UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JEFFREY THELEN, Plaintiff, v. SOMATICS, LLC; and ELEKTRIKA, INC., Defendants.	Case No.: **COMPLAINT FOR DAMAGES** **(Jury Trial Demanded)**

COMPLAINT

Plaintiff JEFFREY THELEN sues Defendants SOMATICS, LLC and ELEKTRIKA, INC., and alleges as follows:

NATURE OF THE ACTION

1. This common-law products liability, negligence and fraud action arises out of serious and debilitating cognitive injuries that plaintiff, JEFFREY THELEN ("Plaintiff" or "Mr. Thelen") sustained as a result of undergoing multiple rounds of electroconvulsive shock treatment with a device manufactured and/or distributed by defendants, SOMATICS, LLC ("SOMATICS") and ELEKTRIKA, INC. ("ELEKTRIKA") (collectively referred to as "defendants").

2. The injuries Mr. Thelen sustained as a result of defendants' shock treatment device, include but are not limited to, brain damage, neurocognitive injuries, severe permanent memory loss, significant decline in his ability to learn and recall information, a disruption and decline in his ability to encode new information, diminished quality of life, additional physical, physiological, psychological and emotional injuries and harms, and lost wages and earning

capacity.

3. Plaintiff alleges that defendants negligently and intentionally concealed and failed to adequately disclose and warn about risks, including but not limited to, brain damage and permanent neurocognitive injuries associated with their shock treatment device. In addition to concealing risks, SOMATICS intentionally, recklessly and overtly misrepresented the safety and efficacy of the shock therapy device.

PARTIES AND VENUE

4. Plaintiff, Jeffrey Thelen, is an adult and a resident and citizen of the state of Nebraska.

5. At all relevant times, defendant SOMATICS is and was a limited liability company formed and existing under the laws of the State of Florida with its principal place of business at 710 Commerce Dr., Unit #101, Venice, FL 34292.

6. SOMATICS is the manufacturer, labeler, promoter and distributor of the "Thymatron" Electroconvulsive Therapy ("ECT") shock device. An ECT shock device is a device used for treating severe psychiatric disturbances by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head. An ECT shock device, in lay terms, is used to administer "shock treatment."

7. At all relevant times, defendant ELEKTRIKA, is and was incorporated, formed, and existing under the laws of the State of New York with its principal place of business at 149 Amityville Street, Islip Terrace, NY 11752. Plaintiff is further informed and believes and based thereon alleges that ELEKTRIKA is a manufacturer and exclusive supplier of "Thymatron" ECT devices for SOMATICS.

8. Upon information and belief, despite an affirmative duty to register with the FDA as a manufacturer or contract manufacturer, ELEKTRIKA has failed to register with the FDA.

9. Upon information and belief, Defendant ELEKTRIKA regularly conducts and transacts business in this judicial district, as it manufactures and assembles "Thymatron" ECT devices for SOMATICS, and it directly ships its product to SOMATICS which is based in Venice, Florida. Defendant ELEKTRIKA also conducts repairs on SOMATICS' "Thymatron" ECT devices and ships and receives repaired devices to and from Venice, Florida. Defendant ELEKTRIKA has thus generated revenue from business conducted within Venice, Florida. This Court has personal jurisdiction over Defendants because they have sufficient minimum contacts in this judicial district to render the exercise of jurisdiction by this Court proper.

10. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

11. Venue is proper in this Court pursuant to § 28 U.S.C. §1391(b)(1). Defendant SOMATICS resides in this judicial district and defendant ELEKTRIKA is subject to the Court's personal jurisdiction because it has sufficient minimum contacts with this judicial district.

GENERAL ALLEGATIONS

A. Brief History of the Discovery of ECT

12. Electroconvulsive therapy ("ECT") is the practice of inducing grand mal motor seizure through application of electricity to the brain. In the late 1930's, after observing slaughterhouses apply electricity to pigs to render them manageable for slaughter, Ugo Cerletti and Lucino Bini, two scientists at the University of Rome thought that electricity could be used to treat schizophrenia. Scientists at the time theorized (incorrectly) that *seizures* could potentially cure or decrease the symptoms of schizophrenia and thus were considering using electricity to induce grand mal seizure with the hopes of curing schizophrenia.

13. Cerletti and Bini began to test their theory by applying electricity to dogs and it was noted by Bini that the majority of the dogs died during the experiment.

14. In April 1938, after having sacrificed sufficient dogs, Cerletti and Bini applied ECT to the first human patient. A 40-year old Italian man who had been found wandering the train station in Rome and speaking gibberish was brought to the University of Rome and had 70 volts of electricity applied to his temple by Cerletti. It has been reported that, while the scientists were deliberating whether they should apply a second higher voltage, the patient pleaded "*Non una seconda! Mortifera!*" ("not again it will kill me!"). Seeing success that the man was speaking lucidly as opposed to his initial gibberish, Cerletti applied a second and higher voltage (110 volts) of electricity. The scientists reported that, after the application of the electricity, the patient became more lucid and was able to speak coherently. The patient was administered approximately a dozen more sessions of ECT and was eventually discharged but subsequently lost to follow-up.

15. In May 1938, Cerletti publicly presented his results on the use of ECT on this patient at the Medical Academy of Rome. Shortly thereafter and starting in the early 1940s, ECT began to gain acceptance for the purported treatment of schizophrenia (and eventually other psychiatric ailments) across Europe and in the United States.

16. It may come as a surprise to some, but ECT shock treatment is still presently prescribed in the United States for various psychological disorders including, but not limited to, depression, bipolar disorder, schizophrenia and catatonia and is used on patients of all ages, including children and the elderly. In an effort to veil the image of patients jolting, jarring and convulsing during the procedure, patients are now placed under anesthesia during the procedure, but as outlined herein, while the use of anesthesia may mask the image of overt

convulsions, the devastating permanent side-effects of ECT on the body and the brain remain the same, and in some cases, exacerbated.

B. Regulatory History of ECT

17. Prior to 1976, medical devices could be marketed without review by the U.S. Food and Drug Administration (FDA). Spurred by the increased technological complexity of devices and mounting disclosures of shortcomings involving pacemakers, intrauterine devices, and intraocular lenses, Congress enacted the comprehensive Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. The primary purpose of the amendments was to ensure that new devices were safe and effective before they were marketed." Kessler DA et al., *The Federal Regulation of Medical Devices*, THE NEW ENGLAND JOURNAL OF MEDICINE, August 8, 1987.

18. The Federal Food, Drug, and Cosmetic Act (hereinafter, the "Act") (21 U.S.C. 301 et seq.), as amended by the Medical Device Amendments of 1976 (the "1976 amendments") (Public Law 94-295), the Safe Medical Devices Act of 1990 (the "SMDA") (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 ("FDAMA") (Public Law 105-115), the Medical Device User Fee and Modernization Act ("MDUFA") (Public Law 107-250) and the medical device provisions of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (Public Law 110-85), along with the applicable regulations in the Code of Federal Regulations, established a framework for the regulation of medical devices intended for human use.

19. Congress established three classes of devices, based on the regulatory requirements needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are Class I, Class II, and Class III. Class I devices present no unreasonable risk of illness or injury and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices

are potentially more harmful and are subject to general controls, but FDA in addition has authority to require that such devices comply with other "special controls" or performance standards. 21 U.S.C. 360c(a)(1)(B). Class III devices present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C)(ii)(II).

20. Examples of Class I devices include bandages and enema kits. Examples of Class II devices include condoms, some pregnancy test kits and powered wheelchairs. Examples of Class III devices include pacemakers and breast implants.

21. In drafting the 1976 amendments, Congress divided medical devices in two different ways: (1) according to three classes noted above — class I, II, or III, and (2) according to seven basic categories — pre-amendment, post-amendment, substantially equivalent, implant, custom, investigational, and transitional. The current regulatory scheme involved weaving these two methods of subdivision into a workable statutory framework.

22. New devices, including any devices that were not in commercial distribution prior to May 28, 1976, generally referred to as post-amendments devices, are classified automatically by statute (section 513(f) of the Act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require a manufacturer to submit to FDA a premarket approval application, unless or until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the Act (21 U.S.C. 360c(f)(2)); or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval.

23. Before a Class III device may be introduced into the market, a manufacturer must obtain a "premarket approval" ("PMA" may refer to either

premarket approval or premarket application) from FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, the manufacturer must submit information to FDA in a premarket approval application that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a), (c), and (d); 21 C.F.R. §§ 814.

24. PMA is the most detailed type of device marketing application and review required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). PMA requires clinical testing to assure safety and effectiveness.

25. However, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as pre-amendments devices, are classified after FDA has: (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

26. A loophole known as the "grandfathering" provision permits Class III devices that were on the market before the 1976 Medical Device Amendment's enactment to remain on the market until FDA initiates and completes a rulemaking requiring the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In addition, Congress created another loophole which permits new manufacturers to distribute similar devices by showing through a premarket notification process that their new devices are "substantially equivalent" to grandfathered devices. 21 U.S.C. 360e(b)(1)(B). This premarket notification process is known as the "Section 510(k) process," referring to the applicable section of the Act (21 U.S.C. 360(k)).

A device is "substantially equivalent" to a grandfathered device only if, among other things, the device has the same "intended use" as the predicate device. 21 U.S.C. 360c(i)(1)(A).

27. It is this grandfathering *loophole* that has allowed the SOMATICS Thymatron ECT device onto the market. Specifically, because various ECT machines had been on the market prior to the 1976 enactments of the Medical Device Amendments, SOMATICS in or about 1984, was able to obtain grandfathering clearance for its ECT device without submitting a premarket approval application (PMA) and without having to submit *any* clinical trials concerning the safety and efficacy of its ECT device.

28. Notably, in September 1979, the FDA issued a Rule classifying ECT machines as Class III devices and requiring all manufacturers of ECT devices to submit a PMA application that includes information concerning safety and effectiveness tests for the devices. *See* 44 Fed.Reg. 172, Sept. 4, 1979, pages 51776-77. However, after pressure from the American Psychiatric Association and in light of the fact that not a single ECT manufacturer submitted the requested PMA, the FDA chose not to enforce its Rule/Order.

29. Thereafter, beginning in 1984, the FDA allowed new ECT manufacturers, including SOMATICS, to simply submit a 510(k) notification (which does not require showing of safety or effectiveness nor does it require presentation of any clinical trial data) to obtain clearance to sell its ECT device.[1]

30. Between the late 1970s and the time that Mr. Thelen received his last ECT treatments in 2016, the FDA had oscillated numerous times as to what

[1] The distinction between PMA approval and 510(k) clearance is significant. The Supreme Court has noted, the PMA approval process usually takes the FDA 1,200 hours to complete, whereas the 510(k) review is completed by the FDA in an average of only 20 hours. Moreover, the 510(k) notification process "requires little information, rarely elicits a negative response from the FDA and gets processed very quickly." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

classification should apply to ECT machines and unfortunately never enforced any of its Rules that had required for PMA approval for ECT machines. This has resulted in the ECT machines currently on the market, including the Defendants' Thymatron ECT Device, never being subjected to a full FDA PMA review, Defendants have never conducted a clinical trial to demonstrate the safety and efficacy of the Thymatron ECT device (or any other ECT device) and Defendants have never submitted clinical trials to demonstrate the safety and effectiveness of the Thymatron ECT device.

31. Contrary to SOMATICs' false advertisements, during the relevant time period and presently, the FDA's position has been that "[t]he long-term safety and effectiveness of ECT treatment *has not been demonstrated*." Emphasis added. Moreover, as previously mentioned, to date SOMATICS has not undertaken a single clinical trial to test the safety and efficacy of its ECT device. Nonetheless, during the relevant time period and to this date, SOMATICS in order to facilitate sales and in order to encourage medical professionals to recommend ECT treatment and in order to convince patients to undergo ECT treatment, states on its website that "ECT remains the safest and most effective treatment for severe depression" – knowing fully that its promotional statements are false and misleading as there is no support nor any clinical trials supporting such an endorsement of safety and efficacy of its ECT device.

32. In fact, according to a recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read of the University of East London, there is no scientifically reliable evidence that ECT works as a treatment for depression, and the negative impact on patients, including permanent memory loss, set against any potential benefits is so appalling that ECT cannot be scientifically or ethically justified, and "should be immediately

suspended."[2]

C. Defendants' Failure to Adequately Test, Investigate, Report and Study the Safety and Efficacy of Their ECT Device

33. Dr. Abrams, the founder, owner and member of SOMATICS, has testified under oath that SOMATICS has *never* performed any studies or tests to analyze the long-term side effects associated with ECT. Dr. Abrams further testified that it is not SOMATICS' business to conduct such safety studies on its ECT device.

34. Furthermore, Defendants have failed to comply with their pharmacovigilance requirements and have failed to comply with their mandatory duty of timely investigating, evaluating and reporting adverse events to the FDA. Under the applicable federal regulations, Defendants, as device manufacturers, had an affirmative responsibility to timely report to the FDA any serious injury that the manufacturer becomes aware of, *from any source* (including as way of example case reports published in scientific articles or other literature), that suggests that the manufacturer's device may have caused or contributed to serious injury. *See* 21 C.F.R. §§ 803 *et seq*.

35. In addition, as medical device manufacturers, Defendants had a duty to investigate all complaints of adverse events (from any source) to determine whether a report should be submitted to the FDA. *See* 21 C.F.R. §§ 803.17, 803.18 & 820.198. Defendants also failed to undertake any such efforts to investigate serious adverse events (such as brain injury or permanent memory loss) that they became aware of through the scientific literature or other sources.

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[2] John Read et al., *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses,* 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).

36. The adverse event reporting requirements that apply to device manufacturers are essential for the FDA as well as medical professionals to learn of adverse events as well as the potential frequency of adverse events. The medical device adverse reports that are reported by manufacturers and other stakeholders are publicly published by the FDA on its Manufacturer and User Facility Device Experience ("MAUDE") database which is accessible to the medical community and stakeholders.

37. On multiple occasions, for example in the mid-1990s when the FDA required ECT manufacturers to submit data and information about their respective ECT devices, Defendants failed to submit any information to the FDA concerning reportable safety risks and adverse events.

38. Likewise, in 2009, in response to FDA's inquiries, SOMATICS informed the FDA that, in the 25-years since obtaining clearance for its Thymatron device, "there has been no occurrence of a reportable adverse event (death or serious injury) related to the use of a Thymatron ECT device…" SOMATICS made this statement notwithstanding the myriad of medical journal publications that discussed adverse events associated with ECT machines, including the Thymatron device. Indeed, SOMATICS made this bogus representation notwithstanding the fact that the FDA had contemporaneously received public comments from medical professionals and the public in response to the same inquiry that included *hundreds* of complaints of cognitive impairment, brain damage and more than a hundred complaints of death associated with ECT devices.

39. Since obtaining clearance in 1984, in response to each and every one of the thousands of instances of Defendants' becoming aware of information reasonably suggesting death or serious injury associated with their device , Defendants conducted no investigation and failed to undertake any pharmacovigilance duties.

40. As a result of the Defendants' conduct in violating statutory requirements and selective withholding and manipulation of the data surrounding ECT devices, failing to warn of known and knowable risks, and failure to comply with the statutory and common law duties under state law running parallel to such requirements, during the relevant time period, the Thymatron ECT devices were manufactured, sold, distributed and remained in use without adequate testing, without adequate dissemination of reliable information and data as to safety and effectiveness of the ECT device and without adequate warnings concerning serious and significant risks, including but not limited to risks of brain damage, brain injury, neurocognitive impairment, encephalopathy, structural brain changes, permanent cognitive impairment and permanent memory loss.

D. Defendants Have Known, or Should Have Known, About Serious Injuries, Including Brain Injury and Permanent Memory Loss Associated With their ECT Device, Yet They Failed to Issue Timely Warnings and Instead Falsely Downplayed the Risks to Promote Sales

41. Adverse events have regularly resulted from administration of ECT shock treatment since ECT's inception in 1938 such as to make it virtually impossible that any ECT manufacturer could escape the obligations to investigate, report and warn about such adverse events. For example, from the early days of ECT to the present day, various psychiatric experts have documented brain damage correlated with ECT. A vocal "ECT survivor community" has been voicing their objection to the continued use of shock treatment for decades. Moreover, during FDA hearings between 2009 and 2011 in which the FDA opened a public docket seeking reports of adverse event complaints, ECT patients submitted thousands of adverse event complaints, hundreds of which alleged serious brain injury. SOMATICS became aware of these adverse event allegations by virtue of

participating in those hearings, and therefore the hearings invoked Defendants' statutory duty to investigate, evaluate, and if necessary independently and more fully report the complaints to the FDA so that they are fully researched and reflected in the MAUDE database. However, there are no manufacturer-submitted adverse event reports in FDA's MAUDE database corresponding to those adverse event allegations, illustrating Defendants' continuous and intentional failure to investigate and/or report adverse events to the FDA.

42. "The Electroshock Quotationary" was published in 2006.[3] It recounts an eighty-year history of serious adverse events including permanent brain damage resulting from ECT shock treatment, as well as the formation of patient advocacy groups united in their continued opposition to ECT shock treatment. Moreover, it references testimony and studies by U.S. psychiatrists, in which the psychiatrists opine that ECT inherently damages the brain. No account of injury resulting from ECT shock treatment referenced in the Electroshock Quotationary were investigated and reported by Defendants.

43. Many studies have suggested or documented reasonably known brain injury resulting from ECT shock treatment. For example, a study in Archives of General Psychiatry documented that cerebral atrophy was significantly more common in those patients who had ever received ECT.[4]

44. A brain scan study confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.[5]

45. A study relating MRI scans of patients demonstrated a strong

[3] LEONARD ROY FRANK, THE ELECTROSHOCK QUOTATIONARY (2006), http://www.endofshock.com/102C_ECT.PDF.
[4] Weinberger et al., *Structural Abnormalities in the Cerebral Cortex of Chronic Schizophrenic Patients*, 36 ARCHIVES GEN. PSYCHIATRY, 935-39 (1979).
[5] Calloway et al., *ECT and Cerebral Atrophy: A CT Study*, 64 ACTA PSYCHIATRICA SCANDINAVICA 442-45 (1981).

correlation between the numbers of previous ECT treatments to loss of brain tissue.[6]

46. Another study found that ECT recipients were twice as likely to have a measurable loss of brain tissue in the front area of the brain and a tripling of the incidence of a loss of brain tissue in the back of the brain.[7]

47. Finally, another study documented intra-cranial bleeding resulting from ECT shock treatment administered using current ECT devices.[8]

48. Defendants, however, remained willfully ignorant or otherwise intentionally failed to follow up or do any investigation on the adverse events in these and other similar published adverse events in an attempt to evade their mandatory reporting duties and keep from having to publicly admit their awareness that a risk of permanent brain damage is associated with the use of their ECT device.

49. Defendants as the leading manufacturer and distributor of ECT devices, knew and certainly should have known about the potential risks of brain injury, permanent cognitive impairment and permanent memory loss associated with their Thymatron ECT Device. In addition to the various scientific journal articles, meta-analyses and case reports addressed *supra*, which raised these risk concerns, scientists testified in governmental proceedings concerning these brain injury risks and their mechanism of action. As way of example, Peter Sterling, Ph.D., a neuroscientist and professor at the University of Pennsylvania and ECT researcher, testified before the New York State Assembly on July 18, 2001

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[6] Andreasen et al., *MRI of the Brain in Schizophrenia*, 47 ARCHIVES GEN. PSYCHIATRY, 35-41 (1990).
[7] R.J. Dolan et al., *The Cerebral Appearance in Depressed Subjects*, 16 PSYCHOL. MED., 775-79 (1986).
[8] Kulkarni & Melkundi, *Subdural Hematoma: An Adverse Event of Electroconvulsive Therapy – Case Report and Literature Review*, CASE REPORTS IN PSYCHIATRY (2012).

regarding the effects of ECT on the brain, and in his testimony to the New York Assembly he stated:

> ECT unquestionably damages the brain, and there are a variety of mechanisms that lead to this damage. In the first place, the electroshock delivered to the skull is basically similar to what you would get out of an electrical wall outlet, except that there is a transformer in the ECT machine that steps up the voltage…when this is done two or three times a week for weeks, it's just completely obvious that this is going to eventually cause some kind of brain damage…
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> Now the second point, source of brain damage for ECT is that it causes…grand mal epileptic seizures…and this causes an acute rise in blood pressure, well into the hypertensive range…And it frequently causes small…hemorrhages in the brain.
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> And wherever a hemorrhage occurs in the brain, nerve cells die, and they are not replaced. And so one can accumulate these hemorrhages over a period of treatments leading to brain damage.
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> A third thing that ECT does is to rupture the blood brain barrier. This barrier normally protects the brain from potentially damaging substances in the blood…breaching this barrier exposes nerve cells in the brain to chemical insults that can kill them…also leads…to swelling of the brain…swelling leads to local arrest of blood supply, to loss of oxygen…and to death of neurons.
>
> The fourth thing…is that ECT…causes neurons to release large quantities of …glutamate. Glutamate excites further neuronal activity…and this becomes a vicious cycle…Neurons literally…kill themselves from over activity…the key manifestation of this brain damage is retrograde memory loss….

50. Dr. Sterling's testimony was given during hearings by the New York Assembly which was considering introducing regulations concerning the use, assurance of informed consent and oversight of ECT procedures. As manufacturers of one of the two main ECT devices in the nation, Defendants

either knew or certainly should have known about the Assembly hearings, the proposed legislation as well as the opinions and medical testimony publicly delivered to the Assembly, including the above opinions and testimony of Dr. Sterling which were directly quoted and referenced in the State Assembly's subsequent March 2002 Report on Electroconvulsive Therapy. Defendants, however, as with their lack of response to the myriad of other previous articles and scientific publications that had raised concerns about the use of ECT and brain injury, did not undertake any efforts to enhance their device warnings.

51. The true electrical current exposure and eventual brain damage risks ECT patients endure is perhaps best encapsulated by Kenneth Castleman, Ph.D., a Biomedical Engineer and former faculty member and Visiting Committee Chairman of the Department of Electrical and Computer Engineering at Caltech, who issued a report in a previous ECT litigation involving allegations of brain injury. In his report, Dr. Castleman went through the electrical currents an ECT patient receives and summarized it as follows:

> So, to put this all in perspective, the amount of electric current that an ECT machine puts through a patient's head is about 200 times what is considered dangerous for ground fault leakage, approximately 100 times what Tasers, cattle prods, and electric fences use, about the same as what is used for stunning pigs, and roughly one-fifth as much as the electric chair. In addition, the amount of voltage applied to the head (460 volts) is about 400 times what is required to damage a single brain cell. Clearly this amount of electricity has the potential to cause injury to the brain.

52. Notwithstanding the above alleged facts, during all times relevant to this action, Defendants never issued adequate warnings about the brain injury, permanent cognitive injuries and permanent memory loss associated with the ECT Thymatron Device.

53. Had Defendants issued warnings to medical providers concerning the

risks of brain injury, permanent cognitive impairment and permanent memory loss as well as the other serious adverse events associated with the ECT Thymatron Device, medical providers would have heeded these warnings and, as is their fiduciary responsibilities, would have passed on those warnings to patients during the informed consent process. However, as a result of Defendants' negligent, reckless and fraudulent conduct, and their failure to issue adequate warnings, Defendants denied patients, including Plaintiff, the ability to make truly informed consent.

54. Sadly, in lieu of issuing appropriate warnings concerning the documented risks associated with ECT, including but not limited to brain damage, permanent cognitive impairment and permanent memory loss, SOMATICS instead prepared a "Patient Information Pamphlet" which it gave to doctors to give to *all* ECT patients, which downplayed any side effects, falsely stated that ECT does not cause brain injury, falsely stated that any memory loss issues are temporary and not permanent, falsely claimed that ECT actually improved memory and to further downplay the risks of ECT. Instead, the Pamphlet pinned any cognitive adverse events to the patients' underlying condition, other medications and aging.

55. It was not until sometime after October 2018 (after settling an ECT brain injury litigation and years after Mr. Thelen had concluded his ECT treatment) that SOMATICS revised its website to issue *new* warnings about adverse events associated with ECT and its Thymatron device – SOMATICS *now* for the first time warns on its website that, "in rare cases" ECT "patients may experience permanent memory loss or permanent brain damage."

56. Somatics also revised its User Manual for the Thymatron device in 2019, which now states in relevant part:

> [Practitioners] should also be familiar with the FDA final order of

> December 26, 2018 (83 FR 66103-66124). Clinicians who administer ECT should participate in continuing education about ECT … It is essential that doctors planning to use the Thymatron System IV device read and follow the warnings and recommendations of the Task Force of the American Psychiatric Association as set forth in "The Practice of Electroconvulsive Therapy" (APA, 2001), which states, in part, that **"A small minority of patients treated with ECT later report devastating cognitive consequences. Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad aspects of cognitive function are so impaired that the patients are no longer able to engage in former occupations … in some patient self-reports of profound ECT-induced deficits may reflect objective loss of function … In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years …"**

Emphasis added.

57. Such warnings and indeed even more conclusive warnings concerning permanent memory loss and brain injury should have been given by Defendants to medical professionals and the public *decades ago* when such risks were first reported and were known to Defendants.

PLAINTIFF-SPECIFIC ALLEGATIONS

58. Plaintiff, Jeffrey Thelen, underwent approximately 92 sessions of ECT shock treatment from approximately May 16, 2014, through July 27, 2016, administered by Arun Sharma, M.D., Hasnain J. Sadiq, M.D., and Imad Alaskaf, M.D., at CHI Health – Immanuel Medical Center in Omaha, Nebraska, with an ECT device manufactured and/or distributed by SOMATICS. On information and belief, the specific device used on Mr. Thelen was a "Thymatron System IV" ECT device. The ECT treatments were prescribed for depression.

59. DEFENDANTS did not provide Mr. Thelen with adequate warnings concerning the risk of brain injury or permanent neurocognitive decline and injuries. Nor did Mr. Thelen receive warnings about the risks outlined herein and which DEFENDANTS and/or SOMATICS knew about, or should have known

about, but failed to warn about, including for example, the fact that the safety and efficacy of ECT for long term use had never been tested, that it was, in essence, an experimental procedure, the fact that ECT presents a material risk of causing structural brain trauma including cell death, hippocampal damage, and subdural hematoma, in a way that wholly debilitates the patient with permanent cognitive impairment, such that many patients cannot live normal lives after receiving ECT shock treatment as well as the various other serious injuries and symptoms outlined in this Complaint.

60. Had Mr. Thelen been warned concerning the risk of brain injury or permanent neurocognitive decline, he would not have consented to ECT treatment.

61. ECT did not generate improvement in Mr. Thelen's symptoms. Instead of improving his symptoms, Mr. Thelen suffered severe and permanent short term and long-term memory loss and cognitive deficits, a constant state of panic and depression due to his inability to focus, concentrate, and remember or learn new things. Mr. Thelen has suffered significant impairment in his day to day functioning, he is often confused, is unable to finish sentences, and has difficulty caring for himself on a daily basis. Mr. Thelen was previously employed in the tree removal and trimming industry, but following ECT, he has lost all ability to recall his skills concerning his trade. As a result, he is permanently disabled and unable to work.

62. Mr. Thelen has sustained numerous injuries, including but not limited to: neurocognitive injuries, impaired visual and verbal memory, severe memory loss, significant decline in his ability to learn and recall information, a disruption and decline in his ability to encode new information, loss of executive function and additional physical and psychological harms, as well as economic injuries. In sum, as a result of his repeated exposure to electricity from ECT shock treatment from SOMATICS' ECT machine, from approximately May 16, 2014, through July 27,

2016, Mr. Thelen has sustained brain damage, neurocognitive injuries and permanent memory loss, in additional to other physical, physiological, psychological and emotional injuries and harms, as well as lost earnings and loss of earning capacity.

63. Following the conclusion of his ECT treatment, Plaintiff did not know and had no reason to know he had sustained a brain injury from ECT, or that the symptoms he was experiencing post-treatment were the result of a brain injury, nor that they would be long-term or permanent. Plaintiff reasonably believed he was experiencing short-term side effects from ECT that would improve over time, as no information to the contrary was given to him by his medical providers. Following treatment, Plaintiff also did not know and had no reason to know or suspect that wrongful conduct of the DEFENDANTS had caused his brain injury, severe and permanent memory loss, neurocognitive injuries, and other injuries. In fact, Plaintiff's medical providers assured Plaintiff that his memory and impaired cognition would improve over time, as the types of injuries Plaintiff complained of were merely short-term side effects from ECT treatment.

64. Plaintiff had no reason to know or suspect that the wrongful conduct of DEFENDANTS was the cause of his permanent injuries until August 2017.

COUNT I

NEGLIGENCE AGAINST ALL DEFENDANTS

65. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

66. At all relevant times, Defendants SOMATICS, LLC and ELEKTRIKA, INC. were the manufacturers, designers, distributors, sellers, and/or suppliers of the Thymatron ECT Device.

67. Defendants owed a duty to Plaintiff and the general public to use reasonable care in the researching, manufacturing, analyzing, testing, selling,

advertising, promoting, distributing, labeling and marketing of their ECT devices, including the Thymatron ECT device.

68. Notwithstanding said duty of care, Defendants, individually, as well as through their agents, servants or employees, negligently, recklessly and carelessly:

i. Failed to provide adequate warnings to the medical community and the public about risks, dangers and side effects associated with the use of their ECT device, including but not limited to failing to warn about the risks of permanent brain damage, brain injury, permanent neurocognitive injury and permanent memory loss.

ii. Failed to adequately research, test and analyze the safety of their ECT device.

iii. Failed to adequately investigate the reports of serious adverse events, including but not limited to permanent memory loss, neurocognitive decline, death, burning and brain injury that they knew about or should have known about.

iv. Failed to adequately report adverse events to the FDA.

v. Failed to comply with applicable federal laws and regulations governing medical device manufacturers, including but not limited to, The Federal Food, Drug, and Cosmetic Act (hereinafter, the "Act") (21 U.S.C. 301 et seq.), as amended by the Medical Device Amendments of 1976 (the "1976 amendments") (Public Law 94-295), the Safe Medical Devices Act of 1990 (the "SMDA") (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 ("FDAMA") (Public Law 105-115), the Medical Device User Fee and Modernization Act ("MDUFA") (Public Law 107-250) and the medical device provisions of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (Public Law 110-85), along

with the applicable regulations in the Code of Federal Regulations, including more specifically, but not limited to: 21 C.F.R. §§ 803.1 - 803.23; 21 C.F.R. §§ 803.50-803.58; 21 C.F.R. § 820.198; and 21 C.F.R. §807.20.

vi. Failed to inform and warn the medical community, patients and the public that the safety and efficacy of the use, in particular long- term safety and effectiveness of ECT treatment, has never been demonstrated.

vii. Defendant SOMATICS falsely assured the medical community, patients and the public that "ECT remains the safest and most effective treatment for severe depression" when it knew or should have known that such a proclamation and assurance of safety and efficacy had never been demonstrated, nor are there any clinical trials to support the veracity of such a statement for the Thymatron ECT Device.

69. As a direct and proximate result of one or more of these aforementioned acts or omissions of the Defendants, as well as the other acts or omissions of the Defendants outlined throughout this Complaint, Plaintiff, Jeffrey Thelen, has suffered, continues to suffer and will suffer indefinitely into the future, severe, serious lasting and debilitating physical and mental pain and suffering, physical injuries, brain damage, permanent neurocognitive decline, permanent memory loss, disfigurement, loss of normal life, some or all of which injuries may be permanent, all in an amount in excess of the jurisdictional minimum of the Court.

70. As a direct and proximate result of one or more of these aforementioned acts or omissions of the Defendants, as well as the other acts or omissions of the Defendants outlined throughout this Complaint, Plaintiff, Jeffrey

Thelen, has lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some or all of which losses are permanent, all in an amount in excess of the jurisdictional minimum of the Court.

71. As a direct and proximate result of one or more of these aforementioned acts or omissions of the Defendants, as well as the other acts or omissions of the Defendants outlined throughout this Complaint, Plaintiff, Jeffrey Thelen, has incurred medical, hospital and related expenses and has sustained other pecuniary losses, and will continue to incur such expenses and pecuniary losses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

WHEREFORE, Plaintiff, Jeffrey Thelen, requests that judgment be entered in his favor and against the Defendants, SOMATICS, LLC and ELEKTRIKA, INC., for all legally appropriate damages as determined in a trial by jury, and such additional amounts as the jury and the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

COUNT II

STRICT LIABILITY AGAINST ALL DEFENDANTS

72. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

73. At the time the Thymatron ECT Device(s) (which were used during Plaintiff's ECT treatment between May 26, 2014 and July 27, 2016), left the control of the Defendants, it was defective and unreasonably dangerous when Defendants manufactured, designed, labeled, promoted and instructed practitioners, who are strictly liable for the injuries caused from its use.

74. The risks attendant to the Thymatron ECT Devices as designed, manufactured, promoted and sold by the Defendants greatly outweighed any possible benefits to be expected.

75. The Thymatron ECT Devices failed to perform in a manner that a reasonable consumer would expect it to perform.

76. Defendants knew that the Thymatron ECT Devices manufactured, designed, labeled, promoted and/or sold by them, when used as Defendants promoted and instructed practitioners, was defective and dangerous in the manners hereinbefore described.

77. Defendants knew that, because said use was dangerous and defective, Thymatron ECT Devices could not be safely used for the purposes intended and promoted.

78. Defendants, knowing that said product when used as intended and promoted was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including Plaintiff, when they placed the product in the stream of commerce without warning of the defects, and knew when so placed that it would be used without inspection for defects when so used.

79. By placing the Thymatron ECT Devices on the market and promoting their use, Defendants impliedly represented it was safe for the purposes intended and intended that medical facilities, purchasers, doctors, patients and members of the public rely on their misrepresentations.

80. As a direct and proximate result of one or more or all of the aforementioned unreasonably dangerous conditions, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering disability, disfigurement and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff, Jeffrey Thelen, requests that judgment be entered in his favor and against the Defendants, SOMATICS, LLC and ELEKTRIKA,

INC., for all legally appropriate damages as determined in a trial by jury, and such additional amounts as the jury and the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AGAINST ALL DEFENDANTS

81. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

82. At all times relevant, Defendants, SOMATICS, LLC and ELEKTRIKA, INC., designed, manufactured, marketed, sold, and/or distributed Thymatron ECT medical devices.

83. Defendants sold the subject ECT Device: the "Thymatron" ECT Device.

84. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Thymatron ECT Device was of merchantable quality and safe for its intended use.

85. Contrary to such implied warranty, the Thymatron ECT Devices that the Defendants manufactured, distributed and sold, and which were used during Plaintiff's ECT procedures, was not of merchantable quality or safe for its intended use.

86. As a direct and proximate result of Defendants breach of their implied warranty of merchantability, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering disability, disfigurement and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff, Jeffrey Thelen, requests that judgment be entered

in his favor and against the Defendants, SOMATICS, LLC and ELEKTRIKA, INC., for all legally appropriate damages as determined in a trial by jury, and such additional amounts as the jury and the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

COUNT IV
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AGAINST ALL DEFENDANTS

87. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

88. At all times relevant, Defendants, SOMATICS, LLC and ELEKTRIKA, INC., designed, manufactured, marketed, sold, and/or distributed Thymatron ECT medical devices.

89. Prior to the time of sale, Defendants had reason to know that medical providers, including but not limited to Plaintiff's medical providers, would use Defendants' Thymatron ECT Devices on their respective patients, including but not limited to Plaintiff.

90. Patients such as Plaintiff as well as medical providers, including Plaintiff's medical providers, relied upon Defendants as the designers, manufacturers, distributors and/or promoters of the Thymatron ECT Devices, to design, manufacture, label and distribute medical devices that were safe and effective for the intended and/or promoted use.

91. In consideration, as part of the sale of the Thymatron ECT Devices, an implied warranty arose that the subject devices would be safe and suitable for the intended and promoted use.

92. In breach of this implied warranty of fitness for a particular purpose, the Thymatron ECT Devices, were not delivered as warranted because they were

not safe or effective for the intended and promoted use.

93. As a direct and proximate result of Defendants' breach of their implied warranty of fitness for a particular purpose, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering disability, disfigurement and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff, JEFFREY THELEN, requests that judgment be entered in his favor and against the Defendants, SOMATICS, LLC and ELEKTRIKA, INC., for all legally appropriate damages as determined in a trial by jury, and such additional amounts as the jury and the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

COUNT V
BREACH OF EXPRESS WARRANTY
AGAINST DEFENDANT, SOMATICS, LLC

94. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

95. At all times relevant, Defendants, SOMATICS, LLC was the manufacturer, distributor, promoter and seller of the Thymatron ECT Device.

96. SOMATICS expressly warranted to the public and the medical community, including Plaintiff's treating physicians and psychiatrists, that its Thymatron ECT Device was "the safest and most effective treatment for severe depression"; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; that its Thymatron ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories; and other similar warranties of safety and efficacy.

97. The aforementioned representations, individually and collectively,

were part of the basis of the bargain between Plaintiff (including his medical providers) and SOMATICS.

98. Plaintiff (including the medical community and his medical providers) directly and indirectly relied on the aforementioned representations by SOMATICS.

99. SOMATICS' aforementioned representations and warranties were false.

100. In breach of SOMATICS' express warranties and representations, there in reality are no clinical trials or any other reliable evidence demonstrating that ECT treatment or treatment with the Thymatron ECT device is the safest and most effective treatment for severe depression. Contrary to SOMATICS's warranties, ECT treatment and its Thymatron ECT Device, can and does cause brain injury. Contrary to SOMATICS's warranties, ECT treatment and its Thymatron ECT Device, can and does cause permanent memory loss. Contrary to SOMATICS's warranties, ECT treatment and its Thymatron ECT Device, can and does cause long-term and persistent effects on intellectual abilities or memories. And, contrary to SOMATICS's warranties, the truth is that the long-term efficacy and safety of ECT treatment has *never* been demonstrated.

101. In fact, according to a recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read of the University of East London, there is no scientifically reliable evidence that ECT works as a treatment for depression, and the negative impact on patients, including permanent memory loss, set against any potential benefits is so appalling that ECT cannot be scientifically or ethically justified, and "should be immediately

suspended."[9]

102. As a direct and proximate result of SOMATICS' breach of its express warranties, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering disability, disfigurement and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff, Jeffrey Thelen, requests that judgment be entered in his favor and against the Defendant, SOMATICS, LLC, for all legally appropriate damages as determined in a trial by jury, and such additional amounts as the jury and the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

COUNT VI
VIOLATION OF NEBRASKA CONSUMER PROTECTION ACT AGAINST DEFENDANT, SOMATICS, LLC

103. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

104. There was in force at the time of the sale of the Thymatron ECT Devices by SOMATICS, LLC, a certain statute in the state of Nebraska known as the Nebraska Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601, *et seq*., which makes it unlawful engage in any unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.

105. At all relevant times, defendant SOMATICS deliberately engaged in deceptive and unlawful marketing in violation of Neb. Rev. Stat. § 59-1602 by representing to the general public, the medical community, including Plaintiff's medical providers that: its Thymatron ECT Device was "the safest and most

[9] John Read et al., *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses,* 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).

effective treatment for severe depression"; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; that its Thymatron ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories; and other similar warranties of safety and efficacy.

106. Plaintiff, the general public, and the medical community, including Plaintiff's medical providers relied upon SOMATICS' deceptive and unlawful marketing practices, including, *inter alia*, the representation that its Thymatron ECT Device was safe and effective; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; and that its Thymatron ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories.

107. Plaintiff personally received 92 ECT treatments and sustained serious injury as a result of SOMATICS' deceptive and unlawful marketing practices, in violation of Neb. Rev. Stat. § 59-1602.

108. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have consented to ECT treatment and would not have incurred related medical costs and injury.

109. Prosecution of this claim will result in a substantial public benefit because this action would prevent SOMATICS from continuing to deceive and mislead plaintiff and all consumers within the State of Nebraska, and will provide an important public health benefit by apprising consumers and prescribing physicians of the lack of proven efficacy and substantial risks associated with its Thymatron ECT Device.

110. As a direct and proximate result of Defendants' actions in violation of Nebraska's consumer protection laws, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical

expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering disability, disfigurement and loss of a normal life.

WHEREFORE, Plaintiff, JEFFREY THELEN, requests that judgment be entered in his favor and against the Defendant SOMATICS, LLC, for all legally appropriate damages as determined in a trial by jury, and such additional amounts as the jury and the Court shall deem proper, along with costs of suit and reasonable attorneys' fees, as provided by Neb. Rev. Stat. § 59-1609, and all other relief the Court determines just and proper.

COUNT VII
FRAUDULENT MISREPRESENTATION AGAINST DEFENDANT, SOMATICS, LLC

111. Plaintiff repeats, incorporates and alleges each prior and subsequent allegation as if fully set forth herein.

112. As a medical device company, SOMATICS had an affirmative duty to warn regarding all risks it knew, learned of or should have known about associated with its medical devices, including but not limited to, its Thymatron ECT Device.

113. SOMATICS knowingly and intentionally concealed adverse event information, and knowingly and intentionally provided misleading and inaccurate information that was material to medical providers and patients, which misled medical providers and patients who were relying directly and/or indirectly upon SOMATICS' representations and concealment.

114. SOMATICS' distribution of false and misleading information concerning the safety and efficacy of its Thymatron ECT devices as well as intentional failure and refusal to properly test, study, report and investigate adverse events associated with its Thymatron ECT devices, caused health care providers, patients and the general public, including Plaintiff and his medical providers, to be misled about the risks and benefits of ECT therapy and the Thymatron ECT

devices.

115. In addition to concealing and not reporting adverse events and risks, upon information and belief, SOMATICS made intentional affirmative misrepresentations to the public, patients, the medical community, including Plaintiff's medical providers, that its Thymatron ECT Device was "the safest and most effective treatment for severe depression"; that its Thymatron ECT Device did not cause brain injury; that its Thymatron ECT Device did not cause permanent memory loss; that its Thymatron ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories; and other similar assurances of safety and efficacy.

116. Upon information and belief, when SOMATICS made these aforementioned representations and/omissions, it knew these representations and/or omissions were false or made recklessly without knowledge of its truth and a positive assertion. Upon information and belief, these representations and/or omissions were made by SOMATICS with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing hospitals, doctors, including Plaintiff's doctors and treaters, to use its Thymatron ECT Device and/or for patients, such as Plaintiff, to consent to ECT treatment.

117. SOMATICS made the aforementioned representations and/or omissions with the intention and expectation that they would be relied upon by patients, doctors and the general public, including Plaintiff's doctors and patients such as Plaintiff.

118. Plaintiff (including the medical community and his medical providers) reasonably and justifiably relied on the aforementioned representations by SOMATICS.

119. SOMATICS' aforementioned representations were false and SOMATICS knew or should have known they were false. In reality, there are no

clinical trials or any other reliable evidence demonstrating that ECT treatment or treatment with the Thymatron ECT device is the safest and most effective treatment for severe depression. Contrary to SOMATICS's statements, ECT treatment and its Thymatron ECT Device, can and does cause brain injury. Contrary to SOMATICS's representations, ECT treatment and the Thymatron ECT Device, can and does cause permanent memory loss. Contrary to SOMATICS's representations, ECT treatment and its Thymatron ECT Device, can and does cause long-term and persistent effects on intellectual abilities and memories. Contrary to SOMATICS's representations, the reality is that the long-term efficacy and safety of ECT treatment has *never* been demonstrated.

120. In fact, according to a recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read of the University of East London, there is no scientifically reliable evidence that ECT works as a treatment for depression, and the negative impact on patients, including permanent memory loss, set against any potential benefits is so appalling that ECT cannot be scientifically or ethically justified, and "should be immediately suspended."[10]

121. Had SOMATICS not made these false misrepresentations, omissions and concealments, and had it issued warnings to medical providers concerning the risks of brain injury, permanent cognitive impairment and permanent memory loss as well as the other serious adverse events associated with the ECT Thymatron Device, as well as the lack of demonstrated long-term safety and efficacy of its device, medical providers, including Plaintiff's medical providers, would have heeded these warnings and as is their fiduciary responsibilities, would have passed

[10] John Read et al., *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses,* 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).

on those warnings to patients during the informed consent process. However, as a result of its willful, wanton and fraudulent conduct, SOMATICS denied patients, including Plaintiff, the ability to make truly informed consent.

122. Had Plaintiff been warned concerning the risk of permanent brain injury or permanent neurocognitive decline and had he been warned about the lack of efficacy and safety for the long-term use of ECT, he would not have consented to any ECT treatment.

123. As a direct and proximate result of SOMATICS' fraudulent statements and concealments, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement and loss of a normal life. These losses are permanent.

124. WHEREFORE, Plaintiff, Jeffrey Thelen, requests that judgment be entered in his favor and against the Defendant SOMATICS, LLC, for all legally appropriate damages as determined in a trial by jury, and such additional amounts as the jury and the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

PRAYER FOR PUNITIVE DAMAGES

125. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and its complete and total reckless disregard for the public safety and welfare.

126. Defendants had knowledge that SOMATICS' ECT Thymatron Device with was defective, unreasonably dangerous, would be used without adequate instructions and warnings, and marketed and distributed the device without adequate knowledge regarding its efficacy, risk, and long-term side effects.

Defendants failed, among other purposeful acts, to inform or warn Plaintiff or Plaintiff's health care providers of the dangers or to establish and maintain an adequate quality and post-marketing surveillance system.

127. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on all counts of the complaint, and each of them, individually, jointly and severally and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. Compensatory damages to Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;
2. Lost wages;
3. Punitive and/or Treble Damages as pursuant to state law;
4. Reasonable attorneys' fees;
5. The costs of these proceedings, including past and future cost of the suit incurred herein;
6. Prejudgment interest as is allowed by law;
7. All ascertainable economic damages; and
8. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

DATED: July 24, 2020

Respectfully submitted,

Mark Schlein

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