 antidepressant literature, is the fact that patients
 3 are brought into the study and they have previously
 4 been taking a medication, in some cases right up to
 5 the day that they enter the study.

6 And then the first seven to ten days in most
 7 of these trials involve taking the patients off of
 8 those previous or pre-existing medications. So seven
 9 to ten days, the person is abruptly cut off from their
 10 previous drug.

11 Now the real stage of the trial begins. So
 12 that first seven- to ten-day window is something that
 13 is called a washout. And sometimes what they'll do is
 14 they'll give everybody a sugar pill in those first
 15 seven to ten days and call it a placebo washout.

16 Now, the use of the term washout has two
 17 meanings. Washout meaning whatever other drugs the
 18 person may have been taking before, those are supposed
 19 to wash out of the system. And the second part -- and
 20 the second meaning of washout is that if someone
 21 begins to improve too much in those seven to ten days,
 22 they are removed from the study.

23 Q So may I interrupt you?
 24 A Sure.
 25 Q Are you saying that when people are withdrawn

1 from the drugs they were taking previously and they
2 improve when they get taken off the drugs, then they
3 are eliminated from the study?

4 A That's right. They take them out of the
5 study. Because they only want to have people
6 remaining in the study who are going to continue to
7 look -- you know, either continue to look bad on the
8 placebo if they continue to stay -- if they are
9 randomized to the placebo part of the trial.

10 Or if they are then switched back on to an
11 active medication, something chemically active instead
12 of a sugar pill, their withdrawal symptoms, having
13 been cut off of a previous drug, will hopefully
14 respond to having another drug that was similar to the
15 previous drug, you know, put back into their system.

16 So you understand completely, they remove
17 people -- and this is important in terms of this case.
18 Because for instance, in the Zyprexa trials, a full
19 20 percent of the people improved so much in the first
20 seven to ten days when they were taken off their
21 previous drugs that they kicked all those people out
22 of the trial.

23 If they had retained them in the trial, they
24 could not have gotten results that made Zyprexa look
25 like it was any better than a sugar pill. It would

1 have biased the results in favor of the sugar pill.

2 Q So now, did you -- did you analyze the
3 studies that the FDA used in --

4 THE COURT: And I am going to cut off here
5 and say what would be helpful to me, Mr. Gottstein, is
6 as I understand it, API is proposing Risperdal here,
7 correct?

8 MR. GOTTSTEIN: Yes.

9 THE COURT: And so if we focused exclusively
10 on that, I think given our time constraint and the
11 proposal, I think that would be the most helpful for
12 me.

13 MR. GOTTSTEIN: Well, Your Honor, one of the
14 problems is that we didn't know until Monday that --
15 you know, that it was Risperdal.

16 THE COURT: But now that we do, if we could
17 focus on that, I think that would help.

18 BY MR. GOTTSTEIN

19 Q Well, are all these -- are all these things
20 that you mentioned also applicable to the Risperdal
21 studies?

22 A As far as I know. And I have no reason to
23 believe from what I've read in the literature -- I
24 haven't had time to read the FDA review on Risperidone
25 as I have done with olanzapine. But based on the

1 trials that I have seen in the regular journals, I
2 have no reason to believe that anything other than
3 this procedure has been used repeatedly.

4 In other words, the placebo washout and
5 actually switching people or removing people who
6 improve too much, it's sort of a standard protocol
7 that you have a certain score in terms of symptoms.
8 And if people don't meet that cutoff, in other words,
9 they begin to improve too quickly, they don't get to
10 stay in the study.

11 So I have no reason to believe that
12 Risperidone was any different than Zyprexa in terms of
13 this method of eliminating people who -- and you know,
14 favoring or biasing the result of the study.

15 Q In the interest of moving forward, is it fair
16 to say there are other methodological problems with
17 these studies?

18 A Oh, absolutely. What many of these studies
19 will do is to allow certain concomitant treatments.
20 In other words, certain additional medicines during
21 the study so that you can't really be sure that the
22 results they are claiming are the result of the actual
23 interventional drug. For instance, Risperdal instead
24 of a benzodiazepine or an antihistamine.

25 Another thing is the way that the data

1 themselves get reported. And one of the things that
2 is frequently done is to use something called LOCF, or
3 last observation carried forward. So what that means

4 is if you were to enter a study for instance, and they
5 started you on Risperdal, and you start to have a
6 severe side effect, let's say Parkinsonian symptoms,
7 and you dropped out of the study at two weeks, but the
8 study is supposed to end at six weeks, they will carry
9 forward your score to the six-week mark.

10 Now, this will sometimes -- people will
11 actually drop out when they have a higher score and
12 they'll carry that forward, as well. But the use of
13 LOCF statistics, especially when they carry forward
14 people who are dropping out on placebo, those are
15 people who are dropping out because they are in
16 withdrawal. They have been cut off from a previous
17 drug.

18 And so they carry forward an end result,
19 which is not a reflection of the underlying illness,
20 let's say, but a reflection of this introductory bias,
21 the placebo washout.

22 So the fact they report all of these LOCF
23 data, meaning the fact that they are just carrying
24 forward the results or the statistics from people who
25 drop out of the study early, biases the results in

1 favor of the drug, when in fact it's not an accurate
2 reflection of what's really going on in the study.

3 And that happens quite often, and that
4 certainly happened in the Risperdal/Risperidone
5 literature.

6 Q So just to kind of finish up this part, would
7 it just generally be fair to say that it would be
8 pretty difficult for a practicing psychiatrist in
9 clinical practice to have this information that you
10 are providing to the court?

11 A Oh, it would be almost impossible. It's --
12 it would be something you would really have to devote
13 your study to.

14 And actually, you know, not only would it be
15 difficult for the ordinary doctor to know this is
16 going on, but he or she would read what is published
17 in the regular journals and see that the results are
18 promising, like 70 to 80 percent response rates,
19 meaning a good response with patient satisfaction, et
20 cetera.

21 And then he or she would be in the real-world
22 setting, and maybe be lucky see 30 or 40 percent of
23 the patients able to even tolerate the drug. So it
24 not only is something that would be hard for doctors
25 to know, but what they're actually being exposed to is

1 so far removed from reality that they are very
2 unlikely to understand what is going on in the real
3 world.

4 Q Okay. So what is going on in the real world?
5 What is the impact of drug -- well, specifically
6 Risperdal on patients?

7 A Well, the real effects in the real world
8 are -- are really in two categories. And as a doctor,
9 you know, I am sort of thinking in terms of safety
10 first. I sort of think of, boy, what do I really have
11 to look out for here if somebody comes into my office
12 and they are receiving this medication or I am asked
13 to begin it?

14 So one of the things that, you know, we are
15 really talking about is safety. Are people dying on
16 these drugs? Do people die from taking Risperidone?
17 Yes. People are actually experiencing shorter life
18 spans.

19 Initially it was felt that the life spans for
20 people on medications like Risperidone were perhaps
21 shortened maybe ten or 15 years. And I think that's
22 even been elevated in the most recent government
23 studies to more like 20- or 25-year shorter life
24 spans. So instead of a male -- and we're usually
25 talking about, you know, males with mental illness,

1 would probably be living, you know, if they were
2 lucky, 72, 74 years of age for men in the United
3 States these days. And we are really talking about
4 something which drops the lifespan down into the 60s.

5 So at the worst what is going on is that we
6 are actually contributing to morbidity, actually
7 shortening people's life spans. And that's -- and
8 that is either through an acute event like a stroke or
9 a heart attack or something called a pulmonary
10 embolism, or we are talking about more chronic
11 illnesses that eventually take their tolls, things
12 like diabetes and heart failure.

13 So at the very worst, what is going on in the
14 United States is an epidemic of early suffering or
15 mortality that was not present before these
16 medications were being used, you know, by such a
17 prevalence -- in such high numbers.

18 The second thing that is going on is that we
19 are arguably worsening the long-term prognosis of
20 people, and in directions that were not previously
21 seen or talked about. And I think my affidavit speaks
22 to this. And also Mr. Whitaker's affidavit speaks to
23 the history and the actual historical outcomes when
24 individuals were being offered something other than
25 just the medication or the priority on medication.

1 And so that is the other big thing in terms of what's
2 going on.

3 What's going on is that people are suffering
4 in great numbers, and that people are dying early, and
5 that people are having what might have previously been
6 a transient, that is a limited episode, converted into
7 a chronic and more disabling form of experience.

8 Q Is -- are these drugs brain damaging?

9 A Well, I try and not sound like I am, you
10 know, really off -- off my rocker. Because people
11 probably wouldn't like it if I actually used a term
12 for what's happening.

13 But I sort of say we have unfortunately
14 contributed to a population of CBI patients, meaning
15 chemically brain injured.

16 I was in the military, so I am very used to
17 TBI patients, traumatic brain injury from, you know,
18 concussions and explosions and what's going on in Iraq
19 and Afghanistan.

20 But what is the elephant in the room that
21 people aren't addressing in psychiatry and neurology
22 is this population of CBI, chemically brain injured.

23 So yes, I actually would say that what we
24 have created, and I think Mr. Bigley is an example of
25 this, is that we are creating dementia on a very large