IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

JEFFREY THELEN,

Plaintiff,

v.

SOMATICS, LLC; AND ELEKTRIKA, INC., Case No.: 8:20-CV-1724

Defendant.

VOLUME I OF VII (pp. 1-252)

JURY TRIAL PROCEEDINGS BEFORE THE HONORABLE THOMAS P. BARBER

> May 31, 2023 8:38 a.m. to 4:56 p.m.

APPEARANCES: FOR THE PLAINTIFF:

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(Proceedings recorded by mechanical stenography, transcript produced by computer-aided transcription.)

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	Vol	. I, Pg. 2
1	INDEX	
2		PAGE
3		
4	Preliminary Jury Instructions	157
5	Opening Statement by Mr. Esfandiari	174
6	Opening Statement by Ms. Cole	185
7	PLAINTIFF'S WITNESSES	PAGE
8 9	JOHN READ, PhD Direct Examination by Mr. Esfandiari	194
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
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Preliminary Jury Instructions

1 2 (Jury was duly sworn.) 3 THE COURT: All right. Members of the jury, now that 4 you've been selected and sworn, I need to explain some basic principles about how a civil trial works and your duty as 5 6 jurors. These are preliminary instructions that will take me 7 about ten minutes to read. At that point, you'll then break 8 for lunch, and then we'll come back and start the trial after 9 you go to lunch. I'll give you more detailed instructions 10 about the law at the end of the trial. 11 It's your duty to listen to the evidence, decide what 12 happened, and apply the law to the facts. It's my job to provide you with the law you must apply, and you must follow 13 14 the law even if you disagree with it. As previously mentioned, 15 this is a civil case. 16 To help you follow the evidence and apply the law, 17 I'll summarize the parties' positions now. 18 Plaintiff, Jeffrey Thelen, claims he sustained 19 injuries in connection with electroconvulsive therapy 20 treatments he received from medical professionals using a 21 device manufactured by Defendant Somatics, LLC, known as the 22 Thymatron System IV. Throughout the course of the trial you may hear the parties and witnesses refer to this as a device or 23 24 a machine or the ECT machine or device. 25 More specifically, Mr. Thelen claims that the ECT

Preliminary Jury Instructions

device was not accompanied with sufficient warnings, and
 because of that, he stained injuries. Defendant Somatics
 denies that warnings were insufficient and further denies that
 Thelen sustained injuries as a result of its action. Somatics
 further maintains that Mr. Thelen's claims are barred by the
 statute of limitations.

How trials work. Before we proceed, it is important
for everyone to understand how trials work. First, each
side -- has anyone been on jury duty that got selected?
Anyone? All right. Three of you have. That's right. We
talked about that. So it is review for some of you. It's new
information for others.

At the beginning, what happens is the attorneys are given an opportunity to make a 15-minute opening statement. This is their opportunity to tell you a preview of what they believe the evidence is going to be. It is not evidence. It is simply a road map of what they expect the evidence to be.

Next, the plaintiff will present his witnesses and ask them questions. After the plaintiff questions witnesses, the defendant may ask the witness questions. This is called cross-examining the witness. Then the defendant will present his witnesses, and the plaintiff may cross-examine them.

You should base your decision on all the evidence, regardless of which party presented it. And we may take some witnesses out of order as the trial goes for everyone's

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convenience. When that happens, I will let you know. But what I just explained is the general way things proceed.

Preliminary Jury Instructions

After all the evidence is in, I will give you a detailed explanation on the law you must apply in deciding this case. After that, the lawyers will present their closing arguments to summarize and interpret the evidence for you. I will then give you one final instruction on the law, and you will go to the jury room to deliberate.

9 Types of evidence. You must decide the case only on 10 the evidence presented in the courtroom, and it can come in 11 many forms. It can be testimony about what someone saw, heard, 12 or smelled. It can be an exhibit or a photograph. In some 13 instances, it can even be someone's opinion.

Some evidence may prove a fact indirectly. Let's say a witness saw wet grass outside and people walking into the courthouse carrying well umbrellas. This may be indirect evidence that it rained, even though the witness didn't personally see it rain. Indirect evidence like this is also called circumstantial evidence. It's simply a chain of circumstances that likely proves a fact.

As far as the law is concerned, it makes no difference whether the evidence is direct or indirect. You may choose to believe or disbelieve either kind of evidence. Your job is to give each piece of evidence whatever weight you think it deserves.

Preliminary Jury Instructions

1 During the trial, you'll hear certain things that are 2 not evidence, and you must not consider them. First, the 3 lawyers' statements and arguments aren't evidence. In their 4 opening statements and closing arguments, the lawyers will 5 discuss the case. Their remarks may help you follow each 6 side's arguments and presentation and evidence, but the remarks 7 themselves aren't evidence and shouldn't play a role in your 8 deliberations.

9 Second, the lawyers' questions and objections aren't 10 evidence. Only the witness's answers are evidence. Don't 11 decide that something is true just because a lawyer's question 12 suggests that it is. For example, a lawyer may ask a witness, 13 "You saw Mr. Jones hit his sister, didn't you?" That question 14 is not evidence of what the witness saw or what Mr. Jones did, 15 unless the witness agrees with it.

16 Objections. There are detailed rules that control 17 what can be considered evidence in a trial. When a lawyer asks 18 a witness a question or presents an exhibit, the opposing 19 lawyer may object if he or she thinks the rules of evidence 20 don't permit it. If I overrule or deny the objection, then the 21 witness may answer the question or the exhibit may be admitted 22 for your consideration. If I sustain or grant an objection, 23 then the witness cannot answer the question and the exhibit cannot be considered. When I sustain or grant an objection to 24 25 a question, you must ignore the question and not guess what the

1 answer might have been.

Sometimes I may disallow evidence, this is also called striking evidence, and order you to disregard or ignore it. That means you must not consider that evidence when you are deciding the case. Or in some instances, I may allow some evidence for only a limited purpose. When I instruct you that I have admitted an item of evidence for a limited purpose, you must consider it only for that purpose and no other.

Preliminary Jury Instructions

9 Credibility of witnesses. To reach a verdict, you 10 may have to decide which testimony to believe and which 11 testimony not to believe. You may believe everything a witness 12 says, part of it, or none of it.

13 When considering a witness's testimony, you may take 14 into account the witness's opportunity and ability to see, 15 hear, or know the things the witness is testifying about, the 16 witness's memory, the witness's manner while testifying, and 17 any interests the witness has in the outcome of the case, any 18 bias or prejudice the witness may have, any other evidence that 19 contradicts the witness's testimony, the reasonableness of the 20 witness's testimony in light of all the evidence, and any other 21 factors affecting believability. At the end of the trial, I'll 22 give you additional guidelines for determining a witness's 23 credibility.

Burden of proof. And I mentioned this earlier, butI'm going to mention it again, the plaintiff has the burden of

Preliminary Jury Instructions

1 proving his case by what the law calls a preponderance of the 2 evidence. That means the plaintiff must prove that, in light 3 of all the evidence, what he claims is more likely true than not. So if you could put the evidence favoring the plaintiff 4 5 and the evidence favoring the defendant on opposite sides of 6 balancing scales, the plaintiff needs to make the scales tip to 7 his side. If the plaintiff fails to meet this burden, you must 8 find in favor of defendant.

9 To decide whether any fact has been proved by a 10 preponderance of the evidence, you may, unless I instruct you 11 otherwise, consider the testimony of all witnesses, regardless 12 of who calls them, and all exhibits that are admitted, 13 regardless of who produced them.

After considering all the evidence, if you decide a claim or fact is more likely true than not, then the claim or fact has been proved by a preponderance of the evidence.

17 Affirmative defenses. On certain issues called affirmative defenses, the defendant has the burden of proving 18 19 the elements of a defense by a preponderance of the evidence. 20 At the close of the case, I'll instruct you on the facts that 21 the defendant must prove for any affirmative defense. After 22 considering all the evidence, if you decide that the defendant 23 has successfully proven that the required facts are more likely true than not, the affirmative defense is proved. 24

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Now, while serving on the jury, you may not talk with

Preliminary Jury Instructions

1 anyone about anything related to this case. You may tell 2 people that you're a juror and give them information about when 3 you must be in court. But you must not discuss anything about the case itself with anyone. Don't read or listen to the news 4 5 accounts of this case, if any. Don't visit any places related 6 to this case or research any fact, issue, or law related to 7 this case. The law forbids jurors to talk with anyone else 8 about the case and forbids anyone else to talk to the jurors 9 about it.

10 You shouldn't even talk about the case with each 11 other until you begin your deliberations. Premature 12 discussions may lead to a premature decision. You want to make 13 sure you've heard everything, all the evidence, the lawyers' 14 closing arguments, and my instructions on the law before you 15 begin deliberating. You must keep an open mind until the end 16 of the trial. For these reasons, the jury is not permitted to 17 deliberate during the course of the trial. It must wait until 18 the close of the case to begin deliberating.

Now, in this age of technology, I want to emphasize that in addition to not talking face-to-face with anyone about the case, you must not communicate with anyone about the case by any other means whatsoever. This includes e-mails, text messages, phone calls, and the Internet, including blogs, chat rooms, social networking websites, and apps, such as Facebook, Instagram, Snapchat, Twitter, and the like. You may not use

Preliminary Jury Instructions 1 any similar technology of social media, even if I have not 2 specifically mentioned it to you here.

3 No independent research. Similarly, you must not seek any information about the case from anyone by any means 4 5 whatsoever. Do not attempt to independently research anything 6 relating to this case, including the facts, people, places, 7 issues, or the law. You are not allowed to gather information outside of court about this case in any way whatsoever, 8 9 including discussions with others, by the library, the 10 Internet, computers, or other electronic means, or any other 11 means or sources of information whatsoever.

Because electronic research and fact gathering has become such a big part of our daily lives, I need to get into that in even more detail. I know this was already covered in the orientation video, but it is an area where we have had problems, so it requires emphasis.

17 You are not allowed to use computer search tools, 18 such as Google or otherwise, to search for any information 19 whatsoever about the case or the laws that apply to the case or 20 the people involved in the case, including the parties, the 21 lawyers, the witnesses, or me. Recognizing that technology is 22 generally regarded as a good and helpful part of our daily lives, it's important for you to understand the reason why I'm 23 24 making such a big deal about this.

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As they mentioned in the orientation video, if you

1 investigate, research, or make inquiries on your own, outside 2 of the courtroom, we have no way to assure they are proper and 3 relevant to the case or that the information you gather on your own can be legally considered under our laws and court rules. 4 5 The parties likewise have no opportunity to dispute the 6 accuracy of what you find or to provide rebuttal evidence to 7 That is contrary to our judicial system, which assures it. 8 every party the right to ask questions about and rebut the 9 evidence being considered against it and to present arguments 10 with respect to that evidence. Independent research and investigation by jurors unfairly and improperly prevents the 11 12 parties from having the opportunity our judicial system 13 promises.

Preliminary Jury Instructions

Any juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over.

A mistrial is a tremendous expense and inconvenience to the parties, the courts, and the taxpayers. I trust that you understand and appreciate the importance of following these rules in accord with your oath and promise. I know you will do so.

Now, I have a few other things I need to mention to you before we actually start the trial. But this is a good point to break for lunch. When you come back, we're going to give you a tablet for note-taking. I'll explain how that

Preliminary Jury Instructions

works.

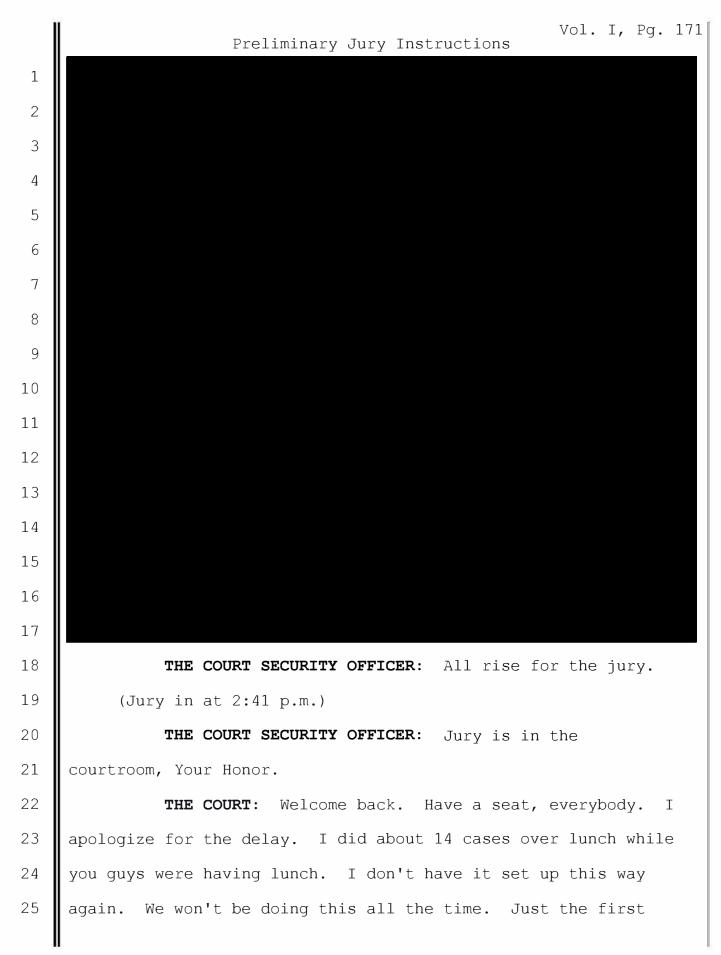
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2 Let's take one hour for lunch right now or an hour 3 and five minutes. So what is it, ten after one? If you'd be 4 back, what, at 2:15? It's a little more than an hour. Now, 5 you can go for lunch. We beat the lunch crowd. Downtown Tampa 6 is set up well for lunch. There's a bunch of restaurants. 7 When you go out the front door, just kind of keep going in that direction. If you go to the right and head north, there's 8 9 nothing there. If you head left to the south, there's some 10 restaurants there. If you go behind the building, you're going 11 to have to walk pretty much to Ybor City before you find 12 anything.

I'd encourage you not to drive in your cars unless you're very familiar with downtown Tampa. There's a lot of one-way streets, parking meters. You'll spend your whole lunch hour driving around if you don't know exactly where to go. But that's up to you. You can do it however you'd like. The restaurants are generally out the front door. Just keep walking straight, and you'll find some stuff.

I think we're good. Anybody have any questions
before you break for lunch? Steve will have some information
for you as well on parking and things like that. Any questions
for me? Yes?



Preliminary Jury Instructions

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day today, we have this little obstacle.

2 We are ready to go. You have been given a notepad 3 there. If you wish to take notes, you may take notes to help 4 you remember things. If you do take notes, please don't share 5 them with anyone until you go to the jury room to decide the 6 case. Don't let note-taking distract you from carefully 7 listening to and observing witnesses. Whether or not you do 8 take notes, you should rely on your own memory of the 9 testimony. Your notes are there only to help your memory. 10 They're not entitled to greater weight than your memory or 11 impression about the testimony. At the close of the case, your 12 notes will be destroyed. They are not kept for inspection or 13 part of the official court record. Nobody, including me, will 14 ever read any notes if you choose to take them.

15 If you want to take notes, even if you don't want to 16 take notes, I'd ask you to just take that first sheet that you 17 have and write your name on the first sheet and then flip the 18 That way, when we collect your tablets at the end of page up. 19 every day, there's a cover sheet on there and we can't see 20 anything that you may have written or not written. Again, the 21 fact that you have a tablet and a pen is not a subtle hint from 22 me that I think you should do this. It's strictly up to you, 23 however you want to do it.

Now, I told you we would take regular breaks. About every hour, you know a break is coming. I kind of watch the

Preliminary Jury Instructions

clock. I might take a break in a little less than an hour. I
 might take a break on a little more than an hour, if it makes
 sense to do that, based on the witness is about ready to finish
 their testimony, let's just get it over with or not.

5 If you need to take a break before then for any 6 reason, just raise your hand and get my attention. If I'm not 7 looking up and I'm looking at my computer, I'm not doing what I 8 gave you a hard time about, researching. That's how I take 9 notes is on the computer. If I don't see you, get the attention of a bailiff or somebody, and we'll take a break if 10 11 you need it. All right. But you know it's coming about every 12 hour, so that helps you stay focused.

13 You may see me go like this, which means I'm going to 14 be whispering over here with the lawyers. I'm whispering 15 because you're not supposed to hear it. So don't try to 16 listen. It's not that interesting. I promise you. All right. 17 Don't be annoyed by it. All right? It can happen a lot 18 sometimes. Hopefully not. But if it does, don't be annoyed. 19 Use it as a stretch break. When I'm over here whispering, 20 that's your opportunity to stand up, move around, and use it in 21 kind of a positive way.

Other than that, if you want to bring snacks and drinks and stuff like that tomorrow, you're welcome to do that. It usually gets really cold in here, so you may want to bring a sweatshirt or a sweater or something. Other than that, I think

Vol. I, Pg. 174 Opening Statement by Mr. Esfandiari 1 we're good to go. 2 Any questions from you-all before we start? Nope. 3 All right. Well, thank you. 4 At this point, the attorneys will now have an 5 opportunity to present their opening statements, if they wish. 6 Each side gets equal time, and the plaintiff goes first. 7 Keep in mind, what you are about to hear is not 8 evidence. Rather, it's the attorney's remarks are intended to 9 aid you in understanding the evidence that they are planning on 10 presenting. Some people call it a road map or a preview of what they expect the evidence will be. All right? 11 12 So, Plaintiff, go ahead whenever you're ready. OPENING STATEMENT BY MR. ESFANDIARI 13 14 MR. ESFANDIARI: Good afternoon. As you know, my 15 name is Bijan Esfandiari, and I, along with my team members, 16 have the pleasure and honor of representing Mr. Thelen, who you 17 met during voir dire. I want to start by, first of all, thanking you for 18 19 the sacrifice that you're taking and serving as jurors in this 20 case, in this action. And all of us in this courtroom are 21 thankful for your time. I know you're taking time away from 22 your work and your family to be here, but we are grateful. 23 This is a simple case. Somatics' electroshock machine causes brain damage. Somatics failed to issue any 24 25 warnings that its machine causes brain damage. As a result,

Opening Statement by Mr. Esfandiari

plaintiff, Mr. Thelen, was exposed to repeated electroshock treatments with Somatics' machine, which he otherwise would not have been subjected to. And due to that repeated exposure, he sustained brain damage, as the evidence will show.

5 You'll hear evidence that since early on, doctors, 6 for whatever reason, have felt that shaking somebody might cure 7 their mental ailment. Goes back to the Greeks in the 1900s. 8 You had doctors who would put mental patients in a chair and 9 spin them around, hoping that the spinning sensation would cure 10 depression and mania. That's where the term spin doctors comes 11 from.

And then you'll hear in this case and more relevant to this case that doctors felt that those who suffered from epilepsy -- and epilepsy is a condition where people have seizures. It's actually a very serious condition. That those who have epilepsy are not prone to have a mental disorder called schizophrenia. Schizophrenia are those who have delusions and hallucinations and so forth.

So doctors in the 1920s thought perhaps we could treat schizophrenia by inducing seizures, causing shaking in these patients. Initially they tried injecting chemicals for inducement of seizures. And then in 1930s, an Italian researcher by the name of Ugo Cerletti thought perhaps electricity could be a means of inducing a seizure.

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To test this theory, what he did in 1938, he found

Vol. I, Pg. 176 Opening Statement by Mr. Esfandiari 1 somebody who was roaming the streets at the train station in 2 Rome, speaking gibberish. He took him, brought him to the 3 hospital, and administered electricity to his brain to see what would happen. The man, startled, protested -- according to 4 5 accounts, protested and said, "Please don't do that again." 6 Undeterred, Cerletti, seeing the man was now speaking, 7 administered another dose of electricity. The history accounts 8 they did this about a dozen times. The patient was

9 subsequently lost to follow up.

But Cerletti and his colleagues published this in the medical literature in the late 1930s in Europe. Almost immediately thereafter, psychiatric hospitals in Europe began administrating electroshock, electricity to mental patients, hoping to cure initially schizophrenia and then depression.

Almost immediately thereafter, ECT crossed the pond and came to the United States by one of its advocates, a gentleman -- a doctor by the name of Lothar Kalinowski. Excuse me. And you'll hear that one of Somatics' owners, Dr. Abrams, was actually -- Dr. Kalinowski was one of his mentors.

Soon, the thought of seeing patients violently jolting while they're receiving this electroshock treatment put a little sore for the eyes -- a sight for sore eyes. So they decided to also administer anesthesia and muscle relaxants during the procedure, so that you would not -- while the person is still having the seizure, you would not see the jolting,

Opening Statement by Mr. Esfandiari

1 that they are having a seizure in their brain, and they're 2 under anesthesia to kind of calm them down. And this began to 3 be referred to as modern ECT. This occurred sometime in the 4 1950s and '60s.

5 Thereafter, they also introduced what's called a 6 We'll have the NASA engineer and other experts brief pulse. 7 explain to you what the difference is. But the initial 8 machines did a constant wave of electricity called a sine wave. 9 The machines from the '70s and '80s were where it was a brief 10 pulse, where it was pulses of electricity being administered to the patient. Yet, the patients were still having seizures and 11 12 being exposed to expensive amounts of electricity.

13 1985, two psychiatrists, Dr. Abrams and Dr. Swartz, 14 who were administering ECT to patients, decided to start 15 profiting off of ECT machines. So they formed a company called 16 Somatics and manufactured their own machine. You'll hear that 17 they did not a single clinical trial. No trials of any 18 patients to test the safety and efficacy of their machine, which they've been selling since 1985 to hospitals around the 19 20 United States.

More important for this case, you'll hear, that from early on, the initial researchers, and even Dr. Abrams, you'll hear his trial testimony by video, they knew that ECT, when you administer electricity to the brains of individuals, causes brain damage. They knew that.

Opening Statement by Mr. Esfandiari

1 You will hear by -- the first witness is actually an 2 expert from London, who's researched ECT extensively, he's 3 published on it, will come and testify concerning the risks and lack of efficacy of ECT. And he'll talk about the fact that 4 5 early on, researchers, psychiatrists admitted that the treatment, actually, the efficacy they felt that they were 6 7 reaching in curing depression was the brain damage that they 8 were causing. That, for whatever reason, these people had too 9 much thought in their mind, and if we could get rid of the 10 parts of the brain, similar to almost lobotomy, which some of 11 you may have heard of, that this was a cure.

Yet, when Somatics released its machine to the market, they never warned of brain damage. They presented a picture that because their machine was this brief pulse, which still induces a seizure, that their machine does not cause brain damage, so no warnings were given concerning brain damage.

Mr. Thelen -- as a result of them not giving any warnings, you'll learn, that Mr. Thelen's psychiatrist, who recommended an administered ECT to him, were not aware that ECT caused brain damage. They said they had no idea, and had they known, they would have relayed that warning to Mr. Thelen and his family.

Now, the only -- the warning provided on the manual
that Somatics released, everyone admits no mention of brain

Opening Statement by Mr. Esfandiari

Vol. I, Pg. 179

1 damage. There is a disclaimer talking about memory loss and 2 persistent or permanent memory loss. Yet, even the owners --3 you'll hear testimony from the owners that when they were 4 drafting that disclaimer, that the warn -- that the owners 5 disagreed.

And one of them actually said, wait, this is not a warning at all. This is not an adequate warning. Yet, they did not want to alienate their customers. They did not want to alienate psychiatrists, so they decided not to use the word brain damage. And it was a very, you'll see, confusing in terms of disclaimer about memory loss. They refer to the permanent memory loss as being very rare and unsubstantiated.

You'll hear from Dr. Read, the expert who's researched ECT, that not only is permanent memory loss, it's far more than rare. It actually occurs, depending on the studies, in 12.4 to 55 percent of patients, yet Somatics called it a rare event and told people that the risk was unsubstantiated.

Mr. Thelen came -- was exposed to ECT at one of the most vulnerable times in his life. He was severely depressed. Mr. Thelen, you'll hear, was very popular in high school. He was runner-up to be prom king. Him and his family are from Nebraska. He wanted to follow in his father's footsteps of becoming a lineman, an electrician that works on power lines in Nebraska. He went to college, striving to go in that regard.

Opening Statement by Mr. Esfandiari

Vol. I, Pg. 180

1 However, he suffered from severe depression. It's no 2 denying it. And the depression was so bad that he would self-medicate with alcohol, and he drank extensively. The 3 medical records will be littered, his testimony, his parents 4 5 will testify he had problems with alcohol. And, finally, when 6 he was diagnosed with depression, the doctors tried to give him 7 various medications, and he's received every single pill one can think of. 8

9 Nothing was working. And the depression would get so
10 severe, he would engage in acts of cutting himself. Sometimes
11 his family was so worried about him, they would call what's
12 called Emergency Protective Services where he would be placed
13 in a psychiatric hospital for 36 hours to make sure he didn't
14 harm himself. This occurred on a number of occasions.

But his memory was intact. He was depressed, though, and he was looking for a cure. He got married when he was 26. Lasted for six years, and he got divorced when he was 32 in 19 -- I apologize, in 2012, 2013. The depression -- the divorce was difficult. The cause of the divorce was likely his depression and also the fact that he was abusing alcohol.

He, again, continued to receive treatment with his therapist. And one of them, he lived in a small town, suggested that he try ECT. But the town that they lived in is small. So he had to drive -- him and his family had to drive two hours to Omaha to meet with Dr. Sharma.

Opening Statement by Mr. Esfandiari

1 Dr. Sharma, you'll hear his videotape deposition, on 2 that very first visit recommended ECT, said this could 3 potentially cure your depression, and warned of memory loss, and warned that at the time that you receive -- but the warning 4 5 that was relayed was that the memory loss would be short-term, 6 and that there would believe some permanent memory loss, but it 7 was, as his family will testify, that when you receive the ECT 8 that day, you will forget that day. You will have some memory 9 loss. And that day, you will never recall ever again, that 10 that memory loss of that day and the days you receive ECT will 11 be permanent. The other parts of your life that may forget, 12 those will all come back, that those, after time, after the ECT 13 is finished, will come back.

You'll learn that Mr. Thelen had 95 ECT treatments over the course of two years. Basically, essentially once every two weeks, where him and his family would have to drive two hours to Omaha. He would be placed under anesthesia, administered the electroshock, and sent back home.

During this treatment, you will hear that Mr. Thelen complained and his family complained to the doctors that his memory -- he was having memory issues. But they assured him that the memory issues would return after the ECT treatment was ended, that this was temporary, and that the ECT was helping him, supposedly.

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Finally, after 95 sessions, Mr. Thelen and his family

Opening Statement by Mr. Esfandiari decided that no more. And thinking that, as the doctors had 1 2 told him, that the memory will eventually occur, and his final 3 session was July 25th, 2016, that they waited for their memory -- his memory to come back. He began seeing other 4 5 doctors, and he continued to complain of memory loss and was 6 not coming back. He was -- the memory of his childhood and his 7 autobiographical information, memories that all of us would 8 remember fondly, he had no recollection of.

Vol. I, Pg. 182

9 Finally, one of the doctors recommended he undergo a 10 test called neuropsych testing to determine whether he 11 sustained any brain damage or if he has any cognitive decline. 12 He went to that testing. It was August of 2017, about a year 13 after his ECT treatment. And that doctor, Dr. Hannappel, 14 you'll also hear his videotape deposition, his testing 15 confirmed that he had indeed -- Mr. Thelen had neurocognitive 16 decline, brain damage, and it is our position, and you'll hear 17 from one of the top brain injury doctors in the country, 18 Dr. Bennet Omalu, this is the doctor who uncovered brain injury 19 in football players and concussions in the football players --20 Objection, Your Honor. Motion in limine. MS. COLE: 21 THE COURT: Well, you'll hear from Dr. Omalu. We**'**ll

just leave it at that in terms of what his testimony will be. Go ahead, please.

24 MR. ESFANDIARI: You'll hear from Dr. Omalu that 25 Mr. Thelen has sustained brain damage as a result of the ECT.

Opening Statement by Mr. Esfandiari

Mr. Thelen, when you get to hear from him, and his parents, you'll learn, you know, as I mentioned, he grew up in Nebraska. He was working before ECT. While he couldn't finish college and become a lineman, he was a tree trimmer, primarily. He had different jobs, but that was one of his primary treatments.

And he wanted to get better. And once the ECT didn't work and now he's lost his memories, it was devastating. When he found out that this is going to be something that he may have potentially permanently, after the neuropsych exam with Dr. Hannappel in 2017, it was very difficult for him.

And you'll learn that shortly thereafter, he initiated this lawsuit. And while this lawsuit was pending and his memory still flawed, last year, in May of 2022, he attempted suicide by going to a field in Iowa and taking a nail gun and shooting himself in the head. Thankfully, it was not fatal. He had to be airlifted to a hospital and had surgery.

Now, this suicide and this nail-gun incident was after he had already been diagnosed with his brain injury by Dr. Hannappel, which, as Dr. Omalu will testify, was as a result of the ECT. But the suicide indicates that also that the ECT was not effective in treating the Depression. If anything, it made it worse.

24THE COURTROOM DEPUTY: Counsel, 15.25MR. ESFANDIARI: I'll be wrapping up.

Opening Statement by Mr. Esfandiari

Mr. Thelen went to receive ECT when he was in a very vulnerable state. He placed his trust in a therapy and an ECT

Vol. I, Pg. 184

2 3 machine manufactured by this defendant. His trust was violated, and he was exposed to a procedure that was 4 5 ineffective and which ultimately robbed him of his memories.

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You'll hear what this memory loss entails. 6 7 Mr. Thelen has no recall of spending times with cousins and 8 siblings. When they get together discussing, "Do you remember 9 we did this, " and "Do you remember we did that," no 10 recollection. The only memories of his past and his childhood 11 that he has, for the most part, are his parents reminding him, 12 others reminding him you used to do this, you used to have a 13 dog or a cat named this. You used to like GI Joe's. He has no 14 independent memory of that.

15 You'll also hear that his cognitive issues are 16 ongoing, where he has to carry a pen and pad all the time to 17 take notes. Otherwise, he would forget what people have told 18 him and forget important events.

THE COURT: Okay. Thank you.

20 MR. ESFANDIARI: One last sentence, Your Honor? THE COURT: Go ahead. 21

22 MR. ESFANDIARI: We will be asking you to hold 23 Somatics responsible for the damage that they have caused Mr. Thelen, and we'll be asking ultimately for you to award 24 25 substantial damages, to award Mr. Thelen for being robbed of

Opening Statement by Ms. Cole

his memories.

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Thank you very much.

THE COURT: All right. Defense.

OPENING STATEMENT BY MS. COLE

MS. COLE: Thank you, Your Honor.

Good afternoon. I have 15 minutes and maybe another minute to discuss the defense of the case with you, and this is a defensible case.

9 What is this case actually about? ECT is not on 10 trial here. What is on trial here is my client, Somatics, and 11 what they knew, what they did, what -- and what happened to 12 Mr. Thelen and what his diagnosis actually is.

13 The issue on trial is very simple. Was there a 14 warning defect in the Somatics' device, which was a cause of 15 Mr. Thelen's claimed damages?

16 What do we know? We know that Mr. Thelen suffers 17 from lifelong depression. He has major depressive disorder. 18 It affects every aspect of his life. Mr. Thelen began drinking 19 at age 12 in 1999. He was still in high school. His 20 depression became obvious when he was in high school. He was 21 sent involuntarily to a rehab center in Nebraska just after 22 high school. He was diagnosed with alcohol dependence and 23 depression. He served his time in the rehab facility, and within two weeks, he began drinking again. 24

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He tried many different courses of antidepressant

Opening Statement by Ms. Cole 1 medication over many, many years. This is 1999, 2000, 2001. 2 He didn't have ECT until 2014.

3 He continued drinking heavily throughout much of that time. He continued being depressed much of that time. He had 4 5 involuntary hospitalizations, which we in Florida call them a 6 In 2003, in 2005, 2007, 2008, 2006, he was sent to Baker Act. 7 another rehab facility by the courts, called Seekers of 8 Serenity. He did not finish that program, because he did not 9 meet the definition of graduation from the program. In other 10 words, he started drinking again, and he broke the rules of the Seekers of Serenity. This is in 2008. He didn't have ECT 11 12 until 2014.

Mr. Thelen's depression got worse. He went to see Dr. Heller in 2013. Dr. Heller was a health-care provider in Norfolk, Nebraska. He described for Dr. Heller that he had multiple attempts at self-harm and suicide before 2014. He did not take his medications as ordered. He drank alcohol because alcohol made him feel better. It was hard to hold a steady full-time job.

This was all told to Dr. Heller by him and his parents. He was resistant to antipsychiatric -- to psychiatric medications. Psychiatric talk sessions did not work. His parents tried to help. But Mr. Thelen was mentally ill, and they were powerless to help him, and what they were trying to help him with was not working.

Opening Statement by Ms. Cole

1 He was married in 2006 to Amy, but he divorced in 2 2012 because of the depression. Modern ECT, as described by 3 Mr. Esfandiari -- sorry -- is known as a tool by physicians to treat psychiatric illnesses, such as major depression and is 4 5 resistant to other forms of therapy. It has been taught to 6 doctors in residency programs since the 1990s. There were 7 fellowship programs at Duke University that Dr. Sharma, his 8 treating psychiatrist, who had administered the ECT --9 Dr. Sharma learned of all of the benefits, risks, and adverse 10 effects of ECT while he was in medical school and while he was 11 doing his fellowship, six years or more, before Mr. Thelen 12 received an ECT.

ECT is used on a hundred thousand patients a year in the United States, on more than a million patients a year worldwide. The method has evolved. It no longer involves a solid pulse. It now involves a quick pulse or an ultra quick pulse, and it is been used in its present form since the 1990s. Medical studies have been published on ECT and its effects.

Now, I'm not going to sugarcoat this. ECT can and does cause cognitive effects. The doctor who treats the patient has to decide whether to prescribe ECT, whether the risk of cognitive effects, which almost -- the vast majority of patients is very mild or goes away very quickly against the risk of a major depressed patient trying to exist in this world.

Opening Statement by Ms. Cole

1 Somatics consists of three people, Dr. Swartz, 2 Dr. Abrams, and a manager -- and an officer manager. 3 Dr. Swartz and Dr. Abrams published extensively about ECT. You'll hear about their books, and their books all describe the 4 5 risk of cognitive effects from ECT. There is no secret here. There is -- Somatics didn't hide anything from the world. This 6 7 was published, discussed at medical meetings, taught to medical 8 students, taught to resident psychiatrists for decades. ECT is 9 only sold to hospitals.

When ECT is administered, it is administered under anesthesia. There's no pain. There's a muscle relaxant that is administered after the anesthesia, so there's no shaking. The pulses are one millisecond, that's one/one-thousandth of a second in length, separated by six milliseconds of no pulse. The whole megillah, the whole machine process takes seven to seven and a half seconds while the patient is under anesthesia.

17 It induces a short seizure in the brain. There is no 18 movement in the brain. It's a short seizure. Sorry. And the 19 brain does not move. There is no jolting. There is no -- the 20 brain tissue doesn't move at all. It receives a jolt of 21 electricity, very short, which induces the brain, which is 22 composed of electrical-firing neurons and axons anyway, to go 23 into a short seizure, which means that all the neurons fire 24 simultaneously, which is thought to help regulate the brain and 25 alleviate depression.

Opening Statement by Ms. Cole

It doesn't cure depression. It was never meant to cure depression. What it does is it alleviates the depression so that the antipsychotic medications and the talk therapy has a chance of working on a patient. It's all recorded on a paper tape. The seizure -- the entire seizure is 30 seconds to 60 seconds in length.

Now, let's look at the Thymatron IV. This case, you
will not see any proof that there was a defect in the design of
the machine. You will not see any evidence that the machine
malfunctioned in any way. It functioned exactly as it's
supposed to function.

12 The plaintiff alleges there should have been 13 different wording in the manual that was sent with the machine 14 in 2012 to the hospital. They think that the wording should 15 say brain damage and that the wording should not say what it 16 does say, and that is permanent memory loss as a risk of ECT.

17 You will hear testimony in this case that even the 18 doctors that the plaintiffs are bringing to you equate the term 19 permanent memory loss to the term brain damage. It is just 20 another way of saying it. But when you say it as brain damage, 21 a layperson will think, oh, my God, it's a stroke, it's a brain 22 bleed, it's an aneurysm. It's something that's going to put 23 you in a coma for the rest of your life. This isn't that. What is described in the brochures and the manuals that went to 24 25 the hospitals is just what the symptom is that the patient

1 needs to know about, that is the possibility of a permanent 2 memory loss.

Opening Statement by Ms. Cole

The instruction manual that goes to the hospital says it is proper -- ECT is a complex medical procedure. Its proper and safe conduct requires a staff of professionals who are experienced with the procedures and familiar with the medical literature concerning the risks, benefits, complications, and methods of ECT.

9 In other words, this is not a machine that's sold to 10 amateurs. This is a machine that's sold to competent, 11 certified, experienced professional psychiatrists who 12 administer ECT.

13 There was -- in addition, there was a disclaimer 14 section in this user's manual. It said a few patients have 15 reported experiencing persisting loss of memories or memory 16 functions after ECT. These are subjective symptoms -- in other 17 words, they can't be seen on x-ray or MRI -- that have not been 18 related to observable structural brain damages. So we have 19 people complaining of this memory loss, but we don't have any 20 proof that it actually damaged the brain.

It further says that we recommend that doctors planning to use the Thymatron System read and follow the recommendations of the Task Force Report of the American Psychiatric Association, that's this book, which has Chapter 2, Chapter 1, Chapter 5, Appendix B. All throughout the book, it

1 2 Opening Statement by Ms. Cole talks about the potential adverse effect of memory loss if you -- if the doctor elects to prescribe this to you.

3 And Dr. Sharma and Dr. Alaskaf and Dr. Sadiq, who treated Mr. Thelen, all told him many times about the potential 4 5 for permanent memory loss. In fact, Dr. -- all three of these 6 doctors who administered this had him sign a consent form each 7 of the 95 times. And on the consent form, that you can't see 8 because it's too small up there. Okay. There we go. The 9 consent form says that there is a risk for permanent memory 10 loss. This was signed by Mr. Thelen 95 times. You know what? All of those forms are coming into evidence for you to see. 11

What does Mr. Thelen claim? He claims he lost all of his memories fallowing a 2015 treatment with ECT. And he claims that he hasn't recovered them. When the date becomes important, the date that is important is when Mr. Thelen realized that he had an injury or damage as a result of what he believes to be ECT. That's the -- that's the date issue in this case.

He claims that he has lost the ability to learn and that he's -- and retain new information and that he's suffered permanent brain damage as a result. Well, we had him tested by another neuropsychologist, Dr. Bilder, who you will hear on Friday. Dr. Bilder tested this claim of inability to learn new things, and he gave a whole series of psychological tests and found that, no, Mr. Thelen does have the ability to retain new

information, and Mr. Thelen does have the ability to function cognitively going forward.

Opening Statement by Ms. Cole

3 Mr. Thelen -- Somatics, of course, denies all of Mr. Thelen's claims and says that the physicians were 4 5 well-trained. They were experienced. They chose how to 6 medically treat their patients. When Somatics makes a machine 7 and sends it to a hospital with trained psychiatrists who know how to use the machine, they have no control over what the 8 9 physicians decide, in their wisdom, to do in treating their 10 patient. Somatics doesn't practice medicine. If these doctors 11 chose to give Mr. Thelen 95 treatments, that's what they 12 thought was best for Mr. Thelen. It was not Mr. 🚍 it was no 13 Somatics' activity that gave him 95 treatments.

Mr. Thelen, the evidence is going to show, his major depression was not caused by, nor was it contributed by ECT. Depression itself can cause many things, including loss of memory. Alcohol abuse can cause many things, including loss of memory. There's a dispute as to the extent and source of the injuries that Mr. Thelen claimed.

20 What's the evidence going to show? The evidence will 21 show that Mr. Thelen does not have brain damage due to ECT.

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THE COURTROOM DEPUTY: Counsel, 15.

MS. COLE: Somatics did not make or sell a defective product, because that's the question you're going to be asked. Was the product defective for lack of a warning? Did the

Opening Statement by Ms. Cole 1 warning make any difference, whether you use the words 2 permanent memory loss or brain damage in the warning? 3 THE COURTROOM DEPUTY: Counsel, 15. 4 MS. COLE: And Somatics was aware of ECT, and so were 5 his doctors. Somatics -- Mr. Thelen does not have brain damage 6 due to ECT. He has had an EEG. He has had several MRIs. He 7 has had a lot of CAT scans. And he has had examinations by 8 many, many doctors. He is still ill. But he -- nobody has 9 found structural brain damage in Mr. Thelen, and they have 10 looked. 11 Somatics did not make or sell a defective product. 12 Somatics was aware of the risks of memory changes with ECT, and 13 so were his doctors. And the doctors will all say that there 14 is no evidence that these doctors would have changed their mind 15 about prescribing ECT to Mr. Thelen under the same or similar 16 circumstances. There is no difference between the word brain 17 damage and permanent memory loss in these instructions that 18 were given to the doctor. The doctors knew what they were 19 doing. 20 THE COURT: Thank you. 21 MS. COLE: What's different is that --22 THE COURT: Out of time. 23 MS. COLE: I'm out of show. We ask that you consider 24 and find that Somatics was not -- did not put out a defective 25 product.

r,	Vol. I, Pg. 194		
	John Read, PhD - Direct Examination		
1	THE COURT: All right. Thank you.		
2	Call the first witness, please.		
3	MR. ESFANDIARI: Thank you, Your Honor.		
4	Plaintiff calls Dr. John Read.		
5	THE COURT: Have him come in. Raise your right hand.		
6	Stop right there. Raise your right hand.		
7	WHEREUPON,		
8	JOHN READ, PhD,		
9	was called as a witness and, after having been first duly		
10	sworn, testified as follows:		
11	DIRECT EXAMINATION		
12	THE COURT: Have a seat right there. Go ahead		
13	when tell us your name and how to spell it, please.		
14	THE WITNESS: Dr. John Read, R-e-a-d.		
15	THE COURT: Pay attention to the podium. He'll ask		
16	you some questions when he's ready.		
17	THE WITNESS: Thank you, Your Honor.		
18	BY MR. ESFANDIARI:		
19	Q. Good afternoon, Dr. Read.		
20	A. Good afternoon.		
21	${f Q}$. Can you please introduce yourself to the jury and let them		
22	know where you're from.		
23	A. So I'm Dr. John Read. I'm a professor of clinical		
24	psychology at the University of East London, which is in		
25	London, in England.		
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John Read, PhD - Direct Examination

1 Q. Thank you for being with us here today, Doctor. And I'm going to interchangeably call you doctor or professor if that's okay.
4 All right. Professor Read, can you give the jury a little bit of information about your educational background, starting with college, please?

7 A. Yes. So I did my undergraduate degree in psychology in
8 Wales, part of the United Kingdom. And then my master's degree
9 and PhD in clinical psychology in Ohio, at the University of
10 Cincinnati.

11 **Q.** When did you receive your PhD, Doctor?

12 **A**. 1983.

13 Q. All right. Can you explain to the jury what is clinical 14 psychology?

15 Α. Clinical psychology is -- involves two sets of skills. 16 It's a scientist practitioner model, it's called. So half of 17 what clinical psychologists do is in the domain of research, 18 science. So understanding and conducting research into the 19 causes and treatments of mental health problems. And the other half, the practitioner part, has been trained to conduct a 20 21 whole range of therapies, psychological therapies for a whole 22 range of mental health problems, such as cognitive behavior 23 therapy, psychodynamic therapy, group therapy, family therapy, et cetera. So those are the two components. 24

25 **Q.** If you can keep your voice up a little bit ==

Ĩ	Vol. I, Pg. 196 John Read, PhD - Direct Examination
1	A. I'm sorry.
2	Q Doctor. Thank you.
3	A. Okay.
4	Q. Dr. Read, I want to be clear, you're not a medical doctor.
5	That's correct?
6	A. No. That's correct.
7	Q. But you your PhD in clinical psychology, you do treat
8	patients. That's true?
9	A. I have done it. I don't anymore. I'm now a scientist
10	researcher, but I have spent 15 years treating patients.
11	Q. Actually, I'd like to go over that briefly. After you got
12	your PhD in 1983 from the University of Cincinnati, what did
13	you do next professionally, Doctor?
14	A. I worked in private practice in Cincinnati for a little
15	while. I then moved back to England where I was born. I'm
16	sorry. Back to England and worked in the NHS, National Health
17	Service, which you may have heard of, as a clinical
18	psychologist in a basically an inpatient unit. So most of
19	my work then and ever since, really, has been with the more
20	extreme end of the dimensions, people who extremely suicidal,
21	extremely depressed, psychotic, et cetera. So that's always
22	been my primary focus. So I did that for a while.
23	And I ran a 24-bed rehabilitation unit for people coming
24	out of psychiatric hospital with a staff of about 12. And then
25	I ran a large NGO. Is that the same term here,
	INTER CENTER DISEDICE CONDE

ĺ	Vol. I, Pg. 197 John Read, PhD - Direct Examination	
1	nongovernmental	
2	Q. Yes, nongovernmental.	
3	A. Charity sometimes people call it.	
4	Q. Yeah.	
5	A. With a staff of about 30 people providing day-care	
6	services and housing services, again, for people with extreme	
7	mental illness.	
8	Q. If I understand correctly, at some point after your	
9	clinical practice, you stated that you moved on to academia and	
10	research. Is that correct?	
11	A. That's correct.	
12	Q. When did that occur, Doctor?	
13	A. 1993, I moved to New Zealand to the University of	
14	Auckland.	
15	Q. Where how long were you at the University of Auckland,	
16	and what were you	
17	A. I was	
18	Q your last position there?	
19	A. Sorry. Sorry.	
20	Q. No problem.	
21	 A. I was Q your last position there? A. Sorry. Sorry. Q. No problem. A. I was there 19 years. And during that time, I progressed 	
22	to professor of clinical psychology. And when I left, I was	
23	running the professional training program and clinical	
24 25	psychology.	
25	Q. And then after New Zealand, where did you go to next,	
,		

John Read, PhD - Direct Examination

Doctor? 1 2 Α. Back to England, to Liverpool, where I had a similar 3 position as a professor of clinical psychology and running their clinical psychology program. 4 5 Q. Where are you at currently, Doctor? 6 Currently, at the University of East London. Α. 7 Q. What is your position there? 8 Α. Professor of clinical psychology. 9 What does a processer of clinical psychology do? Q. 10 A mixture of things. Primarily for me at this point, Α. primarily research, but also training and teaching. 11 12 My main focus is teaching within the clinical psychology 13 So I would be teaching clinical skills, if you like, program. 14 how to assess and treat people. So it's a mixture of research 15 and teaching. 16 Q. The research that you do, does any of it ever end up in 17 being published in the medical literature and peer-reviewed 18 literature? 19 Α. Yes. 20 Approximately how many articles have you published in the Q. 21 peer-reviewed literature? 22 Α. Over 200. 23 Q. And can you explain to the jury what peer-reviewed 24 literature means? 25 A peer review is a process by which scientific Α. Yes.

Vol. I, Pg. 199 John Read, PhD - Direct Examination 1 journals determine which research papers are of high enough 2 quality to be published. So they're sent out to usually 3 between two and four people with academic knowledge in the field that the paper is written about, and they write reviews 4 5 of them, and then the editor decides on the basis of those 6 reviews whether or not the paper gets published. 7 Okay. Has your work also appeared in any books? Q. 8 I have, I think, over 50 book chapters, and I've Α. Yes. 9 also written or edited four or five books myself. 10 Has any of your research and publication, Doctor, been in Q. the field of ECT, electroconvulsive therapy? 11 12 Α. Yes. 13 And our case, as the jury has heard, is a case about ECT, Q. 14 Doctor. Can you explain to the jury what ECT is and describe 15 it, please. 16 Α. Yes. ECT is the use of the application of sufficient 17 electricity to the human brain to cause a convulsion. And it

Q. And can you tell us a little bit about the origins of ECT,
why is it that doc psychiatrists are administering electricity
to patients?

usually involves a series of those treatments, between eight

and twelve usually, spread over a period of three to four

weeks. And as I say, the point is to cause a convulsion.

if the convulsion doesn't occur, then inefficient electricity

So

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has been applied.

1 Α. Two original theories. It was introduced in 1938, I 2 should say. And one of the theories at that point as to why it 3 might be a good idea to cause convulsions in humans is that 4 there was a belief, turned out not to be true, but there was a 5 seriously held belief that if you had epilepsy or seizure disorders, you couldn't have schizophrenia. And if you had 6 7 schizophrenia, you couldn't have seizure disorders. Sort of a 8 mutual exclusivity.

John Read, PhD - Direct Examination

9 There was a lot of that thinking around the 1930s. So 10 they believed that for the possible cure for schizophrenia, 11 which is what ECT was first introduced for, it's now used for 12 depression more, but originally it was used as an attempt to 13 cure schizophrenia.

So the idea was if we can cause epilepsy in schizophrenics, then that might help them. At the same time, they were injecting the blood of schizophrenics into the people with epilepsy to try to cure them. Sounds odd, I know, but that was the theory at the time, written up in medical journals.

Q. Who was the researcher or scientist who introduced ECT,
and how did he go about determining that this was a good idea?
A. You mean the first person to use it?

23 **Q.** Yes.

A. Yes. This was an Italian psychiatrist, Dr. Ugo Cerletti,
who his colleagues had been trying -- people around the world,

John Read, PhD - Direct Examination actually, had been trying different ways to try to cause a convulsion. They had tried insulin coma. So you increase a dosage of insulin until someone goes into a coma, which is a rather unpleasant process. They were looking for a slightly more, I guess, humane, if that's the right word, or less frightening methods.

7 And he got the idea of using electricity. And he just by 8 chance happened to be passing a slaughterhouse and saw pigs 9 being administered electricity to stun them, so that when they 10 were killed, they didn't have any pain. And he thought, well, 11 maybe this is a -- he could say they were convulsing a bit. He 12 thought maybe this is a way to cause convulsions in human 13 beings. That's how he got the idea. Then he experimented on 14 dogs for a while with one electrode on the brain and one in the 15 rectum, and -- but a lot of them died. So then he developed 16 the idea of putting the electrodes on both sides of the brain. 17 Q. And did he ever test it -- you mentioned dogs. Did he 18 ever test it eventually on a patient?

19 **A.** He did.

20 **Q.** Can you tell us about that, please?

A. Yes. He and his colleague, Dr. Bini, found a man wandering around the train station in Rome, speaking in a way they couldn't understand. So they -- I think they probably assumed he had some sort of mental illness. And he may have done it. I don't know. They took him to the offices and

Vol. I, Pq. 202 John Read, PhD - Direct Examination applied electricity to his brain. So the very first ECT. 1 That 2 was in 1938. 3 But the first application of electricity wasn't sufficiently large. The voltage wasn't high enough to cause 4 5 the seizure they were looking for. While they were discussing 6 whether to apply another one, the man -- this is recorded in 7 several accounts, the man shouted out, "No, not another, it 8 will kill me." They went ahead anyway in the first of what's 9 now turned out to be hundreds or possibly thousands of times 10 that a patient has said, "Please don't do this to me," and the 11 doctors ignore it and go ahead anyway. But that was the very 12 first time ECT was used. 13 And did the practice of ECT, then, spread to hospitals in Q. 14 Europe and in the United States?

15 **A**. Yes.

16 Q. Okay. There's been some discussion, the jury has heard in 17 opening statements, about modified or modern ECT. Can you help 18 us understand what is the difference between what Dr. Cerletti 19 was doing in Europe and modern ECT and the evolution?

A. So the first big change came after roughly ten years when they started using general anesthetic and muscle relaxants. Originally, they were literally shocking people and they were conscious at the time, which you can imagine was rather scary and extremely painful. And it also caused high frequency of spinal fractures and other fractures throughout the brain ==

1 throughout the body.

So about ten years in, roughly, in different parts of the world, they started using general anesthetic and muscle relaxers. That's the basic differentiation between what's called unmodified ECT and what's used today, which is called modified. There have been some further changes since then I could talk about.

John Read, PhD - Direct Examination

8 Q. Yeah. Can you talk to us a little bit about the9 additional changes.

10 A. The two main ones which have occurred in the 1980s, again, 11 different times in different parts of the world, but roughly in 12 the 1980s, was what to do with the type of electricity used.

13 So, one -- well, the first one was where the 14 electrodes were placed. So this -- if the position of the 15 electrodes is like this, this is called bilateral, because the 16 electricity goes across both hemispheres. In the 1980s, the 17 idea came about that we should perhaps use unilateral, where the electrodes are placed on just one side of the head. And 18 19 the specific idea, the reason for introducing that was to try 20 and reduce the amount of brain damage being caused, which was 21 fairly well acknowledged that this was causing a lot of brain 22 damage, but unilateral should reduce the brain damage. That 23 was the theory, because you're at least only passing electricity through one side of the brain. 24

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That turned out to be correct. It does reduce the

Vol. I, Pg. 204 John Read, PhD - Direct Examination 1 amount of brain damage caused. So that's one change, bilateral 2 to unilateral, except bilateral is still used a lot. It's not 3 like they got rid of bilateral. We don't know what the percentages are, because there's no national tracking of 4 5 it. You could guess it's 50/50, but we really don't know. But 6 it's certainly still used. But still a very good move forward 7 in terms of reducing the amount of brain damage.

8 The other big change was the type of electricity, as 9 I said. So they -- the electricity used used to be called --10 still used somewhat -- sideways. So I think the clearest way to put it is a continuous flow of electricity. And the idea --11 12 a new idea came about in the 1980s to use what's called brief 13 pulse electricity. So you don't get a continuous flow of 14 electricity. You get lots of little, you know, like -- whether 15 we call them little or not, we'll come back to that -- little 16 pulses like that, which does use overall less electricity. And 17 there's mixed evidence about whether that actually does reduce 18 the amount of brain damage or not.

So modern ECT done as well as possible would involve general anesthetic and muscle relaxants from the 1940s and '50s and unilateral only and brief pulse. That would be a brief summary of the changes of the ---

Q. Okay. Now, you mentioned on your publications and
research, Doctor, have any of those included researching ECT,
both its efficacy and safety?

1		
	Vol. I, Pg. 205 John Read, PhD - Direct Examination	
1	A. No. I haven't conducted research into that.	
2	Q. I'm going to let me use a better language. You've	
3	stated that you've published over 200 papers. Correct?	
4	A. Yes.	
5	Q. And do any of those publications deal with ECT?	
6	A. Yes, yes.	
7	Q. Including its efficacy and safety?	
8	A. Yes.	
9	Q. And I want to show Your Honor, permission I want to	
10	show you one of your publications, Doctor, and just let us know	
11	if this is one of them.	
12	MR. ESFANDIARI: Your Honor, permission to show one	
13	of Dr. Read's publications from 2019?	
14	THE COURT: I don't know what it is.	
15	MS. COLE: Want to show it to us first before you	
16	publish it?	
17	MR. BENKNER: No objection to showing.	
18	BY MR. ESFANDIARI:	
19	Q. Dr. Read, is this one of the articles that you authored?	
20	A. Yes, it is.	
21	${f Q}$. Okay. And what was the title of this article, Doctor?	
22	A. "Electroconvulsive Therapy for Depression: A Review of	
23	the Quality of ECT versus Sham ECT Trials and Meta-Analyses."	
24	${f Q}$. Okay. And this was published in a peer-reviewed journal.	
24 25	Q. Okay. And this was published in a peer-reviewed journal. Correct?	
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John Read, PhD - Direct Examination

1 **A**. Yes.

2 Q. And I see there were other authors there. Who is3 Dr. Kirsch?

Professor Kirsch works at Harvard Medical School in the 4 Α. 5 school of placebo studies. He's a rather well -- probably the most renowned placebo researcher in the field of mental health. 6 7 So Professor Read, I want to talk about four topics with Q. 8 you concerning ECT. The first is going to be efficacy, the 9 second is going to be memory loss, the third is going to be 10 whether ECT causes brain damage, and the fourth is going to be mortality rates or death rates associated with ECT. Okay? 11 12 So in terms of efficacy, Doctor, have you -- and when I 13 use the word research, I'm talking about reviewing the 14 literature.

15 **A.** Yes, I understand.

16 Q. Have you undertaken a review of the literature to
17 determine whether ECT is effective in treating depression?
18 A. Yes, I've done three of those.

19 Q. Okay. And can you -- was one of them the article we just 20 looked at?

21 **A.** Yes.

22 **Q.** With Professor Kirsch?

23 **A**. Yes.

24 Q. Can you please briefly tell the jury your findings based
25 on the -- first of all, tell us what you did and what your

1 findings were.

A. So this paper that we just saw was a review of all the
studies that have ever been conducted that compared ECT with
sham ECT. Now, I want to explain.

John Read, PhD - Direct Examination

5 **Q.** Yeah, please explain.

6 A sham ECT is a placebo. People who have sham ECT are in Α. 7 the placebo group. So they think they've had ECT, but they 8 haven't. And how that is accomplished is that you get one 9 group of people, general anesthetic and the ECT, and the other 10 group of people, the general anesthetic but not the ECT, which 11 means they also, of course, don't get the convulsion. But if 12 all goes well, they don't know whether they've had ECT or not 13 because they had the general anesthetic.

So this is the gold standard way to determine if a medical treatment works. There's other ways to approach that issue, but it's widely accepted today when we're practicing evidence-based medicine, that if you can't establish that a treatment is better than placebo, then it should not be used. So in ECT, there have only ever been 11 such studies. So

I should say for us what we did. Researched the literature using -- there's a whole bunch of ways you do that. There's Medline Psych. There's tools by which you can search all the research literature to make sure you're covering all the studies that have ever been done.

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So our first reviews we did in 2010, we found 11 studies.

Vol. I, Pq. 208 John Read, PhD - Direct Examination We did it again in 2019. There was still only a 11 studies. A 1 2 very small number after 80 years. Sorry. 3 I want to interrupt. Sorry to interrupt you, Dr. Read. Q. But why, if you -- you stated that this placebo clinical trial 4 5 is the gold standard. Why do -- medical community, why do we 6 want to test a product -- first, explain what placebo is and 7 why it's important to do that. So placebo effects are the expectations that we're going 8 Α. 9 to get better because we're about to have a treatment. The 10 hope that we have when a doctor tells us -- well, a psychologist tells us that, okay, we've understood what's wrong 11 12 with you, now we're going to do X. 13 And people tend -- studies show that people tend to feel 14 better as soon as they know something is going to happen. So 15 placebo is about hope and expectation and belief that someone 16 is going to get better, and it can occur in the patient, but 17 also in the doctor as well. So the patient might feel better 18 and the doctor might see improvement, even without the 19 treatment having been administered. It's not a bad thing at 20 all. 21

A psychologist -- I always train my psychology students to instill hope and expectation that things are going to get better, because that's a good thing. Placebo is actually Latin for I please. It comes -- the effect comes from the relationship between the clinician and the patient, but it

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	John Read, PhD - Direct Examination	
1	hasn't got anything to do with the treatment that the patient	
2	is giving.	
3	So if I do cognitive therapy with somebody, and they get	
4	better, I will, of course, think it's because I'm a brilliant	
5	cognitive therapist, but they might have gotten better just	
6	because we kind of got on and they felt heard and listened to.	
7	So does that explain placebo?	
8	Q. Somewhat.	
9	A. Sorry.	
10	Q. For example, if we can put a little meat on it, so let's	
11	say I'm a drug manufacturer, and I want to bring out a drug	
12	that says it's going to cure depression.	
13	A. Yeah, yeah.	
14	Q. And so if I and your testimony is that to test the	
15	efficacy, we need to do a double-blind placebo clinical trial.	
16	Correct?	
17	A. Yeah.	
18	Q. So what happens? Explain to the jury what happens in the	
19	clinical trial.	
20	A. In a clinical trial, of course, which is a bit easier than	
21	a placebo trial with ECT, you just have the let's say	
22	antidepressant. You have a pill, antidepressant, and you have	
23	a similar size, shape, color, tasting capsule with powder.	
24	Q. Which is like a sugar pill, basically?	
24 25	A. A sugar pill, okay, yes. And then you compare the outcome	
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Vol. I,	Pq.	210
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John Read, PhD - Direct Examination of the two groups. And to get approval or --1 2 Q. I don't -- no, no, don't worry about --3 To prove efficacy --Α. 4 Q. I just -- yeah. Thank you. 5 Α. To prove efficacy, you have to demonstrate that the -- any 6 positive effects are because of the treatment rather than 7 because of the placebo effect. 8 Okay. And so when you're talking about sham ECT trials Q. 9 versus ECT, the sham group is the placebo group, and then 10 there's a group that's actually receiving ECT. 11 Α. Correct. 12 Q. And here, because ECT is evasive, it's not simply taking a 13 pill, but you're actually getting electricity, they put both 14 sides of the patients under anesthesia, but only one receives 15 the actual ECT after anesthesia, the other does not. And then 16 you say whether -- who improved, if you think ECT is better 17 than -- obviously, ECT would show better efficacy versus the 18 people who only got anesthesia. Is that correct? 19 Correct, yes. Α. 20 All right. So your investigation and your peer-reviewed Q. 21 publications revealed that since the same ECT hit the scenes, 22 1938 with Cerletti until 2019 and perhaps the present, there's 23 only been 11 such trials? That's correct. 24 Α. 25 MR. BENKNER: Objection. Leading. UNITED STATES DISTRICT COURT

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	Vol. I, Pg. 211 John Read, PhD - Direct Examination	
1	THE COURT: That's a leading question.	
2	Try not to do that, please.	
3	MR. ESFANDIARI: Will do, Your Honor.	
4	BY MR. ESFANDIARI:	
5	Q. In terms of when of these 11 trials, when was the last	
6	one?	
7	A. 1985.	
8	Q. So we haven't had a single clinical trial since 1985?	
9	A. No.	
10	${f Q}$. All right. What did your investigation research and	
11	publication reveal what these 11 clinical trials showed	
12	concerning the efficacy of ECT and curing or helping with	
13	depression?	
14	A. Okay. So of the 11 studies first of all, we evaluated	
15	the quality of the studies to determine whether or not the	
16	studies were good enough to form a view about whether ECT was	
17	effective or not. Our conclusion was the studies were not good	
18	enough to actually form a view whether as to whether ECT	
19	does or doesn't work. The problems were multiple problems.	
20	One of the major ones that they were tiny, tiny studies.	
21	The average size of these 11 studies was 37 people. So on	
22	average 18 people in the ECT group and 18 people in the sham	
23	group, whereas the usual drug trials, there are several hundred	
24	people in each study. So they were tiny. They weren't	
25	double-blind.	
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John Read, PhD - Direct Examination Vol. I, Pg. 212

So to have a proper study, neither the patient nor the assessor, the person assessing the outcome, must know who's in which group. The studies were not blind people. Not all of

4 the studies, but a lot of the studies, people knew who was in 5 each group. The measures were not always the best measures. I 6 won't go into a lot of detail.

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But there was a big question about the quality of them, which is unsurprising since they were very, very old. Science evolves today. They would not be accepted -- they probably wouldn't even get published today. So they were very old-fashioned, poor-quality studies.

Nevertheless, it's important to see what they did find, because that's all we've got after 90 years, nearly 90 years of ECT. That's all we have. There has been none since 1986, which is an important issue we might return to as to why that is.

17 But these are the 11 studies we've got, poor quality as 18 they are. So this is what they found. Five of the eleven 19 found no difference between the two groups, either the 20 short-term during the treatment or afterwards, in the follow-up after the end of the treatment. So five found no difference. 21 22 What does that mean, Doctor, no difference? Q. 23 Α. Sorry. No difference in efficacy. So the standard measure, there would be a measure of depression. Some measures 24 25 better than others. The good ones would use what's called the

Vol. I, Pg. 213 John Read, PhD - Direct Examination Hamilton Depression Scale, which is a 50-item questionnaire, and you look for significant amounts of decrease in the questions that are asked, I suppose, like have you been feeling low for the last three months or those sorts of questions. So you're looking for a difference between the two groups in decreased depression. Does that explain? Okay. Sorry.

7 **Q.** I hope so.

8 **A.** Do tell me if I'm not clear enough.

9 **Q.** I will.

10 Thank you. So five found no difference. Four did find a Α. 11 small difference for proportion of the patients, but only 12 temporarily, so only during the course of the treatment. 13 Remember, I said the treatment lasts for three to four weeks. 14 So during the period of the treatment and at the very -- at the 15 time of the very last treatment, four of the studies did find 16 that there was a slight superiority for ECT over the sham ECT. 17 But that disappeared within a week or as soon as -- the first 18 time they studied after the end of treatment, it was gone. But 19 four did find a temporary difference.

The other two found mixed responses. So they had -- the other two had different groups of people assessing, which is an interesting approach. And one of the studies, for instance, found that the psychiatrists involved did see a difference between the two groups, but the nurses and the patients did not, which is interesting in its own right.

	Vol. I, Pg. 21 John Read, PhD - Direct Examination	
1	So, overall, not a very strong picture in terms of	
2	efficacy. And particularly would like to highlight that none	
3	of the studies found any evidence that there were any long-term	
4	benefits beyond the end of the treatment period, and there have	
5	been no studies since then. So that means we can say there has	
6	never been a single study showing that ECT is better than sham	
7	ECT beyond the end of treatment. So ECT cannot be said to have	
8	any long-term benefits.	
9	Q. So, in your opinion, does did your investigation and	
10	analysis of these studies, did the foregoing studies	
11	sufficiently prove the efficacy of ECT?	
12	A. No.	
13	Q. And, again, why not?	
14	A. Because to prove efficacy from an evidence-based approach	
15	to these things, you to prove that a treatment is better than	
16	placebo.	
17	Q. And it's your testimony that these 11 studies did not do	
18	that?	
19	A. No, they did not do that.	
20	Q. For the reasons you already testified?	
21	A. Yes.	
22	Q. So outside of so what has the medical community what	
23	studies have been occurring since 1985? You said there's no	
24	clinical trial studies that have been performed, and you	
24 25	correct?	
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John Read, PhD - Direct Examination

1 **A.** Correct.

Q. And you've testified that the studies that had occurred prior to 1985, in your opinion, not sufficient to establish efficacy.

5 **A**. Correct.

6 What has the medical field or manufacturers who produce Q. 7 ECT machines, what studies, if any, have they conducted? 8 Studies have continued, as I say, none involving a placebo Α. 9 control group. The sort of studies that have been conducted 10 are comparing different types of ECT, for instance. Remember I 11 mentioned bilateral versus unilateral? So there's quite a lot 12 of studies comparing those two approaches to see which causes 13 the least memory loss and which is the most effective of those 14 two, studies comparing the two different types of electricity, 15 studies comparing ECT with antidepressants, or other types of 16 treatments, but none of them actually measuring whether ECT 17 itself is effective.

18 So even these other studies since in 1985, in your Q. 19 opinion, do any of them establish the efficacy of ECT? 20 No. Can I say a little bit more about why I believe that? Α. Because we get a review of ten years' worth of those kinds of 21 22 studies to see if we could find any evidence, even if it isn't 23 a placebo-controlled trial. Is there any evidence that, short 24 of a placebo-controlled trial, that actually does suggest that 25 ECT is effective, not is one type better than another and all

	Vol. I, Pg. 216 John Read, PhD - Direct Examination
1	of that, but is there any evidence that is actually effective.
2	And we concluded I think we looked over a hundred
3	studies over a eight-year period, and we concluded there wasn't
4	a single study that showed that ECT is effective, largely
5	because I think about 60 percent of them, they left people on
6	antidepressants. So if there was any benefits, you couldn't
7	tell which of the two treatments was causing that benefit. I
8	think it was 85 percent of them had no follow-up whatsoever, so
9	no information whether there was any long-term benefits, and
10	et cetera, et cetera. So within all of those studies, there
11	was just nothing there you could reasonably say was evidence
12	that ECT is effective.
13	${\tt Q}.$ Were those findings of yours that you just testified about
14	also published? Did you publish that in the peer-reviewed
15	literature?
16	A. Yes.
17	Q. What was the name of that article?
18	A. That was Read and Arnold 2017. I'd have to look that up.
19	Q. If you have your CV in front of you.
20	A. Is this all right? So this was Read and Arnold, 2017, "Is
21	Electroconvulsive for Depression More Effective Than Placebo?
22	A Systematic Review of Studies Since 2009." So it covered the
23	period of 2009 to 2017.
24	Q. Thank you for that. Has any explanation been given as to
25	why by the proponents of ECT as to why there should not be
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ŕ	Vol. I, Pg. 217 John Read, PhD - Direct Examination
1	any more placebo clinical trials performed to establish
2	efficacy?
3	And let me back up. So you've testified there haven't
4	
4	been sufficient studies or proper studies to test the safety
	to test the efficacy of ECT. Correct?
6	A. Correct.
7	Q. And I believe do you advocate that such studies take
8	place?
9	A. Yes.
10	Q. And what has the response been to you as to from the
11	proponents of ECT as to why they don't need to do any further
12	studies?
13	A. Well, that's not just a response to me. It's a response
14	to a whole community of people calling for these studies.
15	Q. Thank you.
16	A. The most common response is the argument that it would be
17	unethical to do a study of ECT versus sham ECT. And the
18	argument goes like this. We know that ECT works. And these
19	people that ECT is used for are very vulnerable and very needy.
20	That's true. So it would be unethical to withhold a treatment
21	that we know works to find out whether it works. And that at
22	face value, that's a reasonable, caring sort of thing, position
23	to adopt.
24	Unfortunately, it positions them entirely outside of
25	science, outside of evidence-based medicine. The whole point
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	UNITED STATES DISTRICT COURT

	Vol. I, Pg. 21 John Read, PhD - Direct Examination	
1	of placebo-controlled trials is so that we move on from the	
2	personal opinions of doctors or psychologists about what they	
3	think works, because we all think what we do works. I'm	
4	convinced every time I do psychotherapy it's going to work.	
5	Whether it does or not, I tend to believe that. And,	
6	certainly, the psychiatrists who use ECT believes that it	
7	works. But the fact that they believe it doesn't mean it is	
8	true. There is no evidence that it is true.	
9	So to say we can't research it because we can't withhold	
10	it because we know it works means they really are not part of	
11	the scientific community. They are not abiding by the rules of	
12	evidence-based medicine. It is a nonargument.	
13	Q. Are there other examples in medical history where doctors	
14	believe that a therapy worked and it turned out that, you know,	
15	when tested, it really did not?	
16	A. How long have you got?	
17	Q. We don't have that much time.	
18	THE COURT: Not that long. Not that long. The	
19	answer is yes.	
20	THE WITNESS: Sorry. I'll be brief.	
21	THE COURT: The answer is yes. Next question.	
22	THE WITNESS: I'll be brief, Your Honor. Many	
23	examples. I'll list three or four. Within the field of	
24	psychiatry, we have rotating chairs. We used to rotate people	
25	and spin them into unconsciousness. We have freezing baths.	
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Vol. I, Pq. 219 John Read, PhD - Direct Examination 1 We have standing depressed people next to cannon fire to try to shock -- early form of shock therapy. And, of course, more 2 3 recently, we have lobotomies, all of which at the time, people 4 believe worked and well intentioned, but clearly all of them 5 turned out, looking back, to be, I think we can say, 6 ridiculous. 7 **THE COURT:** I think that's a good resting point to 8 take a break. Yes? I promised to break every hour. We went 9 longer, but this is a five-minute break to go to the restroom, 10 get a drink. I intend to go close to five today, and then 11 we'll break at that point. All right. Thank you. 12 THE COURT SECURITY OFFICER: All rise for the jury. 13 (Jury out at 3:56 p.m.) 14 (Recess from 3:57 p.m. to 4:07 p.m.) 15 THE COURT: Bring the jury back, please. 16 THE COURT SECURITY OFFICER: All rise for the jury. 17 (Jury in at 4:08 p.m.) 18 You want to change? You don't like those THE COURT: 19 seats? You can move around if you want to. Everybody good? 20 All righty. Go ahead. 21 MR. ESFANDIARI: Thank you, Your Honor. 22 BY MR. ESFANDIARI: 23 Q. All right, Doctor. One final topic on efficacy that I 24 want to talk about is, is there any evidence as to whether or 25 not ECT prevents suicide?

John Read, PhD - Direct Examination

1 **A**. No.

Q. In the research that you've conducted, what does the research and the scientific papers reveal as to whether or not ECT prevents suicide?

A. As of the 2019 report, sorry, there were no studies
demonstrating that ECT reduces either suicides itself or
suicidal thinking.

8 There's one or two studies since then. I think the one I 9 would draw attention to, if I can just find it. Bear with me. 10 Sorry. Oh, yeah, sorry. So this is a very large study was 11 done, I think it was 2021, involving 14,000 ECT patients. And 12 that found that they were 16 times more likely to attempt 13 suicide within 12 months of treatment than 58,000 treatments 14 who had not had ECT, sixteen times more likely to try to kill 15 themselves.

16 However, it was a good study, inasmuch as they controlled 17 for a lot of other factors that might explain those 18 differences, and gender is a factor, age is a factor, all sorts 19 of what's called confounding variables. After they'd taken all 20 those into consideration, it was found that the ECT patients 21 were still 1.3 times more likely. That was not a significant 22 difference. Didn't suggest that ECT is causing the suicide. 23 It means there was no difference between the two. So, yet again, it was yet another study finding no difference between 24 25 ECT and nonECT in terms of suicide prevention.

Ĩ	Vol. I, Pg. 221 John Read, PhD - Direct Examination	
1	Q. So according to that study, ECT did nothing in terms of	
2	preventing suicide?	
3	A. Correct. There have been several since then, but still no	
4	robust evidence that ECT prevents suicide.	
5	Q. And in that study, you mentioned there was 14,000 people	
6	who had received ECT, 58,000 who had not. They were all	
7	depressed, I would imagine? Were they all patients	
8	A. They're all patients, yes.	
9	Q. All right, Doctor. I want to change topics into talk	
10	about mechanism of action. Can you explain to the jury what	
11	mechanism of action means?	
12	A. That's essentially trying to find out how something works,	
13	if it does work, what is going on that causes the positive	
14	change, if there is some.	
15	Q. And when it comes to ECT, have they identified has	
16	anyone proven what to those who say that ECT works, have	
17	they put forth anything to suggest as to what the mechanism of	
18	action would be as to how ECT purportedly is treating	
19	depression?	
20	A. Yes.	
21	Q. What is that, Doctor?	
22	A. Well, there's many, many theories and hypotheses. Some	
23	ECT proponents accept that we don't know and just say we really	
24	don't know how it works. Others, however, there's about one a	
25	month, studies coming up, showing what effect ECT has on the	
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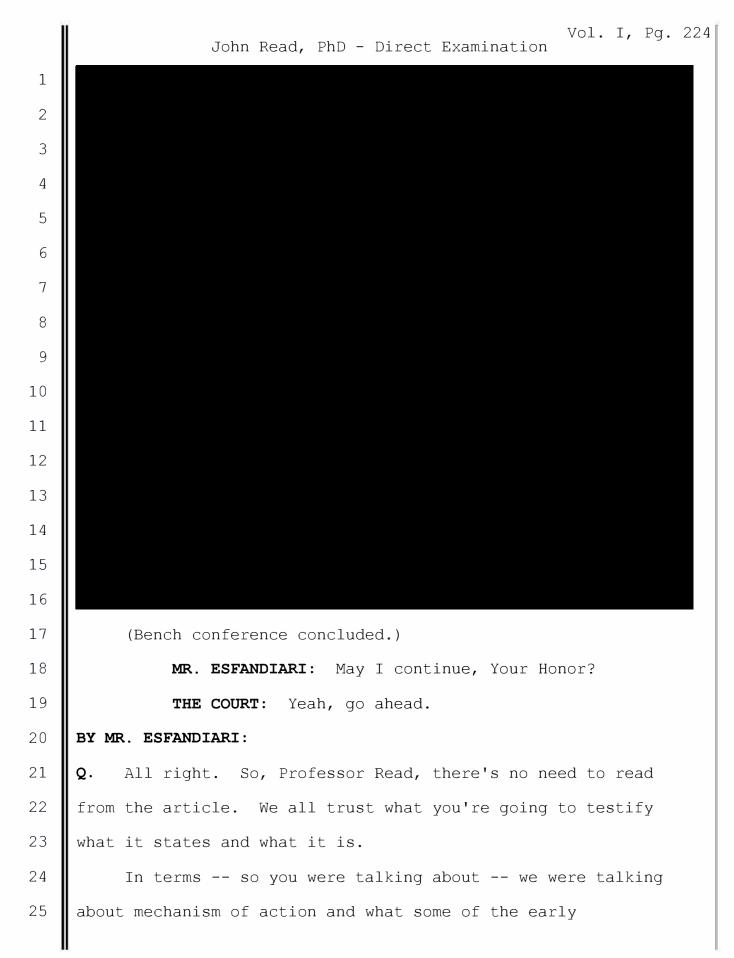
brain. The different -- whole range of different things that ECT does to the brain. And every time they find a new thing that ECT does to the brain, they go, aha, perhaps that's how ECT works, and that's a new theory about how ECT works.

John Read, PhD - Direct Examination

5 So for instance, one study found that it increases 6 connectivity between different parts of the brain. So then the 7 theory becomes, ah, so maybe depression is caused by not enough 8 connectivity, and that's how ECT works.

9 The unfortunate thing about that one is that the next 10 year, almost simultaneously, another group of researchers found 11 it decreased connectivity, and they said that's how it works. 12 And this goes on. This is going on for 20 or 30 -- there 13 are endless hypotheses about how ECT works, but none of them 14 really substantiate to an extent. They can't all be true. 15 Any other hypotheses that have been advanced during the **Q**. 16 history of ECT as to its purported mechanism of action? 17 Α. Myself and my colleagues have advanced to theories about 18 how ECT does have an effect. Shall I talk about those? 19 I would prefer if historically we start, like the early --Q. 20 Of course. Sorry. Well, I mentioned the one about ECT ---Α. 21 about epilepsy, so that was one theory about how it might work. 22 If you can cause epilepsy, then somehow that will cure 23 schizophrenia. But that was clearly nonsense. So we can just 24 discard that one, I think. And it really wasn't about 25 depression anyway.

Vol. I, Pg. 223 John Read, PhD - Direct Examination 1 So another early theory in the 1940s, so within the first 2 decade of it being used, was that ECT works by causing brain 3 damage. That sounds a bit strange. But I can read you two quotes from people at the time trying to explain that. 4 5 MR. BENKNER: Objection. Hearsay. 6 THE COURT: Sustained. 7 Don't read any quotes out of -- don't read any quotes out of reports or things like that. 8 9 MR. ESFANDIARI: Your Honor, this is --10 THE WITNESS: Research papers. 11 THE COURT: I understand that. 12 MR. ESFANDIARI: Let me --13 THE WITNESS: Sorry. 14 THE COURT: He'll ask the questions. 15 MR. ESFANDIARI: Your Honor, this is authoritative 16 text under 803. 17 THE COURT: All right. Come on up. 18 (Bench conference begins.) 19 20 21 22 23 24 25



Vol. I, Pq. 225 John Read, PhD - Direct Examination practitioners of ECT from the '40s believed the mechanism of 1 2 action to be. Can you tell the jury about that, please? 3 Yeah. So several leading proponents at the time argued Α. 4 that ECT works because it reduces the intelligence or level of 5 intellectual functioning of people. So they were arguing that 6 some mental patients have too much intelligence, too much going 7 on in their brains, and it needs to be reduced, and they believed that that was the therapeutic process. 8

9 The other -- the other type of brain damage they said was 10 helpful was that it erased traumatic memories. So if people 11 had upsetting memories from the past, it was a good idea to 12 erase them with electricity. So this idea was generally 13 thought about as what they called brain-damaging therapeutics, 14 which is strange looking back, but at the time, that was a 15 genuinely held belief.

16 Q. So if I understood that correctly, their belief was that
17 the brain damage was actually causing the therapeutic effect?
18 A. Correct.

19 **Q.** And the brain damage caused by the ECT?

20 **A**. Correct.

21 Q. Were there any other treatment modalities that were also 22 inducing brain damage where psychiatrists felt was providing 23 therapeutic effect?

A. Yes. At exactly the same time lobotomies were beingintroduced.

Vol. I, Pq. 226 John Read, PhD - Direct Examination 1 Q. Can you explain to the jury what a lobotomy is, please? 2 MR. BENKNER: Objection. Relevance. 3 **THE COURT:** I'll allow a little of this, as long as the answer is brief. We don't need to go off on a tangent on 4 5 Just go ahead. lobotomies. 6 THE WITNESS: Yes, Your Honor. So, essentially, a 7 lobotomy in its original form was sticking an ice pick 8 underneath the eyeball and hammering it up into the brain to 9 cause lesions, to cause brain damage, on a similar sort of 10 theory that it would be better for people to have less brain 11 function going on. Same theory. 12 BY MR. ESFANDIARI: 13 Q. Thank you, Doctor. 14 And then you mentioned that you yourself had certain 15 hypotheses or theories as to the perspective -- the potential 16 mechanism of action. Can you tell us about that, Doctor? 17 There's two theories that myself and colleagues have put Α. 18 The first I've already talked about, which is the forward. 19 placebo effect. So in all of those 11 studies -- so in 10 of 20 11 one studies I mentioned earlier, the people in the sham ECT 21 group improved. 22 So that's a partial explanation for why some people do get 23 better with ECT. It's nothing to do with electricity, nothing to do with the convulsion. For some people, it's just all the 24

25 extra attention and love -- tender loving care that you get 12

times, 10 times, 12 times, lots of people sort of rooting for you and wanting you to do well and paying you attention. You get anesthesiologists and all sorts of people involved. So that is one partial explanation why some people -- why for some people there's temporary benefit.

John Read, PhD - Direct Examination

And the other, which we have published a review of over a 6 7 hundred studies to support this idea, is it's similar to the 8 original brain-damaging therapeutics idea, and we have, we 9 believe, demonstrated that the effects on the brain that the 10 ECT is very similar to the effects of what's called a 11 closed-brain injury or a mild brain trauma that might come from 12 a car accident or sports injury where two heads connect or 13 So there's changes in the brain that are documented whatever. 14 after ECT, very similar to traumatic brain injury.

15 And one of those, the important one that makes it look 16 like there's an improvement in mood, and in fact, there 17 actually is some improvement in mood, is a sort of artificial 18 euphoria, or I guess to explain, sort of a buzz that comes when 19 you get banged on the head, which does create some sort of 20 feeling of energy, which can be mistaken for a lift of 21 depression. So that's the theory that we published in the 22 paper in 2013, based on a hundred studies. 23 Q. What was the name of that paper, Doctor?

A. Sorry. That was -- that was with Roar Fosse. That wasthe second author on that. Roar Fosse is a Norwegian

Vol. I, Pg. 228 John Read, PhD - Direct Examination urologist. 1 It was called, "Electroconvulsive Treatment: 2 Hypotheses About Mechanism of Action." 3 Thank you, Doctor. Now, I want to get next to the second Q. topic that we're going to talk about ECT, Professor, and that 4 5 is memory loss. Can you tell us a little bit about what the 6 research reveals concerning ECT and memory loss, please? 7 So there are a number of studies suggesting that ---Α. Yes. 8 actually, back up. First of all, there are two types of memory 9 loss that the -- this research is about.

10 So one is the ability to learn new information. So I go 11 home at the end of the evening, I can't remember anything 12 that's happened today. That would be inability to retain new 13 information.

The other sort of memory loss that this research is about, is being unable to remember things that happened in my past, in my childhood, or last week or whatever. So the technical name is not worth getting into. So we call it memory gaps and inability to retain new information. And ECT has been found to cause both of those in significant numbers.

20 **Q.** Okay. Is there any dispute in terms of -- you know, the 21 jury has already heard some discussion during the opening, that 22 when you receive -- the day you're receiving ECT, and they're 23 putting you under, administrating the ECT, is there any dispute 24 in the medical community as to that -- the patient is not going 25 to remember that event and that day?

	Vol. I, Pg. 229 John Read, PhD - Direct Examination
1	A. Not that I'm aware of. I think everybody agrees that that
2	memory for the time immediately before the treatment never
3	comes back.
4	Q. Okay. And that will be a permanent loss? That that day,
5	for example, will be
6	A. Correct, yes.
7	Q. Correct?
8	A. Correct.
9	Q. Okay. And now you were talking about that the research
10	also reveals that people may permanently lose also what I'm
11	going to call autobiographical memories, so their childhood and
12	events of the past.
13	A. Yes.
14	${f Q}$. Is that right? Okay. Can you tell us what the research
15	and your investigation analysis has revealed in terms of the
16	frequency in which that type of memory loss occurs?
17	A. Okay. Well, the studies tell us that there's a range of
18	frequencies, so we the research isn't good enough yet to
19	land on a specific figure. So our analysis indicate that the
20	range of a percentage of the people who get autobiographical
21	memory loss is between 12 percent and 55 percent. So different
22	studies will come out of different points on that range.
23	${f Q}$. And let's just take a look at the conservative number, the
24	12 percent. What study was that, and when did it come out?
24 25	A. That was by Professor Sackeim in 2007. I need excuse
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Vol. I, Pq. 230 John Read, PhD - Direct Examination me, but I do need to add that what we're talking about here is 1 2 not temporary memory loss. This is permanent memory loss. 3 Those figures I gave you are for people who have that sort of memory loss at least six months after the ECT. So it's not one 4 5 week or two weeks later. So this is what's usually referred to 6 as persistent or permanent memory loss. So that 12 percent of 7 55 percent --8 What's the significance of the six months, Doctor? Q. 9 Well, there's not clear agreement on when memory loss Α. 10 becomes permanent, because it is a dimension. The six-month 11 mark seems to be what several researchers have landed on in 12 terms of deciding to -- before they can call something 13 persistent or permanent. That's become the research term for 14 memory loss that is not likely to come back. 15 Q. So if I --16 Α. If I can finish. Sorry. I should acknowledge that some 17 of the memory loss that occurs after ECT does come back over 18 time. So you might -- two weeks after ECT, you might not be 19 able to remember your marriage, for instance, but a few weeks 20 later, it will come back. So what we're talking about in 21 figures I'm giving you are for people for whom that is not

22 going to come back. After six months, it's very unlikely to 23 come back.

24 Q. So if I understood you correctly, then, the belief is that 25 the memory you've lost, if, after six months after ECT, you

-	Vol. I, Pg. 231 John Read, PhD - Direct Examination
1	still can't remember or recall that memory, that means it's
2	most likely lost permanently?
3	MR. BENKNER: Objection. Leading.
4	BY MR. ESFANDIARI:
5	Q. Did I understand you correctly?
6	A. Yes. Yes.
7	THE COURT: Overruled. Overruled.
8	THE WITNESS: But we can't be I have to stress, we
9	can't be certain about that. It is possible some memories
10	might come back after six months. It's unlikely.
11	BY MR. ESFANDIARI:
12	Q. And in terms of the figures you gave, the 12 percent to
13	55 percent, those were people who have lost memories,
14	autobiographical memories that have not come back after six
15	months of ECT. Correct?
16	MR. BENKNER: Objection. Leading.
17	THE WITNESS: That's correct.
18	THE COURT: It's okay this limited way to help move
19	things along a little quicker. Go ahead.
20	MR. ESFANDIARI: Thank you, Your Honor.
21	BY MR. ESFANDIARI:
22	Q. So I want to focus in on the Sackheim study you were
23	telling us about. That's the one that had the more
24	conservative 12.4 percent?
25	A. 12.4 percent.
,	

Vol. I, Pg. 232

John Read, PhD - Direct Examination 1 Q. Okay. Can you please tell the jury what -- who 2 Dr. Sackeim is and also what the study entails? 3 Dr. Sackeim is a professor of psychiatry and a very Α. prominent advocate for ECT, proponent of ECT, supporter of ECT, 4 5 and a very prominent and respected researcher. His -- shall I 6 go in to describe the study?

7 **Q.** Yes, please.

23

Q.

8 A. It was a very, very important study because it was the
9 first time at that point in, what, 70-odd years, that we had a
10 properly designed study to look at the long-term effects of
11 ECT.

12 As Sackeim himself says early on, not quoting, I'm 13 summarizing, it's not acceptable that all the studies we have 14 so far lasted only a few weeks, have very small samples of 20 15 or so people, and were conducted in artificial, sort of 16 laboratory situations. So what he did, he had over 300 people 17 in the real world, people who were having ECT in seven New York 18 hospitals, over 300 people, and he administered, I think, about 19 18 different cognitive tests, including a test of 20 autobiographical memory. And then followed those patients for 21 six months. 22 Should I describe how autobiographical memory is measured?

24 **A**. The results. Well, he found that immediately after ECT

Describe what the results were of his --

25 and six months later, there was a very significant decline in

Vol. I, Pg. 233 John Read, PhD - Direct Examination autobiographical memory. Some people were unable to remember many of the things that they could remember just before ECT about their own lives.

And the level of significance -- this is important. 4 5 There's a P level in research, which tells you how 6 significant -- how certain you can be that the result did not 7 occur by chance. And this level of significance was .0001, 8 which means there was only one in 10,000 -- it was a one in 9 10,000 possibility that the outcome occurred by chance. So it 10 was a really highly significant study, as I say, in the real 11 world with a large sample, controlling for a lot of other 12 variables.

13 And what was the percentage of number of patients who Q. 14 suffered from permanent memory loss in that study? 15 Α. 12.4 percent. He used a very conservative measure. You 16 have -- to get into the 12.4 percent, you had to be -- your 17 memory had to be really, really severely disturbed, but still 18 will accept the 12 percent. Means one in eight people. 19 And then you mentioned that there's studies that go as Q.

20 high as 55 percent?

21 **A.** Yes.

22 **Q.** Can you tell us about that study, please?

A. Well, there's a review of studies published in 2003 by
Professor Diana Rose in London who took a different approach to
establishing memory loss. And it was the approach asking the

Vol. I, Pg. 234

John Read, PhD - Direct Examination 1 patients directly. So she looked at all studies that have gone 2 straight to a sample of patients and asked them the simple 3 question, "Did ECT affect your memory in your view," which you 4 could argue is subjective. You could also argue who would know 5 better than the patients themselves.

So she found four studies, and the range of people who,
after six -- at least six months, said they -- they experienced
persistent or permanent memory loss ranged from 29 percent to
55 percent.

So if we add the Sackeim study onto that, then 12 percent, that's where I get the 12 percent to 55 percent. The largest of those studies that she reviewed by a person called Pedler, over 400 people were asked. And in that study, 40 percent. So the larger study of that kind came up with 40 percent.

15 Q. This was the 40 percent. This is permanent memory loss 16 six months after?

17 A. I think it's safe to say we should call it persistent or
18 permanent at six months. That's the term used by the
19 researchers themselves.

20 **Q.** And that was the six-month mark. Correct?

21 **A**. Yes.

Q. All right, Doctor. The third point I wanted to go over
with you was brain damage. Has -- does ECT cause brain damage,
Doctor?

25 **A**. Yes.

ν.	Vol. I, Pg. 235 John Read, PhD - Direct Examination
1	Q. What are you basing that upon, and also from a historical
2	perspective until the present?
3	A. So I base that opinion on four sources of information.
4	One would be the early autopsies that were conducted during the
5	1940s on animal studies and human beings who died immediately
6	or soon after ECT.
7	The second source of data for that opinion are more recent
, 8	brain scans of the kind that weren't available, of course, in
9	the 1940s. So many studies using modern brain scans find brain
9 10	
10	damage.
	The third is the permanent memory loss we've already
12	discussed, because that is quite clearly a symptom of brain
13	damage. What else could it be?
14	And the fourth is the undisputed factor, convulsions by
15	themselves, whether caused by electricity or naturally
16	occurring, can cause brain damage. That's broadly accepted by
17	everyone concerned.
18	So there's four types of evidence for that statement.
19	Q. Keeping your voice up, if you could.
20	A. Sorry.
21	Q. If you could please let us start with the first one, the
22	autopsy you mentioned. What did they reveal?
23	A. Well, the early autopsies well, there were two types.
24	There was a lot of animal studies. Remember, back then, it was
25	accepted that it caused brain damage. It wasn't a taboo
	INTER CEATES DISTRICE CONDE

Vol. I, Pg. 236 John Read, PhD - Direct Examination 1 subject at all, as we've established that it was actually 2 thought that that's how it works.

3 So there were lots of studies going on then and lots of animal studies, studies on rabbits and rats and dogs and two or 4 5 three other types of animals where you can administer something 6 as close to ECT as you can, close to the conditions of humans. 7 Some closer than others. But then you can immediately, what 8 they call sacrifice the animals -- not very pleasant, sorry --9 and see what's going on in the brain, and they would find a 10 range of findings. Not all the animals were brain damaged. 11 But they found a significant number of animals with cell death 12 and hemorrhaging and so forth.

13 So animal studies, and then there were the autopsy on 14 human beings. By 1951, there was a review in the Lancet, which 15 is a British medical journal with some repute, covering the 16 first 20 years of autopsies. And without quoting, they 17 basically said that the -- all of those studies that they 18 looked at, and then 18 more patients that they added themselves 19 in this paper, left no doubt, and those were the words they 20 used, left no doubt that there was brain damage, mostly 21 irreversible, sometimes reversible. So those autopsies 22 established right there and then that ECT causes brain damage.

I should add there is an argument to put up against those findings, and the argument is that well that was a long time ago. ECT is different now. It's not the same sort of ECT.

Vol.	Τ.	Pq.	237
VOL.	1	IY.	237

John Read, PhD - Direct Examination 1 The problem with that argument is that, yes, we talked about 2 some of the changes that have occurred over the decades. But 3 what hasn't changed is that you still have to administer the same amount of electricity as you always did to cause a 4 5 convulsion. And the other thing that hasn't changed is the 6 convulsion. It's still there. So those studies still apply 7 today. 8 Q. Thank you for that, Doctor. 9 And then I think the second item you mentioned was imaging 10 studies. Correct? 11 Α. Yes. 12 All right. First of all, Doctor, on the imaging study Q. 13 front, because I've seen different arguments made, are you 14 always going to be able to see brain damage including brain 15 damage caused by ECT on an imaging study?

16 Α. No.

17 Q. And why is that?

18 Because there's different types of brain damage occurred. Α. 19 And some of the -- some of the less -- less gross, less 20 structural brain damage is not going to show up on the brain 21 scan. I don't think level is the right word, but electrical 22 damage, damage at a cellular level is not going to show up on 23 brain scans necessarily, but we have had -- sorry. Go ahead. No, no. Go ahead. 24 Q.

25 So there are brain scans, studies which don't find any Α.

Vol. I, Pg. 238 John Read, PhD - Direct Examination brain damage. And then ECT proponents will say, aha, ECT does not cause brain damage, end of story.

1

2

3 However, as I've said, there's lots of brain damage of a different kind that doesn't show up on brain scan, and there 4 5 are some brain scan studies that do find brain damage. The 6 review I just described earlier with my colleague, Dr. Fosse in 7 Norway, looking at effects on the brain, and how similar those 8 effects are to brain-trauma injuries, et cetera, included over 9 a hundred scans, studies, all finding brain damage, not 10 necessarily all permanent. A lot of those studies were at 11 temporary brain damage. We weren't, at that point, interested 12 in the longer term. We were interested in how does ECT improve 13 mood in the first few weeks. There was over a hundred studies. 14 There are other studies that have found reduced gray matter, 15 for instance.

16 Q. Thank you. If I understood it correctly, though, just 17 because it doesn't appear -- those are the exceptions. 18 Correct? In terms of being able to see -- let me ask the 19 question. I apologize, Doctor.

The studies that were able to show brain damage, either structurally or in the imaging, are those the exception or the rule, or how would you describe it?

A. Probably the exception. There are a lot of brain scan
studies that don't find memory loss, that don't find the sorts
of brain damage that scan -- brain scans look for.

Ĩ	Vol. I, Pg. 239 John Read, PhD - Direct Examination
1	Q. Just because someone has brain scan that doesn't show
2	structural brain damage, does that mean confirm that that
3	person did not suffer brain damage?
4	A. No.
5	Q. Why is that again?
6	A. Because our brain-scan techniques do not pick up all types
7	of brain damage.
8	Q. Thank you, Doctor.
9	So based on your extensive research investigation into
10	ECT, your analysis of the literature, and the work you've done
11	on this by the way, how long have you been publishing on ECT
12	and its efficacy and
13	A. 2004.
14	Q. Okay. So 20 years approximately. All right. In these
15	two decades, and the literature that you reviewed, all the
16	studies you've analyzed, your own publications, if someone were
17	to tell say that the risk of permanent memory loss is rare,
18	would that adequately reveal the true risk of permanent memory
19	loss associated with ECT?
20	A. No.
21	Q. And why is that?
22	A. Because it isn't rare.
23	Q. And what is the rate?
24	A. The rate, if you base == if we base it on the persistent
25	or permanent memory loss, the rate is 12 percent or 55 percent.
1	INTER CEATES DISTRICT CONDE

Ĩ	Vol. I, Pg. 240
	John Read, PhD - Direct Examination
1	Q. And it's your opinion that 12 percent or 55 percent risk
2	of permanent memory loss, that's not a rare risk?
3	A. Absolutely not.
4	Q. If someone were to tell state that only a few people
5	have experienced persistent loss of memories or memory function
6	after ECT, would that be an accurate statement of the risk
7	associated with ECT?
8	A. Would you mind reading that again?
9	Q. Sure.
10	A. Make sure I understood.
11	Q. If they were to state that only a few people have
12	experienced persistent loss of memories or memory function
13	after ECT, is that an accurate statement?
14	A. No.
15	Q. Why not?
16	A. Because 12 percent to 55 percent is not a few.
17	Q. And in your opinion, does informing people if you were
18	to tell somebody that ECT may cause permanent memory loss, does
19	that adequately reveal the risk of brain damage?
20	A. No.
21	MR. BENKNER: Objection. Beyond the scope.
22	THE COURT: Sorry?
23	MR. BENKNER: Beyond the scope.
24	THE COURT: Yeah. Overruled.
25	THE WITNESS: Can you repeat the question? Sorry.
ļ	

ĺ	Vol. I, Pg. 241 John Read, PhD - Direct Examination
1	BY MR. ESFANDIARI:
2	Q. Sure. If someone were to inform people that ECT may cause
3	permanent memory loss, would that, in your opinion, adequately
4	reveal adequately warn of the risk of brain damage?
5	A. No.
6	Q. Why not?
7	A. If you want to warn of the risk of brain damage, you need
8	to say there is a risk of brain damage.
9	Q. Thank you, Doctor.
10	And the last topic, Doctor, I have on ECT is mortality.
11	And what I mean by that is death caused as a result of ECT. If
12	someone were to claim that the death rate of ECT is one in
13	40,000, is that consistent with what your investigation and
14	research has revealed as to the risk of death from ECT?
15	A. One in 40,000 patients or one in 40,000 treatments?
16	Q. It's unclear. It just says one in 40,000.
17	A. Either way, the answer is no.
18	Q. Why not, Doctor? What does the research reveal concerning
19	the risk of death from ECT?
20	
20	
21	what the range, what the actual figure is. That sort of figure is often I've seen that sort of figure used in the
23	information leaflets and official documents of various kinds
24	with no research behind it.
25	If you look at the actual research studies that look at
,	INTER CENTER DISEDICE CONDE

	Vol. I, Pg. 242 John Read, PhD - Direct Examination
1	deaths, and I mean the earliest one is back in 1957, which
2	looked at which identified 400 sorry. Let me just get
3	the figures right. It's kind of important. Sorry. Well,
4	actually doesn't that's how many deaths are caused by brain
5	
	death. That's not the number of deaths. I won't go there.
6	Sorry.
7	So we have, for instance, a study in Texas of 8,000
8	people, all the people who had ECT in Texas between 1993 and
9	1998. Seven died within 48 hours of the ECT. If you exclude
10	the two deaths that the researcher said
11	Q. Sorry to interrupt you. Seven out of how many, Doctor?
12	A. Of the 8,000.
13	Q. Okay. So 8,000 patients between 1993 and 19
14	A. Between 1993 and 1998.
15	Q. Has ECT in Texas?
16	A. Yes.
17	Q. And of those eight, how many died?
18	A. Of those eight, seven died within 48 hours. We have to
19	exclude two deaths because the researchers thought they might
20	not be related to ECT. So the five, that's a rate of one per
21	1,600. Now, in that study, eight more died within two weeks of
22	ECT from cardiac failure, which is the most common cause of
23	death from ECT.
24	So if we add those back in, we've now got a rate of one
25	per 600, for instance.
ļ	INTTED STATES DISTRICT COURT

Vol. I, Pg. 243 John Read, PhD - Direct Examination 1 Another study in England, when researchers wanted to 2 interview 183 people one year after ECT, it was reported that 3 two had died during the ECT. That's a rate of one in 91. Another English study -- this is the last one, because I could 4 5 go on, and I know we need to keep moving. But another study by 6 the Royal College of Psychiatry in the UK found that two out of 7 2,594 patients died within 72 hours, and that's one in 650. So 8 there's many studies --

9 Q. Was that two out of 2,000 or four out of --

10 Four -- did I say two? I beg your pardon. Four out of Α. 11 2,594, which is one in 650. The official rate that's often 12 used, 40,000, something like that, does not bear any 13 resemblance to what the research studies actually show. 14 Has there been any current studies, more recently in 2019 Q. 15 and so forth, that have looked at this issue, Doctor? 16 Α. Mortality in general?

17 Q. On mortality, cardiac failure, and so forth, and also18 cardiac failure.

19 A. I haven't gotten any more recent. There have been one or 20 two, all of which are much greater than the -- the official 21 rate. That was one more study that isn't entirely about death, 22 but it's worth mentioning, I think.

It's a review of 82 studies that found that looking at 82 studies, about one in 50 people suffer major adverse cardiac events after electroconvulsive therapy. So 82 studies, about

Vol. I, Pg. 244
John Read, PhD - Direct Examination
one in 50 suffer major adverse cardiac events, remembering that
heart failure is the leading cause of death after ECT.
J P. Dr. Read, ask one final question from you. In your
opinion, to a reasonable degree of medical certainty, does ECT
cause brain damage?

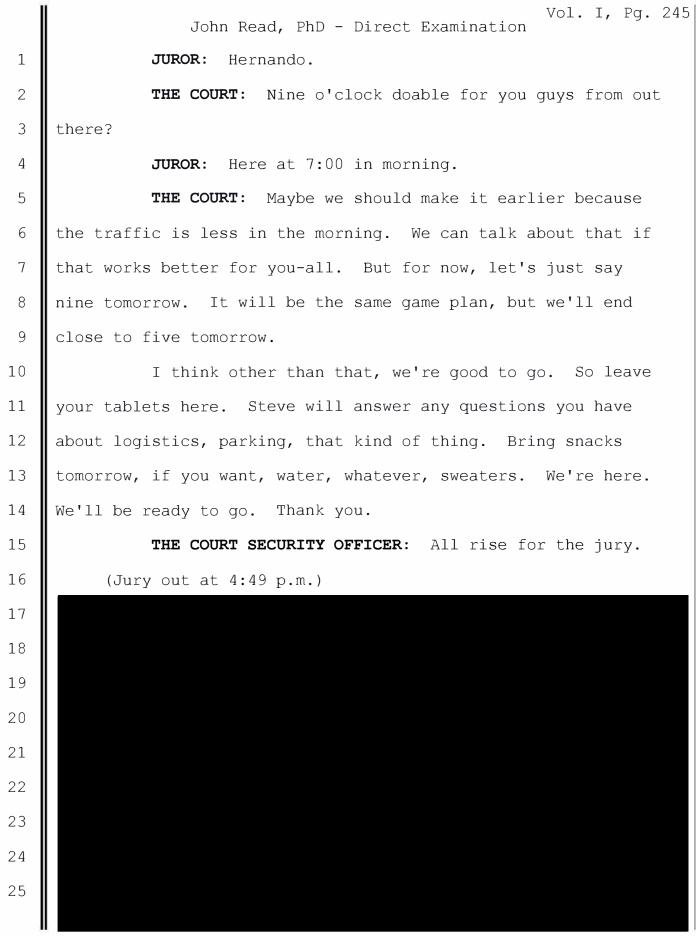
6 A. Yes, it does.

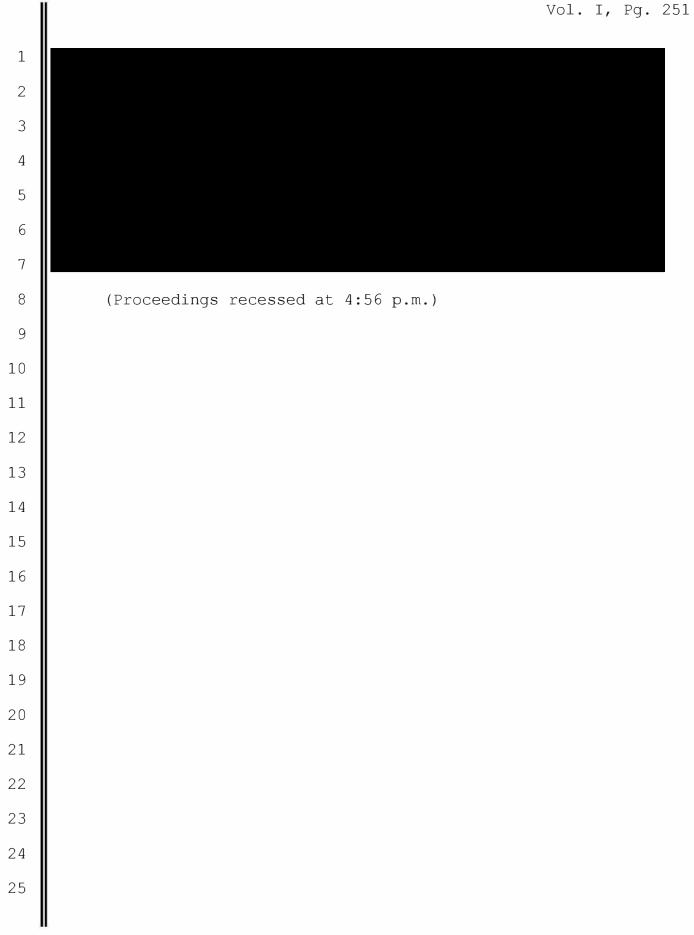
7 MS. COLE: I have no further questions, Doctor.
8 Thank you.

9 THE COURT: All right. Well, this is a good stopping 10 point for the day. We've been here a long time. I appreciate 11 your attention. What we're going to do now is have you leave 12 your tablets on your chairs. Okay. And remember the 13 instruction I gave you at the beginning. Don't go home and 14 start doing any research or Googling or asking your friends 15 about ECT or the legal system or anything like that. We need 16 you to come back tomorrow right where you are today mentally. 17 We'll pick up with the cross-examination first thing in the 18 morning.

19 I'd like you to be here ready to go at nine o'clock.
20 That means if you want to get here at 8:59, that's okay. If
21 you think you need more time, get here -- you know, make
22 arrangements to get here.

Who's -- anyone coming from Polk County? You are.
How about Sarasota? Hernando? Anybody coming from far?
You're coming from -- remind me.





	Vol. I, Pg. 252
1	CERTIFICATE OF REPORTER
2	STATE OF FLORIDA
3	COUNTY OF HILLSBOROUGH
4	I, Rebekah M. Lockwood, RDR, CRR, do hereby certify
5	that I was authorized to and did stenographically report the
6	foregoing proceedings; and that the foregoing pages constitute
7	a true and complete computer-aided transcription of my original
8	stenographic notes to the best of my knowledge, skill, and
9	ability.
10	I further certify that I am not a relative, employee,
11	attorney, or counsel of any of the parties, nor am I a relative
12	or employee of any of the parties' attorneys or counsel
13	connected with the action, nor am I financially interested in
14	the action.
15	IN WITNESS WHEREOF, I have hereunto set my hand at Tampa,
16	Hillsborough County, Florida, this 15th day of June 2023.
17	
18	
19	
20	(Lebekah, Jockwood
21	REBEKAH M. LOCKWOOD, RDR, CRR Official Court Reporter
22	United States District Court Middle District of Florida
23	
24	
25	
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