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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JEFFREY THELEN,

Plaintiff,

vs.

Case No.

8:20-cv-01724-TPB-

SOMATICS, LLC, and ELEKTRIKA,
INC.,

JSS

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

PROCEEDINGS	Page 4
DIRECT EXAMINATION BY MR. SCHIEBER	Page 5
CROSS-EXAMINATION BY MS. COLE	Page 67
CERTIFICATE OF OATH	Page 110
REPORTER'S CERTIFICATE	Page 111
ERRATA LETTER	Page 112
SIGNATURE PAGE	Page 113

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 Elekrika, 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

1 the witness and then counsel may proceed.

2 Thank you.

3 JANET ARROWSMITH, M.D.,

4 the witness herein, being first duly sworn on

5 oath, was examined and deposed as follows:

6 THE WITNESS: I do.

7 THE REPORTER: You're under oath.

8 THE WITNESS: Thank you.

9 MR. SCHIEBER: Good morning,

10 Dr. Arrowsmith. My name is Jeff Schieber. I

11 represent ElektriKa which is one of the

12 defendants in this action.

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

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

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

22 DIRECT EXAMINATION

23 BY MR. SCHIEBER:

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

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

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

8 Does that sound fair?

9 A. Yes.

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

12 A. Well, I graduated from medical school in
13 1979. I did an internal internship and residency
14 and completed that in 1982.

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

19 In 1984 I started an epidemiology
20 fellowship through the Centers for Disease Control
21 in Atlanta, and I was assigned to the U.S.
22 Food and Drug Administration. So starting in
23 1984, I was involved in the conduct of post-market
24 surveillance for pharmaceutical products. At the
25 time, actually, it was both pharmaceuticals and

1 biologics.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 (A recess was taken.)

14 MR. SCHIEBER: On the record at
15 12:11 p.m.

16 BY MR. SCHIEBER:

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

21 A. Sure.

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

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

7 And so from starting probably in late
8 '84, early '85, I joined the faculty at the
9 Georgetown School of Medicine at the department of
10 medicine, internal medicine, and I had Friday
11 afternoon clinic there for several -- several
12 years.

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

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

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

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

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

1 Q. Okay.

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

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

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

22 A. Psychiatry, no, I have not.

23 Q. Have you ever administered
24 electroconvulsive therapy?

25 A. No, I have not.

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

3 A. No, I ever not.

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

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

12 Q. Does Riera ring a bell?

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

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

18 MR. ESFANDIARI: Objection to form.

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

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

4 BY MR. SCHIEBER:

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

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

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

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

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

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

18 A. That's correct.

19 Q. Have you reviewed any of his medical
20 records?

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

24 Q. Understood.

25 Doctor, if you could flip to page 13 of

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

3 Do you see that?

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

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

8 A. Yes.

9 Q. All right. Do you believe that Somatics
10 should have submitted additional safety and
11 efficacy information in conjunction with that
12 510(k) application?

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

21 Q. All right. Towards the bottom -- or
22 lower on page 13, you wrote that a review of the
23 510(k) submission revealed a marked absence of
24 clinical trials or other data indicating or
25 supporting efficacy claims and treating severe

1 psychiatric illness.

2 Do you see that?

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

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

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

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

15 A. Not to my knowledge, no.

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

19 A. Yes.

20 Q. Can you describe that article for us?

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

25 Q. That was going to be my next question.

1 A. Yeah. And I reviewed that recently.
2 It's going to take me a minute or two to find the
3 510(k) application itself, but I did look at that
4 recently and attached here. But I believe -- let
5 me find which page it's on. I believe that this
6 is the -- it's not specifically referenced in this
7 copy that I have.

8 Q. That's okay.

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

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

14 A. Uh-huh (indicates affirmatively).

15 Q. Do you recall what the outcome
16 measurements were?

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

18 Q. Okay.

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

22 Q. Sure.

23 Let's move on to your discussion of the
24 2011 neurological devices advisory committee.

25 What are FDA advisory committees?

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

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

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

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

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

21 Q. Who can submit public comments?

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

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

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

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

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

11 Q. Doctor, moving forward in your report to
12 page 23, you wrote that only 11 clinical trials
13 were conducted starting in the late -- in the late
14 1950s that could arguably be considered controlled
15 trials.

16 Did you look at all of those trials?

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

22 Q. All right.

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

25 Q. And what method did you apply to

1 conclude that those trials were methodologically
2 primitive?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 transcript, the entire transcript.

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

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

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

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

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

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

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

19 A. Sure.

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

1 to determine efficacy and safety.

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

13 Q. Is FDA bound by the advisory committee
14 recommendations?

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

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

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

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

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

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

1 than clinical outcomes.

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

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

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

15 A. Correct.

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

20 A. No, they are not, because it's Class II,
21 so it has been found substantially equivalent to a
22 predicate device that was on the market before
23 1984. And, in general, "substantially equivalent"
24 really refers to, basically, sort of the design
25 and engineering of the device itself, not having

1 anything to do particularly with outcomes,
2 clinical outcomes.

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

6 A. Yes.

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

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

13 What process did you apply to draw that
14 conclusion?

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

25 Q. And your basis for that is --

1 A. And to be --

2 Q. -- your experience over the years?

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

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

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

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

1 their company from injury claims against them.

2 What methodology did you apply to draw
3 that opinion?

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

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

16 Q. Can you explain that logic to us?

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

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

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

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

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

18 BY MR. SCHIEBER:

19 Q. What --

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

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

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

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

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

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

22 I mean, there are reports going back to
23 '93, articles that say that this can happen
24 in up to 55 percent of patients. So better
25 to put that information in the labeling as a

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

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

11 BY MR. SCHIEBER:

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

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

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

1 A. Okay.

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

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

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

7 A. Yes.

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

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

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

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

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

25 THE WITNESS: Okay. That's fine.

1 MR. ESFANDIARI: No objection.

2 MR. SCHIEBER: Thanks.

3 THE VIDEOGRAPHER: Off the record at
4 12:49 p.m.

5 (A recess was taken.)

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

8 BY MR. SCHIEBER:

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

12 A. Yes.

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

17 A. Yes. That is -- yes.

18 Q. How did you come to that determination?

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

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

9 Q. What sort of literature review did you
10 do?

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

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

1 studies.

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

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

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

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

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

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

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

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

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

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

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

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

5 Q. Do you recall which studies those are?

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

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

14 Q. Do you recall what studies those are?

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

24 Q. What safety --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 THE WITNESS: I think I just answered
24 that.

25 BY MR. SCHIEBER:

1 Q. And is your answer no?

2 A. Correct. I have not seen any. I'm not
3 aware of any. I haven't seen any reported.

4 Q. Okay. I assume you believe that those
5 studies should be conducted, correct?

6 A. I think I have said that several times,
7 yes. If you're interested -- if an individual is
8 interested, particularly if you're marketing a
9 device that potentially has these outcomes
10 associated with it, I would think that would spur
11 interest in the extent to which your device is or
12 is not associated with those particular outcomes.

13 Q. Because the Thymatron is Class II device
14 as it relates to treatment-resistant depression,
15 is there a regulatory requirement to conduct such
16 studies on safety and efficacy?

17 A. I have --

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

20 THE WITNESS: I have already answered
21 that as well.

22 BY MR. SCHIEBER:

23 Q. And there's no regulatory requirement,
24 correct?

25 A. That's --

1 MR. ESFANDIARI: Asked and answered.

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

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

6 BY MR. SCHIEBER:

7 Q. That statement is correct?

8 A. Yes.

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

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

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

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

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

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

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

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

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

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

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

4 BY MR. SCHIEBER:

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

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

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

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

25 BY MR. SCHIEBER:

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

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

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

25 Q. Are there any ethical issues posed with

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

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

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

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

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

25 The other option might be an active

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

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

11 MR. ESFANDIARI: Objection: lacks
12 foundation; speculation.

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

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

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

1 put this one in the back.

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

4 THE VIDEOGRAPHER: Off the record at
5 1:20 p.m.

6 (A recess was taken.)

7 THE VIDEOGRAPHER: On the record at
8 1:24 p.m.

9 BY MR. SCHIEBER:

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

13 A. I don't know.

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

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

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

11 BY MR. SCHIEBER:

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

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

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

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

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

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

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

1 reviewed medical literature.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 BY MR. SCHIEBER:

12 Q. Yeah.

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

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

1 is, then it's anybody's guess.

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

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

9 MR. SCHIEBER: Yeah.

10 BY MR. SCHIEBER:

11 Q. So, Doctor, you referenced there were
12 3,000-some public comments in conjunction with the
13 advisory committee.

14 What percentage of those comments
15 related to memory loss?

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

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

25 MR. ESFANDIARI: Dr. Arrowsmith, also,

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

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

6 Okay. Memory dysfunction, 529 such
7 reports; non-memory cognitive complaints,
8 357. So a summary based on
9 Dr. Georgiopoulos's review of the letters and
10 the -- I think it was the letters prior to
11 the actual advisory committee itself, that
12 529 of the reports were of memory
13 dysfunction.

14 BY MR. SCHIEBER:

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

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

25 In that case, it looks like it's

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

4 Q. Moving on to your fourth opinion --

5 A. I'm sorry?

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

8 BY MR. SCHIEBER:

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

12 A. I haven't --

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

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

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

4 BY MR. SCHIEBER:

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

7 A. No, I have not.

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

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

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

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

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

24 MR. ESFANDIARI: Outside the scope.

25 THE WITNESS: Yeah. I don't know that

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

7 BY MR. SCHIEBER:

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

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

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

23 BY MR. SCHIEBER:

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

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

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

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

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

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

1 is the basis for that?

2 MR. ESFANDIARI: Objection to the form.

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

12 BY MR. SCHIEBER:

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

15 A. Yes.

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

19 Where did you see that?

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

22 Q. Of the Somatics facility or of an
23 Elektriika facility?

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

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

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

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

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

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

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

6 Q. Okay.

7 A. It may be a misstatement.

8 Q. Fair enough.

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

13 MR. SCHIEBER: Understood.

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

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

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

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

23 MR. ESFANDIARI: Sure.

24 MR. SCHIEBER: Sure.

25 THE VIDEOGRAPHER: Going off the record

1 at 1:47 p.m.

2 (A recess was taken.)

3 THE VIDEOGRAPHER: On the record at
4 1:58 p.m.

5 MS. COLE: Are we on the record?

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

8 MS. COLE: Thank you.

9 THE VIDEOGRAPHER: You're welcome.

10 CROSS-EXAMINATION

11 BY MS. COLE:

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

14 A. Yeah.

15 Q. A few minutes?

16 A. A few more minutes, yeah.

17 Q. As I introduced earlier, my name is
18 Susan Cole, and I have -- I'm going to just sort
19 of walk us through some of the testimony.

20 Mr. Schieber has asked most of questions that I
21 was going to ask, so I'm going to be moving around
22 from place to place. Let's start by asking you
23 your opinions about controlled trials. And I
24 think that if I heard you right, what you had
25 talked about is that there weren't any, as you put

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

4 Is that what your opinion was?

5 MR. ESFANDIARI: Objection to the form.

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

9 BY MS. COLE:

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

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

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

22 BY MS. COLE:

23 Q. Well, I guess --

24 A. -- and find it for you?

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

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

2 A. I don't know what that is.

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

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

11 Q. Does PMA require studies?

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

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

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

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

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

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

8 BY MS. COLE:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 What do you mean? I don't know what that is.

16 BY MS. COLE:

17 Q. Were there published studies about ECT
18 before 2011?

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

21 Q. Hundreds?

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

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

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

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

8 BY MS. COLE:

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

12 A. Well --

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

15 Go ahead, doctor.

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

1 BY MS. COLE:

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

5 A. Yes, there had been, yeah.

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

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

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

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

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

1 whether it would go to Class II?

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

6 Q. Were they asked to form a committee
7 consensus?

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

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

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

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

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

25 A. He said he did not specifically offer

1 his recommendations on classification.

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

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

9 Q. I see.

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

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

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

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

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

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

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

8 BY MS. COLE:

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

11 A. Yes, I do.

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

14 THE WITNESS: I'm sorry, Bijan.

15 MR. ESFANDIARI: No problem, Doctor.

16 THE WITNESS: I disagree with it, yes.

17 BY MS. COLE:

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

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

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

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

1 don't remember.

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

4 Have you ever designed a study for any
5 medical device?

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

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

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

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

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

1 context of HIV.

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

5 A. Yeah, I sure have.

6 Q. Tell me about that.

7 A. Oh, I --

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

10 THE WITNESS: I'm sorry.

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

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

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

23 BY MS. COLE:

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

1 evaluate ECT as a treatment?

2 A. No.

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

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

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

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

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

12 The visit that was --

13 A. You're meaning inspections?

14 Q. Inspections, yes.

15 A. Inspections. Okay.

16 Q. Inspections, yes.

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

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

23 Q. And the --

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

1 Q. Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Q. I see.

1 A. -- by the inspector --

2 Q. I see.

3 A. -- as deficiencies.

4 Q. I see.

5 So you don't mean they were cited like
6 getting citation or some sort of a -- like an
7 infraction notice, right?

8 A. Well, the observations identify some
9 problems, so they -- these 11 observations mean
10 that these are problems that the company needs to
11 address.

12 Q. And the company did address those?

13 A. Apparently. I believe there was a
14 statement in the 2016 -- part of the 2016
15 inspection that indicated that those previous
16 observations had been resolved.

17 Q. And then there was -- there were other
18 observations made in the 2016 inspection?

19 A. Yes.

20 Q. And do you find any either warning
21 letter or other communication to Somatics that
22 those findings were not voluntarily complied with?

23 A. No, I hadn't -- I haven't seen any
24 additional communications indicating that it was a
25 persistent problem, that there was a persistent

1 problem.

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

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

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

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

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

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

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

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

7 A. Yes.

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

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

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

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

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

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

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

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

20 BY MS. COLE:

21 Q. And did the FDA have that same
22 opportunity?

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

25 Q. Did they have an opportunity to do so?

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

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

10 BY MS. COLE:

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

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

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

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

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

3 BY MS. COLE:

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

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

13 Q. And what was the date of that?

14 A. This submission was July 1st, 2009.

15 Q. Do you know if --

16 A. So -- go ahead.

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

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

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

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

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

14 BY MS. COLE:

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

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

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

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

1 reviewed that entire document.

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

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

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

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

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

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

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

9 BY MS. COLE:

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

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

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

20 MR. ESFANDIARI: Objection.

21 It's outside the scope of your
22 testimony.

23 BY MS. COLE:

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

1 permanent memory loss?

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

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

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

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

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

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

16 BY MS. COLE:

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

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

22 When was that publication?

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

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

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

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

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

18 BY MS. COLE:

19 Q. Was it like 2014? Was it 2013? Was it
20 2017?

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

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

5 Q. Is that the one you were talking about?

6 A. It must be.

7 Q. Okay.

8 A. So it was December 29th, 2015.

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

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

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

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

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

1 exactly what the question was.

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

5 Go ahead.

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

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

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

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

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

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

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

3 THE WITNESS: I don't.

4 MR. ESFANDIARI: Yeah.

5 THE WITNESS: I don't.

6 BY MS. COLE:

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

9 A. Yes.

10 Q. Have you read his conclusions in this
11 case?

12 MR. ESFANDIARI: In the report?

13 MS. COLE: In the report.

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

16 BY MS. COLE:

17 Q. Yes, ma'am.

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

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

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

1 ambiguous as to time.

2 Dr. Arrowsmith, you can answer.

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

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

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

25 And the fact that the company kept

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

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

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

11 THE WITNESS: I'm --

12 MS. COLE: I object to the objection.

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

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

24 BY MS. COLE:

25 Q. Would you agree that the FDA did not

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

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

5 Q. Are you currently affiliated with the
6 FDA?

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

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

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

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

22 Valentine, Vasavada, William McDonald.

23 BY MS. COLE:

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

1 A. I don't remember that name.

2 Q. What about Dr. Kellner, K-e-l-l-n-e-r?

3 A. Yes, I have read -- I have read Kellner,
4 yeah.

5 Q. Do you agree with Dr. Kellner's view of
6 the safety and efficacy of ECT?

7 MR. ESFANDIARI: Objection.

8 THE WITNESS: I don't --

9 MR. ESFANDIARI: Excuse me. Objection;
10 lacks foundation; vague and ambiguous;
11 overbroad.

12 THE WITNESS: You know, can you show me
13 his article? I don't have a copy of it here.
14 I know I have reviewed it, because I remember
15 his name, but I don't remember the specifics
16 of his article. I need to look at it.

17 BY MS. COLE:

18 Q. I don't have it also. I made some
19 things to save on my screen, but that's not one of
20 them that I chose, so I will pass on that question
21 since you haven't -- you don't recall it, but you
22 do recall having read it.

23 Do you think it was inappropriate for
24 Somatics to make reference to, in their manual, an
25 instruction to -- for an ECT provider to read the

1 task force report by the American Psychiatric
2 Association?

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

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

14 BY MS. COLE:

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

18 A. No, I have not, no.

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

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

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

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

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

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

19 BY MS. COLE:

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

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

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

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

25 That's not what we're talking about

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

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

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

1 broad range of literature sources.

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

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

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

15 MR. ESFANDIARI: Objection. Asked and
16 answered.

17 BY MS. COLE:

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

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

25 The fact that FDA instructed them to put

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

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

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

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

16 BY MS. COLE:

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

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

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

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

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

5 (The portion requested was read back for
6 counsel.)

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

10 BY MS. COLE:

11 Q. You can answer.

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

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

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

21 MS. COLE: Sure.

22 MR. ESFANDIARI: Off the record for two
23 minutes.

24 THE VIDEOGRAPHER: Off the record at
25 3:02 p.m.

1 (A recess was taken.)

2 THE VIDEOGRAPHER: On the record at

3 3:08 p.m.

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

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

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

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

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

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

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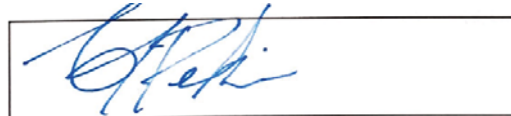
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CERTIFICATE OF OATH

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

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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

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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,
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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

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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

&	1986 7:6	94:16 98:10,10	4
& 2:4,17	1996 10:23	104:18 106:5	4 3:2
0	1999 12:18	2022 1:14 4:6	4/1/2024 110:21
01724 1:6	1:20 51:5	110:12 111:14	40 30:4,14
1	1:24 51:8	112:4	44114 112:2
1 1:23 4:17	1:47 67:1	2023 107:9	5
10/24/2022	1:58 67:4,7	21 68:19 95:12	5 3:3
112:8 113:3	1st 89:14 90:7	95:12	50 34:22 37:20
114:3	2	216-523-1313	50s 35:25 70:14
11 20:12 82:15	20 113:16 114:22	112:3	510 16:6,12,13
84:9	115:22	23 20:12	16:23 17:5,7,12
110 3:5	2000s 71:16	24 1:14	17:23 18:3
1100 112:1	2001 90:15	24th 4:5	36:24 53:25
111 2:17 3:6	2009 18:9 89:14	25002 110:19	69:8,21 70:10,19
11111 2:4	90:1,7,19	111:21	70:25 71:9 72:4
112 3:7	2011 18:24 19:12	25th 110:12	89:2,12 90:6
113 1:23 3:8	23:16 71:1 72:3	111:14	529 59:6,12
12:02 1:16 4:5	72:20 73:5,18	2800 2:18	55 32:24
12:10 10:12	74:1,11 75:2,16	29th 95:3,8	5528172 112:7
12:11 10:15	85:13 91:11,18	3	113:2 114:2
12:49 35:4	94:1 100:2	3 28:3,4 39:3,4	115:2
12:56 35:7	2012 34:5,12	69:1	6
13 15:25 16:1,22	56:10,18 65:3	3,000 58:12	6 64:16
14 17:16	81:10 82:4,12	3,045 19:17	60601 2:18
17 59:1,4 76:18	2013 28:5 31:4	58:18	67 3:4
1750 2:5	31:22 94:19	33134 2:12	7
1820 112:2	2014 94:19	357 59:8	75 37:20
19 71:16	2015 95:3,8,12	36 65:4	76 70:14
1950s 20:14	106:18	360c 69:1	8
1968 17:17 42:15	2016 34:10,14	38 35:9	80 25:16,20 95:3
54:5 104:15	52:17 64:17	3:02 108:25	800s 68:19,19
105:22	81:10 84:14,14	3:08 109:3	81223 95:3
1976 70:13,21	84:18	3:09 1:16 109:16	84 11:8 71:8
1979 6:13	2017 13:4 94:20	109:17	85 11:8 25:20
1982 6:14,15	2018 25:24 32:2		882 95:13
1984 6:15,19,23	34:10 52:17		
27:23 70:19	91:22 93:19		

8:20 1:6	78:10 83:18	48:18 52:3	25:13,15,22 26:8
8th 112:4	85:18 106:2,12	56:12,19 68:7,11	26:10,13 27:3
9	106:24 107:2,5	69:13 74:25	36:6,21 41:14
90025 2:5	111:12,12	105:20	42:25 43:16
910 2:11	actis 7:23	adequately	46:13 52:21
92 59:17	active 21:18	16:16 23:15	55:4,6 57:21
93 32:23	22:16 23:1 31:1	40:10 98:14	58:13 59:11
96 12:4	31:2 37:10 38:1	105:4	72:22,25 73:4,7
999 2:11	49:25 55:22	administer	75:6,23 77:13,16
a	75:12	102:21	85:13 91:18
aaron 1:21 4:23	actively 11:5	administered	92:2,3
110:20 111:4,22	31:13 55:19	13:23 14:2	affiliated 100:5
ability 41:10	activities 23:19	administration	affirmatively
73:6 82:19,25	activity 22:1	6:22	16:4 17:3 18:14
83:3	23:1	administration's	19:15 97:18
able 38:19 52:3	actual 45:23	7:14	affixed 113:15
105:3	50:22 59:11	adverse 28:10,17	114:21
abrams 33:2,15	ad 27:11	29:7,8,15 30:10	afternoon 11:11
33:16,22 48:5	add 107:6	36:12,12 39:13	11:18 12:1
absence 16:23	adding 59:23	52:15,19,22	agencies 7:16
48:8,17 50:22	addition 77:12	53:16 54:11,13	agency 8:6
abstained 77:7	additional 11:19	55:3,15 56:5,9	ago 13:5 65:16
absurd 28:9	13:20 16:10	56:21 57:2,13,16	66:10
abundant 14:24	20:3 54:3,22,24	57:19 58:21	agree 4:15 97:20
85:7	71:25 84:24	59:20 61:19	99:6,25 101:5
acceptable 28:20	86:14 87:13	62:1,16 63:15,18	agreement 76:13
61:1	address 84:11,12	80:20 89:21	ahead 10:19
access 7:25	112:15	advice 19:13	74:15 80:9,12
account 78:5	addressed 34:11	25:22 27:4,6,7	89:16,18 95:1
accounting	34:19 76:2	27:10 46:13,15	96:5
71:17	addressing	77:16	aids 7:12,14,18
acknowledge	95:12 103:7	advise 98:23	7:23,23 8:4,12
113:11 114:16	adequacy 79:21	advised 64:17	8:18 11:13,17
act 113:14	adequate 20:8,9	65:25	12:3 79:18,23
114:20	29:14,22 35:15	advising 19:4,5	alabama 6:16
action 5:12,21	36:1,1,3,20,25	advisory 18:24	alarcon 2:3
29:18,23 56:8	37:4 39:7 42:11	18:25 19:1,13	albuquerque
	42:18,21 43:18	23:16 24:15	13:9

allegation 88:21 alleged 61:8,18 allow 37:9 allowed 71:8 alsakaf 102:16 alumni 100:8 ambiguous 98:1 101:10 103:4 american 90:17 90:20 102:1 amnesic 42:16 analysis 108:20 anecdote 20:6 anesthesia 21:17 22:6,19,22,25 angeles 2:5 answer 6:7 44:1 69:20 93:10 96:22 98:2 108:11 answered 43:23 44:20 45:1 106:16 answering 30:9 antegrade 15:1 31:15 32:4 41:11 105:4 anticipated 62:15 antidepressant 80:16 antiviral 8:20 79:23 anybody 36:5 54:23 anybody's 58:1 anyway 7:22 56:14	apa 90:25 apache 11:1 apart 13:14 47:21 59:22 apologize 95:23 apparent 26:7 apparently 84:13 appear 107:19 107:21 113:11 114:15 appearance 10:18 appearances 2:1 appeared 110:8 appended 114:11,18 apples 69:25 application 16:7 16:12 17:23 18:3 24:24 applications 16:13 17:5 applied 41:16 apply 20:25 28:13 30:2,15 applying 30:13 approach 76:4 appropriate 38:17 39:8,16 appropriateness 30:8 approval 19:4 68:13 69:5,8 71:24 approve 49:5,17 50:8	approved 8:1 9:2 50:3 72:1 99:9,14 area 13:9 22:13 arguably 20:14 aristei 2:4 arm 21:18,20 22:19,20 37:12 arrowsmith 1:10 4:18 5:3,10 58:25 67:12 75:23 92:10 93:4 98:2 99:8 106:2,11 107:8 109:4,11 110:8 111:6 112:8 113:4,9 114:4,13 115:20 article 17:17,20 35:20 101:13,16 102:11 articles 20:20,24 32:23 35:21 74:9 100:10,11 100:17,18,21,25 104:15 105:22 asked 19:2 45:1 67:20 76:4,6 78:21 106:15 asking 67:22 87:2 93:6 94:13 96:17,20 aspects 63:2 assess 21:7 39:21 assessing 21:24 22:4 39:20 79:20	assessment 20:18 22:3 23:12 36:25 37:13 52:8 assessments 21:6 39:22 assign 38:1 assigned 6:21 assignment 113:2 114:2 115:2 assist 19:3 associated 30:12 31:16 32:6 43:3 43:17 44:10,12 46:4 53:8 54:9 62:17 63:15 105:12 association 90:17,20 100:8 102:2 associations 103:9,9 assume 34:22 44:4 assuming 52:7 asylum 13:8 atlanta 6:21 attached 18:4 114:7 attempt 29:25 54:18,23 105:24 attempted 53:9 55:2 attend 23:23 104:11 attention 59:1
--	---	--	--

<p>attorney 111:10 111:11 attributing 39:14 audio 4:14 authority 82:25 110:7 authorize 114:11 authorized 111:5 authors 23:10 36:14 54:15,16 54:24 autobiographi... 41:9 105:2 autographical 32:19 available 7:25 36:19 75:2 78:3 90:13 103:12 104:14 105:10 ave 112:1 aware 15:21 29:20,22 34:18 42:20 44:3 47:22 53:3,6,18 53:19 55:24 56:1 60:10,23 75:18 76:4 77:23 78:6 81:8 85:19 86:8,20 87:3,9,9,11,14 88:11,18,22 90:24 91:25,25 102:22,24 awful 91:6</p>	<p style="text-align: center;">b</p> <p>b 3:13 69:1 back 8:20 9:24 10:8 20:21 23:7 24:11 32:22 33:7,20 35:25 36:13 39:2 40:25 51:1 54:5 61:17 70:14 85:25 96:4 104:15 105:22 108:4,5 112:15 background 6:11 10:19 26:24 56:3 backhanded 31:10 ball 63:19 barrier 49:22 base 37:21 based 20:10 37:18,19 43:5 59:8 63:25 64:13 69:14 105:25 basically 9:4 21:20 25:11 27:24 37:2 47:16 54:19 56:12 61:1 85:21 98:22 basis 23:18 26:6 28:25 33:12 52:13 63:22 64:1 baum 2:4 107:14 began 70:17</p>	<p>behalf 2:2,9,15 behaved 92:13 behavior 106:3 believe 7:9 15:7 16:9 18:4,5,9 31:22 39:16 40:6 44:4 45:9 45:20 47:10 51:11 61:18 62:8 74:19 75:12 78:21 80:15 82:14 84:13 85:25 94:5 believed 82:15 bell 14:12 benefit 45:25 46:1,3,20,21 47:1,3,24 48:9 48:16,21 52:9 benefits 47:18 47:20 better 32:2,24 46:2 bice 2:10 5:17 big 18:19 bijan 2:3 5:19 45:3 78:14 112:5 biological 39:2 biologicals 39:5 biologics 7:1,2 9:11 10:1,2,22 79:20 bipolar 25:6 bit 49:14 blanket 76:3,5</p>	<p>blinded 21:3,4 21:13 22:5,12 37:13 68:2,12 board 49:17 body 21:10 54:4 border 13:10 bottom 16:21 boulevard 2:4 2:11 bound 25:13,15 brain 58:19 59:23 brand 104:22 break 6:5,7 50:25 66:18 96:3 108:18 brief 88:24 briefly 90:7 british 17:17 broad 106:1 bulk 8:11 burns 89:4,6</p> <p style="text-align: center;">c</p> <p>c 4:2 100:20,25 ca 112:25 california 2:5 call 107:15 called 11:15 12:6 39:4 81:18 107:17 calls 107:12 camera 4:10 cardiovascular 42:5 care 6:15,18 8:10,11,15,16 11:1,16 12:8,12</p>
--	--	---	---

<p>12:13 13:3 29:5 29:6 30:6 80:3 80:24 81:4 107:25 case 1:5 14:5,17 15:14 42:1 59:25 78:23 83:5 93:5,15 97:8,11 107:8,22 108:13 112:6 113:3 114:3 cases 32:20 42:1 85:2 cat 10:3,17 50:24 catatonia 25:5 27:13,18 45:21 76:15 causation 15:15 cause 62:19 82:2 82:6,9 95:10 caused 61:10,19 62:9 causes 15:13 42:12 43:19 ccr 110:20 cdc 7:18 center 7:2 8:20 8:21 9:6,6,25 10:2,22 26:22 29:10 79:20 centers 6:20 certain 30:15 103:21 certainly 16:15 16:18 20:2 41:12,21,24 42:3 42:8,15,23,24</p>	<p>43:14 52:19 53:6,22 55:7 56:10 62:4 73:24 78:1 79:10 81:5 82:24 87:11,17 91:7 92:1,6 104:8 certificate 3:5,6 110:2 111:1 114:11 certification 113:1 114:1 certified 111:5 certify 110:7 111:5,10 cfr 68:19 95:12 chair 76:11,23 92:6 chance 51:23 change 34:23 112:13,14 114:8 115:3 changed 85:4 changes 83:4 103:22 112:12 113:7 114:7,9 charged 75:24 chicago 2:18 child 9:23 choice 62:6 choose 27:5 chose 27:10 101:20 chosen 16:20 cindy 2:22 circumstances 56:5</p>	<p>citation 84:6 89:11 cited 20:19,19 56:18 83:15,17 83:22,23 84:5 89:10 citizens 86:3,6,9 86:10,17,25 87:1 87:4,7,17 100:1 100:4 civil 1:19 113:5 114:5 claim 49:14 56:3 claimed 65:11 88:25 claiming 99:1,14 claims 16:25 30:1 88:13,18 clarified 65:15 class 24:23 25:4 25:11 27:13,20 44:13 45:10,13 45:17,18,21 46:7 51:10 71:4,4,11 71:14,20,23 72:8 72:12,14,15,17 72:19 75:8,9,25 76:1,17,18,22 85:6 classification 25:25 27:16 75:19,25 76:3,5 77:1 classified 45:10 51:10 71:13,13 71:22 classify 27:12 46:7</p>	<p>clear 8:14 88:8 clearance 69:5,8 cleared 49:10 69:23 70:24 72:2,4,9 99:1,9 clearly 29:20 53:23 72:13 99:15,17,18 cleveland 112:2 clinic 11:11,15 11:16,18 12:2,3 13:4 105:15 clinical 11:6,24 16:14,17,24 17:10 20:12 24:20,25 27:1 28:2 38:5 47:7 49:2,7 50:9,22 62:10 69:13,15 71:25 79:21 80:22 clinicians 19:7 26:21,22 27:3,4 closed 13:5 code 109:12 coffey's 100:24 cognitive 15:2 31:16 32:6,11,17 38:12 41:12,16 41:17,19 42:9,12 43:2,8 53:7 58:20 59:7,23 63:5 75:4 85:8 90:3 92:4 98:11 103:22 104:16 105:1,2,20,23,25 106:10</p>
--	--	---	--

<p>cole 2:10,10 3:4 5:13,16,16,17 66:15,17,21 67:5 67:8,11,18 68:9 68:22 70:8 73:16 74:8 75:1 78:8,17 80:23 87:20 88:10 89:3 90:14 92:9 92:23 93:6,9,16 94:13,18 95:25 96:12,20 97:6,13 97:16 99:12,24 100:23 101:17 102:14 103:19 106:17 107:16 108:3,10,16,21 collected 98:5 collecting 38:18 com 27:11 come 9:24 13:8 35:18 73:9,14 107:10,17,18 coming 19:3 comment 79:11 82:16 85:12 89:20 commented 56:11 comments 9:15 19:17,18,20,21 19:23,24 20:1,4 20:7,10 26:3 58:12,14,18 73:1 commerce 65:5 commission 110:21,21 113:19 114:25</p>	<p>115:25 committee 12:15 18:24 19:2,13 23:17,24 24:3 25:13,16,22 26:9 26:11,14 27:3 36:6,22 41:14 43:1,16 46:14 52:21 55:4,6 57:21 58:13 59:11 72:22,25 73:4,7 75:6,23 76:6 77:13,17 85:13 91:19 92:2,3 committee's 23:19 24:15 committees 18:25 19:1 communication 65:22 84:21 communications 84:24 companies 12:20 12:24 13:17 company 29:23 30:1 38:25 74:18 83:6 84:10,12 88:18 91:23 98:11,25 103:12 104:2,13 104:19 105:7 106:21,22 107:6 compare 50:6 comparison 42:16 compassionate 30:21</p>	<p>complaints 59:7 59:23 85:20 complete 35:24 111:7 completed 6:14 7:6 40:3 51:23 112:15 completely 63:19 69:19,23 compliance 82:13,22 83:1,3 complicated 22:14 71:6 complied 83:7 84:22 comply 83:20 component 22:23 components 61:2,3 concept 9:9 concern 19:6 82:2 concerned 102:6 concerns 39:11 41:25 43:17 70:23 concise 32:15 conclude 21:1 concluded 23:10 109:17 conclusion 23:14 28:14 conclusions 19:4 23:8,13 97:10 conditions 26:16 81:3</p>	<p>conduct 6:23 17:10 22:12,15 44:15 55:10,18 55:20 62:9 conducted 1:11 4:8 20:13 23:4 44:5 55:22 105:13 conducting 47:12 74:1 confined 68:25 conjunction 16:6 16:11 17:5 58:12 79:17 94:1 connected 111:11 connection 4:10 consciously 23:2 consensus 75:24 76:7,9,11,12,21 consider 36:3 104:23 consideration 24:21 considerations 75:16 considered 19:6 20:14 25:11 26:18 29:3 36:1 74:2 77:13,19 97:22 98:4,18,20 99:23 considering 77:11,12 103:15 103:17 consulting 12:19</p>
--	--	---	--

consumer 19:11 contact 11:24 54:15,15,18,21 54:23 55:2 82:21 contacted 52:22 contention 49:10 context 37:5 39:15 41:7,25 42:7 50:19 80:1 continue 4:14 13:2 43:10 50:16 66:18 93:17 continued 11:20 continues 16:15 contract 65:7,12 65:17 66:12 contractor 64:10 contribute 21:10 contributed 61:13 62:3,4 control 6:20 21:7 22:16 37:11 38:2,6,22 40:23 49:23,24 50:2 controlled 16:17 20:8,14 36:2,4 36:21,25 37:5 40:10 42:11,18 42:21 43:19 48:18 67:23 68:7,12 controls 22:7 68:1 convened 19:12	conveyed 28:24 coordinating 7:15 coordination 7:14 8:5 copy 18:7 101:13 109:7,8 coral 2:12 correct 15:17,18 19:14,18 22:21 27:14,15 44:2,5 44:24 45:2,7 47:12 65:22 72:6 corrections 112:12 114:17 correctly 22:17 counsel 1:17 4:19 5:1 108:6 111:10,11 counted 77:3 counting 77:7 country 9:2 45:15 county 110:5 111:3 113:10 114:15 couple 7:22 8:5 8:13 9:4,13 12:9 60:16 66:10 89:1 course 39:23 61:6 80:16,21 court 1:1 4:22,25 6:4 96:3 108:3 113:7 covered 13:3 95:21	crc 1:21 110:20 111:22 criticizing 106:4 cross 3:4 67:10 crr 1:21 110:20 111:22 curiosity 43:7 curious 26:9 current 98:8 currently 100:5 customers 65:15 65:19 cut 89:17 cutting 104:18 cv 1:6 d d 3:1 4:2 12:6 70:19 d.c. 11:15 12:5 dalmatian 16:2 47:21 damage 58:19 59:24 dan 4:21 danger 83:10 danny 2:22 data 16:24 17:4 17:14 25:18,19 26:13 35:19 36:7,19,20 38:19 45:24 47:7 50:22 51:18 54:19,25 71:25 74:24 75:2 90:13 98:14 database 52:3 66:10 86:1	databases 35:25 date 1:14 89:13 94:13 112:8 113:3,9,19 114:3 114:13,25 115:20,25 dated 111:14 day 110:12 111:14 113:16 114:22 115:22 days 66:10 112:18 de 2:11 deal 61:2 dealt 82:17 dear 112:10 debatable 73:24 december 25:24 95:3,8,12 decided 27:12 77:10 106:8 deciding 62:21 77:25 decision 31:3 62:5,5 71:18 78:7 96:8 declared 72:17 deed 113:14 114:20 deemed 112:19 defects 60:11 defendant 1:17 2:9,15 defendants 1:8 5:12 deficiencies 84:3 define 37:8,8 47:2,19,20
--	---	--	---

105:19 defined 7:11 39:18,19 46:2 defining 46:20 46:20,25 delineating 43:2 deliver 65:19 demand 82:22 demonstrate 46:25 denied 100:4 denominator 59:16,19,22 dental 38:12 department 11:9 112:22 depend 51:17 depending 82:23 depends 4:9 deposed 5:5,25 deposition 1:10 4:7,18 14:10 24:13 109:8,17 111:6 112:8,11 113:1,3 114:1,3 depositions 14:7 102:15 depression 25:6 27:14 39:19,20 39:21 40:6,8 44:14 45:11,22 46:8 49:2 50:10 50:15,17 depressions 40:8 depressive 27:18 depth 23:17 deputy 7:13	derelict 54:6 63:4 derived 20:7 23:9 describe 17:20 described 12:23 22:18 75:4 77:4 89:25 describing 10:18 design 21:13 27:24 60:9,23 61:9,12,12 63:3 63:12 64:6,9 designation 108:9 designed 16:17 40:10 79:4,8 detail 58:22 detailed 58:19 94:3 details 73:8,14 determination 35:18 71:18 98:13 determine 25:1 37:18 38:7,20 39:25 41:17 45:24 46:2,3 50:4 52:24 56:2 74:25 79:16 determined 38:17 71:23 72:11 determining 47:17 48:15 78:3 develop 41:10 105:4	developed 8:8 9:7 12:21 45:24 developing 103:17 development 79:12 device 9:8 19:25 21:22 22:13 26:25 27:22,25 34:2 44:9,11,13 45:10,15 46:12 47:8,18,23 48:9 48:13,15,20 55:15 56:13 60:18 61:5,16 63:16 64:6 65:8 69:10 70:3,16,17 70:18,20 71:5,10 74:24 75:8,11,15 75:15,21 79:5,6 79:9 85:5 99:3 104:4 105:12 devices 9:6,6,21 18:24 25:18,20 25:25 26:19,20 26:22 29:10,12 38:25 45:12,20 46:7 51:12,20 55:17 63:12 65:18,19 69:17 70:1,9,13,19,24 71:12,19 75:11 75:20 78:18 80:18 97:21 diadenosine 9:1 diagnose 8:18 diagnosis 8:9 30:6	difference 37:10 38:5,10,20,21 40:3,23 55:17 different 14:21 14:22 69:8,9,19 69:23 72:21 79:12 96:7 differently 92:7 92:13 difficult 49:15 difficulty 21:21 direct 3:3 5:22 65:17 99:2 directed 87:8,10 88:12 direction 8:17 directly 65:14 director 7:13 disagree 78:16 98:15 disagreed 78:9 discern 18:12 37:9 discharge 60:17 60:21 disclaimer 28:5 28:18 29:13,19 29:24 31:5 33:1 33:10 53:6,12 98:21,22 disclaimers 28:19 disclosed 63:1 discovery 1:18 discuss 23:16 29:16 33:24 discussed 37:6
--	--	--	---

<p>discusses 90:7 discussing 41:7 42:2 79:3 105:22 discussion 18:23 23:18 49:4,12 65:6 78:1 89:19 92:1,3 discussions 42:7 disease 6:20 8:14 11:23 12:15 diseases 26:16 26:16 dishonest 31:21 disorder 25:7,8 27:19 dispense 6:1 disregard 26:7 distinction 75:14 distribution 83:13 district 1:1,1 diverse 54:3 division 1:2 8:20 79:23 docket 42:24 55:6 73:2 85:14 doctor 5:24 6:10 10:17 15:5,25 18:11 20:11 28:3 33:23 34:21 35:9 45:5 51:10 52:12 58:11 66:14,18 69:20 74:15 78:15 80:9 97:2 doctors 102:20</p>	<p>document 81:21 89:24 90:24 91:1,2 documentation 14:21 63:11 64:4 86:15 102:25 documents 14:22 41:1 49:20,21 54:17 54:17 88:21 95:2 dogs 16:2 47:22 doing 10:20 12:19 13:15 21:5 36:15 dr 4:18 5:10 33:2,3,14,15,16 33:22,22 58:25 59:5,9 67:12 75:23 92:10 93:4 95:9 97:7 97:20 98:2 99:7 99:8 100:10,17 100:19,24 101:2 101:5 102:16,16 102:16 106:2,11 107:8 109:4,11 draw 28:13 30:2 59:1 drive 2:17 dropped 63:19 drug 6:22 7:13 8:21,23 9:1 drugs 8:20 9:10 22:14 25:17,20 39:4 79:23</p>	<p>duly 5:4 110:9 duration 40:13 40:21 41:20 43:10 duty 63:4,8,24 dysfunction 15:2 15:2 31:16 32:5 32:6,10,11,17,18 41:18,19 42:13 43:3,8 53:7 59:6 59:13 60:2,3 85:9 104:16 105:2,20,23,25 106:10 dysfunctions 32:8</p>	<p>41:5,11,17 42:12 42:17 43:3,17,19 45:12,15,20,25 46:6,7 50:1,2,9 51:10,11 52:4,7 52:25 53:8 62:6 62:17,21 63:6,12 70:9,13,16,17 71:18 72:23 73:9,17,25 74:3 75:4,11,20 76:14 81:1,7 85:5 86:14 89:25 90:3,16,18,22 91:3,9 94:4 97:21 101:6,25 102:17,20,21 103:2,25 105:15 108:14 edge 104:18 effect 42:17 107:25 effective 11:14 50:21 52:4,5 effectively 104:4 effectiveness 21:7,11 36:8 40:21 47:8 50:5 62:15 64:8 78:4 79:14,16 90:9 effects 54:9 75:4 90:3 efficacy 16:11,18 16:25 20:2,5 25:1 27:17 30:25 35:15 37:10,22 38:8 39:16 44:16</p>
		e	
		<p>e 3:1,13 4:2,2 33:14,21 100:20 100:25 101:2,2 earlier 37:7 57:13 67:17 70:15 71:1 78:22 83:14 early 11:8 71:16 80:16 107:9 east 2:17 ect 15:3,22 16:18 19:14 21:5,12,16 21:18,20 22:11 22:21,23,24 23:3 24:23 25:10,25 26:15 27:13 31:17 32:7,20 35:16 36:8,12,13 36:13 38:3,4 39:15 40:2,13</p>	

62:10 101:6 effort 105:19 eight 11:4 77:3,4 either 7:25 19:3 38:1 50:21 55:3 60:18 72:12 84:20 85:12 87:12 99:20 el 13:9,10,11 electrical 60:17 60:21 electroconvuls... 13:24 14:2,5,10 electrode 89:5 elektrika 1:6 2:15 4:20 5:11 63:1,8,11,23,24 64:5,6,17,23 65:1,25 66:4,11 112:6 113:3 114:3 elektrika's 63:8 eligible 10:24 72:13 email 112:17 employee 111:10 111:11 enclosed 112:11 engagement 61:15 engineering 26:24 27:25 engineers 26:23 england 105:6 enlisted 105:14 105:16 enroll 37:23,24 37:25	enrolling 49:1 ensuring 55:14 entered 114:9 entire 24:1 90:24 91:1 113:5 114:5 entry 69:10 70:7 epidemic 7:12 8:15 epidemiologist 7:7,10 epidemiology 6:19 episodes 15:22 equivalent 27:21 27:23 70:2,20 72:5 errata 3:7 112:13,18 114:7 114:10,18 115:1 esfandiari 2:3 5:14,19,20 14:18 31:6,24 35:1 43:21 44:18 45:1,4 46:9 47:13 50:11 51:14 57:5 58:6 58:25 60:6,13 61:21,24 62:11 64:2 66:23 68:5 68:15 69:18 73:11 74:4,13 77:21 78:12,15 80:8,11 87:5 88:1,15 90:4 91:13 92:14,20 93:2,7,11 94:10 95:14 96:2,9,16	96:24 97:4,12,24 99:8 100:13 101:7,9 102:3 103:3 106:15 107:11 108:1,7 108:18,22 109:4 112:5 especially 25:17 28:17 49:24 esquire 2:3,3,10 2:16 essentially 9:9 14:19,23 established 7:2,3 ethical 30:23 48:25 evaluate 81:1 evaluating 63:15 evaluation 8:9 8:21 9:20,20 25:10,12 29:11 30:7 47:23 91:11,16,17 92:4 event 28:10 29:7 56:6,21 57:2,14 57:16,19 60:19 events 28:18 29:8,15 30:10 36:12 39:13 52:15,20,23,24 53:16 54:3,13 55:3,15 56:9 58:21 59:20 61:19 62:2,16 63:15,18 80:20 89:21 evidence 21:11 69:6,14 85:9	86:16 105:18,23 exact 46:3 72:7 exactly 40:19 50:16 56:3 58:8 77:24 78:5 94:8 96:1 exam 11:21 examination 3:3 3:4 5:22 11:22 67:10 examined 5:5 15:16 example 61:14 exchanges 33:14 excluded 22:2 excuse 101:9 executed 53:3 114:10 execution 113:14 114:19 executive 58:23 exemption 8:24 exhaustive 90:12 existing 72:4 experience 20:10 26:15,20 28:15 28:15 29:2,4,4,6 30:14 41:19 43:11 experienced 15:3 19:8 30:11 experiencing 23:3 40:7 expert 8:7,7 15:6 15:7,15 19:2 26:8 expert's 108:9
--	---	--	--

[experts - follow]

Page 11

experts 8:14 26:11 expiration 113:19 114:25 115:25 expires 110:21 explain 24:17 30:16 explained 17:6 explication 78:7 extent 41:17 43:9 44:11 46:2 46:4 97:1	faculty 11:8 fail 48:3 failed 46:24 47:1 47:6 48:4 52:14 failing 63:17 failure 56:8 60:25 61:9,12,18 62:1,9 83:19 105:3 106:13 failures 57:14 fair 6:8 35:13 52:8 54:4 66:8 73:10 fall 12:18 13:4 31:5 familiar 90:21 102:19 103:2 family 13:3 far 48:5 63:19 65:23 76:13 fashion 41:11 favor 76:17 fda 8:22 12:20 12:25 13:16 16:20 17:8,13 18:25 19:1,3,5 19:12,17 23:16 24:9,14 25:13,21 25:23 27:12 28:15,19 29:6,18 29:22 33:7,19,24 34:5 37:14 38:24 45:18 46:7,12,13,17,21 46:24 47:1 51:19,23 55:12 55:16 56:7 64:17 65:9,13,19	65:25 68:10,14 71:11,14,17 72:17,20,23 73:7 74:17 75:7 77:10,12 78:5,24 80:4,20 82:19,24 83:2 85:3 86:5,6 86:8 87:2,8,21 87:24 88:5,5,6 90:2 91:11,20 92:8 94:7 97:23 98:4,10,12,18 99:2,4,14,19,23 99:25 100:6,8 104:2 106:2,5,7 106:11,20,25 107:2,5 fda's 26:7 74:23 78:9 94:4 99:18 february 107:9 federal 1:19 26:2 63:25 64:14 93:20,25 94:2,11 94:16,23 feel 89:22 feigal 95:9 97:7 99:7 feigal's 97:20 fellowship 6:20 7:6 felt 74:25 field 12:24 fifth 62:24 figure 94:17 filed 53:1 final 25:24 26:5 71:18 91:17,20	finally 56:16 financially 13:12 111:12 find 18:2,5 30:13 57:25 68:24 72:7 84:20 87:15 89:24 94:6 96:11 112:11 findings 83:16 84:22 fine 34:25 45:4 fingertips 41:3 finish 10:19 finished 11:3 65:14,18 95:24 firm 2:10 4:23 5:17 65:11 107:14 firm's 65:10 first 5:4 7:5,24 14:9,13 30:22 35:14 48:7 70:17 five 13:5 24:22 34:24 76:20 108:19 flip 15:25 florida 1:1,22 2:12 110:4,20 111:2 focused 26:25 folks 22:18 50:8 follow 24:14,18 25:21 27:6,10 40:11 46:14 55:8 56:20 77:16 88:20
f			
f 100:25,25 facilities 13:10 53:20 facility 34:6 64:22,23,24 81:10 82:5 86:11 facing 52:10 fact 15:21 27:2 34:19 38:7 39:25 41:20 45:24 47:17 48:16 50:16 52:16 53:5 54:2 56:11 63:2,18 64:11 66:9 78:19 91:22 92:25 98:25 106:25 107:1 factors 48:23 77:13,18,25 90:8 facts 87:6 90:5 100:15			

<p>89:23 followed 62:3 85:15,19 86:16 following 8:19 13:19 32:12 39:6,9 41:16 86:13 94:3 follows 5:5 25:21 food 6:22 7:13 force 90:16,21 102:1,10 foregoing 113:13 114:18 forensics 12:23 form 14:18 28:20 31:6,24 43:21 44:18 46:9 47:13 51:14 57:5 60:14 61:21 62:11 64:2 68:5 68:15 69:18 73:11 74:4,13 76:6 77:21 78:12 87:5 88:1 88:15 90:4 91:13 92:14 97:24 100:13 102:3 103:3 107:11 108:7 formed 75:6 formula 38:24 forth 9:22 39:3 42:6 forward 20:11 33:23 41:11 112:15</p>	<p>found 27:21 35:22 70:2,19 98:8 foundation 31:25 50:12 97:25 100:14 101:10 102:4 four 72:18 fourth 60:4,9 fr 95:1,3,12 frame 83:2 framework 69:24 83:1 frankly 16:16 free 113:14 114:20 frequently 26:24 friday 11:10 friend's 13:3 full 11:25 12:17 12:19 13:13,13 27:8 95:17 fuller 52:23 62:15 fully 46:2 47:2 56:2 77:16 105:19 function 41:12 41:16 42:9,9 58:20 105:21 functionality 26:25 functions 41:8 further 14:25 43:1 85:10 89:1 106:23 109:6 111:10</p>	<p>g g 4:2 gables 2:12 general 17:9 27:23 36:13 39:12 55:21 71:16 generally 19:6 20:1,6,9 21:8 51:19 60:11 georgetown 11:9 11:20 georgiopoulos 24:9 59:5 georgiopoulos's 59:9 getting 84:6 gg975331 110:21 give 27:7 41:1 80:11 98:23 given 21:12 27:16 48:1 75:16 giving 48:14 go 4:15 10:9,19 20:21 23:6 24:11 34:23 40:25 51:2 54:10,12 55:25 68:17,20 74:15 76:1 80:9,12 85:25 89:16,18 95:14 96:4,5 106:6 109:13 goes 22:24 47:11 going 10:11 17:25 18:2 28:3 30:19 31:12</p>	<p>32:22 34:21 35:23 36:17 54:5 61:17 66:25 67:18,21 67:21 71:19,20 71:21 94:4 104:15 goldman 2:4 good 4:4 5:9 46:13 66:20 67:12 68:1 gotten 87:18 graduated 6:12 grandfathered 72:10,10 grandmother 13:15 grant 100:1 granted 75:8 ground 6:1 group 7:3 9:19 38:7 50:2 59:17 74:6 76:10 90:18 groups 74:1 guess 20:20 49:22 58:1,6 65:2 68:23 guesswork 48:19 guidance 29:21 98:24 guidelines 8:8 90:16</p> <hr/> <p>h</p> <hr/> <p>h 3:13 100:20 half 60:1,2</p>
--	--	---	---

hall 2:22 hand 19:9 36:19 110:11 handled 92:8 hands 8:13 happen 32:23 happens 31:11 harm 30:22 48:8 48:10 health 7:17,19 10:25 11:2 46:19 47:17 48:13 63:20 86:13 90:10 healthcare 8:6 12:11 98:6 hear 60:6 95:17 heard 4:12 67:24 104:19 hearings 73:6 74:2,11 75:17 heckham 100:19 hedlund 2:4 107:15 held 72:20 91:19 help 9:4 helpful 42:10 62:14 hillsborough 110:5 111:3 himes 14:8,15 hippocratic 30:22 48:6 hired 7:7 history 65:4,5 hiv 7:12,18 8:10 8:12,18 9:1 11:13,17 12:3	79:23 80:1 holguin 2:22 4:21 hollister 2:17 home 80:14 hospital 11:2 12:13,16 hrsa 7:19,21 huh 16:4 17:3 18:14 19:15 97:18 hundreds 71:12 73:21,25 husband 10:24 i icu 12:14 idea 50:14 61:11 61:14 66:20 107:13 ideally 38:4 identified 34:9 34:12,16 36:22 37:18 60:25 83:23,24 85:2 identify 56:20 84:8 94:25 ii 25:4 27:13,20 44:13 45:18 46:7 71:20 72:13,15,17 75:8 76:1,17,18 85:6 iii 24:23 25:11 45:10,13,17,21 51:11 71:4,4,11 71:14,23 72:8,12 72:19 75:9,25 76:22	illinois 2:18 illness 17:1 47:9 imagine 66:15 immediate 83:10 immediately 58:23 impairment 63:5 implement 61:9 implicated 71:22 important 6:2 importantly 99:17 improvement 37:20,21 inadequacy 78:2 inadequate 92:5 98:9 106:8 107:4 inappropriate 101:23 102:6 include 98:11 103:21 106:21 included 29:9 83:22 88:12 106:22 112:13 incorporated 114:12 incur 64:7 indian 11:2 indicate 40:2 76:9 89:22 indicated 84:15 93:12 indicates 16:4 17:3 18:14 19:15 43:16 53:25 91:24 97:18	indicating 16:24 41:21 79:6 84:24 112:13 indication 25:2,4 40:12 55:1 76:3 76:16,22 indications 24:21 25:9 26:17 45:19 51:11 72:16,18 76:14,20 individual 21:16 21:25 22:24 30:20 39:13 43:9 44:7 48:22 54:20 56:4 87:16,24 individual's 20:10 individuals 21:24 22:4,8,8 41:19 55:2,5 inds 8:24 79:25 industry 9:15 19:10 infectious 8:14 11:23 12:15 inform 30:17 31:9,21 33:4 105:8 information 7:24 8:17 16:11 21:10 24:3 28:10,21,22,23 30:24 32:16,25 33:9 43:15 48:8 49:9 53:14 54:3 54:8,22,24 55:24
---	---	---	--

[information - k]

Page 14

56:2,4 62:18,19 62:20 79:13 86:11,12,12,17 86:19 87:14 96:14 102:7,8 103:11,14,21 104:3,6,13,18 105:3,5,9,9 106:9 108:15 informed 65:7,9 65:12 66:4 informing 29:14 29:15 31:13 infraction 84:7 injunctio 83:13 injuries 14:11 15:13 61:20 62:9 injury 30:1 61:10,13 62:3,19 input 29:8 72:22 72:24,25 73:3 inquire 39:11,12 insight 88:19 inspected 61:5 inspection 34:6 34:9,11,13,14,16 34:20 56:11,19 64:21 65:3,11 82:5,10,12 84:15 84:18 inspections 33:25 60:24 81:13,14,15,16 81:17,18,20,24 81:24,25 82:20 inspector 64:17 65:6,9,15,25	83:22 84:1 inspectors 60:25 81:21 instance 25:2 83:12 104:21 107:6 instances 25:17 32:8,9 institutional 49:17 instructed 106:5 106:20,25 instructing 93:9 107:6 instruction 101:25 instructional 102:25 103:23 intend 15:10,12 intended 71:11 79:12,13 intent 33:3,9,13 interest 7:11 38:6 43:1,7 44:11 46:19,25 47:11,16 48:15 interested 43:13 44:7,8 55:9 98:7 111:12 interesting 52:1 interject 80:12 interjected 95:18,23 internal 6:13 11:10 12:12 internet 4:10 internship 6:13	interstate 65:5 intervals 39:24 intervention 48:20 50:4,20 107:5 interventions 50:5 introduce 5:13 introduced 67:17 investigate 14:25 52:14 53:2,10 56:2,9 57:14 61:19 62:1 investigated 53:9 55:15 57:19,20,24 85:10 87:24 89:1 investigating 54:11,13 investigation 8:23 63:17 85:11 investigators 54:21 invited 19:17 invoke 83:11 involve 71:25 involved 6:23 7:17 9:19 11:5 16:2 74:7 79:10 79:15,20,24 85:17 involving 74:3 irb 49:5,6,8,11 50:8	issue 19:9 25:24 26:5 49:4 60:23 82:20 issues 19:5 34:9 34:12,15,19 38:13 42:4 48:25 92:5 iv 65:8
j			
j 2:10 janet 1:10 4:18 5:3 110:8 111:6 112:8 113:4,9 114:4,13 115:20 january 34:5 jeff 5:10 57:7 58:6 60:7 jeffrey 1:3 2:16 4:20 112:6 113:3 114:3 job 10:25 74:9 74:23,24 john 100:10 joined 8:19 11:8 journal 17:17 105:6 jss 1:6 july 89:14 90:7 jurisdiction 65:6			
k			
k 16:6,12,13,23 17:5,7,12,23 18:3 36:24 53:25 69:8,21 70:10,19,25 71:9 72:4 89:2,12 90:6 100:20			

<p>101:2 kellner 101:2,3 kellner's 101:5 kept 98:25 kind 12:21,22 13:15 27:9 32:15 37:16 41:24 53:12 54:6 kinds 43:2 88:13 knew 96:18,21 97:1 know 6:2,5 13:11 14:7,20 19:19 22:10,25 24:8 25:23 26:1 26:3,19 31:10,11 34:2,4,8,15,19 35:24 36:18 38:3,11 40:10,22 41:6,22 42:1 43:5 46:11 48:4 48:6,6,19,19 49:3,4,8,11,13 49:14,21,24 50:1 50:20,23 51:13 51:24,25 56:16 56:22 57:22,23 59:15,19,21,22 60:15,16,19 61:11,23,25 62:14,17 64:25 65:23 69:2,24 70:9,15 72:14 73:13,15,22 76:13 78:5,18,23 78:25 80:13,17 80:18 82:4,7</p>	<p>85:17,22 88:17 88:23 89:15 90:23 91:2 92:24 94:7 98:17 100:18 101:12,14 102:5 102:9 103:13 104:4,7,17,22 105:5,14,15 106:6 107:13,15 107:22 knowledge 17:13 17:15 56:7 81:7 known 47:19 96:8 knows 21:22 93:6</p> <p style="text-align: center;">I</p> <p>I 101:2,2 label 102:7 104:20 106:6 107:1,3,3,7 labeled 98:15 labeling 32:25 33:18 53:11 85:4 97:21 98:8 98:19 99:3,5,19 99:22 102:9 103:10 106:7,14 106:22 labels 29:7,8,9 lack 36:7 61:15 62:18,19,20 107:23 lacks 31:25 50:11 97:25 100:14 101:10</p>	<p>102:4 language 106:13 106:21,23 107:1 107:23 large 1:22 19:19 68:2 late 11:7 20:13 20:13 71:16 107:9 law 2:10 5:17 107:14 lawsuit 53:1 88:14 learning 103:24 left 11:25 legal 85:18 88:18 88:21 112:1 115:1 length 26:4,4 37:13 leon 2:11 letter 3:7 82:21 83:12 84:21 99:20 112:19 letters 59:9,10 59:17 life 59:24 lifetime 100:7 line 112:13 114:7 115:3 linked 109:9 list 42:3 listed 82:15 114:7,17 listing 114:7 literature 35:22 35:24 36:9,23 42:23 43:15</p>	<p>52:19 53:23,24 54:1,4,14 74:11 77:20 78:3 85:8 90:3 100:12,18 104:9,23 105:10 106:1 litigation 33:6 33:19 little 22:13 49:14 60:2 lizards 69:25 llc 1:6 2:9 4:20 4:20 5:18 112:6 113:3 114:3 llp 2:17 logic 30:15,16 long 40:13,22 42:3 70:4 look 16:17,18 18:3 20:16 23:7 38:5,13 40:15,25 53:24 54:16 64:25 65:2 68:20 73:7 74:9 86:1 101:16 108:19 looked 66:9 102:10 looking 39:19 69:1 75:19 94:24 103:10,11 looks 29:24 59:25 los 2:5 loss 32:5,18 41:8 43:20 56:23,25 57:17 58:5,15,20 58:20 63:5 75:3</p>
--	---	---	--

[loss - meeting]

Page 16

88:14 89:9 91:3 91:5,9,10 92:12 93:1 96:15 103:25 105:2,20 losses 31:15 lot 21:21 39:2 41:21 43:12,14 78:1 86:14,14 91:6 100:17 104:8 lots 73:19,19 lower 16:22	maker's 62:5 making 21:5 49:14 54:20 75:24 78:7 88:13 malfunctions 78:20 manage 8:18 management 12:15 mania 25:6 manual 28:5 31:22 32:2 91:24 101:24 107:24 manufactured 34:3 manufacturer 54:7,10,12 62:25 63:14 64:11,18 65:7 66:11 68:13 69:4 82:22 88:5,8 manufacturer's 74:24 75:20 manufacturers 46:6,12,17,18,24 47:2 48:24 55:15 65:12,17 75:12 87:12 manufacturing 60:10 march 107:9 marked 3:14 16:23 market 6:23 7:3 9:5,10 20:9 27:22 29:12	45:15 51:12,21 51:22 52:7 55:11,18,20,21 69:10 70:1,3,4,5 70:6,10,12,14,21 70:22 71:7,8,13 71:20 72:11 marketing 44:8 48:13,14 70:16 72:1,2,4,9 80:17 88:6 married 10:23 material 103:23 materials 24:12 matter 4:19 48:23 77:7 matters 14:10 85:2 maude 85:4,20 85:23 86:1 mayo 105:15 mcdonald 100:22 mdr 52:18 86:16 mdrs 56:13,17 56:20 62:1 88:20,24 mean 11:23 13:12 28:18 32:13,22 37:4 38:11 40:9 42:3 50:15 51:19 52:25 53:25 55:16 57:18 60:15 72:13,24 73:14,15 74:6,7 75:18 77:25 83:17,18 84:5,9	85:17 88:8 89:17 91:22 92:18,18 98:17 99:17 102:12 meaning 81:13 83:24 meaningful 47:7 means 24:25 29:14 106:7 107:3 meant 99:9 measure 39:17 measured 41:5 42:6 measurements 18:13,16 39:8 41:15 42:8 mechanism 70:6 mechanisms 69:10 mecta 74:22 75:15 87:10 med 13:19 media 4:17 medical 6:12,17 7:7,10 8:22 9:7 9:20 10:1 11:3 15:19,23 28:11 29:11 53:23,24 54:1,4,14 56:13 61:16 74:23 79:5,6 100:11 medicine 11:6,9 11:10,10 12:13 12:17,19 105:14 medline 36:11 meeting 26:14 52:21 55:6
m			
m 2:16 100:20 m.d. 1:10 5:3 110:8 111:6 112:8 113:4,9 114:4,13 115:20 m.d.s 48:5 ma'am 67:6 97:17 machine 63:3 madam 112:10 magnitude 39:20 mail 33:14 mails 33:21 maintain 24:23 41:10 maintained 11:23 maintaining 48:12 major 25:5 27:14,18 majority 24:22 25:3,9 76:16,21			

57:22 71:1 72:3 72:20 73:2,4 85:13 91:19 92:2 94:2,3 meetings 73:5 104:11 member 100:7 members 7:16 24:22 72:25 76:18 92:4 memory 15:1,1 31:15 32:5,11,19 41:8,9,10 42:8,8 43:2,8,20 53:8 56:23,25 57:17 58:4,15,19 59:6 59:7,12 60:1,3 63:6 75:3 85:8 88:14 89:9 91:3 91:5,9,10 92:5 92:12 93:1 96:15 98:12 103:25 105:3,4 105:20 106:9 mentioned 75:3 75:3 81:9 100:19 mentions 91:2,5 merit 111:4 mescalero 11:1 12:1,8 met 9:14 83:6 104:6 method 20:25 methodologica... 21:1 methodology 30:2	mexico 12:5,7,11 middle 1:1 midwest 112:17 115:1 minute 10:5 18:2 minutes 34:22 34:24 66:22 67:15,16 108:23 mirkovich 65:9 misled 46:7,12 46:17,24 misspoken 94:24 misstatement 66:5,7 misstates 87:6 90:5 100:14 monica 2:4 monique 2:3 monitor 38:9,14 38:14,15 month 38:3 months 11:4 38:4 40:2,22 41:23 86:2 moral 30:23 morning 4:4 5:9 67:12,13 motivated 43:13 55:8 motivations 33:21 move 18:23 25:4 28:3 33:23 47:5 52:12 moved 12:4,10 moving 20:11 34:14 60:4 62:24 67:21	n n 3:1 4:2 101:2 name 4:21 5:10 5:16,19 67:17 101:1,15 112:6 113:3,4,15 114:3 114:4,21 names 36:14 nature 21:12 82:23 83:8 nda 8:25 necessary 38:19 89:23 need 6:5 10:5 18:17 29:16 34:23 37:16 38:9 41:4 43:6 46:1 85:25 101:16 107:14 needed 8:16,16 64:18 71:17 83:3,6 needs 84:10 104:3 106:6 negatively 79:7 neither 32:10 neurobiology 26:12 neurological 18:24 neurology 26:12 never 28:16 new 8:23 12:5,7 12:11 104:22 105:6 ni 26:2 nih 7:18	nine 76:17 77:3 77:4 non 59:7 nonconforming 61:3 nonvoting 19:10 notarized 112:14 notary 1:21 110:20 112:25 113:10,18 114:15,23 115:23 note 4:7 112:12 notes 108:20 111:8 notice 1:17 84:7 95:1 noticed 10:4 notified 53:16 november 112:4 number 15:22 19:19 20:17 37:23 73:3 79:11 80:20 90:7,10 93:24 100:17 108:14 112:7,13 numbers 41:18 114:7 numerator 57:25
o			
o 4:2 12:6,6 100:25 oath 3:5 5:5,7 30:22 110:2			

[object - page]

Page 18

object 99:12 objected 95:16 objection 14:18 31:6,24 35:1 43:21 44:18 46:9 47:13 50:11 51:14 57:5 60:13 61:21 62:11 64:2 68:5,15 69:18 73:11 74:4,13 77:21 78:12 80:8 87:5 88:1,15 90:4 91:13 92:14,20 93:2 96:25 97:24 99:12 100:13 101:7,9 102:3,12 103:3 106:15 107:11 108:7 objective 41:15 obligation 30:20 30:23,23 105:8 obligations 54:7 61:15 74:16 observation 47:21 observations 81:18,22 82:11 82:14,15,17,20 82:24 83:9,16,20 83:23 84:8,9,16 84:18 observe 81:21 observed 80:21 occurred 95:16	october 1:14 4:5 110:12 111:14 offer 15:10,12 20:1 75:7 76:25 86:10 offered 14:4 52:6 85:12 86:17 offering 13:17 33:12 50:20 103:18 offers 105:15 office 7:8 9:5,18 71:17 officer 8:23 10:1 official 110:11 113:15 114:21 oh 58:17 59:3 73:19 80:7 ohio 112:2 okay 10:11 13:1 13:19 15:16 18:8,18 19:12 20:4 23:16 24:14 34:1,25 44:4 58:17 59:3 59:6 64:16 66:6 66:21 69:7 81:15 82:1 87:7 90:18 95:7 96:2 103:7 omit 104:5 once 11:13 52:25 55:23 56:1,14 87:11 88:17 ones 40:16 online 18:21	operating 21:4 operators 21:25 opining 103:20 opinion 14:23 16:14 24:16 30:3 33:13 35:14 36:6 37:3 47:6 49:15 52:13,14 60:4,9 61:8,17 62:24 63:22 64:13,16 65:24 68:4 69:16 75:7 92:10 97:20 104:6 opinions 13:18 14:15,16 35:11 67:23 93:5,15 97:15 103:17,18 opportunity 14:24 16:15,16 54:16 55:7 86:4 87:13,22,25 88:3 opposed 66:2 72:1 option 49:25 53:22 72:15 oral 38:12 order 25:24 26:2 26:5 55:10,18,22 68:13 69:5 95:3 109:7 organized 11:14 original 70:16 87:18 ought 50:25 outcome 18:13 18:15 22:3,4	37:8,17,19 39:8 39:17 86:12 outcomes 27:1 28:1,2 38:5,12 38:12 41:4 44:9 44:12 outlined 77:24 outlines 90:10 outside 51:15 61:24 62:12 79:25 92:15,21 93:2,7,11 95:19 96:17,25 108:8 outweigh 47:19 outweighed 45:25 outweighs 48:17 overall 62:14 97:14 overbroad 80:8 101:11 103:5 overlap 7:4
p			
p 4:2 p.l. 2:10 p.m. 1:16,16 4:5 10:12,15 35:4,7 51:5,8 67:1,4,7 108:25 109:3,16 109:17 page 3:2,3,4,5,6 3:7,8,8 15:25 16:1,22 17:16 18:5 20:12 28:3 28:4 35:9 59:1,4 65:4 112:13,15 114:7 115:3			

[pages - position]

Page 19

<p>pages 1:23</p> <p>panel 8:7,8 24:22 25:4,8 26:9,11 76:17 78:2</p> <p>panels 76:16</p> <p>parameters 61:1</p> <p>part 8:25 9:17 19:16 21:17 22:23,25 33:24 48:6 65:2 73:5 77:18 84:14 85:14 95:13 102:11 114:9</p> <p>participant 31:1 31:2</p> <p>participants 4:11 72:21</p> <p>participate 8:3 48:12 63:2 76:24 105:17</p> <p>participated 22:9 63:11 64:5</p> <p>participating 47:16 64:9</p> <p>particular 14:25 44:12 79:25</p> <p>particularly 8:25 22:14 23:15,21 28:1 40:21 44:8 55:25</p> <p>parties 4:15 98:7 111:11,11</p> <p>parts 8:24 9:17</p> <p>paso 13:9,10,11</p> <p>pass 101:20</p>	<p>passive 55:23</p> <p>pathetic 29:25</p> <p>patient 29:17 30:5,6,8,25 38:15,22 59:21 81:6 86:11 92:17</p> <p>patients 6:18 8:2 30:7 31:14 32:10,19,24 33:4 33:10 37:24,25 38:10 39:6,22 49:1 50:2,9 59:20 63:4,6,9 83:10 98:6 103:13</p> <p>paxil 80:16</p> <p>peer 37:14 74:2 74:10 104:12</p> <p>pending 6:7 71:14</p> <p>people 11:17,23 15:3 21:4,5,18 21:19,23 26:14 31:21 52:6,22 54:24 55:4</p> <p>percent 25:16,20 32:24 37:20,20 41:18</p> <p>percentage 58:14</p> <p>performed 68:12</p> <p>period 38:16,17 39:7</p> <p>perkins 1:21 4:23 110:20 111:4,22</p>	<p>permanent 58:19 89:7,8,9 91:10 93:1</p> <p>permitted 1:19</p> <p>persistent 84:25 84:25 89:8,8</p> <p>person 55:3 103:6</p> <p>personally 78:9 113:11 114:15</p> <p>persons 8:9</p> <p>petition 86:3,6,9 86:10,18 87:1,2 87:4,8,17 100:2 100:4</p> <p>petitioner 87:19</p> <p>pharmaceutical 6:24 39:1 50:3 79:9,9</p> <p>pharmaceuticals 6:25 69:17,22,22 70:7</p> <p>phase 39:3,4</p> <p>phone 112:3</p> <p>physical 11:21 11:22</p> <p>physician 11:1 29:6 30:5,17,21 30:24 54:18 80:3,24 104:3</p> <p>physicians 8:11 8:16 29:14 31:14 33:9 48:7 92:11 96:14 103:23,24 104:10 107:24</p> <p>pile 18:19</p>	<p>place 4:15 56:13 56:15,20 67:22 67:22 77:23 107:24</p> <p>placebo 21:7,19 21:20 37:11 49:23,24</p> <p>plaintiff 1:4 2:2 5:20</p> <p>plaintiffs 85:17 86:13</p> <p>planning 107:10</p> <p>please 4:7,25 6:11 108:4 109:9 112:11,11</p> <p>plus 30:4,14,14</p> <p>pma 25:10 38:25 39:3 51:19,22 68:18 69:9,11,12 69:14</p> <p>point 18:21 64:7 98:12,16</p> <p>policy 8:6</p> <p>ponce 2:11</p> <p>population 37:9 37:22 38:16 48:22 68:3</p> <p>populations 40:4 40:7 52:4</p> <p>portion 96:4 108:5</p> <p>pose 83:9</p> <p>posed 48:25</p> <p>posited 50:8</p> <p>position 7:15 8:22 9:3,12,14 9:25 94:4</p>
---	--	---	--

[possible - providing]

Page 20

<p>possible 22:15 39:13 43:13 54:8 91:3,5 post 6:23 7:3 9:5 9:10 20:8,9 55:11,18,20,21 potential 30:9,18 31:14 42:4 45:25 46:4 47:18 49:22 52:8,9 63:15 92:12,25 96:15 103:22,25 105:19,25 potentially 29:15 44:9 54:9 powered 23:15 practice 11:24 12:1,10,22 13:4 13:5,12 48:7 80:22 practiced 12:17 practicing 19:7 30:4 practitioner 28:16 80:2 practitioners 27:5 33:4 53:21 103:2,12 104:10 105:8,17 predefined 39:9 predicate 27:22 70:2 preliminary 26:2 premarket 9:18 9:20 24:24 25:12 71:24</p>	<p>79:19 preparation 22:23 24:12 presbyterian 12:11 prescriber 28:16 29:3,5 prescription 28:11 present 2:21 14:1 presentation 74:19,22 presentations 42:25 104:12 presented 24:3 28:18 36:21 69:4 98:14 100:2 presenter 24:9 presenting 86:4 presumably 77:15 pretending 31:21 pretense 28:9,22 prevented 103:24 previous 7:8 82:17 84:15 previously 91:25 primarily 7:18 12:22 primary 6:15 8:10,11,15,16 11:1,16 12:8,12 12:13 13:3 29:5 29:5 80:3,24</p>	<p>81:4 88:4,7 primitive 21:2 principals 63:1 prior 14:5 26:13 39:23 41:16 59:10 70:12,14 70:21 73:2 86:13 106:18 private 12:10 privileges 12:14 12:14 probably 6:1 11:7 14:13 39:23 60:1 66:15 71:12 problem 42:22 61:13 78:15 84:25 85:1 problems 43:11 53:7 83:21 84:9 84:10 procedure 1:19 46:5 113:5 114:5 procedures 56:19 proceed 5:1 proceedings 3:2 process 17:12 19:17 28:13 53:15 70:10,25 71:9 98:5 processes 61:9 product 28:11 29:9 39:1,2 48:16 54:9 65:14 72:23 79:9 88:6 99:1</p>	<p>production 112:15,17,22 products 6:24 8:1,1 21:8 61:3 70:25 79:22,24 professional 6:11 10:18 97:21 99:21 103:8 104:11 program 102:19 102:23,25 promoting 50:21 promulgated 104:2 proof 19:24 20:2 20:5 proposed 49:7 49:22 95:3 106:19 protect 23:1 33:5,18 provide 13:2 17:10 19:13 30:19,24 47:7 79:13 104:3 provided 11:16 20:24 72:25 102:15,20 106:9 provider 6:16 12:13 29:5 66:12 80:25 81:4 101:25 providers 8:10 8:15 98:6 provides 36:24 48:16,21 providing 28:10 28:21,22,23 29:8</p>
--	---	---	--

33:9 93:4,12,13 93:14 104:13 psychiatric 17:1 47:9 81:3 90:17 90:20 102:1 psychiatry 13:21 13:22 17:18 26:11 public 1:21 7:17 7:25 10:25 19:17,21,23,24 20:1,4 28:24 46:19 47:16 48:12 58:12,18 63:20 73:1 85:12,14 94:23 98:5 110:20 113:10,18 114:15,23 115:23 publication 90:22 93:20,22 106:18 publications 73:25 74:2,18 93:24 94:2 publicly 7:24 publish 91:17 published 9:7 26:1 73:8,17,22 77:19 78:3,6 90:13 91:6 94:9 94:15 100:12 pubmed 36:11 pulled 40:16 pulmonary 42:5 pure 48:19	purposes 1:18 1:18 pursuant 1:17 pursue 54:2,8 pursued 53:14 put 10:8 22:19 32:25 33:1,18 36:14 51:1 53:5 53:11 56:15 67:25 86:5,21 89:11 91:23 104:20 106:13 106:13,25 107:2 q quality 4:8,9 68:1 quantify 105:24 question 6:7 17:25 31:7,25 43:22 44:19 46:10 47:14 51:15,15 52:1 57:6,7,24 60:14 61:22 62:12 63:7 65:21 68:16 69:19 73:12 74:5,14 77:22 78:13 86:23 87:6 88:2 88:16 90:5 91:14 92:15 93:10 94:11 95:15,15,17,22 95:24 96:1,6,10 96:12,19,23 97:25 100:14 101:20 102:4	103:4 107:12 108:2,8 questions 18:11 30:9 66:16 67:20 105:11 108:17 109:6 quick 108:20 quite 108:14 quote 65:17 r r 4:2 12:6 101:2 raised 34:20 randomized 68:2,11 randomly 38:1 range 106:1 rate 43:7 reach 76:11 read 20:18 35:20 35:21 40:1,18,19 40:19 49:5,16 64:5 90:25 95:9 97:7,10 100:17 100:17,21,24 101:3,3,22,25 102:10 108:4,5 113:5,6,12 114:5 114:6,17 read's 100:10 readily 104:14 105:9 reading 112:19 real 63:5 really 27:24 36:24 53:13 realtime 111:5	reason 33:17,17 112:14 114:8 115:3 reasoning 27:8 62:21 reasons 50:7 70:5 recall 18:15 21:9 23:7,10 24:6 40:5,14 49:16 85:16 101:21,22 receipt 112:18 receive 9:15 21:18,20,23 received 21:16 26:3 81:7 96:13 recess 10:13 35:5 51:6 67:2 109:1 reclassification 76:15,19 91:12 reclassified 19:14 45:18 71:21 72:12 reclassifying 85:5 recollection 97:2 recommend 32:14 recommendation 25:3 75:24 recommendati... 24:15,18 25:14 25:16 26:8 77:1 102:8 recommended 25:8 41:14 76:18 80:25
--	---	---	--

[recommended - reporting]

Page 22

<p>103:1,8 recommending 30:19 reconvened 26:10 record 4:5,16 5:14 10:10,12,14 34:24 35:3,6 51:3,4,7 66:25 67:3,5,7 108:22 108:24 109:2,13 109:15 111:7 114:9 recorded 4:13 4:17 recording 4:9,14 records 13:16 15:20,23 recruited 8:6 9:4 refer 104:10,10 reference 16:1,5 17:16,23 33:6 34:5 90:15 101:24 104:15 112:7 113:2 114:2 referenced 18:6 18:10 33:21 58:11 90:18,20 113:11 114:15 references 42:16 referencing 23:5 73:25 104:1 referral 80:25 referred 81:21 86:3 referring 94:14</p>	<p>refers 27:24 regarding 29:19 60:9 regardless 57:3 57:16 register 26:2 64:18 65:13,18 93:21,25 94:3,16 94:23 registered 65:8 66:11 111:4 registration 66:10 94:12 regs 9:14 71:5 88:9 regulated 9:15 12:20,24 regulation 53:2 106:19 regulations 9:8 9:10 17:8 53:17 61:16 63:25 64:14 68:11 71:10 99:3,4,18 104:1 regulatory 12:24 19:5 44:15,23 48:2 63:21 69:24 82:25 103:6 104:7 106:12,24 107:2 107:4 reinspected 34:18 rejected 49:7 relate 56:22 57:17</p>	<p>related 14:10 31:12,16 42:5 56:21,25 57:3 58:15 73:3 89:4 89:6 relatedness 52:24 relates 44:14 45:10 relative 111:10 111:11 relaxed 80:14 relevant 19:8 reliable 18:12 36:7 45:23 reliably 23:9 relied 20:18 relief 100:1 relieve 104:13 relieved 105:7 rely 100:10,16 remain 71:19,22 76:22 remained 72:18 remaining 72:18 remains 48:6 66:9 remediated 34:8 34:15 remember 7:19 7:20 14:6,9 18:21 23:6,13 24:8,10 36:15 40:18 49:19,20 52:17 60:21 68:18 70:15 71:15 74:21,21 78:25 79:1</p>	<p>80:19 85:24 88:23 91:4,7 94:7,8,22,25 101:1,14,15 remotely 110:8 111:6 removed 70:5,22 remunerative 13:12 repeat 108:1 report 15:6,8 16:1 17:16 20:11 28:4 33:24 34:6 35:10 52:25 53:2,20,21 54:11 54:20 56:5 59:2 64:21 80:4 85:3 86:5,25 88:20 94:8 95:9,21 97:7,12,13 102:1 111:6 reportable 32:20 reported 1:21 44:3 54:4,13 57:21 59:19,20 62:2 78:24 80:17 85:20,23 89:21 90:2 reporter 4:23,25 5:7 6:4 54:19 96:3 108:3 111:5,5 113:7 reporter's 3:6 111:1 reporting 9:8,10 52:22 55:3</p>
--	---	---	--

[reports - rules]

Page 23

reports 14:25 16:1,5 32:4,5,9 32:17,22 41:21 43:4,5 52:19 53:7,10,20 55:5 56:13,21 57:3,14 57:16,19 58:4,4 58:7,7 59:7,12 60:1,16,17,20,22 73:8,9,14 80:15 80:20 85:7,12 87:16,24 88:11 88:25 90:2 98:5 105:1 represent 5:11 5:17,20 representative 19:9,11 31:2 65:10 representatives 53:19 59:21 representing 4:21 request 54:16 87:13 114:9,11 requested 100:1 103:1 107:20 108:5 111:7 requests 8:24 require 16:13 25:11 46:22 47:1 69:11,12 71:24 82:25 83:3 104:2 required 16:19 17:4,14 24:24,25 27:17 53:1 55:23,25 56:1,15	65:13,18 69:4 85:21 86:15 91:23 112:25 requirement 17:10,11 44:15 44:23 48:2 83:5 83:11 104:7 requires 17:9 68:11 69:12,13 research 8:7,21 20:3 researchers 27:5 reservation 12:8 reserve 109:10 residency 6:13 13:20 residents 6:17 resistant 27:13 27:18 44:14 45:11,22 46:8 49:2 50:10 resolution 41:20 resolve 32:9,21 41:22 resolved 84:16 resolves 32:12 resources 7:19 respondents 59:4 responding 80:12 response 40:13 responsibilities 53:4 63:21 responsibility 6:17 53:4 63:14 63:20 64:8 88:4 88:7,19	responsible 7:15 29:10 30:5 54:7 55:14 79:22 81:4 restriction 19:23 result 82:11 results 23:11 85:5 retention 41:8 retired 12:18 retirement 10:24 retrograde 15:1 31:15 32:4 returned 112:18 revealed 16:23 review 8:22 9:19 10:1 16:22 18:17 19:3 20:21 23:20,20 23:25 24:2,4,11 36:9 37:14,15 49:17 51:24 59:9 71:14 74:24 79:11,24 90:12 99:5 109:11 111:6 112:12 113:1 114:1 reviewed 8:23 8:24 14:22 15:19,23 18:1,20 20:17,23 21:14 24:8 35:19 36:2 36:11,13,18 53:24 54:1 58:23 74:2,10,17 90:24 91:1 97:22 98:4,18,20	99:22 101:14 104:12 106:7 108:12 reviewer 79:19 reviewing 13:16 13:16 24:7 26:12 29:6,7 53:22 reviews 42:15 riera 14:12,16 right 15:5,9 16:9 16:21 20:22 27:16 41:3 65:23 67:24 74:3 75:9 77:14 84:7 91:12 93:17 95:25 96:20 99:10 109:10 ring 14:12 risk 30:18 45:25 46:20,21,25 47:3 47:24 48:9,17,21 48:23 89:7 91:3 91:6,9 96:15 103:25 risks 46:1,4 47:19,20 52:6,9 63:5 90:10 105:19 rmr 1:21 110:20 111:22 robust 21:10 robustness 37:22 routine 82:3,6,9 ruidoso 12:6,7 rules 1:19 6:1 113:5 114:5
--	---	--	---

[ruling - simply]

Page 24

ruling 93:19	10:4,9,14,16	search 35:24	set 7:23 8:7 9:5
run 11:15	15:4 31:18	searches 35:22	61:1 71:5 75:16
runs 98:23	33:11 34:21	second 9:1,23	seven 35:24
s	35:2,8 43:25	47:5 65:10	severe 16:25
s 3:13 4:2 12:6	44:22 45:6 47:4	80:11	47:9
100:20 112:15	47:25 51:2,9	seconds 108:19	sham 21:6,15
114:8,8 115:3	52:11 57:11	secret 91:10	22:6,15 37:11,11
sackheim 36:15	58:9,10 59:14	section 40:20	sharma 102:16
100:20	60:8 61:4 62:7	sections 29:7	sheet 112:13
sadiq 102:16	62:23 64:12	see 16:3 17:2,21	114:7,10,18
safe 50:21	66:13,24 67:20	37:19,20,23	115:1
safely 104:4	78:21 93:14	40:16 54:22	shield 29:25
safety 16:10,19	schizoaffective	55:1 58:16,16	shipped 65:14
19:24 20:2,5	25:7	64:19 77:9 82:7	short 31:5 66:18
21:11 25:1	schizophrenia	82:8 83:25 84:2	shortened 59:24
27:17 29:11	25:6	84:4 89:9 90:9	show 42:12
30:25 35:16	schizophrenifo...	90:18,19 94:6,24	43:19 51:18
36:8 38:10,13	25:7	95:2 96:16	101:12
39:9,10 40:24	school 6:12 11:3	105:18,23	showed 53:13
41:4,25 42:4	11:9 13:19	seekers 13:8	shown 46:18
43:17 44:16	schools 105:14	seen 4:12 28:12	112:16
47:8 62:10 64:8	scientific 19:2	28:17 35:25	side 42:17 54:8
70:5,22 78:4	69:6,13 74:10	36:4,20,20,22,23	sign 109:11
79:13,14,16 90:8	100:11 104:9,23	44:2,3 49:11	signals 42:23,24
101:6 104:5	105:10	84:23 105:22	signature 3:8
105:9,17	scientifically	seizure 22:1,1	110:19 111:21
sales 53:19	68:3	23:1	112:14
santa 2:4	scientists 19:8	selected 7:12	signed 113:13
save 101:19	26:23 27:6	27:7 100:9	114:18
saw 85:9 86:16	scope 51:16	selective 89:11	significant 32:18
saying 94:22	61:24 62:12	self 39:22	36:7 38:21
says 58:17,18	92:15,21 93:3,7	sense 48:2	104:5
65:5 98:3	93:12 95:19	series 38:13	signing 112:19
scale 39:19	96:17,25 108:8	serious 28:17	similar 9:9 14:16
48:22	screen 4:13	29:15	similarly 63:3
schieber 2:16	101:19	service 7:17,24	simple 38:23
3:3 5:9,10,23	seal 110:11	10:25 11:2	simply 35:15
	113:15 114:21		

[sincerely - subject]

Page 25

<p>sincerely 112:21 single 52:18 sir 112:10 six 11:4,19 24:20 24:20 40:2,22 72:16 76:14 size 37:9,21 68:3 slides 23:21 24:5 24:6,9 small 12:5 21:9 23:8 smaller 40:11 solely 100:16 solicit 55:25 solutions 112:1 115:1 somatics 1:6 2:9 4:20 5:18 14:24 16:6,9,14 17:14 33:13,25 34:6,8 34:15 47:6,11 48:3 52:14 53:15 54:23 55:10 56:8,11,15 57:2 61:15 62:25 63:19 64:22,24 65:22 66:2 70:18 74:21 78:24 81:9 82:5 83:15 83:19 84:21 85:3,10,15,18,19 86:5,16,20,25 87:3,10,15 88:12 88:12 90:2,15 101:24 103:20 105:24 106:3,12 112:6 113:3</p>	<p>114:3 somebody 12:23 21:22 48:13,14 80:25 sops 56:12,13,15 sorry 10:3 40:8 45:3,3 59:3 60:5 60:13 78:14 80:10,13 89:17 99:15 108:2 sort 17:4,14 27:24 31:9 36:9 67:18 78:2 84:6 102:24 sound 6:8 source 54:17,17 54:25 57:16 sources 13:17 37:3 73:3 103:14,16 104:9 106:1 southern 12:5 span 59:24 specific 15:13 39:10 60:23 63:7 75:13,20 86:11,11,12 89:24 93:5,15 94:11 107:23,24 specifically 17:9 17:13 18:6 28:19 33:15,16 33:21 39:11 75:10 76:25 81:25 91:5,8 94:22 95:1 106:20</p>	<p>specifics 53:10 80:19 86:20 87:1,3 101:15 108:12 specified 39:24 82:9 speculation 50:12 107:12 spelled 12:6 spur 43:1 44:10 staff 7:14 stages 79:12 stands 7:21 start 67:22 started 6:19 11:13,25 12:19 starting 6:22 11:7 20:13 state 1:21 77:19 103:9 110:4,20 111:2 113:10 114:15 stated 31:23 32:1,2,3 statement 26:6 45:7 84:14 94:6 99:7 113:13,14 114:19,19 statements 90:25 91:21 states 1:1 29:12 statistical 9:18 statisticians 19:7 statistics 9:21 status 75:8 stay 51:20 75:9 75:25</p>	<p>stayed 8:4 9:3 45:17 52:7 stenographic 111:8 stenographically 111:5 stepped 9:24 stettinius 2:17 stimulate 20:3 stretch 11:4 strike 15:11 28:7 54:11 77:11 stroke 42:5 students 6:17 studies 8:3 16:14 16:17 17:11 18:19 20:8,9 27:17 35:15 36:1,2,21 37:1,5 37:16 39:3,3,4 40:1,5,11,11,14 42:12,21 43:19 44:5,16 47:12 48:18 68:2,8,12 69:11,13,15 71:25 73:8,17,23 79:3,11,15 89:10 89:11 90:11 91:6 105:13,17 study 18:13 22:10 37:12 40:20 42:19 43:14 54:5,21 79:4,8 stuff 31:11 subject 9:11 106:23</p>
--	---	--	---

submission 16:23 36:24 53:25 86:15 89:12,14 90:6,19 submissions 73:1 85:14 submit 19:21 37:14 submittal 89:2 submitted 16:6 16:10 19:18 26:13 49:6 52:18 55:5 56:16,24 57:1,4 88:25 subscribed 113:10 114:14 115:21 substance 14:16 substantially 27:21,23 70:2,20 suddenly 104:18 suffer 49:1 sufficient 37:12 37:13 68:1 suggestions 9:16 suite 2:5,11,18 112:2 summaries 20:23,24 35:20 summarize 35:10 summarized 47:5 52:13 summarizes 90:11 summary 58:23 59:8,20 88:24	superior 112:1 support 49:15 68:13 supporting 16:25 supposed 48:7 sure 10:21 18:22 24:19 25:18 38:18,19 39:5,6 46:23 51:2 52:3 57:8 64:3 66:19 66:23,24 80:5 93:23 94:5 95:18,25 98:21 108:21 surrounding 56:5 surveillance 6:24 9:5 55:11 55:19,20,21 susan 2:10 5:16 67:18 93:8 94:10 95:14 swartz 33:3,14 33:22 48:5 swear 4:25 sworn 5:4 110:9 113:10,13 114:14,18 115:21 system 6:16 12:11 systematically 38:15	table 50:25 taft 2:17 take 4:15 6:6 10:5 18:2 29:18 50:25 63:13 66:17,21 96:3 108:18 taken 4:18 10:13 35:5 51:6 56:8 67:2 76:23 83:18 106:2,11 109:1 talk 6:3 38:11 79:2 81:11 talked 57:13 67:25 71:1 106:14 talking 57:1,2 58:8 68:6 69:7 69:25 94:21 95:5 97:15 104:25 105:1 tampa 1:2 107:18 tapes 34:23 task 90:16,21 102:1,10 taught 11:21 technicality 72:8 techniques 42:16 tell 50:24 68:10 80:6 tells 107:2 ten 66:21 term 83:15 terms 9:21 21:11 40:6 48:11 63:14 76:14	98:11 106:8 testified 94:15 testifying 86:24 testimony 14:4 15:10,12 67:19 90:1 92:22 93:3 109:9 113:6,7 114:6,9,12 tests 41:15 thank 5:2,8 67:8 108:17 109:5,16 thanks 35:2 thelen 1:3 4:19 5:21 14:17 15:6 15:17 78:23 88:13 92:24 96:7,13 102:17 112:6 113:3 114:3 thelen's 15:13 34:3 61:6,10,19 62:8 78:19 92:11 107:22,25 108:13 theory 30:10 therapeutic 30:8 30:18 therapy 13:24 14:2,5,11 thing 6:2 49:23 99:16 things 41:14 69:8 92:7 101:19 think 9:12 14:8 14:13,19,23 17:22 20:18 25:18,19 28:21
	t		
	t 1:21 3:13 110:20 111:4,22		

29:13 33:2,6,16 37:6 40:18 41:4 41:6 42:7,14,21 43:12,23 44:6,10 45:12,14,16 46:6 46:13 48:11 49:3,8 51:25 52:2 53:5,12 56:24 58:2 59:10 62:14 64:24 65:3 66:14 67:12,24 70:14 73:23 82:18 83:11 85:7,24 87:23 90:8 92:6 96:12 98:19 99:4,8 101:23 109:14 third 14:9 52:13 61:17 thirty 112:18 thoroughly 97:22 98:4,18,19 99:5,22 thought 33:5 66:3,3 thousand 57:20 three 7:9 20:20 thursday 11:17 12:1 thymatron 28:5 44:13 45:9,13 47:22,23 56:22 57:3 60:11 63:3 65:8 70:18,24 72:23 75:8,11,13 75:15	time 1:16 6:25 8:11 9:23 10:23 11:3,25,25 12:17 12:19,21 13:6,13 13:14 25:21 26:4 38:2,16,17 39:7 50:1,4 51:22 70:25 72:3 74:11 75:13 83:2 98:1 104:20 109:5 times 5:25 44:6 today 83:14 109:5 told 71:17 92:11 92:25 93:13 96:22 98:10 total 76:13 touch 11:22 87:18 touched 48:1 touches 47:10 town 12:5 tpb 1:6 training 13:20 102:19,22 transcribed 113:7 transcript 23:20 23:22 24:1,1,12 96:4 109:8,12 111:7,7 112:11 112:12 113:5,12 114:5,11,17 transferred 12:9 treat 50:2 treated 22:6,7,8 38:6,21 40:4,23	50:3 81:6 102:17 treating 16:25 47:9 50:14,17 treatment 8:9,12 21:6,12,15,23 22:5,9,16 27:13 27:18 30:6,12 31:3 32:12 34:3 38:2 39:14,23,24 39:25 40:2 44:14 45:11,22 46:8 49:2 50:1 50:10,17 61:6 78:19 81:1 107:25 treatments 22:15 108:14 trial 1:18 21:13 21:14 22:18 23:4,8,11 49:7 49:18 50:9 107:10,17,18 trials 16:24 20:12,15,16,19 20:21 21:1,9,22 21:24 22:13 24:25 47:7 49:2 62:10 67:23 79:21 tried 57:25 107:8 trigger 43:6,6 true 65:16 69:16 70:11 71:2,3 72:5,23 77:5 78:10 81:19 83:7 99:13,16	111:7 truthfulness 49:9 try 49:13 trying 57:15 66:1 72:7 94:17 turn 35:9 turned 60:18 two 7:8 14:7 16:1 18:2 20:19 33:20 45:19 47:21 60:20 69:7,9 72:16 75:12 81:9 108:22 type 26:24
			u
			u 12:6 u.s. 6:21 7:13,17 uh 16:4 17:3 18:14 19:15 79:6,6 97:18 uk 90:18 ultimately 24:14 27:12 72:17 unanswerable 57:18,23 unapproved 7:25 8:1 undergo 25:10 31:3 37:14 62:21 undergone 32:20 63:6 underlying 24:2 26:16 30:15 33:8 50:7

undersigned 110:7 understand 27:7 27:10 42:25 56:14 57:9,15 63:10,13 66:1 86:22 understanding 5:24 14:20 22:17 50:13 52:23 58:3,3 62:16 63:24 75:22 100:3 108:13 understood 15:24 26:15 57:8 66:13 underwent 15:22 21:17 22:9 unethical 50:18 unexpected 60:19,20 unfortunately 17:7 55:13 uniform 76:12 unit 4:17 united 1:1 29:12 university 6:16 untreated 22:7 22:19,20 40:4 use 1:18 8:10 32:6 63:16 104:4 useful 28:22,23 user 53:20 uses 8:1	usually 37:24	visits 81:9 voluntarily 83:7 84:22 voluntary 82:13 volunteer 8:2 13:7 vote 25:9 76:21 76:23,24 77:2,4 77:6,7,8 voted 24:23 76:8 76:10,17 voting 76:18 vs 1:5	106:13 washington 11:15 12:4 way 29:13 31:9 31:10,21 55:23 57:22,23 60:19 71:5,9 76:8 85:22 89:25 92:8 93:18 96:18,21 97:1 ways 13:13 22:12 31:4 we've 6:3 10:4 34:21 57:13 weaver 100:20 weeks 41:22 welcome 67:9 went 9:25 36:11 36:13 whitman 11:16 11:18 12:2 william 100:22 willing 51:20 107:18 wish 102:20 withdraw 96:24 witness 4:12 5:1 5:4,6,8 10:7 14:19 31:8 32:1 34:25 43:23 44:20 45:2 46:11 47:15 50:13 51:17 57:9 59:3 60:15 61:23,25 62:13 64:3 66:19 68:6 68:17 69:21 73:13 74:6,16
	v v 4:20 112:6 113:3 114:3 vague 97:25 101:10 103:4 valentine 100:22 valid 68:3 69:5 104:23 validation 60:10 61:9 various 30:14 vasavada 100:22 verify 48:23 veritect 2:22 veritext 4:22,24 112:1,7 115:1 veritext.com. 112:17 versus 37:11 video 1:10 4:14 109:9 videoconference 1:11 110:9 111:6 videographer 2:22 4:4,22 10:11 34:22 35:3,6 51:4,7 66:25 67:3,6,9 108:24 109:2,15 view 101:5 violation 99:2,18 virtually 4:8 19:22 visit 81:12	w wacker 2:17 wait 95:16 waived 112:19 walk 6:10 67:19 93:18 walker 11:16,18 12:2 want 10:5 30:17 33:23 37:19,20 37:23 38:11,14 39:11 49:8,8 68:17,20 79:2 81:11 83:1 95:18 108:19 wanted 33:17 53:11 96:11 wanting 48:12 87:15 warn 63:4,8,25 warning 28:17 28:20 33:1 82:21 83:12 84:20 99:20	

[witness - yesterday's]

77:23 78:14,16 80:10,13 87:7 88:3,17 90:6 91:15 92:16 96:6 97:3,5,14 98:3 99:11,13 100:16 101:8,12 102:5 103:6 107:13 110:11 112:8,11 113:1,4 113:11 114:1,4 114:15 witness' 112:14 wondered 30:11 word 83:17 wording 89:20 work 11:20 12:20 13:7,15 79:17 worked 10:22 29:9 working 7:8 13:14 38:24 write 99:19 written 18:12 71:10 wrote 9:14 16:22 19:16 20:12 28:4 29:24 47:6 62:25 64:16 65:24	19:19 28:21 29:12 36:12 55:13 57:12 58:9 59:3 60:15 61:25 65:4,23 67:14,16 73:19 74:20 75:5 80:5 81:5 90:9 93:11 95:11,12 96:9 97:4,14,18 101:4 104:21 year 7:5 38:4 years 7:9,10,23 8:5,13 9:4,13 11:12,19 12:9 13:5 26:20 29:2 29:4 30:4,14 65:16 yesterday's 105:6
x	
x 3:1,13	
y	
y 100:25 yeah 10:4,9 14:14 18:1	

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.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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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