EXHIBIT E

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JEFFREY THELEN,

Plaintiff,

vs. Case No. 8:20-cv-01724-TPB-JSS

SOMATICS, LLC, and ELEKTRIKA, INC.,

Defendants.
_____/

VIDEO DEPOSITION OF JANET ARROWSMITH, M.D.

(Conducted Via Videoconference)

DATE: October 24, 2022

TIME: 12:02 p.m. to 3:09 p.m.

PURSUANT TO: Notice by counsel for Defendant for purposes of discovery, use at trial or such other purposes as are permitted under the Federal Rules of Civil Procedure

REPORTED BY: Aaron T. Perkins, RMR, CRR, CRC
Notary Public, State of Florida at Large

Pages 1 to 113

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I N D E X

E X H I B I T S

(NONE MARKED)

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P R O C E E D I N G S

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THE VIDEOGRAPHER: Good morning. We are on the record at 12:02 p.m. on October 24th, 2022.

Please note that this deposition is being conducted virtually. The quality of the recording depends on the quality of camera and Internet connection of participants.

What is seen from the witness and heard on the screen is what will be recorded. Audio and video recording will continue to take place unless all parties agree to go off the record.

This is Media Unit 1 of the recorded deposition of the Dr. Janet Arrowsmith, taken by the counsel in the matter of Thelen, Jeffrey v. Somatics, LLC, and Elektrika, LLC.

My name is Dan Holguin, representing Veritext. I am the videographer. The court reporter is Aaron Perkins from the firm Veritext.

Will the court reporter please swear in

the witness and then counsel may proceed. Thank you.

JANET ARROWSMITH, M.D.,

the witness herein, being first duly sworn on oath, was examined and deposed as follows:

THE WITNESS: I do.

THE REPORTER: You're under oath.

THE WITNESS: Thank you.

MR. SCHIEBER: Good morning, Dr. Arrowsmith. My name is Jeff Schieber. I represent Elektrika which is one of the defendants in this action.

I will have Ms. Cole introduce herself just for the record, too, and Mr. Esfandiari also.

MS. COLE: My name is Susan Cole with the Bice Cole Law Firm, and I represent Somatics, LLC.

MR. ESFANDIARI: And my name is Bijan Esfandiari. I represent the plaintiff in this action, Mr. Thelen.

DIRECT EXAMINATION

BY MR. SCHIEBER:

Q. Doctor, it's my understanding that you've been deposed several times before, so I

will probably dispense with the ground rules here. But, you know, the most important thing is that we don't talk over each other, because we've got the court reporter taking everything down.

If you need a break, just let me know and we'll take one. All that I ask if I have a question pending, you answer it before we break.

Does that sound fair?

A. Yes.

Q. Doctor, can you walk me through your professional background please.

A. Well, I graduated from medical school in 1979. I did an internal internship and residency and completed that in 1982.

From 1982 to 1984, I was a primary care provider in the University of Alabama system with responsibility for medical students and residents and for the care of patients.

In 1984 I started an epidemiology fellowship through the Centers for Disease Control in Atlanta, and I was assigned to the U.S. Food and Drug Administration. So starting in 1984, I was involved in the conduct of post-market surveillance for pharmaceutical products. At the time, actually, it was both pharmaceuticals and

biologics.

The Center For Biologics was established and then established their own post-market group. But, nonetheless, there was an overlap for the first year or so that I was there.

I completed my fellowship in 1986 and was hired as a medical epidemiologist in the same office where I had been working the previous two years. I believe I was there for almost three years as a medical epidemiologist. And then because of my interest in the recently defined epidemic of HIV and AIDS, I was selected as the deputy director of the U.S. Food and Drug Administration's AIDS coordination staff. And in that position, I was responsible for coordinating with other members of other agencies within the U.S. Public Health Service that were involved in AIDS and HIV. And that's primarily the CDC, NIH, and HRSA, Health Resources. And I can't remember what the whole -- I don't remember what all of HRSA stands for.

But, anyway, I was there for a couple of years. I set up the AIDS -- the ACTIS, the AIDS information service. It was the first publicly available public access to either unapproved

products or approved products for unapproved uses so that patients could actually volunteer to participate in studies.

And I was -- I stayed at AIDS coordination for a couple of years and then was recruited to the Agency for Healthcare Policy and Research to set up an expert panel -- an expert panel, which developed guidelines on the diagnosis, evaluation, and treatment of persons with HIV for use by primary care providers, primary care physicians at the time, as the bulk of HIV/AIDS treatment up until then, or up until a couple years before that, had been in the hands of infectious disease experts. But it was clear that the epidemic was such that primary care providers, primary care physicians needed to be -- needed to have more direction and information on how to diagnose and manage HIV/AIDS.

Following that, I was -- I joined the division of antiviral drugs back in the center for -- Center For Drug Evaluation and Research at FDA. And in that position, I was a medical review officer. I reviewed the investigation on new drug exemption requests or INDs. I reviewed parts of what -- well, particularly part of the NDA for the

diadenosine, which was the second HIV drug that was approved in this country.

I stayed in that position and then was basically recruited a couple years later to help set up the post-market surveillance office in the Center For Devices. The Center for Devices had recently developed and published some medical device reporting regulations where -- which were, essentially, very similar in concept to the post-market reporting regulations that both drugs and biologics were subject to.

And in that position -- and I think I was there for a couple years again. In that position, I wrote some of the regs. I met with regulated industry to receive their comments and suggestions.

Part of my -- one of the parts of my office was -- also was the premarket statistical review group, and so I was also involved in the evaluation, premarket evaluation, of medical devices, at least in terms of the statistics, and so forth.

About that time, my second child had come along, and so I stepped back out of that position and went over to the Center For

Biologics, and I was a medical review officer in the Center For Biologics.

I'm sorry, I have a cat that --

MR. SCHIEBER: Yeah, we've noticed. Do you need -- if you want to take a minute, I will --

THE WITNESS: Why don't I do that, and I'll put him in the back.

MR. SCHIEBER: Yeah. We can go off the record.

THE VIDEOGRAPHER: Okay. We are going off the record at 12:10 p.m.

(A recess was taken.)

MR. SCHIEBER: On the record at 12:11 p.m.

BY MR. SCHIEBER:

Q. Doctor, before your cat made an appearance, you were describing your professional background. Why don't you go ahead and finish doing so.

A. Sure.

So I worked at the Center For Biologics until 1996, at which time I was married and my husband was eligible for retirement from the Public Health Service, so I took a job as a

primary care physician at the Mescalero Apache Indian Health Service Hospital. And it just -- as -- from the time I finished medical school, maybe there was a stretch of six or eight months where I did not have or wasn't actively involved in clinical medicine.

And so from starting probably in late '84, early '85, I joined the faculty at the Georgetown School of Medicine at the department of medicine, internal medicine, and I had Friday afternoon clinic there for several -- several years.

And then once I got started in HIV/AIDS, there was a very effective, well organized, well run clinic in Washington, D.C., called Whitman-Walker Clinic that provided primary care to people with HIV and AIDS. And I had a Thursday afternoon clinic there at Whitman-Walker for an additional six years or so.

I continued to work with Georgetown off and on. I was a -- I taught physical exam, physical examination. I was in touch with their infectious disease people. I mean, I maintained that contact, but my clinical practice during that time, up until I left and started full time

practice at Mescalero, my Thursday afternoon clinic was at Whitman-Walker. And it was an HIV/AIDS clinic.

So in '96 we moved from Washington, D.C., to a small town in southern New Mexico called Ruidoso, which is spelled R-u-i-d-o-s-o, Ruidoso, New Mexico. And I was -- and I did primary care out on the Mescalero reservation for a couple of years. And then I transferred to -- or I moved to a private practice through the Presbyterian Healthcare System here in New Mexico, and I was, again, a primary care -- an internal medicine primary care provider. I had hospital privileges, ICU privileges. I was on the infectious disease management committee at the hospital.

And so I practiced full time medicine until the fall of 1999, in which I retired from full-time medicine and started doing consulting work for companies regulated by FDA. And then over time that has developed into the kind of -- primarily the kind of practice I do now, which somebody described it for me recently as forensics in the regulatory field for companies regulated by the FDA.

Q. Okay.

A. So that's -- and I continue to provide primary care. I covered a friend's family practice clinic up until the fall of 2017, until about five years ago. And she closed her practice about that time.

And so I still do some volunteer work for some of the asylum seekers who come to the Albuquerque area from El Paso -- or from the border there in El Paso and some of the facilities in El Paso, so -- but I'm not in -- you know, my practice is not remunerative financially. I mean, it is in other ways, but my full time, as full time as I'm working now apart from being a grandmother, is doing this kind of work, reviewing -- reviewing records from FDA, from companies, from other sources, and offering my opinions.

Q. Okay. Following med school and your residency, have you had any additional training in psychiatry?

A. Psychiatry, no, I have not.

Q. Have you ever administered electroconvulsive therapy?

A. No, I have not.

Q. Have you ever been present while electroconvulsive therapy is being administered?

A. No, I ever not.

Q. Have you ever offered testimony about electroconvulsive therapy prior to this case?

A. Yes, at least -- I don't remember -- I know I have done one -- two other depositions. One, I think, was in the Himes, and I don't remember the first one. But this is my third deposition in matters related to electroconvulsive therapy and injuries.

Q. Does Riera ring a bell?

A. Yes. I think that's probably the first one we did, yeah.

Q. And were your opinions in Himes and Riera similar in substance to your opinions in the Thelen case?

MR. ESFANDIARI: Objection to form.

THE WITNESS: I think essentially, you know, with the understanding that there were -- the documentation was different. The documents I reviewed were different. But I think, essentially, my opinion is that there was abundant opportunity for Somatics, in particular, to further investigate reports of

memory, antegrade, retrograde memory dysfunction and cognitive dysfunction among people who had experienced ECT.

BY MR. SCHIEBER:

Q. All right. Doctor, do you have your expert report in Thelen with you?

A. I believe this is -- this is that expert report.

Q. All right. And before we get into that, do you intend to offer any testimony about -- strike that.

Do you intend to offer any testimony about the specific causes of Mr. Thelen's injuries in this case?

A. No, I'm not a causation expert.

Q. Okay. And you haven't examined Mr. Thelen, correct?

A. That's correct.

Q. Have you reviewed any of his medical records?

A. No. I'm aware of the fact that he underwent a number of episodes of ECT, but I have not reviewed his medical records.

Q. Understood.

Doctor, if you could flip to page 13 of

your report, on page 13 you reference two reports that involved Dalmatian dogs.

Do you see that?

A. Yes, uh-huh (indicates affirmatively).

Q. Is that a reference to reports that Somatics submitted in conjunction with its 510(k) application?

A. Yes.

Q. All right. Do you believe that Somatics should have submitted additional safety and efficacy information in conjunction with that 510(k) application?

A. 510(k) applications do not require clinical studies. It is my opinion that Somatics certainly had an opportunity and continues to have an opportunity, frankly, to do adequately designed, controlled clinical studies to look at efficacy of ECT, and, certainly, to look at safety. But they have not been required to do so by the FDA, and they have chosen not to do so.

Q. All right. Towards the bottom -- or lower on page 13, you wrote that a review of the 510(k) submission revealed a marked absence of clinical trials or other data indicating or supporting efficacy claims and treating severe

psychiatric illness.

Do you see that?

A. Yes, uh-huh (indicates affirmatively).

Q. Is that sort of data required in conjunction with 510(k) applications?

A. No. As I explained that unfortunately -- well, under the 510(k) regulations, no, there are -- unless FDA specifically requires them, there's not a general requirement to provide -- to conduct clinical studies. So, no, that is not a requirement under the 510(k) process.

Q. To your knowledge, has FDA specifically required that sort of data from Somatics?

A. Not to my knowledge, no.

Q. On page 14 of your report, you reference a 1968 article from the British Journal of Psychiatry.

A. Yes.

Q. Can you describe that article for us?

A. Let's see if I have it somewhere. I think that was in the -- that was in the -- or reference to that was in the 510(k) application itself.

Q. That was going to be my next question.

A. Yeah. And I reviewed that recently. It's going to take me a minute or two to find the 510(k) application itself, but I did look at that recently and attached here. But I believe -- let me find which page it's on. I believe that this is the -- it's not specifically referenced in this copy that I have.

Q. That's okay.

A. This is from 2009, but I believe it is referenced in --

Q. Doctor, one of my questions was that you had written that "I can discern no reliable outcome measurements in that study."

A. Uh-huh (indicates affirmatively).

Q. Do you recall what the outcome measurements were?

A. No. I need to re-review that.

Q. Okay.

A. And I have a big pile of studies, but I don't seem to have that one. I may have reviewed it online. I don't remember at this point.

Q. Sure.

Let's move on to your discussion of the 2011 neurological devices advisory committee.

What are FDA advisory committees?

A. FDA advisory committees are within an expert scientific committee that is asked to review -- assist FDA in either coming to conclusions about approval, advising them on -- advising FDA on regulatory issues that are being considered or of concern. And it generally has practicing clinicians, statisticians, other scientists who have experienced relevant to the issue at hand and has a representative from the industry and, often, will have a nonvoting representative of the consumer.

Q. Okay. So in 2011, the FDA convened an advisory committee to provide advice on whether ECT should be reclassified; is that correct?

A. Yes, uh-huh (indicates affirmatively).

Q. And you wrote that as part of that process FDA invited public comments, and 3,045 comments were submitted, correct?

A. I know that, yeah, it was a large number of comments, yes.

Q. Who can submit public comments?

A. Virtually anyone can. There's no restriction as to who can make public comments.

Q. Are public comments proof of safety of the device?

A. Public comments generally do not offer proof of safety or efficacy, but they certainly can stimulate additional research.

Q. Okay. And why are public comments not proof of safety or efficacy?

A. Generally, because they are anecdote. They are not comments that are derived from adequate and well-controlled studies or post -- or adequate post-market studies. These are generally comments based on an individual's experience.

Q. Doctor, moving forward in your report to page 23, you wrote that only 11 clinical trials were conducted starting in the late -- in the late 1950s that could arguably be considered controlled trials.

Did you look at all of those trials?

A. I have reviewed a number of them. I think I also relied on Read by his assessment of those trials in the cited -- in the two cited articles. I guess there are three. But I didn't go back and re-review each one of those trials.

Q. All right.

A. I reviewed his summaries of those -- or the summaries provided in those several articles.

Q. And what method did you apply to

conclude that those trials were methodologically primitive?

A. They were not blinded. Most of them were not blinded, so that the people operating, doing the ECT, were the people making the assessments. There was no -- no sham treatment or other placebo control to assess the effectiveness of the products, and these were generally very small trials, as I recall, and so could not contribute any robust information to any body of evidence in terms of safety an effectiveness.

Q. Given the nature of the ECT treatment, how would you design a blinded trial?

A. There are -- I have reviewed a trial where there was sham treatment, where the individual was -- where you received ECT or not, you underwent anesthesia. And part of those -- the people in the active arm would receive ECT, and the people in the placebo, what would be basically the placebo arm, did not receive ECT.

And there is difficulty in a lot of device trials in that somebody knows who did and did not receive the treatment but the people assessing the individuals in the trials. So the operators whether or not the individual had a

seizure or not, had seizure activity or not. But -- and they had should be excluded from any assessment of outcome.

And the individuals assessing outcome should be blinded to treatment. If you do anesthesia in both the sham treated, or the untreated, and the treated controls -- and the treated individuals, then the individuals who underwent the treatment or participated in the study would not be -- would not know whether they had ECT or not.

So there are ways to conduct blinded trials in the device area. They're a little more complicated than in -- particularly with drugs, but it is possible to conduct sham treatments as a control for active treatment.

Q. So if I'm understanding this correctly, this trial that you just described, so the folks in the untreated arm were put under anesthesia. And is that it for the untreated arm?

A. Correct. They would not have had ECT. But they would have had anesthesia, which is the component of ECT. It's part of the preparation for ECT, is that the individual is -- goes under anesthesia, so that they -- you know, in part to

protect them from active seizure activity, but also to -- so that they are not consciously experiencing the ECT.

Q. Who conducted the trial that you've been referencing?

A. I don't remember. I would have to go back and look at it, but it was -- as I recall, it was a very small trial, and no conclusions could be reliably derived on it.

Q. Do you recall what the authors concluded the results of the trial were?

A. That was my assessment. I don't remember what they -- what their conclusions were, but that was my conclusion that it was particularly not adequately powered.

Q. Okay. You discuss the 2011 FDA advisory committee in some depth.

What's the basis for your discussion of that committee's activities?

A. Review of the transcript and a review of some of the slides, but particularly the transcript.

Q. Did you -- you didn't attend that committee, did you?

A. No, I did not, but I did review the

transcript, the entire transcript.

Q. Did you review any of the underlying information that the committee was presented with?

A. As I said, I did review some of the slides, yes.

Q. How many of the slides do you recall reviewing?

A. I don't remember. I know I reviewed Georgiopoulos' slides, who was an FDA presenter, but I don't remember. It's been a while since I did that. It I did not go back and re-review the transcript or the materials in preparation for this deposition.

Q. Okay. Did the FDA, ultimately, follow the advisory committee's recommendations?

A. In my opinion, no, they did not.

Q. And can you explain to us how they did not follow the recommendations?

A. Sure.

In the six -- it was six clinical indications that were under consideration. For five of those, the majority the panel members voted to maintain ECT in the -- in Class III, which would have required a premarket application, which means it would have required clinical trials

to determine efficacy and safety.

The only instance -- the only indication from which the recommendation by a majority of the panel was to move the indication into Class II was for catatonia. And all of the others, major depression, schizophrenia, bipolar, mania, schizoaffective disorder, schizophreniform disorder. It was -- the panel recommended by a majority vote that -- that those indications should undergo PMA evaluation, that the ECT should be considered Class III and require, basically, premarket evaluation.

Q. Is FDA bound by the advisory committee recommendations?

A. No, they are not bound by advisory committee recommendations. And about 80 percent or more instances, especially in drugs -- I'm not sure what the data are in devices. I think -- I don't think that -- well, I don't have the data for devices. But for drugs, it's 80 or 85 percent of the time they follow -- the FDA follows the advice of their advisory committee.

Q. Do you know why the FDA took until December 2018 to issue its final order on the classification of ECT devices?

A. No. I know that they published a preliminary order ni the Federal Register and received comments on it. But I don't know why it took them this length -- that length of time to issue the final order.

Q. What's the basis for your statement that the FDA's apparent disregard for the recommendations of its own expert advisory committee panel is curious?

A. Because they reconvened the advisory committee panel. They had experts in psychiatry and neurology and neurobiology who were reviewing the data submitted to them prior the advisory committee meeting. These were people who had some experience with ECT and understood they -- the diseases, the underlying diseases or conditions for which it was being -- the indications for which it was being considered.

And, you know, I was in devices for a few years, and my experience in devices is that there are few clinicians -- there are very few clinicians in the Center For Devices. Most the scientists are engineers or have some other engineering type background and, frequently, are focused on the functionality of the device rather

than clinical outcomes.

So the fact that they did have some clinicians on the advisory committee, they did get advice from those clinicians, as well as the other researchers and practitioners, and choose not to follow the advice of the scientists whom they selected to give them advice. I don't understand the full reasoning.

And it's kind of a -- so I don't understand why they chose not to follow the advice of the ad com.

Q. So FDA, ultimately, decided to classify ECT as Class II catatonia and treatment-resistant major depression, correct?

A. Correct.

Q. All right. Given that classification, are safety and efficacy studies required for catatonia and treatment-resistant major depressive disorder?

A. No, they are not, because it's Class II, so it has been found substantially equivalent to a predicate device that was on the market before 1984. And, in general, "substantially equivalent" really refers to, basically, sort of the design and engineering of the device itself, not having

anything to do particularly with outcomes, clinical outcomes.

Q. Doctor, I'm going to move to page 3 of your report. On page 3, you wrote that a disclaimer in the 2013 Thymatron manual --

A. Yes.

Q. -- is the most -- the most -- strike that.

"It's the most absurd pretense of providing adverse event information for a prescription medical product that I have ever seen."

What process did you apply to draw that conclusion?

A. My experience in the FDA, my experience as a practitioner and prescriber. I have never seen a warning, especially for serious adverse events, presented as a disclaimer. And, I mean, FDA has -- has specifically said that disclaimers are not an acceptable form of warning for providing information. So I, yeah, I think it's a pretense of providing useful information rather than actually providing useful information to be conveyed to the public.

Q. And your basis for that is --

A. And to be --

Q. -- your experience over the years?

A. And to be considered by the prescriber. In my experience over the years, my experience as a prescriber and primary care provider, primary care physician, my experience at FDA, reviewing labels, reviewing adverse event sections of labels, providing input on adverse events to be included in product labels, having worked at Center For Devices and having been responsible for the safety evaluation of all of the medical devices on the market in the United States, yeah, I don't think that that disclaimer is in any way an adequate means of informing physicians about potentially serious adverse events and informing them that they need to discuss this with their patient.

Q. Did the FDA ever take any action regarding that disclaimer?

A. Not that I'm aware of, but they clearly, in their own guidance, say that that's not adequate. But I'm not aware that the FDA took any action against the company.

Q. You also wrote that the disclaimer looks like a pathetic attempt to shield themselves and

their company from injury claims against them.

What methodology did you apply to draw that opinion?

A. My own 40-plus years as a practicing physician with patient -- being responsible for patient care, for the diagnosis and treatment of patients, for the evaluation of the appropriateness of a therapeutic for my patient, and for answering their questions about potential adverse events, whether in theory or one that they had actually experienced and wondered if it was associated with the treatment.

So there's -- I find that it is applying my various 40-plus years of experience. Plus, it's just a certain underlying logic that I apply.

Q. Can you explain that logic to us?

A. If you want to inform a physician of a potential risk of a therapeutic that you are recommending or that you are going to provide to the individual -- it is your obligation as a compassionate physician who -- who took the Hippocratic oath, first, do no harm. It is your obligation, your moral, your ethical obligation as a physician to provide as much information to the patient as you can about safety and efficacy, so

that they can be an active participant or their representative can be an active participant in the decision to undergo that treatment or not.

Q. And in what ways does the 2013 disclaimer fall short?

MR. ESFANDIARI: Objection to form of the question.

THE WITNESS: I'd have to say in what -- in what way does it inform? It is sort of a backhanded way to say, you know, if none of it -- if some of the stuff happens, you know, we're not going to say that it's not related, but they are not actively informing physicians and patients of the potential of antegrade and retrograde memory losses or cognitive dysfunction related to, associated with ECT.

BY MR. SCHIEBER:

Q. What --

A. So it is a -- to me, it's -- it's a very dishonest way of pretending to inform people.

Q. What do you believe that the 2013 manual should have stated?

MR. ESFANDIARI: Objection to the form of the question; lacks foundation.

THE WITNESS: It should have stated that -- and it's better stated in the 2018 manual, but it should have stated that there have been reports of retrograde and antegrade memory loss or dysfunction and reports of cognitive dysfunction associated with the use of ECT.

In many instances these dysfunctions resolve, but there are reports of instances in patients in which neither the dysfunction of memory nor the cognitive dysfunction resolves following treatment.

That's not -- it should be -- I mean, it would be -- I would recommend it be more concise than that, but that's the kind of information that should be in there. There have been reports of cognitive dysfunction, of very significant dysfunction, loss of autographical memory of patients who have undergone ECT. And in many reportable cases it doesn't resolve.

I mean, there are reports going back to '93, articles that say that this can happen in up to 55 percent of patients. So better to put that information in the labeling as a

warning than to put it into a disclaimer, which is -- I think as both as Dr. Abrams and Dr. Swartz -- and the intent of that was not so much to inform patients or practitioners but to protect themselves, they thought, from litigation and to -- I think the reference was to get FDA off their back.

There was no -- there was no underlying intent of providing information to physicians and to patients in that disclaimer.

BY MR. SCHIEBER:

Q. What's your basis for offering an opinion as to Somatics' intent?

A. Some e-mail exchanges between Dr. Swartz and Dr. Abrams in which they specifically -- I think it was Dr. Abrams that specifically said that the reason, the only reason, they wanted to put anything in the labeling was to protect themselves from litigation and to get FDA off their back. That was -- those were the two motivations specifically referenced in e-mails between Dr. Abrams and Dr. Swartz.

Q. Doctor, I want to move forward to the part of your report where you discuss FDA inspections of Somatics.

A. Okay.

Q. Do you know when the device used in Mr. Thelen's treatment was manufactured?

A. No, I don't. I don't know that.

Q. You reference a January 2012 FDA inspection of Somatics' facility in your report.

A. Yes.

Q. Do you know whether Somatics remediated any of the issues identified in that inspection?

A. According to the 2018 -- the 2016 inspection, yes, they have addressed many of the issues that were identified in the 2012 inspection.

Q. And moving to the 2016 inspection, do you know if Somatics remediated any of the issues identified in that inspection?

A. No, I don't. I don't have -- I'm not aware that they were reinspected, so, no, I don't know that they have, in fact, addressed the issues raised during that inspection.

MR. SCHIEBER: Doctor, we've been going about 50 minutes. I assume the videographer might need to change tapes. Why don't we go off the record for five minutes.

THE WITNESS: Okay. That's fine.

MR. ESFANDIARI: No objection.

MR. SCHIEBER: Thanks.

THE VIDEOGRAPHER: Off the record at 12:49 p.m.

(A recess was taken.)

THE VIDEOGRAPHER: We're on the record at 12:56 p.m.

BY MR. SCHIEBER:

Q. Doctor, I would like to turn to page 38 of your report where you begin to summarize your opinions.

A. Yes.

Q. Is it fair to say that you're -- the first opinion that you've got here is that there is simply no adequate studies on the efficacy and safety of ECT.

A. Yes. That is -- yes.

Q. How did you come to that determination?

A. By the data that I have reviewed, the summaries of, like, the Read article and several other articles that I have read. And then I have done my own literature searches and have not found any -- and I'm not going to say that I did, you know, a complete literature search of all seven databases back in the '50s, but I haven't seen any

adequate studies that were considered adequate and well controlled or studies that I reviewed that have -- were what I would consider adequate and well controlled, so -- and I haven't seen anybody -- well, that was the -- that was the opinion of the advisory committee, was that there was a very -- a significant lack of reliable data on safety and effectiveness for ECT.

Q. What sort of literature review did you do?

A. I went on PubMed, Medline and reviewed ECT, adverse -- what did I -- yeah, adverse events ECT, ECT, in general. I went back and reviewed -- or put in a few of the authors' last names. Sackheim was one of them that I remember doing recently.

I'm not going to say that I have done, you know, that I have reviewed all of the available data. But on the other hand, I haven't seen -- I haven't seen any data, any adequate and well-controlled studies presented in the advisory committee. I haven't seen them identified in the literature. And I don't -- I haven't seen that the 510(k) submission really provides any assessment of adequate and well-controlled

studies.

So that's basically -- those are the sources for that opinion.

Q. What do you mean by "adequate and well-controlled studies" in this context?

A. Well, I think I already discussed that earlier with you. You have to have -- if you -- you have to define an outcome. You have to define a population size that will allow you to discern the difference between the efficacy of the active control versus the sham -- the sham, the placebo arm of the study. It has to be of sufficient length, sufficient assessment. It has be blinded and undergo peer review, or submit it to the FDA for their review.

But it -- these kind of studies need to be -- you have to -- you have to have the outcome identified and then determine, based on the outcome, based on what you want to see. If you want to see a 50 percent improvement, 75 percent improvement, you base your -- the size of the population on the robustness of the efficacy you want to see, and then you enroll that number of patients. Well, you usually have to enroll more than that. But you enroll the patients. You

randomly assign them either to the active treatment or the control. And then over time, whether it's, you know, a month after ECT, ideally, since months and then a year after ECT, look at the difference in your clinical outcomes of interest between the treated and the control group and determine whether, in fact, there is efficacy.

And then, also, you need to monitor the patients for safety. Is there a difference in, I mean, whether you want to talk about, you know, oral dental outcomes or cognitive outcomes. You look and you have a series of safety issues that you monitor, that you want to monitor, and you systematically monitor those in the patient population over the period of time that you have determined is the appropriate period of time to make sure that you're collecting all of the necessary data and to make sure that you are able to determine that there is a difference, significant difference, between the treated and the control patient.

So it's not -- there's not a simple formula for it. That's why when FDA is working with a company, whether it's a PMA for devices or

whether it's a pharmaceutical product or a biological product, there's a lot of the back and forth in the phase 3 studies, the PMA studies or what are called phase 3 studies in the drugs and biologicals, to make sure you have enough patients, to make sure that you're following them for an adequate period of time, that you have an appropriate outcome measurements, that you've predefined those, that you are following safety.

And you may have specific safety concerns that you want to specifically inquire about and then, in general, inquire about those possible adverse events that the individual is attributing to the treatment.

Q. In this context with ECT, what do you believe would have been an appropriate efficacy outcome to measure?

A. You'd have to -- a well defined -- if you're looking at depression, a well-defined scale for assessing depression, the magnitude of depression, so that you -- and you assess the patients and have them do self-assessments, probably, prior to treatment, during the course of treatment, and then at specified intervals after treatment to determine whether, in fact -- because

there's -- I have read several studies that indicate that six months after ECT treatment is completed, that there's no difference between the treated and untreated populations --

Q. Do you recall which studies those are?

A. -- in terms of depression. I believe these were in populations experiencing depressions -- depression. Sorry.

And those are -- I mean, that's not even in, you know, well designed, adequately controlled studies. Those are in smaller studies with follow up, but there is some indication that maybe the response to ECT does not have a long duration.

Q. Do you recall what studies those are?

A. I would have to look them up. I just pulled some of the ones that I have. Let me see. It may have been -- some of it may have been -- I don't think it was in Read. I can't remember exactly where I read that, but I have read in more than one section with more than one study that the duration of the effectiveness was not particularly long, you know. In six months there was no difference between the treated and the control.

Q. What safety --

A. I'd have to go back and look at all of

the documents that I have to be -- I could give you that later, but I don't have it at my fingertips right now.

Q. What safety outcomes do you think need to be measured for ECT?

A. Well, I think the -- you know, in the context of what we're discussing here and now, memory functions, whether it's loss or retention of autobiographical memory, whether it has to do with the ability to develop and maintain memory in the antegrade fashion from ECT forward and, certainly, their cognitive function.

There should be -- and that was one of the things that the advisory committee recommended is that there be tests, objective measurements of cognitive function applied prior to and following ECT to determine the extent of cognitive dysfunction, the numbers or the percent of individuals who experience cognitive dysfunction, the duration, resolution, if, in fact -- there are certainly a lot of reports indicating that it doesn't always resolve, even, you know, weeks or months later.

And those are the kind -- certainly, those are safety concerns in the context of, you

know, these cases that -- or this case that we're discussing.

I mean, there certainly are a long list of other potential safety issues, having cardiovascular, pulmonary related to stroke, and so forth. That could be measured as well. But I think in the context of these discussions, certainly, measurements of memory and memory function and cognitive function would be very helpful.

Q. Are there any adequate well-controlled studies that show ECT causes cognitive dysfunction?

A. As I said, I think there have been reviews, certainly. Here's one from 1968 that is a comparison of techniques that references amnesic side effect of ECT.

Q. Is that an adequate and well-controlled study?

A. No, no. I'm not aware of there being any adequate and well-controlled studies. I think that's the -- that's the problem. But there certainly are signals in the literature, and there certainly were signals in both the docket and the presentations, as I understand it, of the advisory

committee that should spur interest in further delineating what kinds of memory and cognitive dysfunction is associated with ECT, because there's -- there are just so many reports, you know, that are not based reports that should trigger the need -- that should trigger the interest, the curiosity in, What is the rate of memory and cognitive dysfunction? What's the extent of it in an individual? And what's the duration of it for those who continue to experience problems?

I think there's a lot of -- if you were motivated and interested, it would be possible to study it. But, certainly, there's a lot of information in the literature and, like I said, from the advisory committee that indicates that those are safety concerns associated with ECT.

Q. Are there any adequate and well-controlled studies that show ECT causes memory loss?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: I think I just answered that.

BY MR. SCHIEBER:

Q. And is your answer no?
A. Correct. I have not seen any. I'm not aware of any. I haven't seen any reported.
Q. Okay. I assume you believe that those studies should be conducted, correct?
A. I think I have said that several times, yes. If you're interested -- if an individual is interested, particularly if you're marketing a device that potentially has these outcomes associated with it, I would think that would spur interest in the extent to which your device is or is not associated with those particular outcomes.
Q. Because the Thymatron is Class II device as it relates to treatment-resistant depression, is there a regulatory requirement to conduct such studies on safety and efficacy?
A. I have --
MR. ESFANDIARI: Objection to the form of the question.
THE WITNESS: I have already answered that as well.
BY MR. SCHIEBER:
Q. And there's no regulatory requirement, correct?
A. That's --

MR. ESFANDIARI: Asked and answered.

THE WITNESS: That's correct. I'm sorry. I'm sorry, Bijan.

MR. ESFANDIARI: No, that's fine, Doctor.

BY MR. SCHIEBER:

Q. That statement is correct?

A. Yes.

Q. Do you believe that the Thymatron should be classified as a Class III device as it relates to treatment-resistant depression?

A. I think that ECT devices should be Class III, so not just the Thymatron but the other. At least -- I think there's at least one other ECT device on the market in this country. And, yes, I think they should have been -- they should have stayed in Class III rather than to have been reclassified by FDA into Class II for those two indications.

Q. And why do you believe that ECT devices should be Class III for catatonia and treatment-resistant depression?

A. So that there would be actual reliable data developed to determine whether, in fact, the potential benefit of ECT outweighed the risk. And

both the benefit and the risks need to be more fully defined and better determine the extent to which there's benefit and to determine the exact extent of potential risks associated with the procedure.

Q. Do you think that ECT manufacturers misled the FDA to classify ECT devices as Class II for treatment-resistant depression?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: I'm not -- I don't know that the device manufacturers misled FDA. I think FDA had good advice from its advisory committee and did not follow up on all that advice.

So it's not so much that the manufacturers misled FDA. It's, to me, that they -- that the manufacturers haven't shown any public health interest themselves in defining risk and benefit -- in defining the risk and benefit. And the FDA did not require that of them.

So I'm not sure it's so much that the manufacturers misled the FDA as they failed to demonstrate any interest in defining risk

and benefit. And the FDA failed to require that -- that the manufacturers fully define risk and benefit.

BY MR. SCHIEBER:

Q. Let's move to your second summarized opinion. You wrote that Somatics has failed to provide any meaningful and clinical trials data on the safety and effectiveness of the device in treating severe psychiatric illness.

I believe that touches on what you just said, that -- that that goes to Somatics' interest in conducting such studies, correct?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: Yes, it does. Their interest in basically participating in public health and determining whether, in fact, this device -- that the potential benefits outweigh the known risks. You have to define risks. You have to define the benefits. And apart from the observation of two Dalmatian dogs, I'm not aware that Thymatron has -- the Thymatron device has had any evaluation of risk and benefit.

BY MR. SCHIEBER:

Q. We already touched on this. Given that there's no regulatory requirement, in what sense did Somatics fail?

A. They failed -- well, again, you know, Abrams and Swartz are M.D.s, and you -- as far as I know, you know, the Hippocratic remains part of what physicians are supposed to practice, first do no harm. And in the absence of information on risk and benefit, you can't say that this device does no harm.

So -- and I think that just in terms of wanting to participate in maintaining the public health, that somebody marketing this device, they're not giving them away. Somebody marketing this device would have an interest in determining whether, in fact, their product provides benefit that outweighs risk. And in the absence of adequate and well-controlled studies, I don't know, you know, your -- it's pure guesswork as to whether your device or your intervention is -- provides more benefit than it does risk on a population scale or to the individual, for that matter, if you can even verify risk factors for some of the manufacturers.

Q. Are there any ethical issues posed with

enrolling patients who suffer from treatment-resistant depression in clinical trials?

A. You know, that's something that I think is still an issue for discussion. I know that I have read that an IRB would not approve it. Has anyone submitted it to an IRB? Has anyone proposed a clinical trial and been rejected by an IRB? I think I would want to know -- I would want to have more information on the truthfulness of that contention, that you wouldn't get it cleared by an IRB. I know I have seen that in some of the discussion.

Well, you know, if you don't try, then, you know, making that claim is a little bit difficult to support, in my opinion.

Q. Do you recall where you read that an institutional review board would not approve a trial?

A. I don't remember, since some of the documents it may have been -- I don't remember in those documents, but I know that that has been proposed as a potential barrier to a -- I guess the other thing is you could do a placebo control, especially a placebo control, you know.

The other option might be an active

treatment with the ECT over time, you know, to treat patients with ECT and have a control group that is treated with approved pharmaceutical intervention and determine over time the effectiveness of each of those interventions, compare one to the other.

Q. What are the underlying reasons that folks have posited that IRB would not approve a clinical trial of ECT for patients with treatment-resistant depression?

MR. ESFANDIARI: Objection: lacks foundation; speculation.

THE WITNESS: My understanding is that the idea that you -- that not treating depression and that -- I mean, that's not exactly what -- you could, in fact, continue the treatment. But not treating depression would be unethical.

That, to me, is in the context of offering an intervention that we don't know is either safe or effective and promoting that in the absence of actual clinical data, you know.

I will tell you I've got a cat on the table. We ought to take a break and let me

put this one in the back.

MR. SCHIEBER: Sure. We can go off the record.

THE VIDEOGRAPHER: Off the record at 1:20 p.m.

(A recess was taken.)

THE VIDEOGRAPHER: On the record at 1:24 p.m.

BY MR. SCHIEBER:

Q. Doctor, had ECT been classified as Class III for all indications, do you believe that ECT devices would be on the market?

A. I don't know.

MR. ESFANDIARI: Objection to the form of the question of the question. Outside the scope.

THE WITNESS: They -- it would depend upon what the data would show, if they had to do a PMA. I mean, generally, the FDA has been willing to let devices stay on the market until -- if they're already on the market, until such time as the PMA is completed and the FDA has had a chance to review it. But I don't -- I don't know. I think that's -- that would be -- you know,

it's an interesting question, and we just don't have -- I don't think there is an adequate database to be able to say for sure that ECT is effective and in what populations it's effective, if it is. And what are the risks so that people who might be offered ECT, assuming it stayed on the market, can have a fair assessment of their potential benefit and the potential risks they're facing?

BY MR. SCHIEBER:

Q. Doctor, I would like to move to your third summarized opinion. What's the basis for your opinion that Somatics failed to investigate adverse events?

A. Well, the fact that up until -- what was it? -- 2016, 2018 they hadn't -- I can't remember. They hadn't submitted a single MDR. And there certainly are literature reports of adverse events.

During the advisory committee meeting they could have contacted people reporting adverse events and get a fuller understanding of what those events are and determine the relatedness of the report to -- to ECT. And, I mean, once a

lawsuit is filed, they're required to, by regulation, to investigate the report. And I'm not aware that they have executed that responsibility, those responsibilities.

I think the fact that they put in that disclaimer, they're certainly aware that there are reports of cognitive dysfunction and problems with memory associated with ECT, and yet they haven't -- they've not investigated, not attempted to investigate the specifics of those reports but wanted to put it in their labeling as a disclaimer. So I think they kind of on their own showed that they haven't -- they haven't really pursued information.

Q. What's the process for Somatics to be notified of adverse events?

A. Well, by the regulations, it's something that they become aware of or one of their sales representatives becomes aware of and then reports it. User facilities can report. Practitioners can report. But they're also -- they certainly have the option of reviewing the medical literature. And, clearly, they've reviewed medical literature. Look at the -- I mean, at 510(k) submission indicates that they've

reviewed medical literature.

But the fact that they did not pursue additional information on the diverse events reported in a fair body of the medical literature, like the study going back to 1968, it seems to me that they are kind of derelict in their obligations as a responsible manufacturer to pursue as much information as possible on side effects potentially associated with their product.

Q. How would a manufacturer go about investigating adverse report -- strike that.

How would a manufacturer go about investigating adverse events that are reported in medical literature?

A. You contact the authors. You contact the authors and request the opportunity to look at the source documents. From the source documents, you then attempt to -- you contact the physician or other reporter and get, basically, data from the individual making the report. If it's from a study, you contact the investigators and ask them for additional information. I don't see where anybody from Somatics made any attempt to contact people, the authors, to get additional information on the source data.

And they -- and I see no indication that they attempted to contact individuals who were either in person reporting adverse events at the advisory committee or any of the people -- any of the individuals who submitted reports to the docket before the advisory committee meeting.

So they certainly had the opportunity to follow up if they had been so motivated and interested.

Q. Is Somatics under an order to conduct post-market surveillance?

A. No, they are not, not from FDA, unfortunately. Yeah.

Q. Who is responsible for ensuring that the device manufacturers investigated adverse events?

A. Well, FDA is. I mean, there's a difference between -- for devices, if you are under an order to conduct post-market surveillance, that is -- you have to actively conduct post-market surveillance.

In general, post-market surveillance, not under that active order, is conducted in an almost passive way. But you are required -- once you become aware of information, you're not required to go out and solicit it, particularly,

but you are required once you become aware of information to fully investigate that to determine the -- what exactly the claim is, the background on the individual, and more information on the circumstances surrounding the report of an adverse event.

Q. To your knowledge, has the FDA ever taken action against Somatics for failure to investigate adverse events?

A. Well, they certainly in the 2012 inspection commented on the fact that Somatics basically didn't have any SOPs or the adequate SOPs in place, or MDRs, medical device reports. And, as I understand it, once they -- anyway, they did, Somatics did, put in place the required SOPs, not, you know -- and then finally submitted some MDRs.

But they were cited in the 2012 inspection as not having adequate procedures in place to identify and follow up on MDRs.

Q. Of the adverse event reports related to the Thymatron, do you know how many relate to memory loss?

A. I don't think they've submitted any related to memory loss.

Q. Well, I'm not talking about submitted by Somatics; I'm just talking about adverse event reports related to Thymatron regardless of who submitted them.

MR. ESFANDIARI: Objection to the form of the question.

Can ask you re-ask the question, Jeff? I'm not sure I understood it at all.

THE WITNESS: I don't understand it at all.

BY MR. SCHIEBER:

Q. Yeah.

So we've talked earlier about adverse event reports and failures to investigate those. I'm just trying to understand how many of these adverse event reports, regardless of the source, relate to memory loss.

A. And, I mean, that's unanswerable. If they haven't investigated adverse event reports, if they haven't investigated the several thousand that were reported at the advisory committee meeting, there's no way to -- you know, there's no way to know that. That's an unanswerable question. If they haven't investigated it and if they haven't tried to find out what the numerator

is, then it's anybody's guess.

Q. I don't think they're we're understanding. My understanding is of those reports, how many of the reports are about memory loss?

MR. ESFANDIARI: I guess, Jeff, where -- when you say "of those reports," what reports exactly are you talking about?

MR. SCHIEBER: Yeah.

BY MR. SCHIEBER:

Q. So, Doctor, you referenced there were 3,000-some public comments in conjunction with the advisory committee.

What percentage of those comments related to memory loss?

A. Let me see if that was -- let's see. It says -- oh, well, that's -- okay. It doesn't -- it says, "There are 3,045 public comments, many of which detailed brain damage, permanent memory loss, loss of cognitive function, and other adverse events."

There may be more detail in the executive summary. I haven't immediately reviewed that, so --

MR. ESFANDIARI: Dr. Arrowsmith, also,

I'd draw your attention page 17 of your report.

THE WITNESS: Okay. Oh, sorry. Yeah. Most respondents -- it's on page 17, and that's Dr. Georgiopoulos.

Okay. Memory dysfunction, 529 such reports; non-memory cognitive complaints, 357. So a summary based on Dr. Georgiopoulos's review of the letters and the -- I think it was the letters prior to the actual advisory committee itself, that 529 of the reports were of memory dysfunction.

BY MR. SCHIEBER:

Q. And that's out of -- do we know the denominator there?

A. Not -- there are 92 group letters. Well, no, it doesn't -- no, I don't -- I don't know what the denominator is. It's reported as a summary of the adverse events reported by patients and patient representatives. But I don't know what the denominator is, you know, apart from adding up the cognitive complaints, the brain damage, and shortened life span.

In that case, it looks like it's

probably almost half of the reports were of memory dysfunction, a little less than half with of memory dysfunction.

Q. Moving on to your fourth opinion --

A. I'm sorry?

MR. ESFANDIARI: I didn't hear you, Jeff.

BY MR. SCHIEBER:

Q. To your fourth opinion regarding design validation, are you aware of any manufacturing defects in Thymatron generally?

A. I haven't --

MR. ESFANDIARI: Sorry. Objection to the form of the question.

THE WITNESS: Yeah, I mean, I know there have been some reports, you know, a couple of reports of electrical discharge after the device had been either turned off, or in some way there was an unexpected event. I know there were two reports of unexpected electrical discharge. I don't remember what the other -- what the other reports were. But I'm not aware of a specific design issue, but the -- it was from the inspections that the inspectors identified the failure to

basically set up the acceptable parameters for components and how to deal with nonconforming components or products.

BY MR. SCHIEBER:

Q. Have you inspected the device used during the course of Mr. Thelen's treatment?

A. No, I have not.

Q. Is it your opinion that an alleged failure to implement design validation processes caused Mr. Thelen's injury?

A. I have no idea. I don't know whether that -- there was a design failure, a design problem that contributed to his injury. I have no idea. To me, this is just another example of Somatics' lack of engagement in their obligations under -- under the medical device regulations.

Q. Going back to your third opinion, do you believe that you any alleged failure to investigate adverse events caused Mr. Thelen's injuries?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: I don't know that the --

MR. ESFANDIARI: Outside the scope.

THE WITNESS: Yeah. I don't know that

the failure to investigate MDRs, adverse events reported, that they could have followed up on contributed to his injury. But it certainly might have contributed to the decision, his or his decision-maker's choice of using ECT or not.

BY MR. SCHIEBER:

Q. Do you believe that Mr. Thelen's injuries were caused by a failure to conduct clinical trials on safety and efficacy?

MR. ESFANDIARI: Objection to the form of the question. Outside the scope.

THE WITNESS: That would not be a -- I think overall it would be helpful to know the anticipated effectiveness and have a fuller understanding of the adverse events associated with ECT. I don't know that that -- that that lack of information -- the lack of information did not cause his injury, but the lack of information may have affected the reasoning in deciding to undergo ECT or not.

BY MR. SCHIEBER:

Q. Moving on to your fifth opinion, you wrote that Somatics and its manufacturer,

Elektrika, whose principals disclosed that they, in fact, did participate in some aspects of the design of the Thymatron machine, are similarly derelict in their duty to warn patients about the very real risks of cognitive impairment and loss of memory among patients who have undergone ECT.

My question here is specific to Elektrika. What is Elektrika's duty to warn patients?

A. Well, as I understand it, there's some documentation that Elektrika has participated in the design of ECT devices. And as such, they then, as I understand it, take on the responsibility of the manufacturer in terms of evaluating potential adverse events associated with the use of the device.

So in failing to do any investigation of adverse events, that they have, in fact, just like Somatics, completely dropped the ball as far as their public health responsibility is and their regulatory responsibilities.

Q. What is the basis for your opinion that Elektrika has this -- you said that your understanding is that Elektrika has a duty to warn. Is that based in federal regulations? What

is the basis for that?

MR. ESFANDIARI: Objection to the form.

THE WITNESS: Sure. Because they have -- there's documentation that I have read that Elektrika participated in the design of the Elektrika device, that that is the point at which they then incur some responsibility for safety and effectiveness. If they are participating in the design, then they -- they're not just a contractor; they are, in fact, a manufacturer.

BY MR. SCHIEBER:

Q. And that is -- that opinion is based on federal regulations?

A. Yes.

Q. Okay. In opinion 6 you wrote that Elektrika was advised by the FDA inspector in 2016 that it needed to register as a manufacturer.

Where did you see that?

A. If you -- it's in the -- it's in the inspection report.

Q. Of the Somatics facility or of an Elektrika facility?

A. I think it's in the Somatics facility. They -- I will have to look at it again. I know

that Elektrika was -- maybe it was -- well, let me look before I -- I guess it's in the latter part. This is the 2012 inspection. I think it was the later one. Yeah. Under the history on page 36, it says under the "history," "Interstate commerce jurisdiction discussion. The inspector was informed that the contract manufacturer for the Thymatron IV device is not registered with the FDA. The inspector informed Mr. Mirkovich, again, the firm's representative during the second inspection, claimed that the firm had been informed that such contract manufacturers were not required to register with the FDA unless they shipped the finished product directly to customers. The inspector clarified that while that was true up until a few years ago" -- which is a direct quote -- "all contract manufacturers of finished devices are required to register with FDA whether they deliver devices to customers or not."

Q. My question, though, is this is a communication to Somatics, correct?

A. Right, yes. As far as I know, yeah.

Q. So you wrote, though, in your opinion, that Elektrika was advised by the FDA inspector.

And I'm trying to understand where you got that as opposed to Somatics.

A. I thought that it -- I thought that Elektrika had been informed, but maybe that's -- but maybe it's a misstatement.

Q. Okay.

A. It may be a misstatement.

Q. Fair enough.

A. But the fact remains that I looked on the registration database a couple days ago, and Elektrika is not registered as a manufacturer contract provider, so --

MR. SCHIEBER: Understood.

Doctor, I think that's all I have for you. I imagine Ms. Cole probably has some questions for you.

MS. COLE: I do. Would you like to take a short break, Doctor, before we continue?

THE WITNESS: Sure. That would be a good idea.

MS. COLE: Okay. Let's take ten minutes.

MR. ESFANDIARI: Sure.

MR. SCHIEBER: Sure.

THE VIDEOGRAPHER: Going off the record

at 1:47 p.m.

(A recess was taken.)

THE VIDEOGRAPHER: On the record at 1:58 p.m.

MS. COLE: Are we on the record?

THE VIDEOGRAPHER: Yes, ma'am. We are on the record at 1:58 p.m.

MS. COLE: Thank you.

THE VIDEOGRAPHER: You're welcome.

CROSS-EXAMINATION

BY MS. COLE:

Q. Good morning, Dr. Arrowsmith. I think it's still morning where you are.

A. Yeah.

Q. A few minutes?

A. A few more minutes, yeah.

Q. As I introduced earlier, my name is Susan Cole, and I have -- I'm going to just sort of walk us through some of the testimony. Mr. Schieber has asked most of questions that I was going to ask, so I'm going to be moving around from place to place. Let's start by asking you your opinions about controlled trials. And I think that if I heard you right, what you had talked about is that there weren't any, as you put

it, sufficient or good quality controls, randomized, blinded studies with a large enough population size to be scientifically valid.

Is that what your opinion was?

MR. ESFANDIARI: Objection to the form.

THE WITNESS: Well, what I was talking about was adequate and well-controlled studies.

BY MS. COLE:

Q. Could you tell me where in the FDA regulations that requires adequate randomized, blinded, controlled studies to be performed by a manufacturer in order to support an approval by the FDA?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: So you want me to go -- I don't remember what the PMA -- what the -- it's in the 800s, 21 CFR. It's in the 800s. Do you want me to go and actually look for that --

BY MS. COLE:

Q. Well, I guess --

A. -- and find it for you?

Q. Let me make it more confined. I'm

looking at 360c(a)(3)(b) --

A. I don't know what that is.

Q. -- which seems to me to say that what is required to be presented by a manufacturer in order for clearance or approval is valid scientific evidence.

A. Okay. You're talking about two different things. Clearance is 510(k); approval is PMA. So these are -- those are two different mechanisms for market entry for a device.

Q. Does PMA require studies?

A. They require -- yes. PMA requires clinical studies. It requires adequate scientific evidence, and that would be based for PMA on clinical studies, yes.

Q. And, in your opinion, is that true for both devices and pharmaceuticals?

MR. ESFANDIARI: Objection to the form of the question. It's completely different. I will let the doctor answer.

THE WITNESS: There's no 510(k) for pharmaceuticals. Pharmaceuticals are not cleared, so it's a completely different regulatory framework, you know. We're talking apples and lizards.

Devices can get onto the market by being found substantially equivalent to a predicate device whether it's on the market or not, so long as if it's off the market and it was not removed from the market for safety reasons.

There's no such mechanism for market entry for pharmaceuticals.

BY MS. COLE:

Q. For ECT, we know that those devices came onto the market through the process of a 510(k). Is that true?

A. No, no. They were on the market prior to 1976, so there's -- ECT devices have been on the market prior to '76, I think back in the '50s, maybe earlier. I don't remember. I don't know when the original ECT device was -- when marketing began for the first ECT device.

But the Thymatron device, Somatics' devices were 510(k)'d in 1984. They were found substantially equivalent to a device that had been on the market prior to 1976 and which had not been removed from the market because of safety concerns.

Q. And the Thymatron devices were cleared products under the 510(k) process at the time of

the 2011 meeting that you talked about earlier; is that true?

A. No, that is not true. Well, they were still Class III. They were still Class III according to the way the device regs were set up. So they had been -- they were -- it's complicated. They were -- they were -- they came on the market in '84. They were allowed onto the market through the 510(k) process. But because of the way that the device regulations were written, they were intended to be Class III. The FDA -- there were probably hundreds of devices that were classified -- on the market that were classified as Class III pending FDA review.

Now, I don't remember where -- when it was late 19- -- maybe the early 2000s, the general accounting office told the FDA they needed to make a decision, a final determination about -- for ECT devices, whether they were going to remain on the market as Class II or whether they were going to be reclassified -- or they were going to classified or remain -- it's so implicated -- whether they would be determined to be Class III and then require premarket approval, which would involve clinical studies and additional data to

actually be approved for marketing as opposed to being cleared for marketing.

Q. At the time of the 2011 meeting, they were cleared for marketing as an existing 510(k) equivalent, true?

A. Correct. But they were also -- I'm trying to find the exact -- they were -- there was a technicality that they were Class III. Yes, they were cleared as -- for marketing, but they were grandfathered. They were grandfathered onto the market, and yet they were determined to be Class III and had to be reclassified as either I or II. I mean, they clearly were not eligible for Class I, but they could have -- you know, a Class II was an option.

And for two of the six indications, ultimately, the FDA declared them Class II while the remaining four indications remained as Class III.

Q. When the FDA held its meeting in 2011, there were many different participants who gave input to the advisory committee and also to the FDA about the Thymatron ECT product, true?

A. Well, I'm not -- I mean, input -- the advisory committee members provided input. There

were public comments and submissions to the docket, as well, prior to the meeting. So there were a number of sources of input related to the advisory committee meeting.

Q. And part of the 2011 meetings and hearings was the ability of the -- both the advisory committee and the FDA itself to look at already published studies and reports and details that had come in via reports about ECT; is that fair?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: I don't know. And what do you mean details that come in via reports? What do you mean? I don't know what that is.

BY MS. COLE:

Q. Were there published studies about ECT before 2011?

A. Oh, there were, yeah, lots and lots of --

Q. Hundreds?

A. -- published -- well, you know, whether they were studies or not is, I think, is maybe debatable. But there were certainly, yes, hundreds of publications referencing ECT.

Q. And the groups conducting the 2011 hearings considered the peer-reviewed publications involving ECT; is that right?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: What do you mean the group involved? What do you mean?

BY MS. COLE:

Q. Whose job was it to look at the articles that had been in the peer-reviewed scientific literature at the time 2011 hearings?

A. Well --

MR. ESFANDIARI: Objection to the form of the question.

Go ahead, doctor.

THE WITNESS: Well, the obligations -- well, FDA would have reviewed some of the publications and the company, although I don't believe they did a presentation. I don't -- yeah, they must have. I don't remember. I don't remember whether Somatics did a presentation or MECTA. But it was -- so it was FDA's job and it was the medical device manufacturer's job to review the data and determine if they felt it was adequate.

BY MS. COLE:

Q. And there was available data before 2011 that mentioned memory loss and mentioned what they described as cognitive effects of ECT?

A. Yes, there had been, yeah.

Q. The advisory committee was formed by the FDA to offer an opinion about whether or not the Thymatron device would be granted Class II status or whether it would stay Class III, right?

A. No. It was not specifically the Thymatron device; it was ECT devices. So there I believe were two manufacturers active at that time, so it was not specific to Thymatron, no.

Q. Was there any distinction made between the Thymatron device and the MECTA device and the considerations given during that 2011 set of hearings?

A. Not that I'm aware of. I mean, they were -- they were looking at the classification of ECT devices, not any specific manufacturer's device.

Q. And is it your understanding, Dr. Arrowsmith, that the advisory committee was charged with making a consensus recommendation on classification, whether it would stay Class III or

whether it would go to Class II?

A. No. They were -- they addressed it as by indication, not as a blanket classification. I'm not aware that they were asked to approach it as a blanket classification.

Q. Were they asked to form a committee consensus?

A. Well, they -- yes. They voted as a way to indicate consensus.

Q. And when they voted, did the group as a whole reach a consensus through its chair?

A. There was not uniform consensus. There was not a total agreement on, as far as I know, on any of the six indications for ECT in terms of its reclassification or not. Catatonia was the only indication for which the majority of the panels -- of the panel voted in favor of Class II. Nine out of the 17 voting members recommended Class II reclassification.

For the other five indications, the consensus by a majority vote was that that indication should remain in Class III.

Q. When the vote was taken, did the chair participate in that vote?

A. He said he did not specifically offer

his recommendations on classification.

Q. So he would have been the -- his vote would not have counted in the nine to eight or eight to nine vote as you just described; is that true?

A. Well, he did not vote, so it wasn't a matter of counting his vote. He abstained. He did not -- he did not vote.

Q. I see.

Now, the FDA decided after considering -- strike that.

The FDA, in addition to considering the advisory committee, also considered other factors, right?

A. Presumably, because they did not -- they did not fully follow the advice of their advisory committee.

Q. And part of the factors that they considered was the state of the published literature?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: I'm not aware of any place where they outlined what exactly the -- what the deciding factors were. I mean, we

certainly have a lot of discussion on the panel about sort of the inadequacy of the available published literature in determining both safety and effectiveness. So I don't know exactly what FDA took into account. I'm not aware of the -- of the published explication of their decision-making.

BY MS. COLE:

Q. You personally disagreed with the FDA's action, true?

A. Yes, I do.

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: I'm sorry, Bijan.

MR. ESFANDIARI: No problem, Doctor.

THE WITNESS: I disagree with it, yes.

BY MS. COLE:

Q. Do you know if the devices used in Mr. Thelen's treatment, in fact, had any malfunctions?

A. I believe Mr. Schieber asked me that earlier, and, no, I do not.

Q. Do you know if the Thelen case was reported by Somatics to the FDA?

A. I don't remember. I don't know. I

don't remember.

Q. I want to talk to you now about the studies that you were discussing.

Have you ever designed a study for any medical device?

A. A medical device, no, uh-uh (Indicating negatively).

Q. Have you ever designed a study for any pharmaceutical device or pharmaceutical product?

A. I have certainly been very involved on the review and comment on a number of studies intended to -- at different stages of development intended to provide information about safety or safety and effectiveness. Well, no, it wasn't a -- I have been involved in other studies but not -- to determine safety or effectiveness.

Q. Was that in conjunction with your work on AIDS?

A. No. As a premarket reviewer in the Center For Biologics, I was involved in assessing the adequacy of clinical trials, and there were products that I was responsible for in the division of antiviral drugs that were not HIV/AIDS products. So I have been involved in the review of INDs, in particular in -- outside of the

context of HIV.

Q. Have you -- as a practitioner you, as a primary care physician, have you ever made a report to the FDA about anything?

A. Yeah, I sure have.

Q. Tell me about that.

A. Oh, I --

MR. ESFANDIARI: Objection. Overbroad. Go ahead, Doctor.

THE WITNESS: I'm sorry.

MR. ESFANDIARI: Just give me one second to interject before responding, but go ahead.

THE WITNESS: I know. I'm so sorry. I'm too relaxed. It's home.

I believe that I made reports on the antidepressant Paxil early on in its course of marketing. I know I have reported on devices. I have made -- you know, I don't remember the specifics, but I have made a number of reports to FDA on adverse events that I have observed in the course of my clinical practice.

BY MS. COLE:

Q. Have you as a primary care physician provider ever recommended somebody for referral to

evaluate ECT as a treatment?

A. No.

Q. Is psychiatric conditions something that you primary care provider were responsible for?

A. Yes, yes, I certainly -- yeah.

Q. Have you ever treated any patient that had received ECT, to your knowledge?

A. No, not that I'm aware of.

Q. You mentioned two visits to the Somatics facility, one in 2012 and one in 2016. I next want to talk to you about that.

The visit that was --

A. You're meaning inspections?

Q. Inspections, yes.

A. Inspections. Okay.

Q. Inspections, yes.

Those inspections are -- those inspections also called observations; is that true?

A. No. They're inspections, and what the inspectors observe and document are then referred to as the observations.

Q. And the --

A. The inspections -- the inspections are specifically inspections.

Q. Okay.

A. Sometimes for cause because of a concern and sometimes they're routine.

Q. Do you know in 2012 whether the inspection that was done of the Somatics facility was routine or for cause?

A. I don't know. Let me see. It should have been -- it does not -- I don't see that it is specified whether it was for cause or a routine inspection.

Q. As a result of the observations made during the 2012 inspection, were there -- was there voluntary compliance made?

A. I believe that the observations that were listed were 11 observations. I believed that they -- there was a comment that the -- that those previous observations had been -- had been dealt with. They had, I think --

Q. Now, the FDA has the ability after one of these inspections and observations to issue a warning letter or to otherwise contact a manufacturer to demand compliance.

A. Well, depending upon the nature of the observations, yes, the FDA certainly has within its regulatory authority the ability to require

compliance within a framework, if they want to, within a time frame. But, yes, the FDA has the ability to require compliance with the needed changes.

Q. And in this case, that requirement was not met and it was not needed, because the company voluntarily complied, true?

A. Well -- and the nature of the observations was such that they did not a pose an immediate danger to patients. But, no, they did not invoke the requirement. I think the -- no. There was no warning letter, for instance. There was injunction against distribution.

Q. You used -- earlier today, you used the term that Somatics was cited for these observations or these findings.

What did you mean by the word "cited"? Did you mean that there was some action taken against Somatics because of these -- failure to comply with these observations?

A. No. They were -- these were problems that were cited by the inspector and were included in the observations. They were identified. Cited meaning they were identified by the --

Q. I see.

A. -- by the inspector --
Q. I see.
A. -- as deficiencies.
Q. I see.
So you don't mean they were cited like getting citation or some sort of a -- like an infraction notice, right?
A. Well, the observations identify some problems, so they -- these 11 observations mean that these are problems that the company needs to address.
Q. And the company did address those?
A. Apparently. I believe there was a statement in the 2016 -- part of the 2016 inspection that indicated that those previous observations had been resolved.
Q. And then there was -- there were other observations made in the 2016 inspection?
A. Yes.
Q. And do you find any either warning letter or other communication to Somatics that those findings were not voluntarily complied with?
A. No, I hadn't -- I haven't seen any additional communications indicating that it was a persistent problem, that there was a persistent

problem.

Q. Have you identified any cases or matters that Somatics did not report to the FDA or through MAUDE that would have changed the labeling or the results of reclassifying the ECT device to a Class II?

A. Well, I think there are abundant reports in the literature of cognitive and memory dysfunction, none of which I saw any evidence that Somatics had further investigated.

There was no investigation of the reports offered either as public comment during the advisory committee meeting in 2011, nor as part of the submissions to the public docket that had been -- that Somatics followed up on.

And I don't recall whether they -- I mean, I know there are several plaintiffs involved in legal action against Somatics, and I'm not aware that Somatics has -- has followed up on those complaints and reported them to MAUDE as they are, basically, required to do.

Q. You don't know one way or the other whether those have been reported through MAUDE?

A. I don't remember. I don't think so. I believe not, but I don't -- I need to go back and

look again at the MAUDE database. I haven't done that for several months.

Q. The citizens petition that you referred to about having -- presenting an opportunity, as you put it, to report by Somatics to the FDA, the citizens petition was made to the FDA, wasn't it?

A. Yes.

Q. So the FDA was well aware of the citizens petition?

A. But the citizens petition did not offer patient-specific and facility-specific information and specific outcome information and information about the plaintiffs health prior to and following ECT. So there's a lot of -- a lot of additional documentation that's required for submission of an MDR. And I saw no evidence that Somatics followed up on any of the information offered in citizens petition.

Q. Do you have any information that Somatics was aware of any of these specifics, as you put it?

A. I'm not -- I don't understand the question.

Q. Well, you're testifying that somehow Somatics didn't report these -- the citizens

petition and the specifics of the citizens petition to the FDA. What I'm asking is, was Somatics made aware of any of the specifics of the citizens petition?

MR. ESFANDIARI: Objection to the form of the question; misstates facts.

THE WITNESS: Okay. The citizens petition was directed to the FDA. It was not -- as I'm aware -- I'm not aware that this was directed to Somatics or MECTA. But, certainly, once they became aware of it, they had the -- either of those manufacturers had the opportunity to request additional information, which I'm not aware that Somatics did. Had they been wanting to find out more about the individual reports from the citizens petition, they certainly could have gotten in touch with the original petitioner.

BY MS. COLE:

Q. And did the FDA have that same opportunity?

A. They -- and they -- no, I don't think that FDA investigated the individual reports.

Q. Did they have an opportunity to do so?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: They had the opportunity, but it's the primary responsibility of the manufacturer. If the FDA -- the FDA is not marketing this product. The FDA is not -- it is the primary responsibility of the manufacturer. I mean, that's clear in the regs.

BY MS. COLE:

Q. Are you aware of any reports made to Somatics, directed to Somatics, that included the kinds of claims that Mr. Thelen is making in his lawsuit about loss of memory?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: I don't know if -- once the company becomes aware of the legal claims against them, that insight and responsibility is for them to follow up and report as MDRs the allegation in the legal documents. I'm not aware that they have done that.

I don't know -- I remember they had a brief summary of some of the MDRs, of some reports submitted to them and claimed to have

investigated further, at least a couple of those, that was in the 510(k) submittal.

BY MS. COLE:

Q. And were all of those related to burns from an electrode?

A. No, they were not all related to burns from an -- there's a risk of permanent persistent -- or of permanent -- or persistent or permanent memory loss. So let's see. Now, these are just -- they cited some studies. They're a very selective citation of studies that they put in the -- in their 510(k) submission.

Q. And what was the date of that?

A. This submission was July 1st, 2009.

Q. Do you know if --

A. So -- go ahead.

Q. I'm sorry, I didn't mean to cut you off. Go ahead.

A. So it's somewhere in their discussion. There was some comment about the wording of some of the adverse events reported to them. And that seemed to indicate that they didn't feel it was necessary to follow up on them. And I can't -- and I can't find that specific document. But it had to do with a -- the way ECT was described.

Q. So it's your testimony that in 2009 Somatics reported to the FDA about some reports in the literature about cognitive effects of ECT?

MR. ESFANDIARI: Objection to the form of the question; misstates facts.

THE WITNESS: The 510(k) submission, July 1st of 2009, briefly discusses a number of factors, I think both safety and effectiveness. Let me see this. Yeah. Risks to health and then it outlines a number of -- summarizes a few studies. But I would say this -- this is not an exhaustive review of the available published data.

BY MS. COLE:

Q. Did Somatics make reference to the 2001 guidelines from the task force on ECT of the American Psychiatric Association?

A. Okay. I see the UK ECT group referenced in this 2009 submission, but I don't see the American Psychiatric Association referenced.

Q. Are you familiar with the task force publication on ECT?

A. I have -- I don't know that I have reviewed that entire document. I'm aware of statements by the APA, but I haven't read --

reviewed that entire document.

Q. Do you know if that document mentions memory loss as a possible risk of ECT?

A. I don't remember whether that specifically mentions memory loss as a possible risk. There are an awful lot of published studies that certainly do, but I don't remember whether that one specifically does.

Q. The risk of memory loss from ECT, even permanent memory loss, was not a secret from the FDA when it did its 2011 evaluation of reclassification, right?

MR. ESFANDIARI: Objection to the form of the question.

THE WITNESS: They didn't do their re-evaluation -- well, at least they didn't publish their final re-evaluation for -- well, it was in 2011 that the advisory committee meeting was held, but it was sometime after that before FDA made any final statements.

But, I mean, the fact that in 2018 they required the company to put it in their manual indicates to me that they -- if they were not previously aware, they were aware by

then. And there was certainly discussion in the advisory committee meeting. There was discussion among the advisory committee members that the evaluation of cognitive and memory issues was inadequate, that -- and I think it was the chair who said he certainly would have done things differently from the way the FDA handled it.

BY MS. COLE:

Q. Is it your opinion, Dr. Arrowsmith, that had Mr. Thelen's physicians told him about the potential for memory loss, that he would have behaved any differently?

MR. ESFANDIARI: Objection to the form of the question; outside the scope.

THE WITNESS: That's something you would have to ask of the patient themselves. But at this -- I mean, I -- who -- I mean, that's not --

MR. ESFANDIARI: Objection.

It's outside the scope of your testimony.

BY MS. COLE:

Q. Do you know whether or not Mr. Thelen was, in fact, told about the potential for

permanent memory loss?

MR. ESFANDIARI: Objection. Outside the scope of testimony.

Dr. Arrowsmith is not providing any case-specific opinions.

MS. COLE: I'm just asking if she knows.

MR. ESFANDIARI: It's outside the scope, Susan.

MS. COLE: Are you instructing her not to answer that question?

MR. ESFANDIARI: Yeah. It's outside the scope, as I indicated. She's providing -- she's not providing and she's already told Mr. Schieber she's not providing any case-specific opinions.

BY MS. COLE:

Q. All right. Let's continue on. Let's walk this way.

You said that before the 2018 ruling came out there was a publication in the Federal Register.

When was that publication?

A. I'm not sure. I did say that, but I -- what -- there have been a number of publications in the Federal Register.

Q. When -- in conjunction with the 2011 meeting, were there publications in the Federal Register following that meeting that detailed where the FDA's position was going to be on ECT?

A. I'm sure there were -- I believe there was a statement -- let me see if I can find it -- by FDA, but I don't remember the -- I don't know if it's in my report. I don't remember exactly what was -- what was published.

MR. ESFANDIARI: Susan, if you have a question about a specific federal registration, just ask it.

MS. COLE: I'm just asking for the date for the one she's referring to when she testified that it was published in the Federal Register well before 2018. I'm just trying figure out which -- when that was.

BY MS. COLE:

Q. Was it like 2014? Was it 2013? Was it 2017?

A. We may be talking -- I wouldn't -- I don't remember specifically saying it was in the public -- the Federal Register, but maybe. Let me see. I'm looking for -- I may have misspoken. I don't remember. I can't -- I can't identify

specifically for you an FR notice ahead of the -- let me see if I have it among my documents here. Proposed order December 29th, 2015, 80 FR 81223, so --

Q. Is that the one you were talking about?

A. It must be.

Q. Okay.

A. So it was December 29th, 2015.

Q. Have you read the report of Dr. Feigal in this cause?

A. Yes, yeah. It is -- it is the December 2015 FR, 21 -- yeah. Addressing 21 CFR, part 882.

MR. ESFANDIARI: Susan, before you go on to your next question, the question that I objected to, it occurred to me I didn't wait to hear your full question before I interjected. So I just want to make sure it was something that was outside of her scope and not something that had actually been covered by her report.

Can you ask that question again? And I apologize if I interjected before you finished your question.

MS. COLE: Right now, I'm not sure

exactly what the question was.

MR. ESFANDIARI: Okay. Maybe when we take a break, we can have the court reporter go back to that portion of the transcript.

Go ahead.

THE WITNESS: Was that the question about Mr. Thelen would have made a different decision had he known?

MR. ESFANDIARI: Yeah. And then there was a question after that, and that's one that I wanted to find out.

MS. COLE: I think that was the question about whether or not Mr. Thelen received information from his physicians about the risk for potential memory loss.

MR. ESFANDIARI: I see. And that is outside of her scope. But you were asking whether she knew one way or the other, was your question.

MS. COLE: That's right. I was asking her one way or the other whether she knew, when you told her not to answer that question.

MR. ESFANDIARI: So I will withdraw the objection. It is outside her scope, but to

the extent that you knew one way or the other, Doctor, do you have any recollection?

THE WITNESS: I don't.

MR. ESFANDIARI: Yeah.

THE WITNESS: I don't.

BY MS. COLE:

Q. Did you read the report of Dr. Feigal in this case?

A. Yes.

Q. Have you read his conclusions in this case?

MR. ESFANDIARI: In the report?

MS. COLE: In the report.

THE WITNESS: Yeah, I have. His overall opinions, is that what you're talking about?

BY MS. COLE:

Q. Yes, ma'am.

A. Uh-huh (indicates affirmatively). Yeah, I have.

Q. Do you agree with Dr. Feigal's opinion that the professional labeling of ECT devices has been thoroughly reviewed and considered by the FDA?

MR. ESFANDIARI: Objection to the form of the question; lacks foundation; vague and

ambiguous as to time.

Dr. Arrowsmith, you can answer.

THE WITNESS: But he says it has been thoroughly reviewed and considered by FDA and the public process, that collected reports from patients, healthcare providers, and other interested parties, and that the current labeling has not been found inadequate.

Well, the 2018 -- by 2018, FDA told the company what to include in terms of cognitive and memory. So at that point the FDA had made the determination that those -- that that data was not adequately presented and labeled. So I disagree with it on that point.

And I don't -- I mean, I don't know that the FDA thoroughly reviewed and considered the labeling. I think if they had thoroughly reviewed and considered it, they would have made sure that the disclaimer -- that there was no disclaimer in there, which basically runs against the advise they give in their guidance.

And the fact that the company kept

claiming that their product had been cleared by FDA, when that is in a direct violation of the regulations -- device labeling regulations, makes me think that maybe FDA did not so thoroughly review the labeling.

So, no, I don't agree with that statement by Dr. Feigal.

MR. ESFANDIARI: Dr. Arrowsmith, I think you meant by "approved" and not "cleared," right?

THE WITNESS: I'm --

MS. COLE: I object to the objection.

THE WITNESS: That's true. They were claiming that it was approved by FDA -- sorry -- which is clearly in -- well, it wasn't true, for one thing. And it's clearly -- I mean, it's importantly and clearly in violation of FDA's regulations about labeling. And FDA did not write a warning letter about either of those.

So I can't say that the professional labeling had been thoroughly reviewed and considered by FDA.

BY MS. COLE:

Q. Would you agree that the FDA did not

grant the relief requested by the citizens petition that was presented in 2011?

A. Yes, that's my understanding, that they did not -- that they denied the citizens petition.

Q. Are you currently affiliated with the FDA?

A. No, not other than a lifetime member of the FDA alumni association, no.

Q. Why is it that you have selected Dr. John Read's articles to rely upon other than other articles in the medical and scientific literature that have been published?

MR. ESFANDIARI: Objection to the form of the question; lacks foundation; misstates facts.

THE WITNESS: I didn't solely rely on Dr. Read. I read a lot of articles, a number of articles in the literature, you know. As I mentioned -- what is it? Dr. Heckham. Here's Weaver. Sackheim, S-a-c-k-h-e-i-m, I have read several of his articles. Valentine, Vasavada, William McDonald.

BY MS. COLE:

Q. Have you read any of Dr. Coffey's articles, C-o-f-f-e-y?

A. I don't remember that name.
Q. What about Dr. Kellner, K-e-l-l-n-e-r?
A. Yes, I have read -- I have read Kellner, yeah.
Q. Do you agree with Dr. Kellner's view of the safety and efficacy of ECT?
MR. ESFANDIARI: Objection.
THE WITNESS: I don't --
MR. ESFANDIARI: Excuse me. Objection; lacks foundation; vague and ambiguous; overbroad.
THE WITNESS: You know, can you show me his article? I don't have a copy of it here. I know I have reviewed it, because I remember his name, but I don't remember the specifics of his article. I need to look at it.
BY MS. COLE:
Q. I don't have it also. I made some things to save on my screen, but that's not one of them that I chose, so I will pass on that question since you haven't -- you don't recall it, but you do recall having read it.
Do you think it was inappropriate for Somatics to make reference to, in their manual, an instruction to -- for an ECT provider to read the

task force report by the American Psychiatric Association?

MR. ESFANDIARI: Objection to the form of the question; lacks foundation.

THE WITNESS: I don't know that it was inappropriate. I'm more concerned with the information that was not in the label rather than the information and recommendations that were in the labeling. So I know I have read -- or looked through the task force, at least an article, part of it at least. But I don't, I mean, I don't have any objection to that.

BY MS. COLE:

Q. Have you been provided the depositions of Dr. Alsakaf or Dr. Sharma on Dr. Sadiq who treated Mr. Thelen with ECT?

A. No, I have not, no.

Q. Are you familiar with a training program on ECT that is provided to doctors who wish to administer ECT?

A. No, I'm not aware of such a training program.

Q. Are you aware of any sort of an instructional program or documentation that is

requested that is recommended for the practitioners of ECT be familiar with?

MR. ESFANDIARI: Objection to the form of the question; vague and ambiguous; very overbroad.

THE WITNESS: I'm a regulatory person. Okay? I'm not -- I'm not addressing what may or may not be recommended by professional associations or state associations, or whomever. I'm looking at the labeling. I'm looking at the -- at the information available from the company to practitioners and patients. So there may be, you know, there may be other sources of information, but I -- that's not what I'm considering. Those other sources are not what I'm considering in developing my opinions and offering my opinions.

BY MS. COLE:

Q. Are you opining that because Somatics didn't include certain information about the potential for cognitive changes with their instructional material to physicians, that somehow the physicians were prevented from learning about ECT and the potential risk for memory loss?

A. What I'm referencing are the regulations that FDA has promulgated that require the company to provide the information a physician needs to know to safely and effectively use their device.

If they omit significant safety information, in my opinion, they have not met that regulatory requirement. So, you know, there are -- certainly, there are a lot of -- there are other sources, scientific literature, that physicians can refer to or practitioners can refer to. They can attend professional meetings with peer-reviewed presentations, but that doesn't relieve the company of providing information that is readily available, has been -- there are articles going back to 1968 that reference cognitive dysfunction.

It's not as though this is, you know, suddenly in 2018 this is cutting-edge information that nobody has heard of before and the company hasn't had the time yet to put it in its label. That's the instance in which I say, Yeah, well, you know, if there's something brand new in the scientific literature and it seems valid, consider it.

That's not what we're talking about

here. We're talking about reports of cognitive -- cognitive dysfunction and loss of autobiographical information in memory and failure to be able to adequately develop antegrade memory. This is not information that you can only get from, you know, yesterday's New England Journal.

So, no, the company is not relieved of the obligation to inform practitioners of information, safety information, that's readily available in the scientific literature. And if they had questions about whether it was actually associated with their device or not, they could have conducted studies themselves. They could have enlisted, you know, schools of medicine or the Mayo Clinic. I don't know who all offers ECT, but they could have -- they could have enlisted practitioners to participate in safety studies.

I see no evidence that they made any effort to fully define the potential risks of cognitive dysfunction and loss of adequate memory function, even though, as I said, it's been in -- I have seen articles back to 1968 discussing cognitive dysfunction. And I see no evidence that Somatics made any attempt to quantify the potential for cognitive dysfunction based on a

broad range of literature sources.

Q. Dr. Arrowsmith, has the FDA taken action against Somatics for this behavior that you are criticizing?

A. The FDA instructed them in 2018 what needs to go on the label. So, you know, that, to me, means that the FDA had reviewed the labeling and decided it was inadequate in terms of the information being provided about memory and cognitive dysfunction.

Q. Dr. Arrowsmith, has FDA taken any regulatory action against Somatics for its, as you put it, failure to put warning language that you've talked about in its labeling --

MR. ESFANDIARI: Objection. Asked and answered.

BY MS. COLE:

Q. -- prior to the 2015 publication of the proposed regulation?

A. As I said, FDA specifically instructed the company on language to include in the labeling. Had the company not included that language, they would have been subject to further regulatory action.

The fact that FDA instructed them to put

that language in their label is, in fact, a regulatory action. When the FDA tells you to put this in your label, it means that your label is inadequate without it. So that is the regulatory action and intervention that FDA took in this instance, instructing the company what to add to their label.

Q. If this case is tried, Dr. Arrowsmith, in late February or early March of 2023, are you planning to come to trial?

MR. ESFANDIARI: Objection to the form of the question; calls for speculation.

THE WITNESS: I have no idea, you know. You need to ask the law firm of Baum and Hedlund if they will call me. I don't know.

BY MS. COLE:

Q. If you are called to come to trial, will you be willing to come to trial in Tampa?

A. Yes, yes, I would. I would appear if I were -- if it was requested of me, yes, I would appear.

Q. And do you know in Mr. Thelen's case whether the lack of specific language in a specific place in its manual to physicians had any effect on Mr. Thelen's care and treatment?

MR. ESFANDIARI: Can you repeat that question? I'm sorry.

MS. COLE: Mr. Court Reporter, can you read it back please?

(The portion requested was read back for counsel.)

MR. ESFANDIARI: Objection to the form of the question; outside the scope of this expert's designation.

BY MS. COLE:

Q. You can answer.

A. I have not reviewed any of the specifics of Mr. Thelen's case other than understanding that he had quite a number of treatments of ECT. But, no I don't have any other information about him.

MS. COLE: Those are all of the questions that I have. Thank you.

MR. ESFANDIARI: Can we take one break for five seconds? I just want to look at my notes and make a quick analysis.

MS. COLE: Sure.

MR. ESFANDIARI: Off the record for two minutes.

THE VIDEOGRAPHER: Off the record at 3:02 p.m.

(A recess was taken.)

THE VIDEOGRAPHER: On the record at 3:08 p.m.

MR. ESFANDIARI: Dr. Arrowsmith, I would like to thank you for your time today. I have no further questions to ask you.

I would like to order a copy of the deposition transcript, as well as a copy of the video linked, please, with the testimony.

And, also, we will reserve the right for Dr. Arrowsmith to review and sign her transcript as well, per code.

So with that, we can go off the record, I think.

THE VIDEOGRAPHER: We're off the record at 3:09 p.m. Thank you.

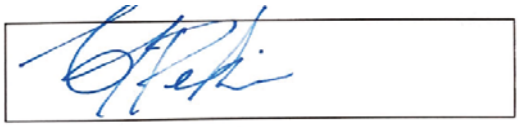
(Deposition concluded at 3:09 p.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA
COUNTY OF HILLSBOROUGH

I, the undersigned authority, certify that JANET ARROWSMITH, M.D., appeared remotely (via videoconference) before me and was duly sworn.

WITNESS my hand and official seal this 25th day of October, 2022.



Aaron T. Perkins, RMR, CRR, CRC, CCR
Notary Public - State of Florida
My Commission Expires: 4/1/2024
Commission No. GG975331

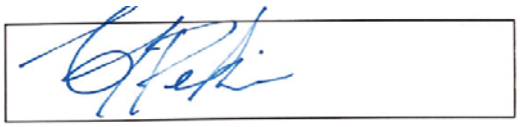
REPORTER'S CERTIFICATE

STATE OF FLORIDA
COUNTY OF HILLSBOROUGH

I, Aaron T. Perkins, Registered Merit Reporter and Certified Realtime Reporter, certify that I was authorized to and did stenographically report the deposition of JANET ARROWSMITH, M.D., remotely (via videoconference); that a review of the transcript was requested; and that the transcript is a true and complete record of my stenographic notes.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

Dated this 25th day of October 2022.



_____
Aaron T. Perkins, RMR, CRR, CRC

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

November 8th, 2022

To: Bijan Esfandiari

Case Name: Thelen, Jeffrey v. Somatics, LLC And Elektrika, Inc.

Veritext Reference Number: 5528172

Witness: Janet Arrowsmith , M.D. Deposition Date: 10/24/2022

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5528172
CASE NAME: Thelen, Jeffrey v. Somatics, LLC And Elektrika, Inc.
DATE OF DEPOSITION: 10/24/2022
WITNESS' NAME: Janet Arrowsmith , M.D.
In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.
I have made no changes to the testimony as transcribed by the court reporter.

_____ _____
Date Janet Arrowsmith , M.D.
Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5528172
CASE NAME: Thelen, Jeffrey v. Somatics, LLC And Elektrika, Inc.
DATE OF DEPOSITION: 10/24/2022
WITNESS' NAME: Janet Arrowsmith , M.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

_____ _____
Date Janet Arrowsmith , M.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 5528172

PAGE/LINE(S) / CHANGE /REASON

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Date Janet Arrowsmith , M.D.

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____

DAY OF _____, 20_____ .

_____

Notary Public

_____

Commission Expiration Date

j

k

p

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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