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

*** CONFIDENTIAL ***

This hearing was public.
Jim Gottstein

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

3AN6308-79
10:17:01
THE COURT: Okay. We are back on record in a case involving Mr. Bigley, who is present here in the courtroom. And we have Mr. Twomey and Mr. Gottstein.
And I received paperwork from you, Mr. Gottstein, yesterday. And in it, it indicated you had not yet received the chart. Has that been remedied, or what is the status there?
MR. GOTTSTEIN: Your Honor, I received -- it was there when I got back from my supreme court oral argument, so yesterday.
THE COURT: All right. And I see a rather lengthy witness list. And I am concerned about the timeframe. So -- and it looks like three are simply to have available for cross examination of the materials you submitted, which I have reviewed; is that correct?
MR. GOTTSTEIN: Yes, Your Honor. I really only have three witnesses I plan to call.
THE COURT: Dr. Jackson, Dr. Hopson, and Camry Altaffer (phonetic)?
MR. GOTTSTEIN: Altaffer.
THE COURT: Altaffer. All right.
Mr. Twomey, are you ready to proceed?

MR. TWOMEY: Yes, Your Honor.
THE COURT: All right. And who would you seek to call first, Mr. Gottstein?
MR. GOTTSTEIN: Dr. Jackson. And her number is area code 910/208-3278.
THE COURT: All right. Thank you.
So did I indicate until noon today we could go, or did I -- is that what I had indicated? Or did I make any indication?
I have to go to an event at noon or there about. So we'll see where we are time-wise. I know it's an important issue for your client, Mr. Gottstein. If we need to find more time in the next couple of days, we can do so. So let's see what progress we can make up until noon.
MR. GOTTSTEIN: You indicated noon.
THE COURT: I did. All right. That was my recollection, but I didn't see it in the log notes. All right.
We are a little late getting started, which was not really my fault, but my reality, anyway.
MR. GOTTSTEIN: Your Honor, I gave the clerk exhibits for this morning.
THE COURT: I have them right here. A through F; is that correct?

MR. GOTTSTEIN: Yes, ma'am. And I gave them to Mr. Twomey.
THE COURT: Mr. Twomey, you have a copy, as well?
MR. TWOMEY: Yes. I received them this morning, Your Honor.
THE COURT: Do I have Grace Jackson on the phone?
THE WITNESS: Yes.
THE COURT: All right. Good morning, Ms. Jackson. My name is Judge Gleason. We have you on a speakerphone here in a courtroom in Anchorage, Alaska.
You have been called as a witness on behalf of the respondent, William Bigley. It is a matter here where I have the lawyer from the state and Mr. Gottstein present.
I am going to be recording your testimony here in just a moment. I will administer an oath to you. But any questions first?
THE WITNESS: No.
THE COURT: All right. If you'd raise your right hand, please.
(Oath administered.)
THE COURT: If you would then please state

and spell your full name.
THE WITNESS: Grace Elizabeth Jackson. That's G-R-A-C-E, Elizabeth, E-L-I-Z-A-B-E-T-H, Jackson, J-A-C-K-S-O-N.
THE COURT: All right. Thank you.
Go ahead, please, Mr. Gottstein.

DR. GRACE JACKSON

called on behalf of the respondent, testified telephonically as follows on:

DIRECT EXAMINATION

BY MR. GOTTSTEIN

Q Thank you, Dr. Jackson. First off, did you send me a copy of your curriculum vitae?
A Yes, I did.
Q And it's 11 pages?
A I believe that is correct, yes.
MR. GOTTSTEIN: I'd move to -- it's Exhibit A. I would move to admit.
THE COURT: Any objection there?
MR. TWOMEY: No, Your Honor.
THE COURT: All right. A will be admitted.
(Exhibit A admitted.)
MR. GOTTSTEIN: Should I give this to the clerk at this point?
THE COURT: That's fine. You can hold on to

it, and we'll get it later, if that's easier for you.
BY MR. GOTTSTEIN
Q Okay. And if I might just take care of the other part of it, too. Did you also send me essentially an analysis of the neuroleptics, neurotoxicity of -- oops, I didn't number it -- 19 pages.
A Yes, that's correct.
Q And is that your work?
A Yes, that is my work.
Q And this analysis is true to the best of your knowledge?
A That's correct.
MR. GOTTSTEIN: I would move to admit that, Your Honor.
THE COURT: That is Exhibit E?
MR. GOTTSTEIN: E.
THE COURT: All right. Any objection to E, Mr. Twomey?
MR. TWOMEY: No, Your Honor.
THE COURT: All right. E will be admitted.
(Exhibit E admitted.)
BY MR. GOTTSTEIN
Q Thank you, Dr. Jackson. Could you briefly describe to the court your experience, training --

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

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

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

A I believed it was very truthful. I thought it was a very accurate presentation of the history of this specific class of medications which we are discussing in this case, the antipsychotic medications.

And also a very succinct but accurate description of some of the problems that have emerged, not only in the conduct of the research, but also in terms of the actual lived experience of patients. So I felt it was a very accurate and very clear presentation of the information as I understand it myself.

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

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

Q And why would you say that is?

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

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

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

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

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

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

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

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

begin to have an exposure to a different perspective.

But the most -- probably the most important thing for me was the lived reality of my patients, just opening my eyes and really paying attention to see whether or not people were improving.

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

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

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

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

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

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

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

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

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

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

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

is actually needed or asked for.
Q Thank you. And so then, just to kind of fill in then this, it's Exhibit C, your neurotoxicity analysis, that would be some of your, you know, more recent work, is that correct, or current state of your research into this issue?
A Yeah. Fairly current.
I am trying to finish a second book this year. And what has really happened over the past two years is that I try to do clinical work to keep myself current with that.
But I also step aside. And probably every single day, I am working on the most current research in the field in order to, you know, lecture and to also write this second book.
What really happened about four years ago is I began to appreciate the fact that most physicians -- and this isn't just a criticism of psychiatry, by any means. But most of us ignore something which is called target organ toxicity. We don't pay attention to how the treatments we're using might actually be adversely affecting the very target we are trying to fix or help improve or repair.
So in my case, about two years ago, I started to just begin focusing on the most current research

that looked at the brain-damaging effects of different kinds of interventions. And that is really what I've been focusing on.
So the document that you have there is a reflection of some of that research. I should say that it's not completely up to date, because some of the research I've been doing more recently even demonstrates that these drugs are more toxic than what I have written in this report.
Q Okay. Thank you. I want to get to that -- get to that also a little bit more. But I'm also -- are there other reasons why clinicians are not really understanding this -- this state of affairs?
A Sure. Well, I think there are so many things that happened.
I'll just take my example. I went to medical school in 1992, graduated in '96, and did my residency until 2000. This was a very pivotal time in what was occurring within the mental health field and also within the United States culturally. And if I just picked, like, maybe four key things.
One is the government decided to name this decade the decade of the brain. In doing so, it sort of attached a governmental license or the (indiscernible) of sanctioning regarding these

phenomena as brain diseases.
The second thing that happened was the birth of something called evidence-based medicine. This was -- actually sort of became official through the Journal of the American Medical Association and other major journals to really elevate an importance, not the actual day-to-day observations that a doctor would be making and not the actual science of what causes illness, but clinical trials that are aimed at just improving or changing symptoms.
The third thing that happened was something that is called direct consumer advertising in 1997, which again was trying to market these drugs and make them more popular or appealing to the public.
And the fourth big thing that has really changed is something called the preemption doctrine. And also, the Daubert litigation.
Daubert was a supreme court decision in 1993 that has really made it quite difficult for toxic tort litigation to occur, so that the implications of that for doctors -- and they don't realize this. It's very much behind the scenes -- is that the pharmaceutical industry began publishing as many papers that they could as fast as possible in the journals in order to meet the Daubert standard of something called weight

of evidence or preponderance of the evidence.
So essentially what happened in the 1990s is that the journals, more than ever before in history, became a tool of marketing, a marketing arm for the drug companies. And drug companies shifted in terms of previous research in the United States.
Most of the research had previously been funded by the government and conducted in academic centers. In the 1990s, that was pretty much over, and most of the funding is now coming from the pharmaceutical industry. So that's really in a nutshell what happened in the 1990s when I was training.
Now, where are we now? What that means is that the journals that most doctors are relying upon for their continuing information continued to be dominated by pharmaceutical industry funded studies and by papers which are being written, if not entirely by the drug companies, then by authors who have part of their finances paid for by the drug companies.
And while I don't believe that it's necessarily going to buy us the information in an article, I think trials have to be funded by someone. Unfortunately what has happened is that there have been too many episodes of the suppressed information,

so that doctors cannot get the whole truth.
Q Well, I want to follow up on that. What do you mean by suppressed information?
A Well, one of the things that has happened repeatedly, and again, most doctors don't realize this, is that the pharmaceutical industry has not been forthcoming in terms of surrendering all of the information to the Food and Drug Administration that they were by law I believe, or at least under ethics, required to do.
For instance, in January of this year, the New England Journal of Medicine published a very important article that had been done. Actually, one of the key authors was a former reviewer at the Food and Drug Administration, who is now back in private practice, or somewhere.
And he and his co-authors had actually had access and reviewed the clinical trial database on the antidepressant medications. And they found that 31 percent of the trials were never published. So 31 percent of that information was never reported in the journals so that doctors could see it.
Okay. Well, you might say who cares. The point of it is that within that 31 percent, had they been published, the overall risk benefit understanding

of this category of medications would have been changed. Instead of favoring these drug treatments, it would have altered the whole face of the journals, and potentially the use of these medications would have become more limited.
Because that 31 percent of the information was showing that the medications were, A, not terribly effective or not more effective than placebo at all, and, B, it really began to reveal the full scope of the hazard. So by not publishing all this information, there is a false view of efficacy and safety.
I should say the same thing has happened with Vioxx. The same thing has happened with the cholesterol-lowering drugs. This is an epidemic right now, which is a real crisis in the integrity of medicine. It's not just psychiatry.
Q Does the same thing happen with respect to the neuroleptics?
A Absolutely, the same thing has happened with respect to the neuroleptics. I think you're a perfect example of someone who has tried to work to bring some of this hidden material to the forefront, because I still think there are concerns among professionals, and I hope among the public, that the Food and Drug

Administration still may not have seen all of the actual data that has been generated in the actual trials. So it is a continuing problem and a continuing concern.
And yes, I believe that most people -- I'll give you an example. When I was working in the VA clinic a couple summers ago in Oregon, I attended a dinner lecture where a speaker for a specific antipsychotic medication slipped out some information that I thought was extremely important. He said that the FDA and the public still has not seen information on Abilify, Aripiprazole, another antipsychotic.
And he alluded to the fact that there was a severe problem with cardiac toxicity, but he would not go any further. He was speaking on behalf of another company. But he said that it would be possible to contact him and perhaps he could share that information.
Well, my point is, why are the rest of the doctors not getting this information that Abilify is eight times more toxic to the heart than the other antipsychotics? I sort of filed that away in the background of my head and said, boy, you know, I'd like to have this information.
But the point is, doctors are not getting the

information. And that's a real problem both for them and it's a problem for their patients.
Q Is it fair to say that you've really devoted your life to -- or your work at this point to ferreting out this sort of information and making it available?
A Right. As best I can. And you know, it's -- it's really sort of a Catch 22. I would love to have the respect of my peers. I would love to be at Harvard teaching. You know, I would love to be an academic able to teach medical students.
But unfortunately, the system is so skewed still in the direction of the pharmaceutical companies and their products that I can't, you know, even get a foot in the door.
So yes, I am full-time researcher trying to do my best to understand this material accurately, and fairly, and objectively, and then to actually act responsibly in response to that knowledge.
Q So in reviewing this information, is it important to carefully look at the data and analyze what's actually presented?
A It's extremely important to look at the methodology. I don't think -- unless a person is actually working at the Food and Drug Administration

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

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

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

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

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

neuroleptic studies of which Risperdal is a member?

A Certainly. One of the things that has happened is that the database or the research (indiscernible), which is actually used to approve medications in this country, psychiatric medications, and then used to continue to argue in their favor, especially in product liability litigation or in a lot of cases. That data set is very limited in terms of generalizability.

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

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

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

problems.

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

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

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

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

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

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

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

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

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

Q So may I interrupt you?

A Sure.

Q Are you saying that when people are withdrawn

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

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

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

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

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

have biased the results in favor of the sugar pill.

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

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

MR. GOTTSTEIN: Yes.

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

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

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

BY MR. GOTTSTEIN

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

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

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

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

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

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

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

Another thing is the way that the data

themselves get reported. And one of the things that is frequently done is to use something called LOCF, or last observation carried forward. So what that means is if you were to enter a study for instance, and they started you on Risperdal, and you start to have a severe side effect, let's say Parkinsonian symptoms, and you dropped out of the study at two weeks, but the study is supposed to end at six weeks, they will carry forward your score to the six-week mark.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q Is -- are these drugs brain damaging?

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

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

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

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

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

scale.
Q And that's -- isn't -- that's a lot of what you referred to as your affidavit, but Exhibit E here, your neurotoxicity paper addresses, isn't it?
A Yes, that's correct. That's really the tragedy of me being born at the time I happened to be born and having to actually live through this and watch this still happening.
But that is, in a nutshell, these are not antipsychotics and they are not neuroleptics. They are prodementics. Or they are medications that are actually contributing to an epidemic of dementia.
I think the states will probably be bankrupted by this in about 20 years. But we are a little bit away from that so far.
Q So is that associated with cognitive declines?
A Oh, this is associated with cognitive decline, it's associated with behavioral decline, where people really have a hard time, you know, modulating self-control and actually modulating their anger and modulating their emotional expression. So cognitive and behavioral.
Q Now, are there physical negatives associated with these drugs, not just -- you mentioned brain --

damage to the brain, but --
THE COURT: And here again, I have to say, it's more helpful for me to hear specifically about the drug that the state's proposing in this case.
BY MR. GOTTSTEIN
Q Is what you're -- Dr. Jackson, is your testimony -- does it apply to Risperidone?
A Certainly. One of the things that's been interesting about Risperidone is that it was the first, quote, unquote, new or -- well, I should back up and say it's actually the second of the newer, quote, unquote, atypicals. The first one was approved in the United States in 1989.
But Risperidone is usually referred to as the first of the new drugs. That's a little bit incorrect. But Risperidone was approved by the Food and Drug Administration in 1993, and really entered use in 1994.
What's been clear in the published studies since its entry into the market is that it is probably the closest to some of the older drugs. 6-milligram and above doses, it replicates Haldol. So even the notion that this is a newer and safer medication has been completely borne out by neuroscience research, that that was a hopeful expectation that has really

not been satisfied.
One of the interesting things about Risperidone compared to some of the other drugs, also, is that it seems to have an association with tumors of the pituitary, prolactinomas. And as prolactin levels stay elevated, men experience sexual side effects, breast enlargement.
But there's also been a long risk, not only in terms of the bones, osteoporosis, but whether or not the prolactin itself could, you know, have any other effect say on the heart or be a reflection of heart damage.
So Risperidone is sort of unique in terms of this connection to brain tumors or the pituitary tumor. So that is one thing.
The other thing that Risperidone, like the other newer medication, is known for is diabetes. So that is one of the main concerns. Not that diabetes can't be treated or can't be regulated in some way, but because of the fact diabetes itself presents risk for further damage to the brain.
And I think it's only in the past, say, three or four years that researchers in the Netherlands have been publishing a series of papers that really demonstrates some of the early dementia changes that

occur in people with diabetes, even if their sugars have been fairly well controlled.
So diabetes itself is tipping into more than just an endocrine disease, but it is becoming a neurological disorder as well.
Risperidone, like the other antipsychotics new and old, but especially these newer medicines, like Seroquel, which is another one, and Risperidone all present risks for other damages to the endocrine system, like the thyroid gland.
And when you actually disrupt thyroid hormone, you also contribute to further damage to the brain in terms of dementia and cognitive abilities. So Risperidone does that, as well.
The other thing with all these medicines, there is the risk for strokes and for heart attacks, and also for leg clots and pulmonary edema. So the risk for sudden death is always there. And that's certainly one of the big concerns with Risperidone.
So diabetes, thyroid disease, heart disease, sudden death, you know, osteoporosis, breast enlargement, sexual changes, and the fact that many of these other problems in the body, again, have an indirect but a potentially very significant effect on the brain function itself. So those are concerns.

Risperidone in animal studies, because we really haven't been doing this yet in humans, also has been shown to increase the levels of a protein called apolipoprotein D, like delta. And this in some studies has been connected with an increased deposition of something called amyloid, amyloid protein or amyloid plaques. And this is one of the main causes or markers of Alzheimers dementia.

So we have some good evidence from the animal studies to understand why it is that patients who already have Alzheimers dementia or people with dementia who have been placed on medicines like Risperidone deteriorate faster and have a progression of their underlying dementia in terms of the actual brain tissue changes themselves.

So Risperidone unfortunately seems to be a medicine that I predict probably in about four or five years, you will see the neurologist will say, hey, people are getting Alzheimers on this medication, or changes that are precursor to Alzheimer's. I am predicting that in about four or five years, that that may be something that we begin to see.

There is already a black box warning on these drugs, including Risperidone, that these drugs are not to be used in elderly people who already have

dementia. But what you're not being told is that these are medications that are actually causing dementia in people who don't already have it.

Q Okay. Now, you refer to them sometimes as antipsychotics. Would you call -- does Risperidone have an antipsychotic property?

A Well, I think what these medications do is that they -- they actually will stop annoying behaviors. And they can make a person so confused or sedated, they can actually inhibit so much brain activity, either electrically or chemically, that the symptoms which some people call psychotic or schizophrenic seem to be at bay. So from that standpoint, people, you know, have called them antipsychotics.

But there is nothing specific about the effects of any class of medication in psychiatry, either a medication is slowing down brain function and brain process or it is speeding them up and enhancing certain brain functioning and processes.

So this whole class of medication which had been historically referred to as neuroleptics or antipsychotics, are in fact medications that are chemical lobotomizers. And I tried to mention some of that history in my affidavit.

The use of the term antipsychotic was really an historic euphemism, once it became unacceptable to mention what these drugs were really doing.

And in fact, what was very important is that in the '60s, and probably throughout the 1960s, doctors were being encouraged it actually give high enough doses of these drugs to cause brain damage, to actually cause Parkinsonian symptoms. And they were trained to believe that until you produced Parkinsonian symptoms in a patient, the drugs were not yet at the level that would actually improve the psychosis itself.

And that has since been borne out as something that was a complete fallacy and a huge mistake. So one thing --

Q If I can stop you.

A Sure.

Q Did you -- and we kind of want to move a little bit faster, if we can. If you can try and really focus on the exact question I ask.

A Sure.

Q But did you -- you reviewed some of Mr. Bigley's history for this, didn't you?

A Yes, I did.

Q And was that that kind of dosing given to

Mr. Bigley during that period?

A Yes. You had shared with me some of the -- some of the records. And I have to say it was limited due to our time constraints.

But the very first hospitalization was -- I just about fell out of the chair when I saw what had happened. I think at one point he was receiving 60, that's 60, 20 milligrams of Haldol three times a day is I think what I read in the record.

The dose of Haldol that is now recognized as, quote, blocking enough dopamine receptors to produce antipsychotic effects, meaning the dose that would typically be thought to be helpful, is 5 milligrams. He was receiving 60 milligrams. So he was receiving a dose that was guaranteed to actually cause Parkinson's disease, and that dose has been shown.

So the short answer to your question is I looked at the doses. And in my opinion, that was really the beginning of, you know, a long demise.

Q Did -- do you recall if those records indicated that Mr. Bigley's symptoms continued in spite of doses that induced Parkinsonism?

A Right. That's why I think the doctor -- well, I know it did, because the doctors themselves were surprised, which made me appreciate the fact that

I was reading a record from 1980 and another record from 1981.

Backing up 27 years ago, 28 years ago, the doctors apparently had been trained in this -- still in the philosophy of care that you administer until you get these side effects. And once you see those side effects, you know the psychosis will be eradicated.

And so when the doctor wrote the note, his delusions continue in their severity and same intensity despite the fact he now has Parkinson side effects, I'm reading to myself, oh, this is fascinating. This is what they used to teach doctors is that they had to give doses to produce Parkinson's in order to heal the psychosis.

But of course, they eventually learned that that did not heal the psychosis. In fact, for many people, including Mr. Bigley, it seemed to make things worse.

Q So is that -- does Risperdal cause psychosis in some people?

A Sure. All of these medications cause psychosis in people. Because of the fact that as you damage the brain and you leave unresolved the initial cause of a person's psychosis, you are really not

treating the initial problems.

I know that Mr. Whitaker has also explained some of this in his affidavit. But the thinking had always been that as you block certain receptors in the brain, research demonstrates that the body reacts to that. And as much as you may try to block something, the brain tries to increase or up-regulate some of those receptors.

And so some patients appear to become more sensitive to those changes. And as their brain responds or adapts to the presence of the drug, it can sometimes go the opposite direction and make the initial symptoms worse. That is called supersensitivity psychosis.

Q So is it fair to say that drugs like -- including Risperdal cause psychosis when it's given and also when it's withdrawn?

A It can be both, either. And it's also fair to say that what many people go on to demonstrate is something which is called tardive, that's T-A-R-D-I-V-E, in many different formations, or many different varieties.

For instance, there have been papers written on the subject of tardive psychosis. And what that means is it's a delayed onset. Tardive basically

means delayed onset. So for tardive psychosis, the implication is that you might start off thinking that you have things licked and that you've really delivered something that seemed to improve things.

Q So --

A But then as -- yeah, as time wears on, things actually are being induced or stirred up by the drug itself.

Q So as I understand it, the withdrawal psychosis symptoms are caused by changes in the brain as a result of the drug such as Risperdal; is that correct?

A Right. I should preface.

Q Okay. And --

A Yeah.

Q And then over time, is it possible if someone is off the drugs for a fairly lengthy period of time that the brain will then re-adjust and the symptoms will go away?

A They are not only possible, but actually been demonstrated in many cases. The key here is to understand how to actually assist people who are trying to come off of medications if they're still taking them, and how to deliver effective intervention so that they're not left with no help or no treatment

at all.

Q So is it fair to say that when someone comes off these drugs, that they -- they ought to be given a fair -- that their initial condition would worsen and they ought to be given, you know, a fairly lengthy period of time to see where they can get to off the drugs?

A I think that's fair. I think there are two phases to drug withdrawal. There is an immediate phase which reflects changes as the drug is actually leaving the brain. And that can take some time. And also changes in the brain receptors, you know, the ones that I mentioned previously that seem to increase in number as the drug is being taken and given. But that is sort of an immediate phase of withdrawal.

There is a longer-term phase of withdrawal in terms of what the brain has experienced in terms of rewiring or anatomic structural damage. And so that long-term phase of withdrawal means that someone might appear to be better for a while, and then five or six months later might have some setbacks.

And many people unfortunately are still not trained enough to understand the fact that the recovery process, the rehabilitation or repair of the brain actually can require many months. So I think it

would be fair to say that withdrawal takes some time.
Q Okay. I'm going to try to move it to another topic here.
THE COURT: And, Mr. Gottstein, just to give you a head's up, we've been close to an hour here. So what's your timeframe?
MR. GOTTSTEIN: Well, I -- I'm really concerned about that, too, and especially we've got -- I think this is important, obviously, and I know Your Honor does, too.
One of my big concerns is I've got people standing by for cross examination.
THE COURT: So maybe we need to finish up. I have really tried to indicate several times that hearing about medications generally is not as helpful as hearing about what is -- what the state's proposal is in this particular case.
MR. GOTTSTEIN: Well, and I understand, Your Honor, that she is actually saying all of this applies to Risperdal.
BY MR. GOTTSTEIN
Q But one of the things that the state's proposed is -- or the hospital has proposed is to include a benzodiazepine, I think Ativan, was it, and Clonopin I think. What can you say about that

combination?
A Well, I don't think the combination is anything that really eliminates or speaks to the problems I've already identified. It certainly is not going to prevent Risperidone's effects in terms of causing, you know, or enhancing dementia that's already there. It's not going to prevent diabetes. It will prevent the other problems.
So while I think it's better to use perhaps benzodiazepine briefly for someone who is having certain kinds of problems, its addition in this case, in no way avoids the concerns or the problems of Risperidone by itself.
Q Okay. Now, you indicated before that you reviewed I think the -- was it the submission for representation hearing and attachments to that?
A I have to go back to the documents. I reviewed the affidavits I believe by --
Q Was one of those Paul Cornils?
A Yes. Mr. Cornils is the one that I have read, and the affidavit by -- is it Bassman or Bassman?
Q Bassman, Dr. Bassman.
A Dr. Bassman. And also have read Mr. Whitaker's affidavit and portions of the record,

yes.
Q Now, do you have any comments about Mr. Cornils' affidavit?
A Well, I thought the plan that Mr. Cornils had outlined was an exceedingly thorough, and one that I was, to be quite honest, envious of. If I were in the situation of API or a provider at that facility, I would want to have many of Mr. Cornils' and plans like this.
So I thought this looked like a very solid and a very reasonable proposal, you know, as a first step.
Q Okay. And from what you can tell, how much of -- what do you think is seen in Mr. Bigley's behavior is a result of brain damage from the drugs?
A Gosh, I think at this point it becomes very difficult to separate out in my opinion what would be appropriate outrage at what had happened even 28 years ago and what's biological. I think it's -- it's reasonable to address both psychological contributions and the biological. So I can't give you an exact answer to that.
Q Okay. Now, do you think that it's wise to continue with this neuroleptic medication for -- at this point?

A I think it would be very unwise for a lot of reasons.
Q Okay. And finally, this I think will be my last question. What would you say about if -- about Mr. Bigley saying, quote, you just wanted to throw me in a cage, lock me up like an animal, take all my money, and try to poison me, end quote?
A Well, if one just heard that without understanding the context or this person's history, one might think that sounds a bit outrageous or a bit extreme. But having read even the few notes from this person's medical history, I would say that sadly enough, that's exactly what has been happening to this man for 28 years.
MR. GOTTSTEIN: I have no further questions, Your Honor.
THE COURT: Thank you.
Mr. Twomey, go ahead, please.
MR. TWOMEY: Yes. Thank you, Your Honor.
DR. GRACE JACKSON
testified telephonically as follows on:
CROSS EXAMINATION
BY MR. TWOMEY
Q Dr. Jackson, have you ever practiced medicine in the State of Alaska?

A No, I have not.
Q Are you familiar with the standard of care for physicians practicing psychiatry in Anchorage, Alaska?
A Actually, I sort of don't know how to respond to the words standard of care. That is a legal term. But maybe if you explain what you mean by that, I could answer your question more clearly.
Q Are you critical of psychiatrists based on the fact that they prescribe neuroleptics?
A I'm not critical of psychiatrists per se. I am critical of the lack of attention or consideration of informed consent and science.
Q Would you agree that psychotropic medication is widely accepted within the psychiatric community as an effective treatment for psychosis, particularly schizophrenia?
A Oh, I would agree that it has wide acceptance. But I would disagree with the imputation or the inference that it is, you know, effective.
Q And that's despite the fact that the Food and Drug Administration has approved these medicines?
A No. It's based on the fact that the Food and Drug Administration, by its own admission, doesn't receive all the information that they need to even

weigh on the safety or effectiveness of these drugs.
Q So you are critical of the process, is that correct, in terms of approving these drugs?
A Oh, I am critical of the process of approving, and I am critical of the process of oversight after they are approved, and I am critical of the way in which they are used.
Q Have you ever met Mr. Bigley?
A No, I have not.
Q Have you reviewed his entire medical history?
A No. I have reviewed some select portions of it.
Q Are you being paid for your testimony today?
A Yes. I will be paid for my testimony.
Q What do you charge?
A Usually I charge $2,000 for a full day of court hearings, or $1,000 for a half a day. And Mr. Gottstein or the Law Project for Psychiatric Rights had agreed to compensate me according to my usual wage or rate of $1,000 for a half a day.
Q How much time have you spent reviewing and preparing for today's testimony?
A Probably about ten hours. Those are not being reimbursed, by the way. I am only being paid for my testimony today.

Q What is your understanding of what it is that the state is proposing to do with regard to Mr. Bigley at this point?
A Well, my understanding of the situation is that the state was going to be doing business as usual. And that is to continue sort of the in and out cycle of hospitalizations, revamping previous or new treatment plans, and then discharging, and then sort of repeating that process over again as it might become necessary.
Q And what do you base that understanding upon?
A I have looked at the records. I have also reviewed -- let me see if I can cite the right document for you, because I want to be sure I understand how it's been referenced.
Mr. Gottstein had sent me a copy of the motion for less-intrusive alternatives. And basically, I am basing my understanding of the state's proposal on that motion.
Q Does Mr. Bigley suffer from dementia?
A I really can't diagnose Mr. Bigley from being in North Carolina, not having reviewed his full medical records and not having met with him.
But I can say that from what I know already of his previous treatments and from what I have seen

in the records that have been made available to me, I would say it would not be unreasonable to suggest that he is chemically brain injured at this point.
And there are elements which would support an argument for dysmentia, if not dementia. There are two different ways of using that term. But I would hesitate -- to answer your question, Mr. Twomey, I would not want to apply a diagnosis in a haphazard fashion on a patient I have not met.
Q Does Mr. Bigley have diabetes at this point in time?
A There is nothing I have seen in the records that were given to me that showed diabetes. But on the other hand, I should say there is nothing that demonstrates he has been tested for the same.
Q Would you agree with me that many drugs have side effects, yet it is still appropriate for physicians to prescribe such medicines?
A Oh, I -- sure, I would agree that many, many medications have side effects. And their use really is dependent upon an accurate and fully informed consent. Unfortunately, that is lacking in the case of most psychiatric drugs.
Q Is it your opinion that Risperidone should not be prescribed in any case?

A I would have to think about that. You sort of catch me off guard. There may be some uses that we have not fully thought through.

For instance, I would have to review the literature on cancer and see if Risperidone has some possible uses in cancer.

But for the current indication of attempting to assist a person with psychotic symptoms, let's say, I would be concerned about its use as really taking people further away from the intended result.

Q Have you ever prescribed Risperidone in your practice?

A Certainly I did when I was in my medical school -- in medical training, and while I was in the service.

And if I have been -- in studying since that time, the Department of Corrections or in the Veteran's Administration system, where people were previously on that drug, I do not endanger people by abruptly stopping therapies or treatments.

But I have not started any patients on Risperidone since I came to the realization of what these medications are doing and what the alternatives are.

Q And what did you come --

A (Indiscernible.)

Q I'm sorry. When did you come to the realization --

A The first awareness was in 2001. But I really crystallized that view, so about 2001, and then 2002.

Q Okay. So am I correct in understanding that since that date, you have not started any of your patients on Risperidone?

A That's correct.

Q Okay. But you have continued patients on Risperidone; is that correct?

A Certainly. I would not endanger people by abruptly stopping treatments that other doctors have begun.

Q Okay. What dangers are presented by what you say, abruptly stopping treatment?

A Well, if a person is not going to have care from a doctor who will be able to monitor the interruption or cessation of therapy, some patients can have problems. So that would be the main one, is to be able to have continued oversight, to not just cut people off and not be able to see how they're doing as the medication is actually leaving their system.

Q Are you able to quantify in Mr. Bigley's case any of the risks presented by Risperidone at this point in time?

A I'm sorry; your question was quantify?

Q Yes. In terms of likelihood or percentage.

A Oh, likelihood or percent. Gosh, you know, that is an interesting question. I don't think I've ever been asked that before. I don't typically quantify for anyone percentages of what might happen.

But I'll tell you, there is one exception, and that is in terms of what's been published on the possibility of tardive, T-A-R-D-I-V-E -- tardive dyskinesia. And to address that, I should probably mention that one of the studies that I have found very important, you know, since it was published in 2006 is a study that found that Risperidone and the other drugs like it actually had a 5 percent prevalence of tardive dyskinesia. This was just in the first years of their use.

And for people who have been on the medications for longer than just starting them, you know, for just being on them brand-new, say like within the first month, 20 percent of the patients on drugs like Risperidone had already developed tardive dyskinesia.

So I usually tell people that you know there is, you know, a real risk, not just an imaginary risk, that the new drug, including Risperidone, is a medicine that can cause tardive dyskinesia, even in the first years of use. And I think it's really important for patients to know that that is a real risk.

So as high as 5 to 20 percent of the patients on Risperidone will develop tardive dyskinesia symptoms in the first years of use.

Q Is that a risk that is commonly understood in the psychiatric community?

A No, not at all. Most doctors ignore this. They don't really pay attention to it.

That's why this paper was so important when it was published. It was published by Jose DeLeon in 2006 in Kentucky. And it was based on doing a cross-sectional survey of inpatients and outpatients over 500 patients that were participating in another study.

And fortunately, these authors are the people doing the study. Once they were finding that so many people on the new drugs, even people who had just started the new drug, were having tardive dyskinesia, they took the time to write it up and publish it.

It's not commonly known, but it should be.
Q Does Mr. Bigley suffer from tardive dyskinesia?
A I don't know. I haven't evaluated him in person to know if he has those symptoms. I haven't seen them mentioned in the records that were shown to me. I have seen references to Parkinsonian symptoms before. And Parkinsonian symptoms, even if they are historical, are believed to place people at greater risk for developing or having tardive dyskinesia, as well.
Q Are you able to quantify the risk of tardive dyskinesia in Mr. Bigley's case at this point?
A Oh, I would -- quite realistically, I would say that he should have tardive dyskinesia. It is astounding to me that he doesn't already have it.
And I would say that there is a high likelihood that Mr. Bigley will have it within the next five to ten years if he's placed back on Risperidone.
There is also a high likelihood he is simply just going to die in the next five years if he is placed on Risperidone. I don't think that's really unreasonable or irrational to make that comment based on what he's had before.

Q Exhibit E, your analysis of neuroleptic toxicity, has that been peer reviewed?
A Oh, that document itself has not been peer reviewed, but all the studies that I have cited have been peer reviewed and appear in mainstream or major journals.
MR. GOTTSTEIN: I have nothing further for you. Thank you.
THE COURT: Mr. Gottstein.
MR. GOTTSTEIN: Yes.
DR. GRACE JACKSON
testified telephonically as follows on:
REDIRECT EXAMINATION
BY MR. GOTTSTEIN
Q Dr. Jackson, I would like to just briefly go through maybe what you reviewed. Did you review the -- I think it was called submission for representation hearing and exhibits to that, including the affidavit of -- affidavits of Mr. Whitaker, Dr. Bassman, Paul Cornils, and then the medical records attached to that?
A I don't believe I know -- I can tell you what I've looked at. I don't believe I've looked at everything you might be citing because it was a very large document, that I communicated to you I was

having problems opening.
I have looked at and reviewed the affidavit of Dr. Bassman, the affidavit of Mr. Cornils. I have reviewed the motion for less-intrusive alternative. I have reviewed Mr. Whitaker's affidavit.
And I have also reviewed portions of the medical history. And I can tell you exactly which ones I have seen. I have seen hospital records from the initial hospitalization dated -- date of admission was April 15. That's 4/15/1980, the discharge summary.
I have then reviewed the admission -- or I'm sorry, the discharge note, discharge summary from a hospitalization which was in February of 1981 through May of 1981.
And I believe the last portion of the records that I had been sent would be the hospital record -- this was February of 2007, API hospitalization No. 68.
And then again, I think the last thing that I had seen was a medical progress note which was signed by a Dr. Lucy Curtis dated March 16, 2007, and an API contact of March 19, 2007 with regard to blood tests for Depakote.
And that is the extent of the records that I have seen. Oh, I have also seen the log -- log sheet

from Monday, May 12th, 2008.
Q Okay. Thank you. Now, you testified that -- that it would be preferable I think to gradually withdraw someone from Risperidone because of problems with abrupt withdrawal; is that correct?
A Right. I think a lot of that depends on context. It's hard to make a general statement. It depends on the previous dose and if there is an emergency situation.
Q Now, what about if someone refuses to take it?
A If someone refuses to take it, again, I think it depends on the context. I think if someone is refusing to take it, there is no reason to start it over again for the sake of doing a withdrawal. It really depends on the context.
Q Okay. With respect to tardive dyskinesia, is this 5 -- 5 percent, is that considered cumulative for example, that 5 percent per year? So the second year would tend to be 10 percent, third year 15 percent? Is that your understanding?
A Well, I believe the idea of cumulative risk really came out of a Yale study, and was mostly speaking about the older antipsychotic medicines. Nobody that I know of has yet published data on

cumulative incidents or the cumulative, you know, risk for the newer medications.

And the study that I had just briefly mentioned, Jose DeLeon study that was published two years ago, was unfortunately not able to really give us an incidence or cumulative incidence. It was more a cross-sectional shotgun, people who had never been on the drugs who were just newly started.

And 5 percent of those people who were just beginning these new drugs developed tardive dyskinesia early in the course of their exposure. In that study, 20 percent of those who had already been on the atypicals for just a short period of time had TD.

Q Thank you. And then Mr. Twomey asked you about your analysis not being peer reviewed. That was true of your analysis of olanzapine in 2003 in the Myers case, isn't it?

A That's correct, that analysis (indiscernible).

Q And that is your analysis of olanzapine, which is Zyprexa? Has that been borne out by subsequent studies and revelations?

A It's actually been borne out in terms of the attachment of black box warnings that pretty much were pertinent to my testimony.

MR. GOTTSTEIN: Okay. I have no further questions.

THE COURT: Follow-up at all on those topics, Mr. Twomey?

MR. TWOMEY: I have nothing further, Your Honor.

THE COURT: All right. Thank you very much, Dr. Jackson. You can be excused at this time.

THE WITNESS: Thank you, Your Honor.

THE COURT: Okay. Bye bye.

THE WITNESS: Bye bye, now.

(Witness excused.)

THE COURT: Your next witness is Dr. Hopson.

MR. GOTTSTEIN: Your Honor, I've -- Dr. Bassman and Mr. Whitaker both had to adjust their schedules to be available for a cross examination. I'm wondering if maybe we could do their cross examination now.

THE COURT: Do you have questions for either Dr. Bassman -- it was Dr. Bassman or who else?

That's fine. Go ahead.

MR. BIGLEY: I'm truly sorry, okay.

THE COURT: That's all right. Go ahead.

MR. GOTTSTEIN: Bill -- he would like to be excused.

THE COURT: He can be excused. That's fine.

That's fine, Mr. Bigley. You can be excused. You're all right.

All right. So, Dr. Bassman, do you have cross examination?

MR. TWOMEY: Well, I may not, Your Honor, depending on whether we can have a stipulation that Dr. Bassman is not familiar with the standard of care here in Anchorage.

THE COURT: Any disagreement with that?

MR. GOTTSTEIN: I think you should explore that with Dr. Bassman.

THE COURT: All right. I cannot go after 12:00 today. I just have to go on record in that regard.

MR. TWOMEY: Your Honor, my preference would be to --

MR. GOTTSTEIN: I don't think that that's relevant to his testimony.

THE COURT: Well, you can certainly explore the issue on cross. The standard of care in Alaska, I think --

MR. GOTTSTEIN: I would stipulate to that.

THE COURT: All right. That Dr. Bassman is not familiar with the standard of care as to what

issue specifically?

MR. TWOMEY: As to the administration of Risperidone by psychiatrists in the State of Alaska.

THE COURT: I am showing Dr. Bassman as a Ph.D., correct?

MR. GOTTSTEIN: And his testimony was really on less-intrusive alternatives.

THE COURT: So Dr. Bassman is not testifying about medication administration at all? I mean, I'd have to go back and look at his affidavit.

MR. GOTTSTEIN: There's some in there. But it's mainly about --

THE COURT: But he is a psychologist, not a psychiatrist?

MR. GOTTSTEIN: Correct.

THE COURT: So your proposed stipulation, just to state it again, Mr. Twomey?

MR. TWOMEY: Well, one moment, Your Honor. I want to take a look at Dr. Bassman -- or Ronald Bassman's affidavit. If I could have a stipulation that Ronald Bassman is not a medical doctor, but he is --

THE COURT: That's fine.

MR. TWOMEY: That his affidavit goes only to the issue of a less-restrictive alternatives.

MR. GOTTSTEIN: Less intrusive, I think.
MR. TWOMEY: Less-intrusive alternative.
THE COURT: All right. Is that the entirety of your proposed stipulation?
MR. TWOMEY: Yes, Your Honor.
THE COURT: All right. That Dr. Bassman is not a medical doctor, and his affidavit is intended to focus exclusively on the less-intrusive alternative. Am I stating it correctly, your position, Mr. Twomey?
MR. TWOMEY: Yes, Your Honor.
THE COURT: All right. Mr. Gottstein, is that stipulation acceptable?
MR. GOTTSTEIN: That's fine.
THE COURT: All right. So that then with that stipulation, Mr. Twomey, you are not seeking to have Dr. Bassman for cross; am I correct?
MR. TWOMEY: That's correct, Your Honor.
THE COURT: That brings us then next, Mr. Gottstein, there was another individual you indicated.
MR. GOTTSTEIN: Yes. Mr. Whitaker.
MR. TWOMEY: If we could have a stipulation, Your Honor, that Mr. Whitaker is a journalist and not a medical doctor.
THE COURT: Any disagreement with that

proposed stipulation?
MR. GOTTSTEIN: Well, I can stipulate that he is not a medical doctor. But he is also an expert in the study in analyzing clinical trials. He actually had a business that did that, that was so well thought of that it was purchased. So he's an expert in the analysis of clinical studies.
THE COURT: The state's proposing the stipulation that Dr. Whitaker is a journalist.
MR. GOTTSTEIN: It's Mr. Whitaker.
THE COURT: I'm sorry, Mr. Whitaker. And I see that as the first phrase of paragraph 1, that he is a journalist. So there is no dispute there; is that correct?
MR. GOTTSTEIN: Correct.
THE COURT: And what is the balance of the stipulation that, Mr. Gottstein, you were proposing?
MR. GOTTSTEIN: Well, I think the affidavit speaks for itself. But I would just -- and it talks about his history of and expertise in analyzing clinical studies.
THE COURT: From the perspective of a journalist; is that agreeable?
MR. GOTTSTEIN: But he also had a business of analyzing clinical studies, and people paid money to

get that -- those analyses.
THE COURT: Is that discussed in the --
MR. GOTTSTEIN: I think that it is. 1D.
THE COURT: 1D. On what page is that?
MR. GOTTSTEIN: It's the first page.
THE COURT: Oh, I see. So --
MR. TWOMEY: Well, Your Honor, I'll stipulate that he owned a company from 1994 to 1998 when he sold the company. And --
THE COURT: It reported on the clinical development of new drugs?
MR. TWOMEY: Yes.
THE COURT: All right. Is that agreeable? That's what the individual said in that affidavit.
MR. GOTTSTEIN: Yeah. And I certainly would stipulate to that. Also he is an expert on this -- on the analysis of clinical studies.
MR. TWOMEY: Well, the analysis of clinical studies is not at issue in this case, Your Honor. I propose that we stipulate that Mr. Whitaker has no direct testimony pertaining to Mr. Bigley or the treatment proposed for Mr. Bigley in this case.
THE COURT: How about -- does the affidavit simply speak for itself? I mean, I haven't heard anything yet that's not in the affidavit. You

certainly have the right to cross if there are topics you wanted to explore. But is it --
MR. GOTTSTEIN: (Indiscernible.)
THE COURT: Well, no. But --
MR. TWOMEY: I am not really particularly interested in cross examining this witness on issues that don't relate to Mr. Bigley.
THE COURT: Is there any reference at all in this to Mr. Bigley? As I understand it, there is none.
MR. GOTTSTEIN: No.
THE COURT: All right. So, Mr. Twomey, can the affidavit stand as written?
MR. TWOMEY: Yes.
THE COURT: No stipulation from either side? It's simply he is the journalist as indicated in his affidavit. All right. Very good.
Then that brings us to -- Mr. Twomey, do you seek to cross examine Mr. Cornils on his affidavit?
MR. TWOMEY: Yes, Your Honor.
THE COURT: All right. And then who else is available right now?
MR. GOTTSTEIN: We've got Dr. Hopson and Ms. Altaffer here.
THE COURT: All right. Well, what can we

A Yes.
MR. GOTTSTEIN: Okay. No further questions.
THE COURT: Okay. Any redirect? We're done.
MR. TWOMEY: I'm not sure where we were, Your Honor. I think I was questioning.
THE COURT: I think you might have been.
MR. GOTTSTEIN: Oh, I thought -- I thought we were on cross.
THE COURT: Oh, no. The clerk agrees with you there, Mr. Twomey. Go right ahead. I think I was, and that's what got us a little off track there. So go right ahead.

DR. RAYMOND HOPSON,
testified as follows on:

RECROSS EXAMINATION
BY MR. TWOMEY

Q Dr. Hopson, have you had an opportunity to review the affidavit of Robert Whitaker?
A Yes.
Q All right. Do you have any comments upon the conclusions set forth in his affidavit?
A I would have to see his direct conclusions again. It's been a few weeks. However, I would disagree with them.
MR. GOTTSTEIN: Objection, Your Honor, in

terms of this would not be based on again the Daubert objection.
THE COURT: Well, he's indicated he's not -- I guess I don't find Dr. Hopson's testimony in this particular point that helpful when he indicated he hadn't reviewed this in a few weeks. So if there is specific points you wanted to bring up, and then we can see.
But I have to leave here. So what we can do is continue this tomorrow. I want to give each side an opportunity.
I also don't want to have the doctor inconvenienced any more than necessary. So what is your thought on how to proceed?
MR. TWOMEY: How much more time do you have available?
THE COURT: Negative five minutes.
MR. TWOMEY: Well, then I guess we will have to come back tomorrow.
THE COURT: I can do 10:00 a.m. tomorrow. Is that convenient for both sides? And we can take up Dr. Hopson then. I apologize for that. But let's do 10:00 a.m. tomorrow.
And then you'll have an opportunity if you'd like to look at the affidavit again, knowing that

that's the next question.
Anything further today, Mr. Twomey?
MR. TWOMEY: No, Your Honor.
THE COURT: All right. And 10 to 12, will that complete -- that is an extra two hours, Mr. Gottstein. I am going to assume that is more than sufficient. Am I reasonable in that assumption?
MR. GOTTSTEIN: I think it should be.
THE COURT: Well, I guess it has to be, is what I am indicating.
MR. GOTTSTEIN: Oh, okay. Yeah.
You said you wanted to cross examine Mr. Cornils?
MR. TWOMEY: Yes, Your Honor. Or yes.
THE COURT: All right. So he will be available, as well, tomorrow.
So 10:00 a.m. tomorrow. We can go off record. Thank you all. We'll see you tomorrow. Thank you.
(Off record.)
12:06:22

TRANSCRIBER'S CERTIFICATE

I, Jeanette Blalock, hereby certify that the foregoing pages numbered 103 through 194 are a true, accurate, and complete transcript of proceedings in Case No. 3AN-08-00493 PR, In the Matter of WB: William Bigley, Motion Hearing held May 14, 2008, transcribed by me from a copy of the electronic sound recording, to the best of my knowledge and ability.

_____
Date Jeanette Blalock, Transcriber