No. 21-55517

S273887 *In the*

United States Court of Appeals

for the

Ninth Circuit

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN;

Plaintiffs-Appellants,

vs.

SOMATICS, LLC,

Defendant-Respondent.

Appeal from an Order of the United State District Court for the Central District of California, Case No. 2:17-cv-06686-RGK- JCx
Hon. R. Gary Klausner

APPELLANTS' EXCERPTS OF RECORD
VOLUME 5 OF 6

Bijan Esfandiari
Monique Alarcon
R. Brent Wisner
BAUM, HEDLUND, ARISTEI & GOLDMAN, PC
10940 Wilshire Blvd., Suite 1600
Los Angeles, CA 90024
(310) 207-3233
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
rbwisner@baumhedlundlaw.com

Counsel for Plaintiffs-Appellants

Does Including Participants Who have had ECT Before a Study Un-blind the Study and Thereby Exaggerate ECT Superiority Over SECT?

Only one study (Lambourn & Gill, 1978) provides data that can test the hypothesis that having previously had ECT un-blinds participants because they know that ECT is always followed by headaches and disorientation and, therefore, know if they have had ECT in a study. Among the 16 people in the SECT group, the 10 who had had one or more previous courses of ECT improved less (20.3 Hamilton points) than the six who had never had it before (27.2). Furthermore, the number of previous courses of ECT was related to degree of improvement on the Hamilton scale (r = .51; p = .044). So greater familiarity with the immediate adverse effects of ECT reduced the probability of benefitting from the placebo effects of SECT because they were more likely to know they had not received ECT. Analysing just the data for the 11 people who had never had ECT before shows that the SECT group had slightly more improvement (27.2 points; SD = 17.2) than the ECT group (20.0; SD = 17.0). Analysing the data for the 25 who had had ECT previously shows the opposite, with the ECT group improving more (29.1 points; SD = 18.3) than the SECT group (20.3; SD = 23.2). This suggests that by not excluding people who have previously had ECT all 11 studies exaggerated the difference between ECT and SECT in ECT's favor, and that none were truly blind studies.

Cost-Benefit Analysis

The fact that we don't know whether ECT has any short- or long-term benefits must be weighed against what we do know about its adverse effects, which are summarized briefly.

Brain Damage and Memory Dysfunction. Although ECT has a range of adverse psychological and emotional effects (Johnstone, 1999), the best documented findings are that ECT causes both major types of memory loss: anterograde amnesia (inability to retain new information) and, more commonly, retrograde amnesia (loss of memory for past events).

A 2003 review identified four studies of memory loss at least 6 months post-ECT (n = 597), and found a frequency range of 51% to 79%, and a weighted average of 70% (Rose, Wykes, Leese, Bindmann, & Fleischmann, 2003). Four studies (n = 703) found a range for "persistent or permanent memory loss" of 29% to 55%, with a weighted average of 38% (Rose et al., 2003). In 2007 ECT proponent Professor Harold Sackeim et al. conducted the largest prospective study to date and found that autobiographical memory was significantly worse than pre-ECT levels (p < .0001) 6 months later (Sackeim et al., 2007). Degree of impairment was significantly related to number of treatments. Even with the conservative cut off of two standard deviations worse than pre-ECT scores, 12% had "marked and persistent retrograde amnesia," with higher rates for the two demographic groups who receive ECT disproportionately—women and older people. Impairment was also greater among those who received bilateral ECT rather than unilateral ECT.

The most recent review (Mosti & Brook, 2019, p. 153) concludes that:

> Recent meta-analyses suggest the most prominent deficits are on measures of attentional/executive control (i.e., tests measuring cognitive flexibility, inhibitory control, and processing speed) and auditory verbal learning/recall (i.e., unstructured list learning), a memory task that is also strongly correlated with executive functioning.

ECT proponents often argue that these adverse effects are caused by depression not ECT (Read & Bentall, 2010, p. 343; Read, Cunliffe, Jauhar, & Mcloughlin, 2019), but a 2006 review concluded that "There is no evidence of a correlation between impaired memory/cognition after ECT and impaired mood, much less a causal relationship" (Robertson & Pryor, 2006, p. 230). The Sackeim et al. (2007) study confirmed that conclusion.

A New Zealand Government report stated "ECT may permanently affect memory and sometimes this can be of major personal significance" and noted the "slowness in acceptance by some professional groups that such outcomes are real and significant in people's lives" (Ministry of Health, 2004, p. 16). The American Psychiatric Association (APA) (2001) has admitted "In some patients the recovery from retrograde amnesia will be incomplete, and evidence has shown that ECT can result in persistent or permanent memory loss."

Sadly, the severity and significance of the brain damage and memory loss is rarely studied. It is not hard, however, to find hundreds of personal accounts of debilitating levels of disruption to people's lives. See, for example: https://ectjustice.com/ect-survivor-stories/ and https://www.madinamerica.com/2016/04/comments-by-shock-survivors-and-their-loved-ones/.

A recent USA class action lawsuit was settled on eve of trial at a Federal Court, which had ruled "A reasonable jury could find that the ECT device manufacturer failed to warn plaintiffs' treating physicians of brain damage resulting from ECT ("Breggin, 2018; Schwartzkopff, 2018). The manufacturer, *Somatics*, immediately issued a Regulatory Update to add "permanent brain damage" to the list of risks (Somatics, 2018, p. 4).

"Brain Damaging Therapeutics." The UK ECT Review Group found that bilateral ECT produces greater cognitive impairment than unilateral. Gregory et al. (1985) also discuss the "undoubtedly greater memory impairment produced by bilateral ECT" (p. 523). The 170-page review by Greenhalgh et al. (2005) concluded that any gains of using bilateral rather than unilateral ECT "are achieved only at the expense of an increased risk of cognitive side-effects" (p.1).

If the modest, temporary effects on depression are only to be found if the shock is passed across both temporal lobes, thereby causing maximal memory loss, this would confirm the early theories about how ECT works. Early postmortem examinations had led to the article "Brain damaging therapeutics" where the psychiatrist who introduced ECT to the US wrote, "The greater the damage the more likely the remission. . . . Maybe it will be shown that a mentally ill patient can think more clearly and more constructively with less brain in actual operation" (Freeman, 1941). A colleague had explained: "There have to be organic changes or organic disturbances in the physiology of the brain for the cure to take place. I think the disturbance in memory is probably an integral part of the recovery process" (Myerson, 1942).

A review (involving JR) of the effects of ECT on the brain put it this way:

> We suggest that the temporarily improved scores on depression instruments following ECT reflect the combination of frontal and temporal lobe functional impairments and activation of the HPA axis and the mesocorticolimbic dopamine system. These effects as well as other detailed changes observed in structures such as the hippocampus appear consistent with those typically seen after severe stress-exposure and/or brain trauma. (Fosse & Read, 2013, p. 6)

Mortality Rates. The idea that the mortality rate is "1 per 10,000 patients or 1 per 80,000 treatments" has been promulgated, without supporting evidence, by psychiatric associations (APA, 2001; Royal College of Psychiatry [RCP], 2017) and the USA's Food and Drug Administration (2011). A recent study put it even lower, at "2.1 per 100,000" treatments (Tørring, Sanghani, Petrides, Kellner, & Østergaard, 2017); but this was based on medical records (relying on staff recording that they had caused a death). Numerous studies (see Read & Bentall, 2010; Read et al., 2013) have found mortality rates many times greater than these claims. For example, of 8,148 ECT recipients in Texas, seven died within 48 hours (Shiwach, Reid, & Carmody, 2001). Excluding the two which the researchers argued were "unlikely to have been related to ECT" this is one per 1,630. Eight more died within 2 weeks, of "cardiac event" (the most common ECT-related cause of death). If these are included the rate becomes one per 627. When researchers wanted to interview 183 people, 1 year after ECT, it was reported that two (one in 91.5) had died during the ECT (Freeman & Kendell, 1980). A 1980 study (relying on British psychiatrists' reports of deaths from the ECT they had administered) found that four out of 2,594 ECT patients had died within 72 hours (one per 648.5; Pippard & Ellam, 1981). It could not be determined whether the one death (4 days post-ECT) among 75 French ECT recipients was ECT-related. This study, by anesthetists, found "potentially life-threatening complication" for 12 (16%; Tecoult & Nathan, 2001).

The oft repeated claim that ECT causes no more deaths than general anaesthesia unashamedly ignores the fact that people are subjected to an average of eight such procedures.

LIMITATIONS

The major limitation of any review designed to determine whether ECT works is the low quantity and poor quality of the available studies. The goal of the current review, however, is different; to evaluate the quality of the studies and of the meta-analyses that cite them.

Given the small number of studies, caution should be exercised when interpreting non-significant *t* tests involving the 11 studies, which might have been significant had there been more studies.

CONCLUSIONS

The scarcity and poor quality of most of the findings suggesting that ECT has short-term benefits for some depressed people, the complete lack of evidence of long-term benefits, and the absence of evidence that it prevents suicide, together with the high risk of permanent memory loss and small increased risk of death, broadly confirms the conclusions of previous reviews (Read & Arnold, 2017; Read & Bentall, 2010; Read et al., 2013; Ross, 2006) and books (Andre, 2008; Breggin, 2008). For example (Read & Bentall, 2010):

> Given the strong evidence of persistent and, for some, permanent brain dysfunction, primarily evidenced in the form of retrograde and anterograde amnesia, and the evidence of a slight but significant increased risk of death, the cost-benefit analysis for ECT is so poor that its use cannot

> be scientifically justified (p. 333). . . . The very short-term benefit gained by a small minority cannot justify the significant risks to which all ECT recipients are exposed. (p. 344)

Perhaps, however, given the outcome of this first ever analysis of the quality of the 11 studies that have attempted to determine if ECT is better than placebo, a more accurate conclusion, rather than "a very short-term benefit gained by a small minority" is that we just don't know whether ECT is better than, worse than, or no different from, placebo.

What can the 11 SECT studies tell us about seven specific sub groups? Firstly, we can reasonably conclude that there is no rigorous evidence whatsoever that ECT has any benefit for the three conditions for which it is primarily recommended today: (a) severely depressed people, (b) acutely suicidal people, and (c) people for whom antidepressants and/or psychological therapies do not work. Women and older people are the target demographics for ECT in the 21st century, but there is hardly any specific evidence that ECT is better than SECT for (d) women, in the short-term, and none regarding the long term; plus women are particularly likely to suffer long-term memory loss. There is no evidence whatsoever that ECT is superior to SECT in (e) older people, who are also differentially susceptible to memory loss. There is no evidence that ECT is effective (f) when given under compulsion, as it so often is. There is also no evidence that it is effective for (g) children or adolescents.

Our conclusions regarding depression parallel those of a recent commentary on Cochrane reviews of ECT for "schizophrenia" (Shokraneh, Sinclair, Irving, & Aali, 2019):

> What is common in all versions of these Cochrane reviews is that in spite of seven decades of clinical use of ECT for people with schizophrenia, there still is a lack of strong and adequate evidence regarding its effectiveness and the question "should we stop using electroconvulsive therapy?" is currently unanswered for people with schizophrenia.

The remarkably poor quality of the research in this field, and the uncritical acceptance of that research by psychiatry's meta-analyses, and its professional bodies, all of which endorse ECT as an effective and safe treatment, is a sad indictment of all involved, and a grave disservice to the public.

REFERENCES

American Psychiatric Association. (2001). *The practice of ECT: A task force report* (2nd ed.). Washington, DC: Author.

Andre, L. (2008). *Doctors of deception: What they don't want you to know about shock treatment.* New Brunswick, Canada: Rutgers University Press.

Beck, A., Ward, C., Mendelson, M., Mock, J., & Erbaugh, J. (1961). An inventory for measuring depression. *Archives of General Psychiatry, 4*, 561–571. https://doi.org/10.1001/archpsyc.1961.01710120031004

Brandon, S., Cowley, P., McDonald, C., Neville, P., Palmer, R., & Wellstood-Eason, S. (1984). ECT results in depressive illness from the Leicestershire trial. *British Medical Journal, 288*, 22–25. https://doi.org/10.1136/bmj.288.6410.22

Breggin, P. (2008). *Brain-disabling treatments in psychiatry.* New York, NY: Springer Publishing.

Breggin, P. (2018). *Victory in ECT manufacturer lawsuit paves way for more.* Retrieved from https://www.madinamerica.com/2018/10/huge-breakthrough-ect-lawsuit

Brill, N., Crumpton, E., Eiduson, S., Grayson, H., Hellman, L., & Richards, R. (1959). Relative effectiveness of various components of ECT. *Archives of Neurology and Psychiatry, 81*, 627–635. https://doi.org/10.1001/archneurpsyc.1959.02340170093010

Buchan, H., Johnstone, E., McPherson, K., Palmer, R., Crow, T., & Brandon, S. (1992). Who benefits from electroconvulsive therapy? Combined results of the Leicester and Northwick Park Trials. *British Journal of Psychiatry, 160*, 355–359. https://doi.org/10.1192/bjp.160.3.355

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences*. New York, NY: Routledge.

Fahy, P., Imlah, N., & Harrington, J. (1963). A controlled comparison of ECT, imipramine and thiopentone sleep in depression. *Journal of Neuropsychiatry, 4*, 310–314.

Fleiss, J. (1981). *Statistical methods for rates and proportions* (2nd ed.). New York, NY: John Wiley.

Food and Drug Administration. (2011). *FDA executive summary for January 27–28 meeting of the neurological devices panel to discuss the classification of ECT*. Washington, DC: Author.

Fosse, R., & Read, J. (2013). Electroconvulsive treatment: Hypotheses about mechanisms of action. *Frontiers in Psychiatry, 4*, 94–103. https://doi.org/10.3389/fpsyt.2013.00094

Freeman, C., Basson, J., & Crighton, A. (1978). Double-blind controlled trial of ECT and simulated ECT in depressive illness. *Lancet, 311*, 738–740. https://doi.org/10.1016/S0140-6736(78)90857-7

Freeman, C., & Kendell, R. (1980). E.C.T, patients' experiences and attitudes. *British Journal of Psychiatry, 137*, 8–16. https://doi.org/10.1192/bjp.137.1.8

Freeman, W. (1941). Brain-damaging therapeutics. *Diseases of the Nervous System, 2*, 83.

Friedberg, J. (1976). *Shock treatment is not good for your brain*. San Francisco, CA: Glide.

Gábor, G., & László, T. (2005). The efficacy of ECT treatment in depression: A meta-analysis. *Psychiatria Hungarica, 20*, 195–200.

Greenhalgh, J., Knight, C., Hind, D., Beverley, C., & Walters, S. (2005). Clinical and cost-effectiveness of electroconvulsive therapy for depressive illness, schizophrenia, catatonia and mania: Systematic reviews and economic modelling studies. *Health Technology Assessment, 9*, 1–170. https://doi.org/10.3310/hta9090

Gregory, S., Shawcross, C., & Gill, D. (1985). The Nottingham ECT study. *British Journal of Psychiatry, 146*, 520–524. https://doi.org/10.1192/bjp.146.5.520

Hamilton, M. (1960). A rating scale for depression. *Journal of Neurology, Neurosurgery and Psychiatry, 23*, 56–62. https://doi.org/10.1136/jnnp.23.1.56

Harris, J., & Robin, A. (1960). A controlled trial of phenelzine in depressive reactions. *Journal of Mental Science, 106*, 1432–1437. https://doi.org/10.1192/bjp.106.445.1432

Higgins, J., Atman, D., Gøtzsche, P., Moher, D., Oxman, A., Savović, J., . . . Sterne, J. (2011). The cochrane collaboration's tool for assessing risk of bias in randomised trials. *British Medical Journal, 343*, d5928. https://doi.org/10.1136/bmj.d5928

Janicak, P., Davis, J., Gibbons, R., Eriksen, S., Chang, S., & Gallagher, P. (1985). Efficacy of ECT: A meta-analysis. *American Journal of Psychiatry, 142*, 297–302. https://doi.org/10.1176/ajp.142.3.297

Johnstone, E., Deakin, J., Lawler, P., Frith, C., Stevens, M., McPherson, K., & Crow, T. (1980). The Northwick park ECT trial. *Lancet, 316*, 1317–1320. https://doi.org/10.1016/S0140-6736(80)92393-4

Johnstone, L. (1999). Adverse psychological effects of ECT. *Journal of Mental Health, 8*, 69–85. https://doi.org/10.1080/09638239917652

Kho, K., Vreewijk, van., M, Simpson., S, & Zwinderman, A. (2003). A meta-analysis of electroconvulsive therapy in depression. *Journal of ECT, 19*, 139–147. https://doi.org/10.1097/00124509-200309000-00005

Kingsley, C., & Patel, S. (2017). Patient-reported outcome measures and patient-reported experience measures. *BJA Education, 17*, 137–144. https://doi.org/10.1093/bjaed/mkw060

Lambourn, J., & Gill, D. (1978). A controlled comparison of simulated and real ECT. *British Journal of Psychiatry, 133*, 514–519. https://doi.org/10.1192/bjp.133.6.514

Leiknes, K., Jarosh-von Schweder, L., & Hoie, B. (2012). Contemporary use and practice of electroconvulsive therapy worldwide. *Brain and Behaviour, 2*, 283–344. https://doi.org/10.1002/brb3.37

Lorr, M., Jenkins, R., & Holsopple, J. (1953). Multidimensional scale for rating psychiatric patients. *Veterans Administration Technical Bulletin, 10*, 507.

Ministry of Health. (2004). *Use of ECT in New Zealand: A review of efficacy, safety and regulatory controls*. Wellington, New Zealand: Author.

Montgomery, S., & Asberg, M. (1979). A new depression scale designed to be sensitive to change. *British Journal of Psychiatry, 134*, 382–389. https://doi.org/10.1192/bjp.134.4.382

Mosti, C., & Brook, M. (2019). The cognitive effects of electroconvulsive therapy: A critical review. *Psychiatric Annals, 49*, 152–156. https://doi.org/10.3928/00485713-20190313-02

Mutz, J., Vipulananthan, V., Carter, B., Hurlemann, R., Fu, C., & Young, A. (2019). Comparative efficacy and acceptability of non-surgical brain stimulation for the acute treatment of major depressive episodes in adults: Systematic review and network meta-analysis. *British Medical Journal, 364*, l1079. https://doi.org/10.1136/bmj.l1079

Myerson, A. (1942). Fatalities following ECT. *Transactions of the American Neurological Association, 68*, 39.

National Institute of Clinical and Health Excellence. (2009). *Depression in adults: Recognition and management. Clinical guideline [CG90]*. London, England: Author. Retrieved from https://www.nice.org.uk/guidance/cg90/chapter/1-Guidance

O'Leary D, Gill D, Gregory S, Shawcross C. The effectiveness of real versus simulated electroconvulsive therapy in depressed elderly patients. International Journal of Geriatric Psychiatry 1994; 9(7):567-71. https://doi.org/10.1002/gps.930090711

Pagnin, D., Queiroz, de., V., Pini, S, & Cassano, G. (2004). Efficacy of ECT in depression: A meta-analytic review. *Journal of ECT, 20*, 13–20. https://doi.org/10.1097/00124509-200403000-00004

Pippard, J., & Ellam, L. (1981). *ECT in Great Britain*. London, England: Gaskell.

Rasmussen, K. (2009). Sham electroconvulsive therapy studies in depressive illness: A review of the literature and consideration of the placebo phenomenon in electroconvulsive therapy practice. *Journal of ECT, 25*, 54–59. https://doi.org/10.1097/YCT.0b013e3181719b23

Read, J., & Arnold, C. (2017). Is electroconvulsive therapy for depression more effective than placebo? A systematic review of studies since 2009. *Ethical Human Psychology and Psychiatry, 19*, 5–23. https://doi.org/10.1891/1559-4343.19.1.5

Read, J., & Bentall, R. (2010). The effectiveness of electroconvulsive therapy: A literature review. *Epidemiology and Psychiatric Sciences, 19*, 333–347. https://doi.org/10.1017/S1121189X00000671

Read, J., Bentall, R., Johnstone, L., Fosse, R., & Bracken, P. (2013). Electroconvulsive Therapy. In J. Read & J. Dillon (Eds.), *Models of madness: Psychological, social and biological approaches to psychosis* (2nd ed., pp. 90–104). Hove, UK: Routledge. https://doi.org/10.4324/9780203527160

Read, J., Cunliffe, S., Jauhar, S., & Mcloughlin, D. (2019). Should we stop using electroconvulsive therapy? Maudsley debate. *British Medical Journal, 364*, k5233. https://doi.org/10.1136/bmj.k5233

Read, J., Harrop, C., Geekie, J., & Renton, J. (2018). An audit of ECT in England 2011–2015: Usage, demographics, and adherence to guidelines and legislation. *Psychology and Psychotherapy: Theory, Research and Practice, 91*, 263–277. https://doi.org/10.1111/papt.12160

Robertson, H., & Pryor, R. (2006). Memory and cognitive effects of ECT: Informing and assessing patients. *Advances in Psychiatric Treatment, 12*, 228–238. https://doi.org/10.1192/apt.12.3.228

Rose, D., Wykes, T., Leese, J., Bindmann, J., & Fleischmann, P. (2003). Patients' perspectives of electroconvulsive therapy: Systematic review. *British Medical Journal, 326*, 1363–1366. https://doi.org/10.1136/bmj.326.7403.1363

Ross, C. (2006). The sham ECT literature: Implications for consent to ECT. *Ethical Human Psychology and Psychiatry, 8*, 17–28. https://doi.org/10.1891/ehpp.8.1.17

Royal College of Psychiatry. (2017). *Mental health information*. Retrieved from http://www.rcpsych.ac.uk/mentalhealthinformation/therapies/electroconvulsivetherapy,ect.aspx

Sackeim, H., Prudic, J., Fuller, R., Keilp, J., Lavori, P., & Olfson, M. (2007). The cognitive effects of ECT in community settings. *Neuropsychopharmocology, 32*, 244–254. https://doi.org/10.1038/sj.npp.1301180

Schiele, B., Baker, A., & Hathaway, S. (1943). The minnesota multiphasic personality inventory. *Lancet, 63*, 292–297.

Schwartzkopff, D. (2018). *DK Law Group announces ECT settlement.* Retrieved from http://ectjustice.com/dk-law-group-announces-ect-settlement

Shiwach, R., Reid, W., & Carmody, T. (2001). An analysis of reported deaths following electroconvulsive therapy in Texas, 1993–1998. *Psychiatric Services, 52*, 1095–1097. https://doi.org/10.1176/appi.ps.52.8.1095

Shokraneh, F., Sinclair, D., Irving, C. B., & Aali, G. (2019). Electroconvulsive therapy for people with Schizophrenia: Updating a cochrane systematic review for two decades. *BMJ* 2019; 364:k5233. https://www.bmj.com/content/364/bmj.k5233/rr-8

Somatics. (2018). *Regulatory update to Thymatron system IV instruction manual.* Retrieved from http://www.thymatron.com/downloads/System_IV_Regulatory_Update.pdf

Tecoult, E., & Nathan, N. (2001). Morbidity in ECT. *European Journal of Anaesthesiology, 18*, 511–518. https://doi.org/10.1097/00003643-200108000-00005

Tørring, N., Sanghani, S., Petrides, G., Kellner, C., & Østergaard, S. D. (2017). The mortality rate of electroconvulsive therapy: A systematic review and pooled analysis. *Acta Psychiatrica Scandinavica, 135*, 388–397. https://doi.org/10.1111/acps.12721

UK ECT Review Group. (2003). Efficacy and safety of ECT in depressive disorders. *Lancet, 361*, 799–808. https://doi.org/10.1016/S0140-6736(03)12705-5

Ulett, G., Smith, K., & Gleser, G. (1956). Evaluation of convulsive and subconvulsive shock therapies utilizing a control group. *American Journal of Psychiatry, 112*, 795–802. https://doi.org/10.1176/ajp.112.10.795

van der, Wurff., F, Stek., M, Hooogendijk., W, & Beekman, A. (2003). Electroconvulsive therapy for the depressed elderly. *Cochrane Database of Systematic Reviews, 2003*(2), CD003593.

West, E. (1981). Electric convulsion therapy in depression: A double-blind controlled trial. *British Medical Journal, 282*, 355–357. https://doi.org/10.1136/bmj.282.6261.355

Wilson, I., Vernon, J., Guin, T., & Sandifer, M. (1963). A controlled study of treatments of depression. *Journal of Neuropsychiatry, 4*, 331–337.

Disclosure. The authors have no relevant financial interest or affiliations with any commercial interests related to the subjects discussed within this article.

Funding. The author(s) received no specific grant or financial support for the research, authorship, and/or publication of this article.

Correspondence regarding this article should be directed to John Read, PhD, University of East London, School of Psychology, London E15 4LZ, UK. E-mail: john@uel.ac.uk

EXHIBIT 41

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

OCT 9 1984

D.C. Number : K843923
Received : 10-5-84
Product : Thymatron

Somatics, Incorporated
ATTN: Richard Abrams, M.D.
910 Sherwood Drive Unit 6
Lake Bluff, IL 60044

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-~~7230~~ 8162.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

K843923

SOMATICS, Inc.
910 SHERWOOD DRIVE, UNIT 16 (312) 295-6868
LAKE BLUFF, ILLINOIS 60044

September 27, 1984

Bureau of Medical Devices (HFK-20)
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

RE: 510(k) notification
Electroconvulsive therapy
device

Attention: Document Control Clerk

This letter constitutes premarked notification that our firm proposes to manufacture and introduce into interstate commerce a medical device for human use at least 90 days from now. We are providing the following information pursuant to the requirements of 21 CFR 807.87.

1) Classification name: Electroconvulsive therapy device
Common/usual name: Electroconvulsive therapy device
Trade/Proprietary name: Thymatron

2) Establishment registration number: 1420295

3) Device class: III

4) No performance standards applicable to Electroconvulsive therapy devices have been established by the Food and Drug Administration.

5) Draft labeling: We propose to advertise the Thymatron as an electroconvulsive therapy device to be used in the treatment of selected psychiatrically-ill patients.

The front panel will contain the following statement:

"WARNING: Federal law prohibits use of this instrument by anyone except licensed qualified physicians."

The directions for its use are contained in the enclosed draft document, "Thymatron Instruction Manual" which will accompany each device distributed. Promotional literature and advertisements for the device have yet to be prepared.

6) The Thymatron is substantially equivalent to two already marketed electroconvulsive therapy devices (MECTA Model D, Portland, Oregon; Medcraft B24-III, Medcraft Corp., Darien, Connecticut). These devices have been in commercial distribution since before 1976. The equivalency of these three devices is supported by the attachments which compares the electrical parameters of the three devices and state their specifications.

Attachment I- Comparison of electrical parameters of the MECTA, Medcraft and Thymatron machines
Attachment II- MECTA Model D brochure
Attachment III- Medcraft Model B24-III brochure
Attachment IV- Draft Thymatron instruction manual
Attachment V- Front and back views of Thymatron.

The actions of the three machines for the purpose of delivering an electrical stimulus for the induction of a seizure are comparable.

Somatics, Inc. requests that the Food and Drug Administration hold as confidential our intent to market the Thymatron electroconsulsive therapy device and the information contained in this 510(k) notification, pursuant to section 807.95(b). This request is supported by these points:

1. Somatics, Inc., considers its intent to market the Thymatron confidential commercial information and therefore exempt from public disclosure.

2. Neither Somatics, Inc., nor to the best of its knowledge, anyone else, has disclosed through advertising or any other manner to scientists, market analysts, exporters or other individuals its intent to market the Thymatron. The only exception concerns the directors of Somatics, Inc., and its paid consultants, and its commercial insurers and advertising consultants, with appropriate safeguards made for secrecy.

3. We will immediately notify the Food and Drug Administration if we disclose the intent to market the Thymatron to anyone, except employees of, or paid consultants to, this firm or individuals in an advertising, insurance, or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy.

4. We have taken precutions to protect the confidentiality of the intent to market the device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

If you have any questions or require additional information or data, please call me at (312) 578-3331.

Sincerely yours,

Richard Abrams, M.D.
President

Enclosures

Attachment I- Comparison of electrical parameters of the MECTA, MEDCRAFT and THYMATRON machines

	MECTA	THYMATRON	MEDCRAFT
Stimulus type	bidirectional pulsed square wave	bidirectional pulsed square wave	bidirectional continuous sine wave
Current limit (avg. over one cycle)	0.8 amp	0.9 amp ✓	no limit
Voltage limit	320 volts	400 volts	170 volts
Maximum pulsewidth	1.5 msec.	1.0 msec. ✓	does not apply
Maximum frequency	70 Hz.	70 Hz.	60 Hz.
Maximum energy delivered at 220 ohms (patient avg.)	59 joules over 2 sec.	100 joules over 4 sec.	131 joules over 1 sec. about 170 joules with "glissando" on
Maximum energy delivered at any impedance	108 joules over 2 sec.	182 joules over 4 sec.	exceeds 200 joules over 1 sec. over 250 joules with "glissando" on

Model B24 III
Electroconvulsive Therapy Unit
— Specifications —

Physical Characteristics

Size: Approximately 13"L x 8"W x 8½"H

Weight: 6 pounds

Color: Gray

Electrical Characteristics

Supply requirements

Voltage: 100-135 VAC, RMS or 220 VAC

Frequency: 60 hz or 50 hz

Power: 115 watts

Operating Controls

POWER ON-OFF Applies AC power to unit

LINE VOLTAGE (S_2) Used to compensate for variation in line voltages; 8 steps, 5 volts/step

TREATMENT VOLTAGE (S_1) Adjusts output voltage to value indicated, from 70 VAC to 170 VAC in 10 volt increments with a load impedance of 400Ω.

TREATMENT TIME (S_4) Adjust time which output is delivered, variable from .1 sec. to 1 sec. in .1 sec. increments

GLISSANDO When activated, this switch causes the output voltage to slowly rise to the pre-set treatment voltage. Approximately .8 sec. is required for the output to reach full amplitude.

TREAT Activates output terminals for application of voltage.

S_3 This switch is used to switch the meter indicator from the line voltage compensation mode to the output voltage reading.

Foot Switch Auxiliary switch used in place of TREAT button.

Mode of Stimulus Delivery.

The stimulus delivered to the output terminals is a constant voltage sine wave whose amplitude is determined by the TREATMENT VOLTAGE setting.

Stimulus Parameters

Stimulus Voltage: 70-170 VAC RMS ± 5%, with a resistive load of 400Ω, 10 VAC increments

Stimulus Frequency: 60 hz nominal

Stimulus Duration: .1 to 1 sec. nominal ± 10%, .1 sec. increments

Glissando: rate of increase is .8 sec. nominal

Indicators

Power-on lamp: indicates that POWER ON-OFF switch is in ON position

Output lamp: lights when stimulus voltage is applied

Meter: used to indicate line voltage adjustment range and relative output amplitude

Stimulus Abort

The stimulus can be aborted by release of the treatment button or foot switch, if so used.

Pre-Test Capability

The device permits the user to test the electrical integrity of the stimulus output path prior to the time of patient stimulation.

Electrical Safety

The Model B24 III is listed with **Underwriter's Laboratories** and is in compliance with UL-544.

Medcraft
Medcraft Corporation
433 Boston Post Road
Darien, CT 06820

EXHIBIT 42

Medical Psychology and Neuropsychology Services

Dr. Dennis J. Robinson, ABMPP, ABPDC, CPQ, FACFEI (Fellow) and DABPS (Forensic Neuropsychology)
In the Practice of Medical Psychology and Clinical Neuropsychology
Licensed Psychologist (psy11012)
Dr. Sherry L. Robinson, Reg. Psych. Assist (psb20902)
Mailing Address: 4872 Cambridge Street
Montclair, CA. 91763-2237 Phone:(909)-624-1850 (Fax/Voice-24/7)

Locations: BARSTOW - CHINO - DIAMOND BAR - MONTCLAIR - On Site Visits by Appointment Only

CONFIDENTIAL

(NOTICE: If the reader of this report desires a second opinion, it is strongly suggested the reader obtain the services of a licensed psychologist in the practice of clinical neuropsychology with experience in the use and interpretation of the Halstead-Reitan Neuropsychological Test Battery - HRNB.)

NAME: Mrs. Marcia Stefanon-Benjamin [redacted]
DOI: Since 1983 to 2014 over a series of questionable medical treatments
EDUC.: Bachelor of Architecture, Certificate in Environment and Certificate in Environmental Design, and Certified by the California Council for Interior Design.
MARITAL STATUS: Married OCCUPATION: Architect and currently not working and disabled
EMPLOYER: N/A DOT: 1/17/17, 3/6/17, 4/10/17 and 4/18/17 HANDEDNESS: Right Handed

Introduction

Referral Source (s):

The Patient at the encouragement of Dr. Stephen Meyer, Psychologist in the practice of Neuropsychology.

Referral Question(s):

Does the Patient demonstrate the presence of brain-behavior (neuropsychological) deficits? If so, what are her brain-behavioral strengths and weaknesses.?

Significant elements related to the need for neuropsychological assessment and evaluation.

1. The Patient suffers from hypothyroidism, which historically has been present in her family.
2. The Patient was medically treated for the symptoms of hypothyroidism rather than focusing on the hypothyroidism as the cause. This resulted in provoking her Hypothyroidism symptoms to the point of changing the focus of her treatments. This involved two physicians (**For more detail the reader is referred to a Patient composed summary dated January 16, 2017**):
   a. Dr. David Gudeman, whose treatments resulted in prescribing Xanax at a dosage level of 6 to 8mg. daily (the usual daily dosage range for an adult is 0.25 to 4mg.*) the equivalent of 120 to 130mg of Valium, for depression and anxiety (the expected secondary effects of Hypothyroidism).

The Patient reported she was switched from Xanax to Valium at the clinic for her withdrawal. Dr. Gudeman also referred the Patient to the second physician.

b. Dr. Michael Frankel, whose treatment involved ECT in an initial series of 6 administrations and, based upon the Patient's "failure" to respond, 14 more ECT administrations for a total of 20 ECTs. Dr. Frankel suggested maintenance on Lithium, which the patient refused and was given instead 36 Transcranial Magnetic Stimulation sessions, by Dr. Gudeman, to the right side of her head. She was continuing to take her Valium (switched at the detox clinic.

3. The Patient, then found her current Primary Care Physician (PCP), Dr. Michael Hirt, whose report composed on October 14, 2016, stated, "... she (the Patient) received the electroshock therapy without cause." **(The reader of this report is encouraged to read his report for more details.)** The Patient also stated Dr. Hirt indicated she had symptoms of cerebral swelling, blood pressure irregularities, and an abnormal EKG.

4. The Patient, after the events listed in sections 2, 2a and 2b above, contacted Dr. Raymond G. Armstrong, Physician, and Dr. Bill Code, Physician who are associated with Point of Return, Inc., a medically based drug tapering program. The Patient was gradually tapered off her medications over a period of 18 months. A report created by Dr. Raymond G. Armstrong (October 21, 2016) indicated "... she again had continuing problems with "faulty" management of her thyroid problem, not clearly defined, and recurrence of anxiety and depression." **(The reader of this report is encouraged to read this report for more details.)**

5. Finally, The Patient provided the author of this report with a copy of a Neuropsychological Evaluation created by Dr. K. Drorit Gaines, Psychologist and Neuropsychologist, dated April 8, 2016. The Patient was submitted to a "battery" of tests based upon a flexible or hypothesis methodology. This approach, unfortunately, lacks coordinated norms using known neurologically normal subject's performance data, as well as, known brain-damaged subject's performance whether they have lateralized damage or bilateral brain damage. This report did not give a clear conclusion with regard the status of the Patient's brain (brain impairment vs. absence brain impairment) and the functional nature of her brain-behavioral (neuropsychological) performance.

This report was reviewed by the Patient, in October 10, 2016 and resulted in 6 page list of corrections of Dr. Gaines's report pointing out errors and omissions, as well as, factual inconsistencies. The Patient noted that the report brought up the idea of PTSD which the Patient felt made no sense.

(The reader of this report is encouraged to read both Dr. Gaines' report and the report created by the Patient for more details.)

Pre-Assessment Intake Interview Results:

The patient was interviewed with regard to her current brain-behavior dynamics using the Neuropsychological Symptom Checklist (NSC) as a structured guide. The patient reported the following as present and since her injuries:

1. The Patient indicated having blurred vision, some loss of vision or a darkening of vision to the right upper aspect of her visual field (she had successful Lasik eye surgery), but claimed some

CONFIDENTIAL

blank spots in her vision and occasional flashing lights in her vision.

2. She also indicated having some loss of hearing and ringing in the ears (possible Tinnitis).

3. She stated she now experience muscle weakness (with the left hand being weaker), spasms, trouble walking (involving her right foot), and muscle tremors or shaking to the right leg.

4. The Patient claimed the presences of numbness to the right side of her face, tingling to the ends of her fingers, with the left hand being more involved than the right hand, and pins and needles sensations to both the legs and arms.

5. The Patient stated continued headache pain to the right side of her head.

6. Memory problems were indicated with her getting lost, forgetting time, day and meetings.

7. She pointed to possible general cognitive slowness with her claimed inability to think as quickly as before her "treatments", as well as, difficulty thinking clearly and having trouble with making "common sense".

8. Possible thought processing difficulty was suggested by her claimed problems in telling right from left, having trouble remembering the "right" word when talking and in understanding others during conversations. She also stated difficulty with her speech, her reading, and her writing.

9. The Patient stated the presence of sadness and anger when she wonders, "Why me?" and when she believes she wasn't smart enough to know what was happening. She engages in "What If" negative thinking along with feeling betrayed by those she trusted. She is angered by the idea of being a victim.

10. She admitted to the childhood illness of Rheumatic Fever and being exposed to the Epstein Bar "Bug". She also admitted to playing soccer, including 10 to 12 head ball hits and a head impact with the cross bar on the goal with mental clouding but no loss of consciousness (LOC).

11. Currently, the Patient is pre-diabetic and has a fatty liver (which may be the result of her medication history). She indicated she has had some difficulty with her kidney with two tubes being placed in her right kidney, as well as, having a TIA postpartum with the birth of her second child. Further, she was diagnosed with a Mitro-valve Prolapse in 1982. Finally, she stated she was diagnosed with a cyst around her Pineal Gland by way of MRI imaging (date ~~unknown~~). 5/8/12 & 6/19/16).

12. The Patient denied any history of psycho-pathology or mood disorder which could not be explained by the presence of a medically treated condition (Hypothyroidism).

Results: The Four Methods of Inferential Analysis

The four methods of inferential analysis are based upon HRNB measures empirically shown to be sensitive to the condition of the brain (Reitan R.M. and Wolfson, D. 1993. *The Halstead-Reitan Neuropsychological Test Battery: Theory and clinical interpretation.* Tucson, Arizona: Neuropsychological Press). The Patient's performance data is translated into the categorical classifications of 0=Perfectly Normal, 1=Borderline Normal/Mildly Impaired, 2=Abnormal/Moderately Impaired and 3=Abnormal/Severely Impaired called Neuropsychological Deficit Scale (NDS) scores. However, some of the Patient's deficits may not be readily seen during

CONFIDENTIAL

specific day to day activities (usually those classified as borderline normal/mildly impaired), but over time they would become apparent. Finally, the presence of neuropsychological or brain-behavior disability(ies) exist if any one or more of the four methods of inferential analysis are present.

Method One - Level of Performance Analysis (See Profile - A):

The Patient's performance, on the 19 tests which make up this method of analysis, was perfectly normal (similar to neurologic controls) on 7 (37%) of the tests, and similar to those with a borderline normal/mildly impaired status on 4 (21%) of the tests and abnormal (either moderately or severely impaired) on 8 or 42% of the tests. This resulted in a total NDS score of 23 or and averaged NDS of 1.21 or Borderline Normal/Mildly Impaired. The Patient's abnormally performed tests were as follows:

1. The Category Test - The purpose of the Category Test (CT) is to determine the patient's ability to use both negative and positive experiences as a basis for altering her performance (i.e. developing different hypotheses to determine the theme of each sub-test). It can be presumed that every item in the test affects the patient's responses to ensuing items. The CT is probably the best measure in the HRB of abstraction, reasoning and logical analysis abilities. These abilities are essential for organized planning. The CT requires organized memory and is probably a more meaningful indication of memory in practical, complex everyday situations than most so-called "memory" tests. The CT is probably the best single test in the HRB in terms of showing the adverse effects of cerebral damage and is routinely sensitive to cerebral damage regardless of the location of the lesion.

The Patient's performance was a classification of severely impaired.

Conclusion: Abnormal and Severely Impaired.

2. The Tactile Form Recognition Test - This is an evaluation of tactile form recognition ability. The patient is asked to identify flat plastic shapes and they are individually placed in the patient's hands out of the range of vision. The patient feels the plastic shape and, with the other hand, points to one of the four shapes mounted on a board corresponding to the shape in her hand. The response (time) element of this task is deliberately minimized and the input sensory (afferent) aspect, together with central (cerebral) processing, predominates. Response time for each trial, and the total time for the four trials for each hand is determined. The total number of errors for each hand is recorded as a separate score.

The Patient's performance was free of errors with regard to identifying the shape of the objects. Her sensory-motor response rate (with both hands) was impaired and with her dominant right hand being slightly slower than her slow non-dominant (left) hand.

Conclusion: Abnormal and Severely Impaired and likely involving the sensory (anterior parietal) and (posterior motor) cerebral areas in their feedback loop processing rates.

3. The Finger-Tip Number Writing Test - This procedure requires the patient to identify numbers written on the fingertips of each hand without the use of vision. The primary information gained from this test is based upon differences in performance on the two sides of the body. Inferences regarding contra-lateral parietal lobe damage or dysfunction can be drawn when one hand is definitely deficient compared to the other hand.

Patient produced a total of 16 errors (9 from her left and 7 from her right hand). Although her left hand demonstrated more errors (9 errors) vs. her right hand with 7 errors, the conclusion of her parietal cerebral areas being involved is supported.

CONFIDENTIAL

Conclusion: Abnormal and Severely impaired with her processing of information to her right parietal area slightly more impaired than her left parietal area.

4. The Tactual Performance Test - Total Time - This test (TPT) requires the ability to non-visually manipulate wooden blocks and to identify the shape of the block to the shape of its space on an inclined wooden board and then to transport the block to the space. If done correctly the block will fit in the identified space if not the block will not fit and may fall out. Once all the blocks have been correctly placed first by the dominant hand, then the non-dominant hand and finally using both hands the blocks and board of spaces are removed and the Patient is allow to see again. Finally, a blank piece of unlined white paper is given to the Patient and the Patient is asked to draw the blocks from memory and to draw them so the blocks are in the correct location to each other as well. The times taken to perform the task by each hand and both hands and the memory of their shapes and their placement relative to each other are separately scored.

The Patient's timed performance (11.03 minutes with her dominant - right hand) was the determining negative factor. Her subsequent performance with her non-dominant (left hand) exhibited the expected 1/3 performance improvement (7.35 minutes) over her previous dominant hand time.

Conclusion: Abnormal and Moderately impaired sensory-motor processing rate with information sent to her left parietal-motor feedback loop.

5. The Finger Oscillation (Tapping) Test - This test, which uses a specially adapted manual tapper, is a measure of finger-tapping speed. Measurements are made first with the subject using the index finger of the dominant hand. Next, a comparable set of measurements is obtained with the non-dominant hand. Five consecutive trials, each trial for ten seconds, are acceptable performances. However, if the patient is unable to produce five consecutive trails with a tapping rate within five taps of each other then ten trials are done and the average rate of taps are used for the comparison. Rest periods are given after the first three trials and as needed thereafter. Performance fatigue and fatigue recovery are to be observed and recorded.

The Patient's performance was seen as representing the status of her contra-lateral cerebral hemisphere motor functioning. Normally the dominant hand is 10 to 15% faster than the non-dominant hand. The Patient's dominant (right) hand motor performance was slower than her non-dominant (left) hand or the opposite of what would normally be expected. This pointed to the Patient's left cerebral hemisphere motor area being at deficit.

Conclusion: Abnormal and Moderately Impaired in motor performance from her left cerebral hemisphere.

6. The Trail Making Test/Parts A & B - The Trail Making Test is composed of two Parts, A and B. Both parts are composed of 25 circles with Part A have the circles numbered one to 25 and Part B have circles numbered 1 to 13 and lettered A to L and the numbers and letters are alternating. The score is the time required for the Patient to complete each Part. The Trail Making Test requires immediate recognition of the symbolic significance of numbers and letters, ability to scan the page continuously to identify the next number or letter in sequence, flexibility in integrating the numerical and alphabetical series and completion of these requirements under the pressure of time. It seems likely that the ability to deal with the numerical and language symbols (numbers and letters) is sustained by the left cerebral hemisphere, the visual scanning task necessary to perceive the spatial distribution of the stimulus material is represented by the right cerebral hemisphere, and speed and efficiency of performance may be a general characteristic of adequate brain function.

The Patient's performance indicated equal abnormal and moderately impaired performance with

CONFIDENTIAL

both Part A and Part B which suggested sluggish mental flexibility with processing and responding to the demands of this test.

Conclusion: Abnormal and Moderately impaired mental flexibility.

7. Sensory Perception (Visual) Double Simultaneous Stimuli Recognition - These procedures are designed to determine the accuracy with which the Patient can perceive bilateral simultaneous sensory stimulation after it has been established that perception of unilateral stimulation of each side is intact. Patients with lateralized cerebral lesions are often able to identify unilateral stimulation correctly, but when submitted to bilateral simultaneous stimulation the damaged cerebral hemisphere is often revealed.. Visual perception is a function of the more posterior parts of the cerebral hemispheres. The Patient exhibited a failure to perceive visual stimuli presented simultaneously to the upper left visual field suggesting slowed processing to the back portion of the right cerebral hemisphere.

Conclusion: Abnormal and Moderately Impaired ability to respond to visual stimuli to her upper left visual area.

Method Two - Pathognomonic Signs Analysis (See Profile - B):

This gave the patient an NDS score of 4 (Reitan, R. M. 1984. *Aphasia and sensory-perceptual deficits in adults.* Tucson, Arizona: Neuropsychological Press) or an averaged NDS score of 0.33 which was a classification of normal. She produced two dysphasic signs. First, she failed to give the meaning of a simple 4 word sentence other than a paraphrasing of the sentence. She did not explain the implicit meaning of the sentence or exhibited **Auditory-Verbal Dysgnosia**. She also showed **Left-Right Confusion** by failing to analyze the oral command to perform so as to realize the performance would not be possible until she actually attempted the movement. The presence of two dysphasic signs, despite the HRB research indicated that no neurologic normal would show Auditory Verbal Dysgnosia, can be seen with those who are viewed as within the normal range of functioning.

Conclusion: Normal (The possibility of left posterior temporal involvement with the presence of Auditory-Verbal Dysgnosia needs to ruled out).

Method Three - Pattern Analysis (See Profile - C):

The Patient's performance, when analyzed using this method, was perfectly normal with high to above average general ability. Her performance on the Halstead tests used to determine performance consistency resulted in a Halstead Impairment Index (HII) of 0.4, or 3 of the 7 tests were not performed normally, as opposed to 4 done in a normal manner. This was borderline normal, since if she only performed normally on 3 of the 7 tests she would be seen as impaired. Therefore, her NDS score was 0.

Conclusion: Normal.

Method Four - Left-Right Differences (Laterality) Analysis (See Profile - C):

This method of brain-behavior performance analysis is focused on the presence or absence of typical or normal differences in performance. For example, a right handed person will normally perform right handed movements faster than left handed movement. If the "normal" and expected differences are not seen, then an abnormal performance is present.

The Patient's left vs. right performances resulted in a total NDS score of 10 or an averaged NDS score of 1.11 and a classification of Borderline Normal/Mildly Impaired. Of the 9 tests, 4 of them (45%) were performed in a perfectly normal manner by the Patient, as opposed to 3 (33%) of them being performed in an abnormal fashion.

Conclusion: Borderline Normal/ Mild Impairment with right side of body deficits pointing to the left cerebral hemisphere involving the sensory-motor feedback system.

General Indicators and Conclusion

General Indicators:

The patient's **General Neuropsychological Deficit Score (GNDS)** was calculated by totaling the NDS scores from each of the four methods of performance data analysis which was as follows:

Method	NDS
Level of Performance	23
Pathognomonic Signs	4
Pattern	0
Laterality Left-Right Differences	10
Total:	37

Conclusion: Abnormal and Mild Impairment (Borderline Normal). No neurologically normal subjects, reported in the HRB literature, would have a GNDS above 34. However, 17% of the brain-damaged subjects had a GNDS score of 26 to 40.

The patient's performance across the seven measures which make up **The Halstead Impairment Index (H.I.I.)** was a score of 0.4. Her performance on 3 of the 7 measures (Category Test, Tactual Performance Test - Total Time, and Finger Oscillation Test - Dominant Hand) was in the impaired range. The normal HII score range is 0.0 to 0.3, and the impaired range is 0.4 to 1.0.

Conclusion: Borderline Normal/Mild Impairment.

Left and Right Hemisphere NDS Profiles (See Profiles D and E):

The HRB measures which reflect the performances of either the left hemisphere or right hemisphere (in right handed subjects only) were profiled and their respective NDS score calculated for each hemisphere. The Patient's Left Cerebral Hemisphere profile resulted in an NDS score of 11 (see Profile D) as opposed to the Patient's Right Cerebral Hemisphere profile having a NDS score of 5. The NDS score difference was an NDS score of 6 and just short of the NDS score difference (NDS of 7) which would suggest the need to consider a significant lateralized difference in her brain-behavior performance.

The Patient's left hemisphere profile D demonstrated 5 areas of less than perfectly normal performance. Of the measures performed outside the normal parameters, 3 (60%) were scored as severely impaired and the two remaining measures were classified as borderline normal/mildly impaired.

CONFIDENTIAL

Looking at the Patient's right hemisphere profile E, 3 areas were performed in a less than perfectly normal manner. Of those measures, 2 were scored as abnormal and moderately impaired (67%) and one measure was within the borderline normal/mildly impaired range. However, none of the less than perfectly normal performed measures were scored as severely impaired.

Conclusion: Both Hemisphere Profiles demonstrated some brain-behavior deficits. The left profile exhibited more measures at error and with greater severity of impairment than the right profile. However, the difference in their NDS scores was not great enough to suggest a unilateral bias in her performance. Therefore, she showed deficits to both cerebral hemispheres with greater deficits to the left hemispheres in her sensory-motor processing areas of her brain.

Brain-Behavioral Functional Analysis (See Profile F)

This section was created by re-arranging the various HRNB measures into nine (9) functional analysis profiles. The composition of these profiles were measures taken from both the inferential analysis and measures on The HRNB that are less sensitive to the condition of the brain, but reflective of the patient's knowledge and experience, and may be more indicative of day to day functioning when not under stress or duress. The functional analysis profiles are based upon a rational approach, as opposed to an empirical approach, and content validity was a major consideration in the organization of these profiles.

1. Motor Functions Profile:

The patient's averaged NDS score was 1.00 or a classification of borderline normal/ mildly impaired. The Patient's pure motor performance from both hands were less than perfectly normal with her dominant (right hand) being abnormal and moderately impaired. Her abnormal and moderately impaired performance on the TPT Total time suggested a general suppression of normal ability coming from her motor areas of her brain. Since there was no abnormal difference in her left and right hand TPT performance the presences of equal impairment with both hands on the TPT measure can be assumed to be present.

Conclusion: Borderline Normal/Mildly Impaired.

2. Sensory Functions Profile:

The patient's performance on the five (5) measures of this profile was an averaged NDS score of 1.00 or a classification borderline normal/mildly impaired. Her visual perceptual difficulty was unilateral and seen in her upper left visual field under double simultaneous stimulation, and support her initial statements concerning her present symptoms. On the other hand, the Patient's abnormal and severely impaired finger-tip # writing performance was beyond normal performance limits (left hand 9 errors - 45% and right hand 7 errors - 35%). This pointed to bilateral deficits in processing direct pressure stimuli to her finger tips which confirms her initial symptom statement of numbness to her fingers following her treatments. Both sides of her brain in the anterior parietal areas are involved in the absence of evidence of peripheral damage.

Conclusion: Borderline Normal/Mildly Impaired.

3. Visual-Spatial Skills Profile

The patient's averaged NDS score of 0.80 was a classification of borderline normal/mildly impaired. This was the product of abnormal and moderately impaired performance on both Part A and Part B of the TMT. In this case the Patient's speed of performance under the influence of visual scanning accuracy provoking an movement (motor) response was to be considered the source of her difficulty which can not be lateralized and thus is a general indicator.

Conclusion: Borderline Normal/Mildly Impaired.

4. Alertness and Concentration Profile:

The patient's normal performance status was created by her averaged NDS score of 0.33. Her borderline normal/mildly impaired WAIS/Digit Span performance suggested difficulty in keeping her learning and memory organized so as to respond in the order the information was given. Whereas, her perfectly normal performance on the SRT and SSP measures pointed to the use of attention and concentration needed to determine the presence or absence of a correct response, which was normal and present.

Conclusion: Normal.

5. Verbal Abilities and Skills Profile:

The averaged NDS score of 0.17, which the patient achieved on this profile, was a classification of normal. It also suggested a good pre-morbid status. Her two dysphasic signs (Auditory-Verbal Dysgnosia and Right-Left Confusion), although within the range of that seen with neurologic normals, needs to be mentioned and possibly ruled on at a later time.

Conclusion: Normal.

6. Incidental Memory Profile:

The averaged NDS score of 1.00, obtained by the Patient on the two HRNB measures which made up this profile, was a classification of borderline normal/mildly impaired. Her performance suggested borderline ability to remembered the tactile nature of concrete and manipulated objects, likely caused by her sensory perceptual difficulties (see profile 2, the sensory functions profile). Additionally, she demonstrated less than perfectly normal ability in creating a mental spatial map of the locations of the unseen objects in relation to each other when she was asked to draw their positions

Conclusion: Borderline Normal and likely to get lost in space unless she can create a verbal relationship memory structure.

Special Note:

Because the measures in The Incidental Memory Profile are few (2) and come from tasks with an emphasis on sensory-motor stimuli and deep kinesthetic sensations, to language based information, memory and learning tasks taken from the work of the neuropsychologist A. R. Luria were

CONFIDENTIAL

administered to the Patient.

The Lurian Memory and Learning Tests (LMT) results:

The Lurian Words and Numbers Memory and Learning Curve -

The Patient was given a series of 10 low associated words (See Profile G) and numbers (See Profile F) to remember and learn and ultimately repeat in the order they were given. The minimal normal performance is being able to learn all tens words or numbers without regard for order of presentation by or before the 5th trial and to repeat them in order by or before the 7th trial.

Profile G illustrates the Patient's performance on the ten word memory and learning curve. Her ability to learn the words, without regard for their order, was a normal performance. However, she failed to repeat the words in their order of presentation by or before the seventh trial. This failure to organize her learning persisted until the maximum ten trials was reached. Further, her efforts to repeat them in their order of presentation caused a decay of her learning for the ten words. Memory and learning organization was seen as her weakness.

On Profile H, the Patient exhibited a ten number memory and learning pattern similar to that seen in her performance on the ten words. However, this measure is slightly more demanding because her recall was stopped whenever she repeated a number not given twice or a number not given at all.

Conclusion: Abnormal for her ability to organize her memory and learning.

The Lurian Words Memory Test (Stressed)-

The Patient was given two groups of three words, which were categorically similar (colors and numbers). She was able to demonstrate normal learning (three verbatim repetitions the first time). Between her learning of each group she was exposed to 10 seconds of questions designed to create an element of distraction before she was asked to recall the groups. However, when she was asked to recall the first group of words, she did so and in the order of their presentation. When she was asked to recall the second group of words, she was only able to respond with "I don't remember". She was then given the verbal retrieval cue of "The second words had to do with numbers!" to which she responded with "No!, My address? I don't remember!" The Patient, despite exhibiting normal initial learning, also presented with proactive inhibition of learning caused by the presence of verbal questions as distractions to her memory and learning.

Conclusion: Abnormal memory and learning with proactive inhibition of learning created by external verbal distractions.

The Lurian Sentences Memory Test (Low Stress) -

The Patient was given two sentences of moderate complexity and of equal length . Between her learning and mastery of each sentence she was given 10 seconds of silence so as to assess if information complexity, as opposed to distractions, would create memory and learning difficulties. The Patient learned the sentence in a normal fashion so as to meet the learning criteria of three verbatim repetitions of the sentence. She was able to learn the second sentence in a normal manner

thus meeting the learning criteria of three verbatim repetitions of the sentence. When the Patient was asked to remember and recall the sentences, she repeated the second sentence in a simplified form when she was asked to recall the first sentence. This suggested retroactive inhibition of learning of the last sentence removed the first learned sentence from memory. However, when she was asked to recall of the second sentence, she did so preserving the essence of the sentence but with a reversal of the descriptive modifier of the noun and the descriptive modifier of the object in the prepositional phrase within the sentence. Finally, she was given the retrieval cue of "The first sentence had to do with an automobile!". She then repeated the first sentence in a simplified form.

Conclusion: Abnormal with retroactive inhibition of learning being demonstrated along with spontaneous simplifications of the information. The retrieval cue, for the primary sentence (first given), did work but with a within category reversal of noun/object modifiers.

Conclusion

The Patient demonstrated abnormal performance on the memory and learning curves due to poor data organization, and with the negative effects of verbal distractions and/or when information is increased in length.

The Reitan Story Memory Test Results:

The patient was given, by tape recorder, a story to learn and recall which the patient failed to do (by not obtaining the minium learning score of 15 by or before the 5th exposure trial). She obtained a 5th trial score of 14 for an overall learning score of 2.8 (the minimal normal learning score is 3.0). The Patient was then told to remember the story, because she would be asked to repeat the story four (4) hours later. The Patient's recall was 78.6% of what she had learned (or a 21.4% loss of memory for the story). The warning of a delayed request to recall the story was designed to provoked her to mentally rehearse the story until she was asked to recall the story. (Note: no such warning of possible recall was given to the Patient on the other memory measures.)

Conclusion: Abnormally slow learning of a standardized story and recall memory loss of 21.4% of the story which exceeded the maximum acceptable memory loss of 15%.

---

7. Abstraction and Concept Formation Profile:

This Profile was the patient's most impaired performance profile with an averaged NDS score of 1.75 or Abnormal and Moderately Impaired. The Patient's severely impaired Category Test score suggested difficulty in her use of her memory ability, so as to remember and compare the auditory feedback to her responses, in attempting to determine the underlying idea or concept of a series of visual stimuli for which the desired idea or concept, when discovered and used, would result in the correct answer to every stimuli presented. Her abnormal and moderately impaired TMT Part A and Part B performance, pointed to an general and impaired mental flexibility in cerebral functioning. On the other head, her perfectly normal ability to determine the common elements of the meanings of two apparently dissimilar words suggested a good pre-morbid verbal/language ability.

Conclusion: Abnormal and Moderately Impaired status in remembering and learning

ideas and concepts. This is general indicator of cerebral functioning.

8. Learning Ability (Problem-Solving) Profile:

The patient's averaged NDS score of 0.33 or a classification of normal was obtained by her ability to recognize prior measures and to respond them in at least the same way if not better than the first time. However, her performance on the Digit Symbol Sub-test of the WAIS was less than perfectly normal (the most brain sensitive of the WAIS Sub-tests). It indicated a slowness in using her memory in associating over learned verbal abstracts to non-sense symbols (associative learning).

Conclusion: Normal.

9. Emotional Indicators Profile:

The Patient's averaged NDS of 0.50 was a classification between perfectly normal (0.00) and borderline normal (1.00) and thus was considered as a borderline normal/mildly impaired status. Her performance in presenting pro-social verbalizations to described situations (WAIS Comprehension Sub-test) was normal, as opposed to her borderline normal/mildly impaired performance in arranging a series of pictured human interactions in a manner which could be verbally described in a sensible or logical fashion.

Conclusion: Borderline Normal/Mildly Impaired.

Special Note:

The Patient did not exhibit an inability to be aware of her environment and the relational activities present at any given moment. She did not exhibit any frank psycho-pathology or emotional expressions without a rational statement of the causes for the emotion.

As a result, the patient was assessed for the presence of depression (Beck Depression Inventory - BDI), anxiety (Clinical Anxiety Scale - CAS), anger and hostility (Aggression Quotient - AQ), and Post-traumatic Stress Disorder (PCL-Civilian Form) with the following conclusions:

1. The Patient's Total Raw Score on the BDI was 6.5 or a Z-Score of -0.54 which was in the absent depression range. Those items endorsed by the Patient were those having to do with physical discomfort and physical efforts needed to perform and sleep disturbances.

Conclusion: Absent Clinical Depression dynamics.

2. The Patient's Total Raw Score on the CAS was 23.4 or a Z-Score of +1.06 resulting in a classification of mild anxiety. She endorsed items suggested anxiety surrounding certain situations such as going out of her house alone, along with, uncomfortable physical sensations like feeling dizzy and hands, arms or legs trembling.

Conclusion: Mild Clinical Anxiety.

3. The Patient's Total Raw Score on the AQ was 31 or a Z-Score of -2.19 or below average aggressiveness when compared to adult females rated by their peers as non-aggressive. Her Anger

Scale was a raw score of 09 (Z-Score of -1.33) or low average Anger compared to non-aggressive adult women. Finally, her Hostility Scale was a raw score of 08 (Z-Score of -1.94) or below average compared to non-aggressive adult females.

Conclusion: Absent Anger and Hostility.

The Patient was given the PCL-Civilian Version* and obtained a total score of 24 which was below the cutoff score of 50 separating those with clinical Post-traumatic Stress Disorder (PTSD) from those without symptoms. The Patient endorsed only 2 of the 17 items in the direction of being PTSD symptoms. These were "Trouble *remembering important parts* of a stressful experience from the past?" and "Feeling *jumpy* or easily startled?"

Conclusion: Absent PTSD symptoms.

Conclusion

The patient's Overall Performance across the nine functional profiles was viewed as Borderline Normal/Mildly Impaired. This was based upon the fact that none of the 9 profiles were performed in a Perfectly Normal manner, and 3 were classified as normal and 9 were classified as borderline normal/mildly impaired. Her overall averaged NDS score was 0.76.

Conclusion, Diagnoses and Recommendations

Conclusion:

The Patient on the HRNB performed in a manner indicating brain-behavior impairments or disability (ies) pointing to her left cerebral hemisphere (the central division) being at least slow in processing and responding to input sensory data. Her right cerebral hemisphere had, to a lesser degree, input processing impairment. Her Level of Performance and Left-Right (Laterality) Differences failed to demonstrate performance data supporting a normal neurological control subject's performance. Her performance on memory and learning measures indicated memory and learning difficulties and neuro-cognitive problems in organizing memory based learning and in being able to determine the presence of ideas and concepts to be remembered and learned. In short, the Patient exhibited Neuro-Cognitive Disorders coming from multiple etiologies (Hypothyroidism and the resulting medically based treatments - Medications, Electroshock and Transcranial Magnetic Stimulation).

Diagnosis(es):

Axis 1a. F02.80, Major Neuro-Cognitive Disorder due to multiple etiologies without Behavioral disturbances.

Axis 2. F45.21, Illness Anxiety Disorder (mild).

Recommendations:

1. It is most important that the Patient's hypothyroidism is properly treated and her required medications are stabilized.

CONFIDENTIAL

2. The Patient's mild clinical anxiety can best be treated with use of Cognitive Behavior Therapy (CBT), along with the use of self-ratings of tension states and the use techniques such as Progressive Relaxation, Hypnosis or Meditation.

3. General Memory enhancing methods such as the following, could be helpful:

a. The use of numeric clumping to consolidate numeric data and thus reduce her memory load. This would allow more numbers being retained.

b. The use of the method of translating verbal information into mental imagery so as to improve her recall of the verbal data. This training must start with simple sentences with delayed recall gradually increasing, with and without verbal distractions being present.

c. The use of the spatial enhancing technique of verbal instructions given to the Patient with the demand to physically respond in accordance to the instruction's movements.

d. The use of a method of improving her sensory sensitivity through active tactile stimulation to her left and right hands and finger-tips.

4. The use of digital base techniques could be used to practice attention, concentration and timed response rates to the following "Games" coming from The Mind Games app.:

a. Attention Training program.
b. Changing Focus program.
c. Memory Racer Level 1 program.
d. Memory Racer Level 2 program.
e. Spatial Memory program.
f. Divided Attention Level 1 program.
g. Mental Flex Level 1 program.
h. Mental Flex Level 2 program.

This list of programs, are available for smart phones, Android, I-pod and I-pad devices through the App Stores. Performance on these programs should be geared to achieve and maintain at least 85 to 90% accuracy.

Thank you for this referral and the opportunity to meet, assess and evaluate Mrs. Marcia Benjamin.

If you have any questions be at liberty to call me.

Sincerely,

Dennis J. Robinson, Ed.D 07/31/2017

Dr. Dennis J. Robinson, Licensed Psychologist (CA. #psy11012)
In the Practice of Medical Psychology and Neuropsychology

CONFIDENTIAL

References

* **Zuckerman, Ed and Kaden, Pamela. (2015).** Checklist of doasges and uses of 100 common psychotrophic medications by trade name. *www.CliniciansToolBox.com.*

***Weathers, Litz, Huska & Keane. (2003).** A government document in the public domain. National Center for PTSD - Behavioral Science Division. www.PDHealth.mil.

Bijan Esfandiari, Esq., State Bar No. 223216
Monique Alarcon, Esq., State Bar No. 311650
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
BAUM HEDLUND ARISTEI & GOLDMAN P.C.
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
(310) 207-3233 Tel
(310) 820-7444 Fax

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; AND DANIEL BENJAMIN,

Plaintiffs,

v.

SOMATICS, LLC;

Defendants.

Case No.: 2:17-CV-06686-RGK- JCx

[Assigned to Hon. R. Gary Klausner, Court Room 850]

DECLARATION OF MARCIA BENJAMIN IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT

Date: May 3, 2021
Time: 9:00 AM
Courtroom: 850

DECLARATION OF MARCIA BENJAMIN

I, MARCIA BENJAMIN, declare and state as follows:

1. I am a Plaintiff in this action and have personal knowledge of the facts stated below. If called to testify as a witness, I could and would do so competently.

2. Since 2008, I have been treated for hypothyroidism and have taken medication to manage my condition.

3. In March 2011, my thyroid medication dosages were increased, and I was at home when I suddenly felt my heart racing. I began to feel uncomfortable, dizzy, and had chest pain. I went to the emergency room at Los Robles Regional Medical Center, where I received a diagnosis of "anxiety" and was prescribed Xanax. On or about March 2011, I sought out the care of Dr. David Gudeman, a psychiatrist in my area who a friend recommended to me, so that he could oversee my use of Xanax.

4. Dr. Gudeman increased the dose of Xanax from what was previously prescribed to me in the emergency room and I began to feel extremely ill. I felt as though I could not even sit upright in a chair, and without knowing it, I developed a tolerance to Xanax. In late 2011 to early 2012, I sought treatment at an affordable detox clinic in Sao Paulo, Brazil to help me safely detox from Xanax. Dr. Raymond Rosenberg, a psychiatrist in Sao Paulo, helped me titrate off Xanax by prescribing Valium and Tegretol.

5. I was at the clinic in Brazil for approximately one month before I returned to Dr. Gudeman's care, per Dr. Rosenberg's guidance. When I saw Dr. Gudeman again, instead of keeping me on Valium and Tegretol, he switched me to Klonopin. The Klonopin made me feel worse. Dr. Gudeman informed me that, because I was "not responding" to medication, ECT was the next treatment option. I trusted Dr. Gudeman's medical opinion.

6. In September 2012, Dr. Gudeman referred me to Dr. Frankel for an ECT consult. My husband, Daniel Benjamin, and I went to the ECT consultation together. I was assured by Dr. Frankel that ECT was a safe and effective treatment, and I

understood that at the conclusion of ECT, I would no longer need psychiatric medication. Dr. Frankel only advised me that the side effects of ECT included some confusion after the time of treatment and short-term memory loss that would be temporary.

7. From September 28, 2012 to March 4, 2013, I underwent 20 treatments of electroconvulsive shock therapy (ECT) at Northridge Hospital Medical Center. My treatments were administered by Michael Frankel, M.D.

8. In early March 2013, Dr. Frankel recommended, for the second time, that I begin taking Lithium while I continued "maintenance" ECT treatments. At this point, my husband suggested that I stop ECT treatment because we were told that ECT would help me get off medication. My last ECT treatment was on March 4, 2013.

9. After my last ECT treatment with Dr. Frankel in March 2013, I returned to Dr. Gudeman's care who performed Transcranial Magnetic Stimulation (TMS) treatment in lieu of additional "maintenance" ECT. I had TMS treatments approximately twice per month until October 2013. I complained of headaches, and in June 2013, Dr. Gudeman ordered a brain MRI. The brain MRI returned normal, but showed I had a small cyst that I had prior to ECT and TMS. During this time, I was taking Valium and Tegretol, prescribed and monitored by Dr. Gudeman.

10. In late October 2013, I received a call from someone at Dr. Gudeman's office informing me that my future appointments with Dr. Gudeman were cancelled because his medical license had been revoked by the Medical Board of California. I was told that two of his patients died from overdosing on medication prescribed by Dr. Gudeman. I later learned that five other patients had complained to the Medical Board that Dr. Gudeman overprescribed them medication.

11. My husband and I were upset to learn that the doctor who had been prescribing me various treatments had his medical license revoked. At this time, I was on Klonopin, as that is what Dr. Gudeman had prescribed me again, so I searched for another clinic to help me safely detox from the medication. In late October 2013, I

contacted Dr. Raymond Armstrong (internist and cardiologist), to help me taper off the psychiatric medications. I detoxed from the medication over the course of 18 months (October 2013 to March 2015).

12. In September 2014, I was so disappointed in psychiatry because of the improper treatment Dr. Gudeman prescribed me. I was in the process of detoxing from psychiatric medications that made me extremely ill and I became interested in reading about psychiatry. I discovered Dr. Peter Breggin, a psychiatrist who speaks out against harmful psychiatry. I watched a few of his videos and read some of his materials. On September 26, 2014, a friend shared an article about psychiatry that caught my attention because it displayed a book titled "Toxic Psychiatry" and the book's cover had a photo of many pills. This book cover really spoke to me because I felt like it depicted exactly what I went through due to Dr. Gudeman's over prescription. I did not read the article further than the headline. I simply shared the article to my Facebook page. Now that I have seen a full copy of the complete article, I know I did not read or even scroll through the entire article, because it contains a Nazi flag with a swastika symbol. As a woman of Jewish faith, I would not want to post something that contains this hateful symbol. Had I read the article and seen the Nazi flag in the article, I would not have posted it. I have never read the book titled "Toxic Psychiatry."

13. In October 2014, I needed a primary care physician to oversee my care and hyperthyroidism before my detox program ended, so I began treatment with Dr. Michael Hirt. When I completed the detox program in March 2015, I was still feeling the effects of the psychiatric medication and I still had difficulty walking on my own. Dr. Hirt put me on a treatment plan consisting of IVs (administered multiple times per week) and vitamins and supplements. I told Dr. Hirt that I was still having problems with my memory and concentration and he told me that, once I was able to walk on my own again, he wanted me to see a neuropsychologist.

14. In July 2015, I requested my medical records from Dr. Frankel, but he failed to release them to me, even after I called his office twice to follow up on my

request.

15. In late 2015, I was mostly able to walk on my own again and only used a wheelchair when necessary. I began searching for a neuropsychologist and I contacted K. Drorit Gaines, Ph.D. and she told me that her soonest available appointment for a neuropsychological examination was in March 2016. In April 2016, Dr. Gaines called to discuss her final report with me, and she informed me that my difficulty recalling names and faces, concentrating, completing math, and reading were due to Post-Traumatic Stress Disorder (PTSD). During my call with Dr. Gaines, she told me my examination results revealed "processing deficits." In September 2016, while I waited for Dr. Gaines' final report, I started to suspect that my processing deficits may have been from a brain injury that I suffered as a result of the treatments Dr. Gudeman recommended and prescribed me. In September 2016, I finally received a copy of my medical records from Dr. Frankel.

16. I did not receive a copy of Dr. Gaines' written neuropsychological evaluation report until Dr. Gaines mailed it to me in October 2016. When I received it, I was confused by Dr. Gaines' assessment, because her diagnosis of PTSD still did not make sense to me and I was upset because there were various errors in her report. Overall, I was not pleased with her care, so I went on to obtain a second opinion.

17. On January 16, 2017, I underwent a neuropsychological examination with Dennis Robinson, Ph.D. The neuropsychological testing took place over the course of four different sessions, from January to April 2017. In July 2017, Dr. Robinson discussed his written report with my husband and me. Dr. Robinson informed me that I had suffered a brain injury as a result of ECT treatment.

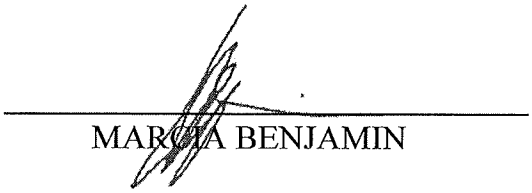
18. Before consenting to ECT, I was never warned that permanent memory loss, brain injury, or inability to create new memories were side effects of ECT. Had I been warned, I never would have consented to ECT.

//

//

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct.

Executed on this 12th of April 2021 at Thousand Oaks, California.



MARCIA BENJAMIN

CERTIFICATE OF SERVICE

I, Bijan Esfandiari, hereby certify that, on April 12, 2021, I electronically filed the foregoing with the Clerk for the United States District Court for the Central District of California using the CM/ECF system, which shall send electronic notification to counsel of record.

/s/ Bijan Esfandiari
Bijan Esfandiari

Bijan Esfandiari, Esq., State Bar No. 223216
Monique Alarcon, Esq., State Bar No. 311650
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
BAUM HEDLUND ARISTEI & GOLDMAN P.C.
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
(310) 207-3233 Tel
(310) 820-7444 Fax

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; AND DANIEL BENJAMIN,

Plaintiffs,

v.

SOMATICS, LLC;

Defendants.

Case No.: 2:17-CV-06686-RGK- JCx

[Assigned to Hon. R. Gary Klausner, Court Room 850]

DECLARATION ON MICHELLE HIMES IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT

Date: May 3, 2021
Time: 9:00 AM
Courtroom: 850

DECLARATION OF MICHELLE HIMES

I, MICHELLE HIMES, declare and state as follows:

1. I am a Plaintiff in this action and have personal knowledge of the facts stated below. If called to testify as a witness, I could and would so competently.

2. I was born in Las Vegas, Nevada and lived there until 2009. In 2008, I married my husband, Paul Himes, and in 2009, we moved to San Diego, California. My husband is in the United States Navy, so we moved to San Diego where he was stationed at a Naval base.

3. I had a difficult childhood and I struggled with depression throughout most of my young adult life. I was hospitalized on various occasions for suicidal ideations, and I was prescribed at least nine different antipsychotics and antidepressants. The medication did not help my symptoms; it made me feel worse.

4. From 2009 to 2011, my primary psychiatrist was Dr. Trenton Moyer. As my symptoms of depression worsened, I attended an inpatient program at Sharp Mesa Vista Medical Center (Sharp). Dr. Raymond Fidaleo was my inpatient psychiatrist at Sharp.

5. I am informed that my husband was with me during my initial consultations with Dr. Fidaleo, where he recommended ECT treatment for me. I have difficulty remembering this time period.

6. I have reviewed the consent form that I signed before undergoing ECT treatment. The consent form does not warn that permanent memory loss, brain injury, or an inability to create new memories are side effects of ECT. I was never warned that ECT would permanently affect my cognitive abilities. Had I been warned of these risks associated with ECT, I would never have agreed to the treatment.

7. While I was at Sharp and under Dr. Fidaleo's care, I was administered 26 ECT treatments from April 13, 2011 to January 3, 2012. I have no recollection of Dr. Fidaleo ever checking up on me after my ECT treatment ended.

//

8. After my ECT treatment, my husband, daughter, and I moved back to Las Vegas, Nevada so that my daughter and I could stay with family while my husband was stationed in Korea. While I was living in Las Vegas, I was hospitalized in April 2013 when my depressive symptoms returned. At that time, I was receiving psychiatric care with Dr. Keith Breiland. When I was hospitalized, I told Dr. Breiland that my primary care doctor had requested an MRI of my pituitary gland, to rule out any possible pituitary tumor, because my protactin levels were extremely high. In April 2013, the MRI of my pituitary gland was completed and the results came back normal. At this time, I had no reason to believe that I had suffered any injury as a result of ECT.

9. When my husband returned from Korea in September 2013, we moved to Camarillo, California. I was still taking psychiatric medications which made me feel foggy, fatigued, and my depressive symptoms had not fully gone away.

10. When I was pregnant with my second child, I stopped taking psychiatric medications and my second daughter was born in November 2014.

11. In approximately December 2015, I learned that I was pregnant with my third child. In my second trimester (approximately February 2016), women from my church would ask me how my third pregnancy compared to my prior two pregnancies, and I realized that I could not remember much about my prior pregnancies, if anything at all.

12. During my third pregnancy, I noticed I did not feel as cloudy as I did when I was on medications, so I started reading about the side effects of psychiatric drugs. I read the book "Mad in America" and it validated my feelings that the psychiatric medications were actually more harmful to me than helpful. At the time, I thought the medications might have contributed to my difficulty remembering past events.

13. My third child was born in July 2016 and in December 2016, my family and I moved to Oak Harbor, Washington because my husband was re-stationed at Whidbey Island Naval Base.

//

14. After moving to Oak Harbor, Washington, (in 2017) I began noticing that, in addition to memory difficulties, I was having difficulty communicating, which is not something I had noticed before, so I started researching psychiatric medicine again, and I specifically began looking into ECT. I looked at websites that were pro-ECT and anti-ECT, and I learned that other people felt as though ECT caused them brain injury.

15. Once I suspected that ECT could have caused my memory problems, difficulty communicating, and difficulty writing and reading for pleasure like I once could, I sought out an attorney.

I declare under penalty of perjury under the laws of the United States and the State of Washington that the foregoing is true and correct.

Executed on this 12th of April 2021 at Oak Harbor, Washington.

MICHELLE HIMES

CERTIFICATE OF SERVICE

I, Bijan Esfandiari, hereby certify that, on April 12, 2021, I electronically filed the foregoing with the Clerk for the United States District Court for the Central District of California using the CM/ECF system, which shall send electronic notification to counsel of record.

/s/ Bijan Esfandiari
Bijan Esfandiari

POOLE SHAFFERY & KOEGLE, LLP
David S. Poole (CA SBN 94690)
dpoole@pooleshaffery.com
Jason A. Benkner (CA SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway, Suite 250
Santa Clarita, CA 91355
(661) 290-2991 Tel.
(661) 290-3338 Fax

Attorneys for Defendant
SOMATICS, LLC

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC;

Defendant.

Case No.: 2:17-CV-06686-RGK-JCx
Assigned to Hon. R. Gary Klausner

SOMATICS, LLC'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES

[Filed concurrently with Statement of Undisputed Facts and Conclusions of Law; Declarations of Jason A. Benkner and Conrad Swartz; [Proposed] Order]

Date: May 3, 2021
Time: 9:00 a.m.
Ctrm.: 850

Trial Date: June 15, 2021

TO THE HONORABLE COURT, PLAINTIFFS, AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, on May 3, 2021, at 9:00 a.m., or as soon thereafter as this matter may be heard in Courtroom 850 of the above-entitled Court located at 255 East Temple Street, Los Angeles, California 90012, Defendant

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

SOMATICS LLC ("Somatics" or "Defendant") will, and hereby does, move this Court for summary judgment or, in the alternative, partial summary judgment, in its favor and against Plaintiffs MICHELLE HIMES ("Ms. Himes"), MARCIA BENJAMIN ("Ms. Benjamin"), and DANIEL BENJAMIN ("Mr. Benjamin") (collectively "Plaintiffs"), pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56-1.

This motion is made on the following grounds:

1. Plaintiffs' claims are barred by the applicable statute of limitations;
2. Plaintiffs cannot establish that their alleged injuries were caused by any purported failure by Somatics' to warn of risks associated with electroconvulsive therapy (ECT) treatment; and
3. Plaintiffs cannot establish that any purported adulteration or misbranding of Somatics' ECT devices caused Plaintiffs' alleged injuries.

This motion is based upon this Notice of Motion and the accompanying Memorandum of Points and Authorities, the concurrently-filed Declarations of Conrad Swartz, M.D., Ph.D. and Jason A. Benkner, and exhibits thereto, the files in this action, and all other matter properly presented to the Court prior to its ruling.

This motion is brought following the conference of counsel pursuant to L.R. 7-3, which took place on March 22 and 23, 2021.

Dated: March 31, 2021

POOLE SHAFFERY & KOEGLE, LLP

By: /s/ Jason A. Benkner
David S. Poole
Jason A. Benkner
Attorneys for Defendant, SOMATICS, LLC

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

TABLE OF CONTENTS

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

In June 2018, the Court granted Defendant's Motion to Dismiss the claims brought by Plaintiffs Michelle Himes ("Ms. Himes"), Marcia Benjamin ("Ms. Benjamin"), and Daniel Benjamin ("Mr. Benjamin"; collectively "Plaintiffs") as being barred by the statute of limitations. (*See* Minute Order Re: Defendant's Motion to Dismiss Based on Statute of Limitations, etc., dated June 19, 2018, Docket No. 70.) The Ninth Circuit Court of Appeals concluded that the dates of Plaintiffs' alleged injuries were not definitively established on the face of the complaint, so the timeliness of the Plaintiffs' claims could not be determined at the pleading stage. (*See* Ninth Circuit Memorandum Decision, Docket No. 168.) Following remand, discovery has confirmed that Plaintiffs either suspected or should have suspected that they had suffered an injury during the course of their ECT treatment or soon thereafter, at which time they were put on inquiry notice.

By Plaintiffs' own allegations, reports of adverse events resulting from ECT have been publicized for decades, including through thousands of public complaints submitted to the FDA in 2009 and 2010 (Pl.s' Fifth Am. Compl. ("5AC") ¶ 59, Docket No. 178); through the publication of "The Electroshock Quotationary" in 2006, a free, web-accessible, 154-page publication that claims to expose the "tragic reality of electroshock" (*Id.* ¶ 60); and through a "vocal 'ECT survivor community'" that has been objecting to the continued use of shock treatment for decades. (*See id.* ¶¶ 59-65.) These and many other resources would have been available to Plaintiffs had they performed a reasonable investigation when they first suspected or should have suspected they had been injured. Nevertheless, Plaintiffs did not commence this action until well after the limitations periods had run on their respective claims. Therefore, Defendant is entitled to summary judgment in its favor on all claims.

Furthermore, notwithstanding the untimeliness of Plaintiffs' claims, Defendant is also entitled to summary judgment in its favor because Plaintiffs cannot establish a

causal link between their purported injuries and the warnings provided by Somatics under the learned intermediary doctrine.

In addition, as previously confirmed by this Court in granting partial summary judgment for Defendant on the claims brought by the former plaintiffs Riera and Chase, Plaintiffs' claims for negligence and strict liability based on adulteration and misbranding fail because Plaintiffs cannot establish that any such purported adulteration or misbranding caused Plaintiffs' alleged injuries. (*See* Minute Order re Plaintiffs' Motion for Partial Summary Judgment and Defendant's Motion for Summary Judgment, dated September 14, 2018, Docket No. 134.) Therefore, Defendant is entitled to partial summary judgment on First and Fourth Causes of Action. (*See* 5AC, Docket No. 178.)

Finally, because the Fifth Claim for Loss of Consortium by Mr. Benjamin is derivative of the claims brought by his wife, the claim fails along with hers.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Background

Defendant, Somatics, LLC, markets and sells an electroconvulsive therapy ("ECT") device called the Thymatron System IV ("Thymatron"), which is used to treat severe psychiatric disturbances in patients. Plaintiffs Ms. Benjamin and Ms. Himes each received ECT treatment from medical professionals using the Thymatron device and now allege that they suffer ECT-induced concussive brain trauma and ensuing physiological, psychological, and emotional injuries including permanent brain dysfunction and memory loss. (5AC ¶ 5, Docket No. 178.)

1. Plaintiff Michelle Himes

Ms. Himes received ECT treatment at Sharp Mesa Vista Hospital from Dr. Raymond Fidaleo between April 13, 2011 to January 9, 2012. (Declaration of Jason A. Benkner ("Benkner Decl."), Ex. A (Michelle Himes' Responses to Interrogatories Propounded by Somatics, Set One), at 26:3-13, 28:1-9, Docket No. 231-3.)

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Ms. Himes contends that ECT cause her to experience cognitive impairment resulting in permanent loss of past memories, chronic and lasting short term memory difficulties, and the ability to recall or retain information. (Benkner Decl., Ex. C (Michelle Himes' Responses to Interrogatories Propounded by Mecta, Set One), at 3:13-18, Docket No. 231-5.)

2. Plaintiff Marcia Benjamin

Ms. Benjamin received ECT treatment at Northridge Hospital from September 28, 2012 to March 4, 2013. (Benkner Decl., Ex. E (Marcia Benjamin Responses to Interrogatories, Set One), at 26:10-19, 28:6-13, Docket No. 231-7.) Dr. Michael Frankel, M.D. recommended and administered ECT to Ms. Benjamin. (Benkner Decl., Ex. F (Transcript of Deposition of Michael Frankel, M.D. ("Frankel Depo.")), at 20:2-20, 25:19-26:8, 35:23-36:17, Docket No. 231-8.)

B. Procedural Background

On September 11, 2017, Ms. Himes initiated this lawsuit against Defendant. (Compl., Docket No. 4.) On November 7, 2017, the Benjamins were added as parties to this action with the filing of the First Amended Complaint. (First Amended Compl., Docket No. 22.)

Defendant moved to dismiss the Plaintiffs' claims, arguing that they were barred by the statute of limitations (*see* Docket No. 55) and that Plaintiffs could not allege sufficient facts to establish the necessary elements of causation or duty to warn (*see* Docket No. 56). On June 19, 2018, the Court dismissed all of Plaintiffs' claims as being time barred. (*See* Minute Order Re: Defendant's Motion to Dismiss Based on Statute of Limitations, etc., dated June 19, 2018, Docket No. 70.) On October 30, 2018, Plaintiffs filed a notice of appeal from the order dismissing them from this action. (*See* Notice of Appeal to Ninth Circuit Court of Appeals, Docket No. 161.) On April 7, 2020, the United States Court of Appeals for the Ninth Circuit reversed and remanded this Court's order dismissing Plaintiffs. (*See* Ninth Circuit Memorandum Decision, Docket No. 168.) The Ninth Circuit reasoned that it was

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

premature to dismiss Plaintiffs' claims as untimely at the pleading stage because the operative complaint did not identify the dates that Plaintiffs were allegedly injured. (*See id.*, at p. 3.)

On June 15, 2020, Plaintiffs filed the Fifth Amended Complaint ("5AC"), which is the operative complaint. (Docket No. 178.) In the 5AC, Ms. Himes and Ms. Benjamin allege four claims against Somatics: (1) Negligence/Negligence Per Se (Adulteration & Misbranding); (2) Negligence/Negligence Per Se (Failure to Warn, Failure to Timely Investigate, Evaluate, and Report Adverse Events); (3) Strict Liability—Failure to Warn; and (4) Strict Liability (Adulteration & Misbranding). (*Id.*) The Fifth claim for Loss of Consortium is brought solely by Mr. Benjamin. (*Id.* at p. 28.)

III. SUMMARY JUDGMENT STANDARD

In deciding a motion for summary judgment under Rule 56, the Court applies the rules established by *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986), *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), and their Ninth Circuit progeny. "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

The Ninth Circuit has defined the shifting burden of proof governing motions for summary judgment where the non-moving party bears the burden of proof at trial:

> The moving party initially bears the burden of proving the absence of a genuine issue of material fact. Where the non-moving party bears the burden of proof at trial, the moving party need only prove that there is an absence of evidence to support the non-moving party's case. Where the moving party meets that burden, the burden then shifts to the non-moving party to designate specific facts demonstrating the existence of genuine issues for trial. This burden is not a light one. The non-moving party must show more than the mere existence of a scintilla of evidence.

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Coomes v. Edmonds Sch. Dist. No. 15, 816 F.3d 1255, 1259 n.2 (9th Cir. 2016) (quoting *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010)).

The Court's function at this stage is not to "weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 252. A genuine issue is one about which there is more than "some metaphysical doubt as to the material facts ...." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation omitted). Instead, to establish a genuine issue, the non-moving party must come forth with sufficient evidence from which a jury could reasonably render a verdict in the non-moving party's favor. *See Coomes*, 816 F.3d at 1259 n.2; *see also Matsushita*, 475 U.S. at 587 ("Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'").

Even though "all justifiable inferences" from the non-movant's evidence "are to be drawn in his favor," *Anderson*, 477 U.S. at 255, "[n]evertheless, inferences are not drawn out of the air, and it is the nonmoving party's obligation to produce a factual predicate from which the inference may be drawn." *Disney Enter., Inc. v. VidAngel, Inc.*, 371 F. Supp. 3d 708, 714 (C.D. Cal. 2019) (citing *Richards v. Nielson Freight Lines*, 602 F. Supp. 1224, 1244-45 (E.D. Cal. 1985), *aff'd*, 810 F.2d 898 (9th Cir. 1987)). A motion for summary judgment may not be defeated by evidence that is "merely colorable" or "is not significantly probative." *Anderson*, 477 U.S. at 249-50.

IV. PLAINTIFFS' CLAIMS ARE BARRED BY CALIFORNIA'S TWO-YEAR STATUTE OF LIMITATIONS

Under California law, Plaintiffs' claims are subject to a two-year statute of limitations for an action for "injury to . . . an individual caused by the wrongful act or neglect of another." *See* CAL. CODE CIV. PROC. § 335.1; *Edison v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 893 (N.D. Cal. 2013); *Viramontes v. Pfizer, Inc.*, No. 2:15-cv-1754 TLN AC (PS), 2015 WL 9319497 (E.D. Cal. Dec. 23, 2015) (discussing loss of consortium claim). The statute of limitations typically begins to run when all the

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

elements of the claim have occurred. *Soliman v. Philip Morris Inc.*, 311 F.3d 966, 971 (9th Cir. 2002).

The discovery rule "postpones accrual of a cause of action until the plaintiff discovers, or has reason to discover, the cause of action." *Edison*, 981 F. Supp. 2d at 893. Under the rule, discovery occurs once the plaintiff has reason to suspect the factual basis for his or her claim even if the plaintiff does not know the specific facts necessary to establish the claim. *See Gutierrez v. Mofid*, 39 Cal. 3d 892, 896-897 (1985). "A patient is charged with 'presumptive' knowledge of his negligent injury, and the statute commences to run, once he has 'notice or information or circumstances to put a reasonable person on inquiry, or has the opportunity to obtain knowledge from sources open to his investigation." *Gutierrez*, 39 Cal.3d at 897. "Once the plaintiff has a suspicion of wrongdoing, and therefore an incentive to sue, she must decide whether to file or sit on her rights. So long as a suspicion exists, it is clear that the plaintiff must go find the facts, she cannot wait for the facts to find her." *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1111 (Cal. 1988) (emphasis added).

Although the defendant has the burden of proving statute of limitations as an affirmative defense, the burden of pleading and establishing "belated discovery" is on Plaintiffs as the party relying on the discovery rule to toll the limitations period. *Czajkowski v. Haskell & White, LLP*, 208 Cal. App. 4th 166, 174-75 (Ct. App. 2012) (citations omitted); *accord Yamauchi v. Cotterman*, 84 F. Supp. 3d 993, 1011 (N.D. Cal. 2015).

A. Ms. Benjamin's Claims Are Time Barred.

1. Ms. Benjamin Had Actual Suspicion That ECT Caused Her Injury In March 2013.

Ms. Benjamin testified that when she stopped ECT treatment on March 4, 2013 she was experiencing unendurable side effects, including "[m]emory loss, pain in [her] body, bleeding, … difficulty walking, [and] complete confusion…." (Benkner Decl., Ex. G (Transcript of Deposition of Marcia Benjamin ("M. Benjamin Depo.")),

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

at 58:18-59:8, Docket No. 231-9.) She further stated that Dr. Frankel told her the side effects would be temporary and were expected to last about a month-and-a-half to two months. (*Id.* at 59:9-14.) Ms. Benjamin stated that she experienced side effects beyond the duration of time Dr. Frankel had indicated and, when she addressed this with him, he then told her that the side effects could persist for six months. (*Id.* at 59:21-60:7.) M. Benjamin testified that once Dr. Frankel said this, she no longer trusted him. (*Id.* at 60:1-14.)

Following the conclusion of her ECT treatments, Ms. Benjamin returned to see Dr. Gudeman, the doctor who had originally referred her to Dr. Frankel for ECT treatments, and she remembers Dr. Gudeman being shocked that Dr. Frankel had given her 20 ECT treatments when Dr. Gudeman had only asked for 6. (*Id.* at 60:16-20.) This was further grounds for Ms. Benjamin to be suspicious about a potential injury.

Ms. Benjamin later confirmed to another physician, Dr. Hirt, that she knew she was the victim of iatrogenic medicine (injury caused by medical treatment) in March 2013 after begging Dr. Frankel to stop her ECT treatment. (*Id.* at 98:13-99:8; Benkner Decl., Ex. I (Ex. 10 to M. Benjamin Depo.), at p. 1, Docket No. 231-11.) By her own admission, Ms. Benjamin not only suspected, but was actually convinced, that she suffered injury undergoing ECT treatment not later than the time she ceased treatment in **March 2013**. (*Id.*) This suspicion started the statute of limitations and required her to file a lawsuit no later than March 2015. *See Gutierrez*, 39 Cal. 3d at 897.

2. Ms. Benjamin's Actions Confirm That She Was Investigating Her Suspicions During the Two-Year Period Following the Conclusion of Her ECT Treatment.

That Ms. Benjamin knew or reasonably suspected that she was injured by ECT is evident by her actions in the two years following her ECT treatment. On **September 26, 2014**, Ms. Benjamin posted on her personal Facebook page a comment stating, "Excellent work!", with a link to an article titled, "A Prescription

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

for Love: An Introduction to Toxic Psychiatry." (Benkner Decl., Ex. G (M. Benjamin Depo.), at 106:5-107:17, 108:5-109:19, Docket No. 231-9; Benkner Decl., Ex. J (Ex. 15 to M. Benjamin Depo.), Docket No. 231-12; Benkner Decl., Ex. K (Ex. 14 to M. Benjamin Depo.), Docket No. 231-13.) The article to which Ms. Benjamin's September 26, 2014 Facebook post linked contains claims that individuals ended up with permanent brain dysfunction and damage from shock treatment. (*Id.*, Ex. K at p. 3.)

Furthermore, on **July 16, 2015**, Ms. Benjamin requested that Dr. Frankel provide all of her ECT records, including records identifying the machine model used in her treatment. (Benkner Decl., Ex. G (M. Benjamin Depo.), at 94:18-95:8, Docket No. 231-9; Benkner Decl., Ex. H (Ex. 8 to M. Benjamin Depo.) at p. 1, Docket No. 231-10.) Ms. Benjamin testified that she requested these records because she "wanted to understand what had been done to [her]." (Benkner Decl., Ex. G (M. Benjamin Depo.), at 94:9-12, Docket No. 231--9.)

Notwithstanding her confirmed knowledge of a potential claim in March 2013, Ms. Benjamin's documented investigation in September 2014 and July 2015 renders her claims, which were not brought until November 7, 2017, time barred. *See Jolly*, 44 Cal. 3d at 1110 ("Under the discovery rule, the statute of limitations begins to run when the plaintiff suspects or should suspect … that someone has done something wrong to her." (Emphasis added)).

B. Mr. Benjamin's Loss of Consortium Claim Is Time Barred.

Given that Mr. Benjamin's loss of consortium claim is derivative of Ms. Benjamin's time barred claims, his loss of consortium claim is also time barred. *Viramontes*, 2015 WL 9319497 at *10. Moreover, Mr. Benjamin testified that his loss of consortium claim originated when Ms. Benjamin began undergoing ECT treatment. (Benkner Decl., Ex. L (Transcript of Deposition of Daniel Benjamin) at 44:15-45:15, Docket No. 231-14.)

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

C. Ms. Himes' Claims Are Time Barred.

A reasonable person in Ms. Himes' position would have suspected that ECT caused her injury no later than Autumn 2012. Ms. Himes contends that ECT caused her, in part, cognitive impairment resulting in permanent loss of past memory, chronic and lasting short term memory difficulties, and the inability to recall or retain information. (Benkner Decl., Ex. C (Michelle Himes' Responses to Interrogatories Propounded by Mecta, Set One), at 3:13-20, Docket No. 231-5.) Ms. Himes further stated that she had a total blackout period where she could not recall anything extending from the period when she underwent ECT (April 13, 2011 to January 9, 2012) and lasting for several months afterward, until the Autumn of 2012. (Benkner Decl., Ex. D (Transcript of Deposition of Michelle Himes ("Himes Depo.")), at 31:20-32:2, 36:14-20, 37:5-24, Docket No. 231-6.) According to Ms. Himes, her ECT physician, Dr. Fidaleo, did not warn her that she could experience long-term impairment of her ability to learn and retain new information (anterograde amnesia). (Benkner Decl., Ex. A (Michelle Himes' Responses to Interrogatories Propounded by Somatics, Set One), at 26:3-13, 28:10-17, Docket No. 231-3.) Nevertheless, Dr. Fidaleo testified that he advises his patients that they may experience anterograde amnesia for approximately two months following ECT treatment. (Benkner Decl., Ex. B (Fidaleo Depo.), at 30:17-31:20, Docket No. 231-4.) At a minimum, a reasonable person would have reason to suspect that she had suffered an injury from ECT once the "blackout period", which extended considerably more than two months following her ECT treatment, had lifted. At that point, especially given the severity of the injury she alleges, Ms. Himes had inquiry notice and would be deemed to have presumptive knowledge of a possible claim. *See Gutierrez*, 39 Cal. 3d at 897. Ms. Himes therefore had an affirmative obligation to investigate the source of her injury once the blackout period lifted, and the limitations period on her claim began to run. *Jolly*, 44 Cal. 3d at 1111. Instead, Ms. Himes indicated that, for personal reasons, she affirmatively avoided pursuing any investigation into her purported injury or its

source. (Benkner Decl., Ex. D (Himes Depo.), at 40:15-23, Docket No. 231-6.) By failing to bring her lawsuit by Autumn 2014, two years after her blackout period lifted, Ms. Himes' claims are barred by the statute of limitations.

V. PLAINTIFFS CANNOT ESTABLISH CAUSATION BETWEEN THEIR ALLEGED INJURIES AND DEFENDANT'S WARNINGS

A. The Learned Intermediary Doctrine Applies to Plaintiffs' Failure to Warn Claims.

California follows the learned-intermediary doctrine, which provides that the manufacturer's duty to warn runs only to the physician, not the patient. *Renteria v. Ethicon, Inc.*, No. CV 20-5673-MWF-KESx, 2020 WL 7414744, at *7 (C.D. Cal. Nov. 18, 2020) (citations omitted). The doctrine applies to product liability claims challenging the adequacy of a product's warnings, regardless of the theory attached, be it negligence or strict liability. *See Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 989 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659, 660-61 (9th Cir. 2004). "Thus, a manufacturer discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient." *Id.* at 990-91. Where the doctrine applies, it is the plaintiff's burden to prove "not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Id.* at 991; *see Latiolais v. Merck & Co.*, 302 F. App'x 756, 757 (9th Cir. 2008).

"[I]nadequacy of the warning and causation are *separate* elements of [the plaintiff's] affirmative burden." *Tucker v. Wright Med. Tech., Inc.*, No. 11-CV-03086-YGR, 2013 WL 1149717, at *16 (N.D. Cal. Mar. 19, 2013) (emphasis in original).

///

///

///

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

B. Plaintiffs Cannot Establish That Any Additional Warnings Would Have Changed Their ECT Doctors' Decisions to Recommend and Administer ECT.

A product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the physician's decision to prescribe the treatment at issue. *Motus*, 196 F. Supp. 2d at 991. Even if additional warnings from a device manufacturer might have caused a treating physician to alter the warnings he or she provided to patients, that does not establish a genuine dispute as to whether the physician's decision to recommended that treatment course would have been altered by such an additional warning. *Id.* at 997. "The burden [is] on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product *for the plaintiff*." *Id.* at 995-96 (emphasis added).

1. Additional Warnings Would Not Have Altered Dr. Fidaleo's Recommendation of ECT to Himes.

"Where a physician did not read the manufacturer's product warnings, there is no causal connection on the failure to warn claim as a matter of law." *Renteria*, 2020 WL 7414744 at *7 (citing *Motus*, 358 F.3d at 661); *see also Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 556 (1993) (where the product warnings were not read, "there is no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury."). "Where the physician did not read warnings, adequacy [of those warnings] is irrelevant." *Tucker*, 2013 WL 1149717, at *16 (granting the defendant's motion for summary judgment on failure to warn because plaintiff could not show a stronger warning would have change plaintiff's physician's mind as he failed to read the warning which was given). At the time in question, Somatics provided warnings disclosures in its operator's manual and in a patient information pamphlet. (Declaration of Conrad Swartz, M.D., Ph.D. ("Swartz Decl.") ¶ 6, Docket No. 231-16.) Dr. Fidaleo did not read either. (Benkner Decl., Ex.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

B (Fidaleo Depo.), at 14:7-9, 94:10-95:9, Docket No. 231-4.) Accordingly, a causal connection between Ms. Himes' claimed injuries and Somatics' warnings cannot be established as a matter of law.

Moreover, Dr. Fidaleo's deposition testimony makes it clear that he still would have recommended ECT even if he had been informed of other potential risks proposed by Plaintiffs. Specifically, Dr. Fidaleo discussed how Ms. Himes presented to him in dire status, including numerous prior hospitalizations for a progressively worsening condition that made her an imminent threat to herself and a potential threat to her family, having failed to respond to other forms of less-intrusive treatment.[1] (Benkner Decl., Ex. B (Transcript of Deposition of Raymond Fidaleo, M.D. ("Fidaleo Depo.")), at 22:17-23:5; Benkner Decl., Ex. M (Redacted Portions of Fidaleo Depo. Pending Application to File Under Seal), 24:2-25:12, 26:19-27:8, Docket No. 231-15.) So, according to Dr. Fidaleo, ECT treatment was necessary to save Ms. Himes' life as well as to ensure the safety of her family. (Benkner Decl., Ex. M (Redacted Portions of Fidaleo Depo. Pending Application to File Under Seal), at 26:19-27:8.)

Dr. Fidaleo further stated that he was not concerned about a risk of brain damage because it is a treatment of last resort to help people who have no other alternatives. (Benkner Decl., Ex. B ("Fidaleo Depo."), at 34:15-35:5.) He confirmed that being informed of a risk of permanent memory loss would not deter his recommendation of ECT (*id.* at 64:19-65:8), and further that being informed of a risk of the inability to form new memories would need to be corroborated by his own clinical observations; and in his decades of performing ECT treatment, he has never observed such a problem. (*Id.* at 67:9-68:25.) Therefore, Dr. Fidaleo's determination of the pressing need for Ms. Himes to undergo ECT would not have been affected by

---

[1] To protect Ms. Himes' privacy, portions of the testimony of Dr. Fidelio identified as Ex. M to Benkner Decl. (Docket No. __-15) have been redacted subject to a pending Application for Leave to File Under Seal (Docket No. __.) Defendant will provide an unredacted copy of the exhibit testimony upon the issuance of a ruling on the Application.

any further warnings from Somatics.

2. Additional Warnings Would Not Have Altered Dr. Frankel's Recommendation of ECT to Ms. Benjamin.

Even in instances where a physician reads a manufacturer's warnings, summary judgment is still appropriate when a doctor confirms that he did not rely on those warnings. *See Renteria*, 2020 WL 7414744 at *7; *Sharp v. Ethicon, Inc.*, No. 2:20-CV-2028, 2020 WL 1434566 (W.D. Ark. March 24, 2020).

Here, Dr. Frankel confirmed that he did not rely on <u>any</u> representation from Somatics to aid his understanding of the risks of ECT treatment. (Benkner Decl., Ex. F (Frankel Depo.), at 14:4-15:7; Docket No. 231-4.) Dr. Frankel also indicated that stronger warnings would not affect his decision to recommend ECT treatment. (Benkner Decl., Ex. F (Frankel Depo.), at 18:16-19:7, 54:6-11, Docket No. 231-4.) Accordingly, causation between Ms. Benjamin's purported injuries and Somatics' warnings cannot be established. *See Plummer v. Lederle Laboratories,* 819 F.2d 349, 358 (2d Cir. 1987) (applying California law) (doctor's testimony that he would not have changed his recommendation despite any additional warnings generally entitles defendant to summary judgment).

VI. PLAINTIFFS CANNOT ESTABLISH CAUSATION FOR THEIR CLAIMS OF ADULTERATION AND MISBRANDING

In addition to the foregoing, and as separate and independent grounds, Defendant is also entitled to summary judgment in its favor on Plaintiffs' First and Fourth Claims alleging liability for adulteration and misbranding. (*See* 5AC.) To prevail on their adulteration and misbranding claims, Plaintiffs must establish a causal link between any alleged adulteration or misbranding by Defendant and the Plaintiffs' injuries. *See De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1095 (N.D. Cal. 2016). Plaintiffs allege that, if not for Somatics' failures to warn, the FDA would have been alerted to the risk of long term or permanent cognitive impairment and brain damage and would have taken the Thymatron off the market. (5AC, ¶ 75, p. 22,

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

Docket No. 178.) However, in their own pleading, Plaintiffs expressly concede that the FDA knew claims of the type alleged by Plaintiffs were being made by virtue of submissions to a public docket opened from 2009 to 2010 to consider reclassification of ECT devices. (*Id.*, ¶ 59, 59:20-23) Indeed, according to the FDA's own summary, it received over 3,000 submissions to its public docket, the majority of which cited adverse events from ECT treatment as the basis for opposing reclassification of ECT devices. *See* 80 Fed. Reg. 81226 (Dec. 29, 2015). "The most common type of adverse event mentioned in the public docket were memory adverse events, followed by other cognitive complaints, brain damage, and death." *Id.* Notwithstanding these submissions, and the FDA's awareness of the same, the FDA has not prevented Somatics from selling or marketing its device to customers or potential customers. (Swartz Decl. ¶ 3, Docket No. 231-16.) On the contrary, the FDA has expressly acknowledged the significant risks associated with ECT but continues to believe that "the probable benefit to health from use of the [ECT] device outweighs the probable injury or illness from such use." 80 Fed. Reg. 81227 (Dec. 29, 2015). Therefore, even if, *arguendo*, Plaintiffs were able to establish that Defendant failed to properly warn of the risks of ECT treatment, Plaintiffs cannot establish the element of causation with respect to their claims for adulteration and misbranding because they cannot establish that the FDA would have prevented Defendant from selling or marketing its devices. As a result, Defendant is entitled to summary judgment in its favor on Plaintiffs' adulteration and misbranding claims.

VII. CONCLUSION

Based on the foregoing, Defendant requests that the Court grant summary judgment in its favor and against Plaintiffs on the grounds that all of Plaintiffs' claims are barred by the statute of limitations, that Plaintiffs cannot establish a causal connection between any alleged failures by Somatics to warn of risks from ECT treatment, and that Plaintiffs cannot establish a causal connection between any purported adulteration or misbranding of Somatics' ECT devices and Plaintiffs'

alleged injuries.

DATED: March 31, 2021

POOLE SHAFFERY & KOEGLE, LLP

By: /s/ Jason A. Benkner
David S. Poole
Jason A. Benkner
Attorneys for Defendant, SOMATICS, LLC

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **March 31, 2021**, I served the foregoing document described as: **SOMATICS, LLC'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **March 31, 2021**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

Nicole Lyons, Declarant

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

SERVICE LIST

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

Bijan Esfandiari, Esq.
Monique Alarcon, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
T: 310-207-3233
F: 310-820-7444
For e-service:
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
CHall@BaumHedlundLaw.com
vadlivankina@baumhedlundlaw.com
jjoseph@baumhedlundlaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY & KOEGLE, LLP
David S. Poole (CA SBN 94690)
dpoole@pooleshaffery.com
Jason A. Benkner (CA SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway, Suite 250
Santa Clarita, CA 91355
(661) 290-2991 Tel.
(661) 290-3338 Fax

Attorneys for Defendant
SOMATICS, LLC

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC;

Defendant.

Case No.: 2:17-CV-06686-RGK-JCx
Assigned to Hon. R. Gary Klausner

SOMATICS, LLC'S STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW

[Filed concurrently with Motion for Summary Judgment; Declarations of Jason A. Benkner and Conrad Swartz; [Proposed] Order]

Date: May 3, 2021
Time: 9:00 a.m.
Ctrm.: 805

Trial Date: June 15, 2021

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56-1, Defendant SOMATICS, LLC ("Somatics") submits this Statement of Uncontroverted Facts and Conclusions of Law in support of its Motion for Summary Judgment.

///

///

///

///

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

UNCONTROVERTED FACTS

Uncontroverted Fact	Supporting Evidence
1. On September 11, 2017, Plaintiff MICHELLE HIMES ("Ms. Himes") filed a complaint against SOMATICS, LLC ("Somatics") in this action.	Complaint, Docket No. 4.
2. On November 7, 2017, Plaintiffs MARCIA BENJAMIN ("Ms. Benjamin") and Plaintiff DANIEL BENJAMIN ("Mr. Benjamin") were added as parties to this action with the filing of the First Amended Complaint.	First Amended Complaint, Docket No. 22.
3. On June 19, 2018, Ms. Himes, Ms. Benjamin, and Mr. Benjamin (collectively, "Plaintiffs") were dismissed from this action pursuant to a Motion to Dismiss.	Minute Order dated June 19, 2018, Docket No. 70.
4. On October 30, 2018, Plaintiffs filed a notice of appeal from the order dismissing them from this action.	Notice of Appeal to Ninth Circuit Court of Appeals, Docket No. 161.
5. On April 7, 2020, the United States Court of Appeals for the Ninth Circuit reversed and remanded this Court's order dismissing Plaintiffs.	Ninth Circuit Memorandum Decision, Docket No. 168.

Uncontroverted Fact	Supporting Evidence
6. The Ninth Circuit reasoned that this Court erred in dismissing Plaintiffs' claims as being time barred because the operative complaint did not identify the dates that Plaintiffs were injured.	Ninth Circuit Memorandum Decision, p. 3, Docket No. 168.
7. On June 15, 2020, Plaintiffs filed the Fifth Amended Complaint ("5AC"), which is the operative complaint.	Fifth Amended Complaint ("5AC"), Docket No. 178.
8. Ms. Himes underwent electroconvulsive therapy ("ECT") at Sharp Mesa Vista Hospital from Dr. Raymond Fidaleo between April 13, 2011 to January 9, 2012.	Declaration of Jason A. Benkner ("Benkner Decl."), Ex. A (Michelle Himes' Responses to Interrogatories Propounded by Somatics, Set One), at 26:3-13, 28:1-9, Docket No. 231-3.
9. Ms. Himes contends that ECT cause her to experience cognitive impairment resulting in permanent loss of past memories, chronic and lasting short term memory difficulties, and the ability to recall or retain information.	Benkner Decl., Ex. C (Michelle Himes' Responses to Interrogatories Propounded by Mecta, Set One), at 3:13-20, Docket No. 231-5.
10. Ms. Benjamin underwent ECT at Northridge Hospital from September 28, 2012 to March 4, 2013.	Benkner Decl., Ex. E (Marcia Benjamin's Responses to Interrogatories, Set One), at 26:10-19, 28:6-13, Docket No. 231-7.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Uncontroverted Fact	Supporting Evidence
11. Dr. Michael Frankel, M.D. recommended and administered ECT to Ms. Benjamin.	Benkner Decl., Ex. F (Transcript of Deposition of Michael Frankel, M.D. ("Frankel Depo.")), at 20:2-20, 36:6-17, Docket No. 231-8.
12. Ms. Benjamin stated when she stopped ECT treatment on March 4, 2013 she was experiencing unendurable side effects, including "[m]emory loss, pain in [her] body, bleeding, … difficulty walking, [and] complete confusion…."	Benkner Decl., Ex. G (Transcript of Deposition of Marcia Benjamin ("M. Benjamin Depo.")), at 58:18-59:8, Docket No. 231-9.
13. Ms. Benjamin stated that Dr. Frankel advised her that the side effects she was experiencing during her ECT treatment would last about a month and a half to two months.	Benkner Decl., Ex. G (M. Benjamin Depo.), at 59:9-14, Docket No. 231-9.
14. Ms. Benjamin stated that when she advised Dr. Frankel that the side effects of her ECT treatment were persisting longer than two months after treatment ended, he told her that they could persist for six months.	Benkner Decl., Ex. G (M. Benjamin Depo.), at 59:21-60:7, Docket No. 231-9.
15. When Dr. Frankel revised his opinion regarding the duration of ECT side effects to six months, Ms. Benjamin stated that she no longer believed him to be honest.	Benkner Decl., Ex. G (M. Benjamin Depo.), at 60:1-14, Docket No. 231-9.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Uncontroverted Fact	Supporting Evidence
16. Ms. Benjamin testified that she returned to see Dr. Gudeman, the doctor who had originally referred her to Dr. Frankel, after her ECT treatments and she remembers Dr. Gudeman being shocked that Dr. Frankel had given her 20 ECT treatments when Dr. Gudeman had only asked for 6.	Benkner Decl., Ex. G (M. Benjamin Depo.), at 60:16-20, Docket No. 231-9.
17. Ms. Benjamin reported to Dr. Hirt that she knew she had been the victim of iatrogenic medicine in March 2013 after begging Dr. Frankel to stop her ECT treatment.	Benkner Decl., Ex. G (M. Benjamin Depo.), at 98:13-99:8, Docket No. 231-9; Benkner Decl., Ex. I (Ex. 10 to M. Benjamin Depo.), at p. 1, Docket No. 231-11
18. On September 26, 2014, Ms. Benjamin commented "Excellent work!" and posted a link on her Facebook page to an article entitled, "A Prescription for Love: An Introduction to Toxic Psychiatry".	Benkner Decl., Ex. G (M. Benjamin Depo.), at 106:5-107:17, 108:5-109:19, Docket No. 231-9; Benkner Decl., Ex. J (Ex. 15 to M. Benjamin Depo.), Docket No. 231-12; Benkner Decl., Ex. K (Ex. 14 to M. Benjamin Depo.), Docket No. 231-13.
19. The article to which Ms. Benjamin's September 26, 2014 Facebook post linked contains claims that individuals ended up with permanent brain dysfunction and damage from shock treatment.	Benkner Decl., Ex. K (Ex. 14 to M. Benjamin Depo.), at p. 3, Docket No. 231-13.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Uncontroverted Fact	Supporting Evidence
20. Ms. Benjamin stated that she had seen and recognizes the article to which her September 26, 2014 Facebook post linked and that she has read materials and viewed videos published by Dr. Peter Breggin, the author of the book *Toxic Psychiatry*, which is the subject of the posted article.	Benkner Decl., Ex. G (M. Benjamin Depo.), at 106:5-107:17, 108:5-109:19, Docket No. 231-9; Benkner Decl., Ex. K (Ex. 14 to M. Benjamin Depo.), Docket No. 231-13.
21. On July 16, 2015, Ms. Benjamin requested her ECT records from Dr. Frankel, including identification of the machine model used in her treatment.	Benkner Decl., Ex. G (M. Benjamin Depo.), at 94:18-95:8, Docket No. 231-9; Benkner Decl., Ex. H (Ex. 8 to M. Benjamin Depo.) at p. 1, Docket No. 231-10.
22. Ms. Benjamin stated that she sought her ECT records from Dr. Frankel because she "wanted to understand what had been done to her."	Benkner Decl., Ex. G (M. Benjamin Depo.), at 94:9-12, Docket No. 231-9.
23. Mr. Benjamin testified that his sexual relationship with Ms. Benjamin was adversely affected when Ms. Benjamin underwent ECT treatment.	Benkner Decl., Ex. L (Transcript of Deposition of Daniel Benjamin) at 44:15-45:15, Docket No. 231-14.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Uncontroverted Fact	Supporting Evidence
24. Ms. Himes stated that she experienced a blackout period that she attributed to ECT where her ability to remember events was totally impaired, extending from a period when she underwent ECT until Autumn 2012.	Benkner Decl., Ex. D (Transcript of Deposition of Michelle Himes ("Himes Depo.")), at 31:20-32:2, 36:14-20, 37:5-24, Docket No. 231-6.
25. According to Ms. Himes, Dr. Fidaleo did not warn her that she could experience long-term impairment to her ability to learn or retain new information.	Benkner Decl., Ex. A (Michelle Himes' Responses to Interrogatories Propounded by Somatics, Set One), at 26:3-13, 28:10-17, Docket No. 231-3.
26. Dr. Fidaleo stated that Ms. Himes presented to him in dire status, including numerous prior hospitalizations for a progressively worsening condition that made her an imminent threat to herself and a potential threat to her family, having failed to respond to other forms of less-intrusive treatment.	Benkner Decl., Ex. B (Transcript of Deposition of Raymond Fidaleo, M.D. ("Fidaleo Depo.")), at 22:17-23:5, 24:2-25:12, 26:19-27:8, Docket No. 231-4.
27. Dr. Fidaleo testified that he warns his patients that their ability to remember and to work and to function would come back within two weeks to two months following treatment.	Benkner Decl., Ex. B (Fidaleo Depo.), at 30:17-31:20, Docket No. 231-4.

Uncontroverted Fact	Supporting Evidence
28. Ms. Himes indicated that, for personal reasons, she did not inform her doctors of the ongoing problems she was experiencing after ECT.	Benkner Decl., Ex. D (Himes Depo.), at 40:15-23, Docket No. 231-6.
29. Up through the dates that Ms. Himes and Ms. Benjamin underwent ECT treatment, Somatics' warnings regarding the risks of ECT treatment were published in two sources: (1) in the operator's manual provided with the device and (2) in a patient information pamphlet.	Declaration of Conrad Swartz, M.D., Ph.D. ("Swartz Decl."), ¶ 6, Docket No. 231-15.
30. Dr. Fidaleo stated that he did not recall reading the operator's manual for Somatics ECT device.	Benkner Decl., Ex. B (Fidaleo Depo.), at 14:7-9, Docket No. 231-4.
31. Dr. Fidaleo stated that he had not seen Somatics' patient information pamphlet.	Benkner Decl., Ex. B (Fidaleo Depo.), at 94:10-95:9, Docket No. 231-4.
32. Dr. Fidaleo stated that he was not concerned that brain damage was a risk of treatment because ECT is a treatment of last resort to help people who exhibit suicidality.	Benkner Decl., Ex. B (Fidaleo Depo.), at 34:19-35:5, Docket No. 231-4.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Uncontroverted Fact	Supporting Evidence
33. Dr. Fidaleo stated that if he were informed by the manufacturer that ECT carried a risk of permanent memory loss, it would not prevent him from recommending ECT treatment.	Benkner Decl., Ex B (Fidaleo Depo.), at 64:19-65:8, Docket No. 231-4.
34. Dr. Fidaleo stated that even if a manufacturer told him there was a risk of losing the ability to form new memories, he would need to see evidence of it himself in his clinical practice.	Benkner Decl., Ex B (Fidaleo Depo.), at 67:9-68:25, Docket No. 231-4.
35. Dr. Fidaleo has never spoken with anyone from Somatics, LLC.	Benkner Decl., Ex B (Fidaleo Depo.), at 7:8-16, Docket No. 231-4.
36. Dr. Frankel stated that he did not rely on any disclosures from Somatics to inform him of the risks of ECT.	Benkner Decl., Ex. F (Frankel Depo.), at 14:4-15:7, Docket No. 231-4.
37. Dr. Frankel testified that he does not pay much attention to updated safety information provided by manufacturers of drugs or devices.	Benkner Decl., Ex. F (Frankel Depo.), at 54:6-11, Docket No. 231-4.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Uncontroverted Fact	Supporting Evidence
38. Dr. Frankel testified that he was not concerned about complaints of cognitive disturbances in patients because he is careful to make sure that every other treatment option has been exhausted before using ECT and that patients will almost exclusively choose ECT despite the possibility of side effects.	Benkner Decl., Ex. F (Frankel Depo.), at 18:16-19:7, Docket No. 231-4.
39. Dr. Frankel does not recall having any conversations with anyone from Somatics, LLC.	Benkner Decl., Ex. F (Frankel Depo.), at 7:4-18, Docket No. 231-4.
40. At all times during its existence, Somatics has operated with permission to sell its ECT devices from the Food and Drug Administration ("FDA") though Section 510(k) clearance.	Swartz Decl. ¶ 3, Docket No. 231-15.
41. Between 2009 and 2011, the FDA was directly advised of thousands of purported adverse event complaints resulting from ECT treatment.	5AC, ¶ 59., 18:20-23, Docket No. 178; 80 F.R. 81226.

Uncontroverted Fact	Supporting Evidence
42. The FDA has expressly acknowledged the significant risks associated with ECT but continues to believe that "the probable benefit to health from use of the [ECT] device outweighs the probable injury or illness from such use."	80 F.R. 81227.

///

///

///

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

CONCLUSIONS OF LAW

1. In deciding a motion for summary judgment under Rule 56, the Court applies the rules established by *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986), *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), and their Ninth Circuit progeny. "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

2. The Ninth Circuit has defined the shifting burden of proof governing motions for summary judgment where the non-moving party bears the burden of proof at trial:

> The moving party initially bears the burden of proving the absence of a genuine issue of material fact. Where the non-moving party bears the burden of proof at trial, the moving party need only prove that there is an absence of evidence to support the non-moving party's case. Where the moving party meets that burden, the burden then shifts to the non-moving party to designate specific facts demonstrating the existence of genuine issues for trial. This burden is not a light one. The non-moving party must show more than the mere existence of a scintilla of evidence.

Coomes v. Edmonds Sch. Dist. No. 15, 816 F.3d 1255, 1259 n.2 (9th Cir. 2016) (quoting *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010)).

3. The Court's function at this stage is not to "weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 252. A genuine issue is one about which there is more than "some metaphysical doubt as to the material facts ...." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation omitted). Instead, to establish a genuine issue, the non-moving party must come forth with sufficient evidence from which a jury could reasonably render a verdict in the non-moving party's favor. *See Coomes*, 816 F.3d at 1259 n.2; *see also Matsushita*, 475 U.S. at

587 ("Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'"). "A motion for summary judgment may not be defeated, however, by evidence that is 'merely colorable' or 'is not significantly probative.'" *Anderson*, 477 U.S. at 249-50.

4. Under California law, Plaintiffs' claims are subject to a two-year statute of limitations for an action for "injury to . . . an individual caused by the wrongful act or neglect of another." *See* CAL. CODE CIV. PROC. § 335.1; *Edison v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 893 (N.D. Cal. 2013); *Viramontes v. Pfizer, Inc.*, No. 2:15-cv-1754 TLN AC (PS), 2015 WL 9319497 (E.D. Cal. Dec. 23, 2015) (discussing loss of consortium claim).

5. The discovery rule "postpones accrual of a cause of action until the plaintiff discovers, or has reason to discover, the cause of action." *Edison*, 981 F. Supp. 2d at 893. Under the rule, discovery occurs once the plaintiff has reason to suspect the factual basis for his or her claim, even if the plaintiff does not know the specific facts necessary to establish the claim. *See Gutierrez v. Mofid*, 39 Cal. 3d 892, 896-897 (1985).

6. "A patient is charged with 'presumptive' knowledge of his negligent injury, and the statute commences to run, once he has 'notice or information or circumstances to put a reasonable person on inquiry, or has the opportunity to obtain knowledge from sources open to his investigation." *Gutierrez*, 39 Cal.3d at 897. "Once the plaintiff has a suspicion of wrongdoing, and therefore an incentive to sue, she must decide whether to file or sit on her rights. So long as a suspicion exists, it is clear that the plaintiff must go find the facts, she cannot wait for the facts to find her." *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1111 (Cal. 1988) (emphasis added).

7. Although the defendant has the burden of proving statute of limitations as an affirmative defense, the burden of pleading and establishing "belated discovery" is on Plaintiffs as the party relying on the discovery rule to toll the limitations period. *Czajkowski v. Haskell & White, LLP*, 208 Cal. App. 4th 166, 174-75 (Ct. App. 2012)

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

(citations omitted); *accord Yamauchi v. Cotterman*, 84 F. Supp. 3d 993, 1011 (N.D. Cal. 2015).

8. Plaintiff Ms. Benjamin suspected or should have suspected that she suffered injury undergoing ECT treatment more than two years prior to filing her suit against Defendant. When she first suspected injury, she had presumptive knowledge of her claims. This suspicion started the statute of limitations and required her to file a lawsuit prior to November 7, 2015. *See Gutierrez*, 39 Cal. 3d at 897. Therefore, Ms. Benjamin's claims are time-barred.

9. Plaintiff Mr. Benjamin's loss of consortium claim is derivative of Ms. Benjamin's time-barred claims and, therefore, is also time barred. *Viramontes*, 2015 WL 9319497 at *10.

10. Plaintiff Ms. Himes suspected or should have suspected that she suffered injury undergoing ECT treatment more than two years prior to filing her suit against Defendant. When she first suspect or should have suspected injury, she had presumptive knowledge of her claims. This suspicion started the statute of limitations and required her to file a lawsuit prior to September 11, 2015. *See Gutierrez*, 39 Cal. 3d at 897. Therefore, Ms. Himes' claims are time-barred.

11. California follows the learned-intermediary doctrine, which provides that the manufacturer's duty to warn runs only to the physician, not the patient. *Renteria v. Ethicon, Inc.*, Case No. CV 20-5673-MWF-KESx, 2020 WL 7414744, at *7 (C.D. Cal. Nov. 18, 2020) (citations omitted). The doctrine applies to product liability claims challenging the adequacy of a product's warnings, regardless of the theory attached, be it negligence or strict liability. *See Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 989 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659, 660-61 (9th Cir. 2004). "Thus, a manufacturer discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient." *Id.* at 990-91. Where the doctrine applies, it is the plaintiff's burden to prove "not only that no warning was

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

provided or that the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Id.* at 991; *see Latiolais v. Merck & Co.*, 302 F. App'x 756, 757 (9th Cir. 2008).

12. A product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the physician's decision to prescribe the treatment at issue. *Motus*, 196 F. Supp. 2d at 991. Even if additional warnings from a device manufacturer might have caused a treating physician to alter the warnings he or she provided to patients, that does not establish a genuine dispute as to whether the physician's decision to recommended that treatment course would have been altered by such an additional warning. *Id.* at 997.

13. "Where a physician did not read the manufacturer's product warnings, there is no causal connection on the failure to warn claim as a matter of law." *Renteria*, 2020 WL 7414744 at *7 (citing *Motus*, 358 F.3d at 661); *see also Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 556 (1993) (where the product warnings were not read, "there is no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury."). "Where the physician did not read warnings, adequacy [of those warnings] is irrelevant." *Tucker*, 2013 WL 1149717, at *16 (granting the defendant's motion for summary judgment on failure to warn because plaintiff could not show a stronger warning would have change plaintiff's physician's mind as he failed to read the warning which was given). Even in instances where a physician reads a manufacturer's warnings, summary judgment is still appropriate when a doctor confirms that he did not rely on those warnings. *See Renteria*, 2020 WL 7414744 at *7; *Sharp v. Ethicon, Inc.*, No. 2:20-CV-2028, 2020 WL 1434566 (W.D. Ark. March 24, 2020).

14. Ms. Himes cannot establish that any additional warnings by Defendant about the risks of ECT treatment would have altered the decision by her ECT physician, Dr. Fidaleo, to recommend ECT treatment for her. Therefore, Plaintiff Ms.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Himes cannot establish a causal connection between Defendant's warnings and her alleged injuries.

15. Ms. Benjamin cannot establish that any additional warnings by Defendant about the risks of ECT treatment would have altered the decision by her ECT physician, Dr. Frankel, to recommend ECT treatment for her. Therefore, Ms. Benjamin cannot establish a causal connection between Defendant's warnings and her alleged injuries.

16. To prevail on their claims based on adulteration and misbranding, Plaintiffs must establish a causal link between any such adulteration or misbranding by Defendant and the Plaintiffs' injuries. *See De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1095 (N.D. Cal. 2016).

17. Even if Plaintiffs were able to establish that Defendant failed to properly warn of the risks of ECT treatment, Plaintiffs cannot establish the element of causation with respect to their claims for adulteration and misbranding because they cannot establish that the FDA would have prevented Defendant from selling or marketing its devices.

DATED: March 31, 2021

POOLE SHAFFERY & KOEGLE, LLP

By: /s/ Jason Benkner
David S. Poole
Jason A. Benkner
Attorneys for Defendant,
SOMATICS, LLC

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **March 31, 2021**, I served the foregoing document described as: **SOMATICS, LLC'S STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **March 31, 2021**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

Nicole Lyons, Declarant

SERVICE LIST

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

Bijan Esfandiari, Esq.
Monique Alarcon, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
T: 310-207-3233
F: 310-820-7444
For e-service:
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
CHall@BaumHedlundLaw.com
vadlivankina@baumhedlundlaw.com
jjoseph@baumhedlundlaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY & KOEGLE, LLP
David S. Poole (CA SBN 94690)
dpoole@pooleshaffery.com
Jason A. Benkner (CA SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway, Suite 250
Santa Clarita, CA 91355
(661) 290-2991 Tel.
(661) 290-3338 Fax

Attorneys for Defendant
SOMATICS, LLC

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC;

Defendant.

Case No.: 2:17-CV-06686-RGK-JCx
Assigned to Hon. R. Gary Klausner

DECLARATION OF JASON A. BENKNER IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Date: May 3, 2021
Time: 9:00 a.m.
Ctrm.: 805

Trial Date: June 15, 2021

DECLARATION OF JASON A. BENKNER

I, Jason A. Benkner, declare:

1. I am an attorney at Poole Shaffery & Koegle, LLP, counsel for Defendant Somatics, LLC. I am authorized to practice before this Court, and I am not a party to this action. I have personal knowledge of all facts set forth herein and, if called as a witness, I could and would testify competently thereto each of them.

2. Attached hereto as **Exhibit A** (Docket No. 231-3) is a true and correct copy of the pertinent pages from Plaintiff Michelle Himes' Responses to Interrogatories Propounded by Somatics in this action.

3. Attached hereto as **Exhibit B** (Docket No. 231-4) is a true and correct copy of the pertinent pages from the transcript of the Deposition of Raymond Fidaleo, M.D., taken in this action on February 12, 2021, which has been redacted as necessary to protect the privacy rights of Plaintiff Michelle Himes.

4. Attached hereto as **Exhibit C** (Docket No. 231-5) is a true and correct copy of the pertinent pages from Michelle Himes' Responses to Interrogatories Propounded by Mecta in this action.

5. Attached hereto as **Exhibit D** (Docket No. 231-6) is a true and correct copy of the pertinent pages from the transcript of the Deposition of Michelle Himes, taken in this action on February 25, 2021, which has been redacted as necessary to protect the privacy rights of Ms. Himes.

6. Attached hereto as **Exhibit E** (Docket No. 231-7) is a true and correct copy of the pertinent pages from Marcia Benjamin's Responses to Interrogatories Propounded by Mecta in this action.

7. Attached hereto as **Exhibit F** (Docket No. 231-8) is a true and correct copy of the pertinent pages from the transcript of the Deposition of Michael Frankel, M.D., taken in this action on February 19, 2021, which has been redacted as necessary to protect the privacy rights of Ms. Benjamin.

8. Attached hereto as **Exhibit G** (Docket No. 231-9) is a true and correct copy of the pertinent pages from the transcript of the Deposition of Marcia Benjamin, taken in this action on February 17, 2021 ("M. Benjamin Depo."), which has been redacted as necessary to protect the privacy rights of Ms. Benjamin.

9. Attached hereto as **Exhibit H** (Docket No. 231-10) is a true and correct copy of Exhibit 8 to the M. Benjamin Depo., which has been redacted as necessary to protect the privacy rights of Ms. Benjamin.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

10. Attached hereto as **Exhibit I** (Docket No. 231-11) is a true and correct copy of Exhibit 10 to the M. Benjamin Depo., which has been redacted as necessary to protect the privacy rights of Ms. Benjamin.

11. Attached hereto as **Exhibit J** (Docket No. 231-12) is a true and correct copy of Exhibit 15 to the M. Benjamin Depo.

12. Attached hereto as **Exhibit K** (Docket No. 231-13) is a true and correct copy of Exhibit 14 to the M. Benjamin Depo.

13. Attached hereto as **Exhibit L** (Docket No. 231-14) is a true and correct copy of the pertinent pages from the transcript of the Deposition of Daniel Benjamin, taken in this action on March 4, 2021.

14. Attached hereto as **Exhibit M** (Docket No. 231-14) is a true and correct copy of the pertinent pages from the transcript of the Deposition of Raymond Fidaleo, M.D., taken in this action on February 12, 2021. These passages have been redacted and are subject to a pending Application for Leave to File Under Seal. Following the Court's ruling on that application, a unredacted copy of the passages will be submitted either publicly or under seal.

The foregoing is within my personal knowledge, and if called as a witness, I could and would competently testify thereto. I declaration under penalty of perjury that the foregoing is true and correct. This declaration was executed on the 31st day of March, 2021, at Huntington Beach, California.

Jason A. Benkner

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **March 31, 2021**, I served the foregoing document described as: **DECLARATION OF JASON A. BENKNER IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **March 31, 2021**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

Nicole Lyons, Declarant

SERVICE LIST

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

Bijan Esfandiari, Esq.
Monique Alarcon, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
T: 310-207-3233
F: 310-820-7444
For e-service:
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
CHall@BaumHedlundLaw.com
vadlivankina@baumhedlundlaw.com
jjoseph@baumhedlundlaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

David M. Karen, Esq.
State Bar No. 117883
dk@dk4law.com
Kimberly Offenbacher, Esq.
State Bar No. 166318
ko@dk4law.com

DK LAW GROUP, LLP
3155 Old Conejo Road
Thousand Oaks, CA 91320
Tel: (805) 498-1212
Fax: (805) 498-3030

Attorneys for Plaintiffs JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN; DANIEL BENJAMIN

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN and DANIEL BENJAMIN, individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MECTA CORPORATION; SOMATICS, LLC; and DOES 1 through 10, inclusive,

Defendants.

Case No.: **2:17-cv-06686 RGK(PJWx)**

PLAINTIFF MICHELLE HIMES' RESPONSE TO INTERROGATORIES FROM SOMATICS, LLC, SET ONE

PROPOUNDING PARTY: **SOMATICS, LLC**

RESPONDING PARTY: **MICHELLE HIMES**

SET NO.: **ONE (1)**

subsequently acquired or learned by Responding Party or inadvertently omitted in this response.

INTERROGATORY NO. 6

If YOU contend that YOU received treatment with a SOMATICS ECT device, for each treatment session:

a. State the date of treatment;

b. State the model of the ECT device used to treat YOU;

c. State the address where treatment was administered;

d. State the IDENTITY of the HEALTH CARE PROVIDER(S) who administered treatment to YOU; and

e. State all warnings YOU received, including whether the warnings were verbal or written, as well as the IDENTITY of any person providing such warnings, prior to receiving treatment.

RESPONSE TO INTERROGATORY NO. 6

Objection. As phrased, this request is vague, ambiguous, overly broad, oppressive, burdensome, harassing, seeks documents protected from disclosure by the attorney-client privilege or confidential attorney work product and premature disclosure of expert information, including that it relies on the terms "treatment" and "warnings" which are not defined and the term "YOU" which as defined violates privileges. Additionally, propounding party does not limit this request in time or scope and it is irrelevant in that the request seeks documents that are not relevant to the party's claims or defenses in this action nor likely to lead to discovery of admissible evidence, including that identifying the particular ECT device that was used on each putative plaintiff is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. ECT devices are defined in the FDA's regulations without reference to any specific manufacturer, and any ECT device on the market since 1976 must be "substantially equivalent" to the pre-1976 devices, and to each other. Every device must have the same intended use – the inducement of a grand mal seizure

(a-d): To the extent Responding Party has been able to discover, Responding party received "treatment" with a Thymatron device administered by Raymond Fidaleo, MD, located at Sharp Mesa Vista Hospital, 7850 Vista Hill Ave., San Diego, CA 92123, on the following dates: April 13, 2011; April 15, 2011; April 18, 2011; April 20, 2011; April 22, 2011; April 25, 2011; April 27, 2011; April 29, 2011; May 2, 2011; May 4, 2011; May 13, 2011; May 20, 2011; June 2, 2011; June 22, 2011; July 7, 2011; July 28, 2011; August 10, 2011; August 15, 2011; August 22, 2011; August 29, 2011; September 15, 2011; September 28, 2011; October 12, 2011; November 16, 2011; December 12, 2012, and January 9, 2012.

e: Documents served concurrently herewith may evidence "warnings" received by Responding Party prior to receiving "treatments" by HEALTH CARE PROVIDERS at Sharp Mesa Vista Hospital. No "warnings" other than those provided in Responding Party's production, are recalled by Responding Party. Responding party was not informed before ECT treatment that ECT may cause permanent brain damage, long-term retrograde and anterograde amnesia, severe cognitive impairment, acute organic brain syndrome, or death. Instead, Responding Party was informed that ECT would end or reduce depression, agitation and disturbing thoughts.

Responding Party may have received additional "treatment" which Responding Party has not yet been able to identify. The following response is based on discovery and investigations that are ongoing and not yet complete. This response is made without prejudice to Responding Party's right to utilize subsequently discovered evidence at trial or in connection with pretrial proceedings, or to amend these responses in the event that any information is subsequently acquired or learned by Responding Party or inadvertently omitted in this response.

INTERROGATORY NO. 7

If YOU contend that YOU received treatment with a MECTA ECT device, for each treatment session:

a. State the date of treatment;

VERIFICATION
Riera, et al. v. Mecta Corp., et al.
Case No.: **2:17-cv-06686-RGK (PJWx)**

I, the undersigned hereby declare, as follows:

I have read the foregoing document entitled: **PLAINTIFF MICHELLE HIMES'S RESPONSES TO INTERROGATORIES FROM SOMATICS, LLC, SET ONE**, and know its contents.

I am the Plaintiff in this matter and, as to the matters stated herein, they are true of my own knowledge except as to those matters which are stated on information and belief and, as to those matters, I believe them to be true. Certain requests seek legal conclusions and, as to those matters, I have relied on my counsel.

I declare under penalty of perjury under the law of the United States of America that the above is true and correct. Executed on this 30 day of April 2018, at _____, California.

Michelle Himes
MICHELLE HIMES, Declarant

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

-vs-

SOMATICS, LLC,

Defendant.

CASE NO. 2:17-CV-06686-RGK-PJW

VIDEOTAPED DEPOSITION OF
RAYMOND FIDALEO, M.D.
TAKEN ON BEHALF OF THE DEFENDANT
VIA VIDEOCONFERENCE
ON FEBRUARY 12, 2021

REPORTED BY: TRENA K. BLOYE, CSR
Job No. CS4452015

A Yes, I have.
Q Approximately how many times?
A Five times.
Q Five times? Are you comfortable dispensing with the typical admonitions we go over at the start of this depositions?
A Yes, I am.
Q Okay. So, as I indicated at the outset, I represent a company calls Somatics, LLC. Have you heard that of company before?
A Yes, I have.
Q How have you heard them?
A I use their machine in my practice. It's a Thymatron.
Q Have you ever spoken with anyone at Somatics?
A No, I have never spoken to anybody there.
Q Okay. And when you say "machine," "Thymatron," are you referring to an electroconvulsive therapy device.
A Yes. The hospital, Mesa Vista, owns it and I practice at Mesa Vista and so I use their equipment.
Q Okay. To get started, can you give us a little bit of a background from your -- a little bit of your medical background starting with where you went to medical school?

sort of like automatic. It works. You just have to set the setting. And then you -- if you have -- if they have the impedence right then the machine let's you treat it. If it isn't, if the impedence of the electrodes is not correct it won't let you treat. So there is a safety built in.

Q Okay. Do you recall reading the operator's manual for the Thymatron device?

A No, I don't recall that.

Q Okay. Do you know if the operator's manual is made available by the hospital?

A It's -- it's made available. The technician usually is the one that knows it. There's a technician that does all the ECT and he's the one that refers to the book if there is an issue, or we call the company if there is an issue, you know.

Q Okay. The technician that you're referring to, is that person a full-time employee of the hospital?

A Yes, he is.

Q Okay. The technician and -- if you know, do you know who the technician was for Sharp Vista Hospital in 2001 or 2002?

A Yeah. I'm pretty sure it was Dave Munden. I'm not accurate, but he's been there forever, so I think it was him. David Munden, M-u-n-d-e-n.

week, you know.

Q Okay. All right, Doctor. Now I want to shift gears here and talk about treatment with one specific patient, Michelle Himes, who is a plaintiff in this case.

A Okay.

Q Have you had an opportunity to review your medical records that you have with respect to this patient?

A Yeah. I have the medical records. I don't have the ECT records, per se. Okay. I know what I did, but I don't have the records of those.

Q When you say the ECT records, you mean the actual documented ECT --

A The treatment, yeah. They couldn't pull that for me.

Q Okay. So I'm going to share my screen with you, show you a document I'm going to mark as Exhibit No. 1.

A Okay.

Q Do you see that document in front of you?

A I see it, yes. It looks like it is a progress note.

Q Yeah. Let me zoom in a little bit here. It looks like it's dated April 12th, 2011. Do you see

that?

A Right.

Q Okay. Do you recognize this as a progress note that you drafted?

A I dictated it, yes.

Q Dictated it. Got it. And -- one second. I'm trying to think about the best way to do this. Do you have a paper copy of this progress note in front of you?

A I can get it, yeah. I have it. Hold on a minute.

Q Okay.

A I'm pretty sure I have the right one. Go ahead.

Q Okay. Can you tell me generally what this progress note is?

A I was trying to see if that's not the discharge summary. I'm trying to -- I think that was actually a discharge summary. It says the title is Admission and History, but --

Q Doctor, let me do it this way. Why don't you just focus on the document on the screen instead. I'm not sure you're looking at the same --

A Right.

Q -- progress note that I've put up on the screen here.

So I did consult with him. The question is whether she was with him at that time and I discussed it with him. I don't know.

Q Okay. When you discussed it with -- strike that.

As part of your consultation on this first visit did you explain the risks of ECT to Ms. Himes?

A Yes. There is a state form that we have to go over. The consent is based on a standardized form that all the hospitals have to use, you know. So you have to go over that form and they have to sign that consent. Okay.

This consent is very specific in terms of what can happen. Not that it does happen, but, you know, they talk about, you know, potential death, even, you know, from ECT.

Q Okay. Can you recall what you told Ms. Himes about the risks of treatment?

A Yeah. I went over the consent with her, you know. And I gave it to her and she had 24 hours to review it. And then we asked if she had any questions again, you know. So the consent talks about everything, you know, in terms of the procedure.

Q Okay. Did you tell her that there was a risk of long-term or permanent memory loss?

A Yeah. With ECT usually you get permanent memory loss the period of time that the person is significantly depressed. Certainly the time that you're doing the treatments, if you are doing bilateral treatment, they won't remember. Okay.

So it's like you have a lacuna, a period of time in your life that you don't remember. And it's usually the time when you're seriously depressed. It's always the time when you have the treatments, if you're doing bilateral, you won't remember day-to-day. Okay.

That's not true that you don't know what's going on. But in terms of when your time out of the ECT then you start to -- within two weeks to two months you start to have present recall, things that take place in your life you recall.

You'll have a lapse for that period of time when you were treated, what was going on. If people visited you in the hospital, you won't remember that they visited you, things like that. So that period of time gets blocked.

But the reality is, you know, we all forget, you know, that's part of life, so we don't have absolute memories of what took place in our past. Okay. But the ability to remember and to work and to function, that comes back.

know, it's like -- usually we talk about memory we're talking deficits, short-term and long-term memory. Okay.

Q Right.

A I'm trying to tell you there are going to be lapses of long-term memory. But in short-term memory, you know, that comes back.

Q And short-term memory, are you referring to the ability to learn and retain new information?

A Right, yes. And do your job. If you're a physician, your skills come back, you can work, you know. The physicians, they get the treatments, they are not -- they don't lose their skills. I mean, they still have them.

Q Gotcha. Did you advise Ms. Himes that she could experience brain damage from ECT?

A No. There is no literature that supports brain damage.

Q Okay. Have you ever been concerned in your own practice that brain damage could be a risk of treatment?

A No.

Q And why is that?

A Because people go back and function normally after ECT. ECT is, you know, used to say it's like a last resort. It doesn't have to be a last resort, but

we don't do ETC right off the bat. You try to get people better with medications and therapy.

If they can't get better and if they are profusely depressed and they are thinking of killing themselves then that's the treatment of choice. Okay?

Q Okay. I'm going to share my screen with you once more.

A You should know that, like, movies like "One Flew Over the Cuckoo's Nest," that's not an accurate picture. And we dont' do ECT every day. You know, it's a series and you do it three times a week, not every day.

This would be a treatment report, yeah.

Q Yeah, yeah. So I'm gonna mark this as Exhibit No. 2 I believe I'm on. Do you recognize this as a treatment report that you've completed, that you filled out?

A Yes, I did.

Q Okay. And, again, I will represent to you I got this from Sharp Hospital directly. And based on my review here it looks like ECT number 26 was the last date that you treated Ms. Himes with ECT.

A Right, right.

Q Does that comport with your recollection of that?

Alzheimer's where you get in trouble. That kind of a memory loss is a problem.

Q Well, how about the kind of memory loss where somebody cannot recall, for example, their wedding day. And someone who is young. I'm not talking about someone who is in their 80s and 90s and, because of the passage of 60 years may have forgotten. But somebody who cannot -- who is young and, as a result of either medication or treatment, injury that she sustained is no longer able to remember her wedding day. Would you consider that to be an injury?

A Not necessarily, because she can get that back is what I'm saying. You know, you don't get the experience back, but you can relearn it. That's what we do. My kids do that to me all the time. "Dad, don't you remember this?" And then you relearn it. You don't remember it. You see pictures of it and say, "Oh, yeah, that's me," you know.

Q But if -- if a treatment that you were planning on using, if the manufacturer informed you that it carries with it the risk of permanent memory loss, is that something you would relay to the patient?

A I do relay they are going to have memory loss. And some people can have memory loss outside of the period when you get the treatments. The treatments are

given because you are trying to --

Q Doctor, I'm asking a very simple question. I'm asking --

A It wouldn't stop me. You have to take the whole thing. All drugs and all things have memory loss. If you forgot your wedding date, but you knew how to function, I wouldn't consider that a reason not to give treatment.

Q I'm not asking whether you want to give treatment or not. I'm simply asking you if the manufacturer informed you that, "Our product carries with it a risk of permanent memory loss," is that information you would relay to the patient?

A We did that.

Q I'm asking you, wouldn't you?

A Yes, we do. That's the -- that's -- the consent form says that. That's what we do. We tell them that.

Q All right. We'll look at the consent form and we'll see what it says.

A Go ahead.

Q And if a medication or a procedure had a risk of the patient losing the ability to formulate new memories, is that a risk that you would have alerted patients to?

been provided to you by Somatics, you would have relayed that to your patients. Correct, Doctor?

MR. BENKNER: Objection. Incomplete hypothetical, calls for speculation.

A Yeah. It's like I do warn them they are going to have memory loss. Okay.

Q (By Mr. Esfandiari) No, no. Okay. Let me -- in light of the objection.

If Somatics had informed you that the use of their ECT device could potentially cause patients to lose the ability to formulate new memories, is that --

A That would be significant. But I would have to see it also myself.

Q But I'm asking you, Doctor, is that information you would have presented or at least informed your patients about?

A Yes, we would inform them.

Q Okay.

A If it was to this -- if the drug company is saying, Hey -- or if the machine company is saying, "Hey, guys, this is a problem we're getting.

You have to understand when we use the first machine we crank it up, they had severe memory losses. That was a problem. The MECTA cut that down. The Thymatron cut it down even more.

So, I mean, you know, you go by what you see clinically. Okay. Clinically is what you go by. If I see patients can't function after I give them ECT, that's going to concern me. I'm giving them ECT to get back functioning, the depression or psychosis is preventing it. If I give them a new disease, so to speak, if they can't remember anything, can't process life, I'm not helping them. Okay. I'm just -- I'm switching just -- I'm switching one for another one. That's no good.

I don't see that. That's what I'm trying to get across to you. You know, it's nice to say they have memory loss, some people do have spotty losses outside. That's true. But does that stop them from functioning and having new memories. That's not true. That's the issue.

If they told me the machine causes people to no longer be able to remember new information, that would be a serious concern, yeah, I would tell them. But I would be seeing that myself and I'm not seeing that with my patients. Okay. Patients that have ECT and have a recovery from it, they will come back and say, Doc, I need ETC again. I'm too seriously ill at this point. Help me. Okay. You save their lives. Okay. I'm not saving their lives to give them something else.

Q Absolutely. You agree with me that a patient who is present voluntarily in a hospital and is provided a medical option after being adequately informed, that patient has the right to refuse treatment if they feel the risks outweigh the benefits?

A Absolutely true.

Q Doctor, you mentioned that there is a video that is shown to patients; is that right?

A Yes.

Q Okay. Do you recall if there were also any -- because we have understood through the discovery we have done in this case from Somatics, that Somatics releases a patient information, kind of a brochure to give to doctors to give to patients. Do you recall if that was also provided to Ms. Himes or your patients?

A No, I don't think so. We're not -- I have never given them a document like that. We have given them some written documents on ECT they can read if they want, but not --

Q Let me show --

A Not a Somatics pamphlet, just our document.

Q I'm putting up as document that Somatics has produced in this case. Do you see it, Doctor?

(A document was displayed, which was later marked as Exhibit 7.)

A Yeah, I see that.
Q "What You Need to Know About Electroconvulsive Therapy."
A Right.
Q Do you see that?
A Yes, I see that.
Q Is this a document -- refresh your recollection? Have you ever seen this document before?
A No. I haven't seen that, no.
Q Is it -- you stated that the video is shown to the patients by the nursing staff; right?
A Yes.
Q Yeah. Is it possible that the nursing staff may have provided this form to patients?
A No.
Q No?
A I have never seen it before, so I --
Q The literature that you stated that you have distributed, do you still possess that literature?
A No. No, I don't have it. No. I'm just saying it's some stuff that was written to explain ECT that we give the patients as well. But that's not the form, no.
Q Does the hospital still have that literature or form?
A I don't -- I don't know. I'm not sure.

C E R T I F I C A T E

STATE OF OKLAHOMA)
) SS:
COUNTY OF OKLAHOMA)

I, Trena K. Bloye, Certified Shorthand Reporter within and for the State of Oklahoma, certify that RAYMOND FIDALEO, M.D., was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth, in the case aforesaid; that the witness chooses to read and sign the deposition; that the above and foregoing videotaped deposition was taken by me in shorthand and thereafter transcribed; that the same was taken on February 12, 2021, at 9:18 a.m. PST, via videoconference; that I am not an attorney for, nor a relative of any of said parties or otherwise interested in the event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 20th day of February, 2021.

Trena K. Bloye, CSR
State of Oklahoma CSR No. 1522

David M. Karen, Esq.
State Bar No. 117883
dk@dk4law.com
Kimberly Offenbacher, Esq.
State Bar No. 166318
ko@dk4law.com

DK LAW GROUP, LLP
3155 Old Conejo Road
Thousand Oaks, CA 91320
Tel: (805) 498-1212
Fax: (805) 498-3030

Attorneys for Plaintiffs JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN; DANIEL BENJAMIN

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN and DANIEL BENJAMIN, individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MECTA CORPORATION; SOMATICS, LLC; and DOES 1 through 10, inclusive,

Defendants.

Case No.: **2:17-cv-06686 RGK(PJWx)**

PLAINTIFF MICHELLE HIMES' RESPONSES TO INTERROGATORIES FROM MECTA CORPORATION, SET ONE

PROPOUNDING PARTY:	**MECTA CORPORATION**
RESPONDING PARTY:	**MICHELLE HIMES**
SET NO.:	**ONE (1)**

INTERROGATORIES AND RESPONSES

INTERROGATORY NO. 1

Describe the nature of any injury or harm YOU have experiences as a result of the conduct underlying the allegations in YOUR COMPLAINT.

RESPONSE TO INTERROGATORY NO. 1

Objection. As phrased, this interrogatory is vague, ambiguous, overly broad, seeks information protected from disclosure by the attorney-client privilege and confidential attorney work product privilege, and seeks premature disclosure of expert opinion information.

Without waiving these objections but subject to them, and with the understanding this request seeks information pertaining to injuries suffered personally by Responding Party as alleged in the Complaint, Responding Party answers: Responding Party's injuries include, but are not limited to: unwarned concussive brain injury from ECT resulting in cognitive impairment resulting in permanent loss of past memory, chronic and lasting short term memory difficulties, chronic cognitive impairment, pain, suffering, inconvenience, and severe psychological and emotional distress. Responding Party is suffering memory loss, including the ability to recall information learned, the ability to retain newly learned information, loss of the knowledge and skills obtained and lost cherished memories of her children, family, friends and events. Responding Party is extremely exhausted daily and accomplishing everyday tasks in difficult and sometimes impossible. Prior to ECT Responding Party was an avid reader, now it is difficult for Responding Party to read as she must read the same paragraphs several times over and she cannot recall the meaning of words previously known. Responding Party is also terrified to go to hospitals or doctors, suffering extreme anxiety and panic attacks and requiring assistance to simply make it to the provider. Responding Party's sense of smell has been compromised and certain smells now trigger severe anxiety.

///

VERIFICATION
Riera, et al. v. Mecta Corp., et al.
Case No.: **2:17-cv-06686-RGK (PJWx)**

I, the undersigned hereby declare, as follows:

I have read the foregoing document entitled: **PLAINTIFF MICHELLE HIMES'S RESPONSES TO INTERROGATORIES FROM MECTA CORPORATION, SET ONE**, and know its contents.

I am the Plaintiff in this matter and, as to the matters stated herein, they are true of my own knowledge except as to those matters which are stated on information and belief and, as to those matters, I believe them to be true. Certain requests seek legal conclusions and, as to those matters, I have relied on my counsel.

I declare under penalty of perjury under the law of the United States of America that the above is true and correct. Executed on this ____ day of May 2018, at _____, California.

Michelle Himes
MICHELLE HIMES, Declarant

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

VS.

SOMATICS, LLC,

Defendant.

Case No. 2:17-cv-06686-RGK-PJW

VIDEOTAPED VIDEOCONFERENCE DEPOSITION OF MICHELLE HIMES
TAKEN REMOTELY ON BEHALF OF THE DEFENDANT
IN OKLAHOMA CITY, OKLAHOMA
ON FEBRUARY 25, 2021

REPORTED BY: DAVID BUCK, CSR

Job No. CS4464908

Q. (By Mr. Benkner) Do you see that in front of you?

A. Yes.

Q. Okay. I'll represent to you that this is an ECT log which I believe is from your treatment. It's kind of hard to read, the handwriting is not the greatest but that's how doctors are sometimes. Anyway, from what I can understand from this Exhibit Number 6 it identifies treatment number 26 there.

Do you see that?

A. Yes.

Q. Okay. And then there's a date below which looks like it's January either 8th or 9th, 2012.

Do you see that too?

A. Yes.

Q. Okay. So, the question I have for you is do you have a recollection of undergoing ECT at any point after January 8th or 9th, 2012?

A. No.

Q. Okay. So, after your treatment with ECT had concluded, did you ever observe in yourself any side effects or symptoms that you were experiencing that you thought might have been caused by ECT?

A. I don't remember anything until that autumn.

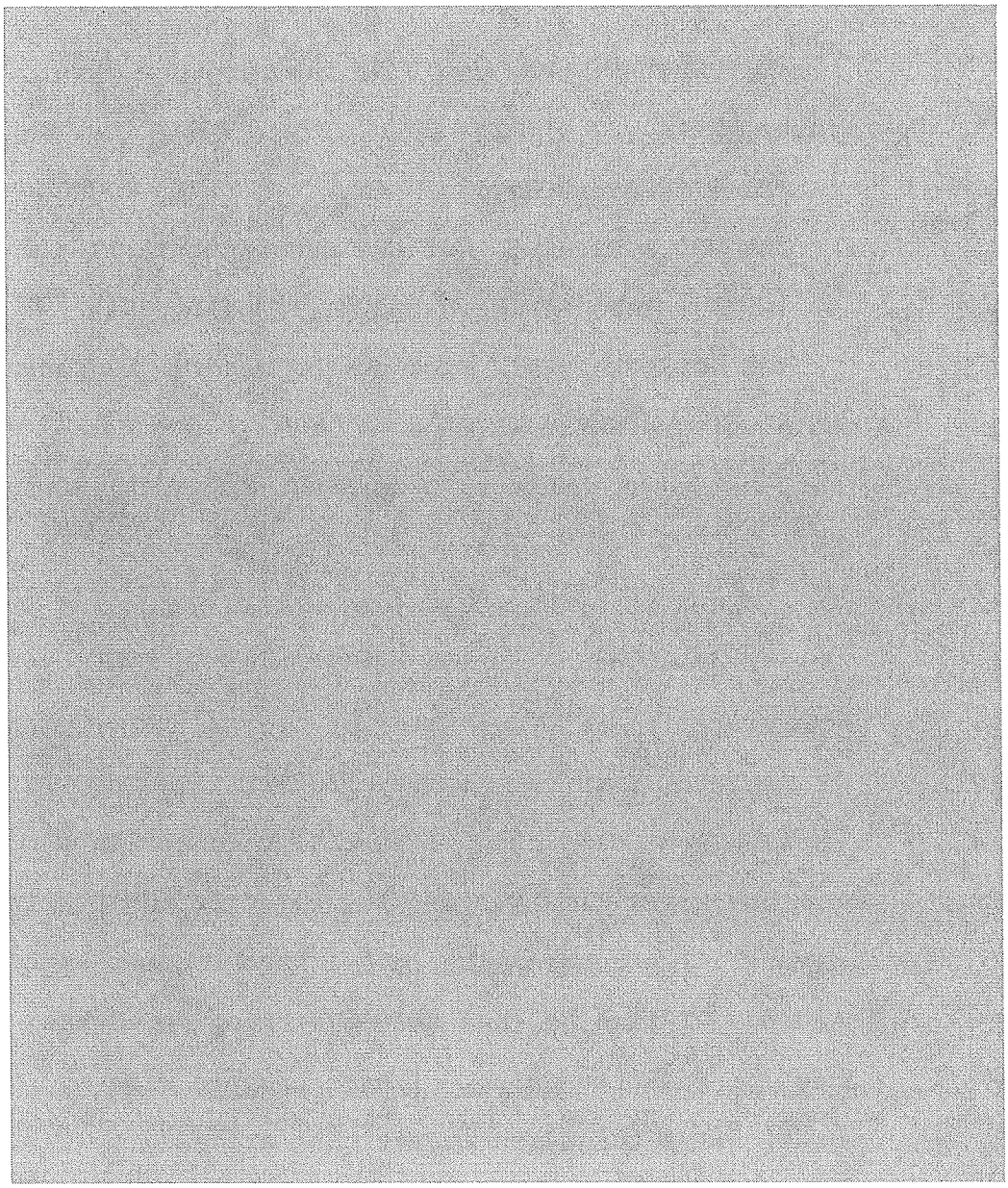
Q. And when you say that autumn, are you talking

about autumn 2012?

A. Yes.

Q. Okay. And what's the first thing you recall from autumn 2012?

A. Cleaning my house in Las Vegas.



a little bit here, do you recall meeting with any kind of doctor or therapist that was located at 1601 Carmen Drive in Camarillo?

A. No. I know where Carmen Drive is but I don't, I don't remember seeing her.

Q. Okay.

MR. BENKNER: Why don't we take another five minute break.

THE WITNESS: Okay.

THE VIDEOGRAPHER: Off the record at 11:17 a.m.

(A recess was here had 11:17 to 11:25.)

THE VIDEOGRAPHER: Back on the record, beginning media unit three at 11:25 a.m.

Q. (By Mr. Benkner) Okay. Ms. Himes, thinking about any symptoms or side effects that you experienced after ECT, can you explain if you've in your observations experienced anything that you think was related to ECT?

A. Yes. I have a long period of time that is completely blacked out. I have trouble making long term memories. I -- I used to write. I don't write anymore. I struggle with it. I have trouble with reading. I have to read the same thing more than once. I didn't used to. I have trouble with my words. I've forgotten people that are --

Q. Anything else?
A. Off of the top of my head, no. Um --
Q. Sorry, you were going to say something?
A. No, I say um a lot. I'm sorry.
Q. That's all right, I do the same.
All right, let's -- I'm going to kind of go over them one by one with you. The first one that you talked about was the long period of time that you -- that's blacked out. Are you referring to that period after undergoing ECT until about autumn of 2012?
A. And the entire time period I was undergoing ECT. There's a lot that's missing for going back years and even after my memory started coming back it's very spotty.
Q. And did you first realize that you could no longer recall events from that time period in autumn of 2012?
MS. ALARCON: Objection, misstates her testimony.
Q. (By Mr. Benkner) Yeah, I'll rephrase the question.
So, the question I have is you indicated that you couldn't recall anything prior to autumn 2012. Is that right?
A. Going back several years, yeah.
Q. Going back several years, right.

(A brief pause.)

Let me ask it a different way, it might be a better way to do this.

Were you having trouble forming long term memories while you were living in San Diego?

A. Not that I can remember. I --

Q. Do you know if you were having trouble with long term memories when you were living -- when you moved back to Las Vegas leaving from San Diego?

A. I don't know.

Q. Do you know if you were having trouble forming long term memories when you moved -- when you lived in Camarillo?

A. I don't know.

Q. And have you told any of your doctors that you have trouble forming long term memories?

A. I don't recall. I don't think so.

Q. And is there any reason why you haven't told any of your doctors?

A. Yes.

Q. What's the reason?

A. I -- I do not want my ability to care for children to be called into question.

Q. Okay. Moving to the number -- the -- the third thing you talked about, struggling with your

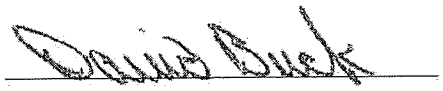
Page 55

C E R T I F I C A T E

STATE OF OKLAHOMA)
) SS:
COUNTY OF OKLAHOMA)

I, David Buck, Certified Shorthand Reporter within and for the State of Oklahoma, do hereby certify that MICHELLE HIMES was by me first duly sworn to testify the truth, the whole truth and nothing but the truth, in the case aforesaid; that the above and foregoing remote deposition was taken in shorthand and thereafter transcribed; that the same was taken on February 25th, 2021, in Oklahoma City, Oklahoma; that I am not an attorney for nor a relative of any said parties, or otherwise interested in said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 2nd day of March, 2021.



David Buck, CSR #1585

David M. Karen, Esq.
State Bar No. 117883
dk@dk4law.com
Kimberly Offenbacher, Esq.
State Bar No. 166318
ko@dk4law.com

DK LAW GROUP, LLP
3155 Old Conejo Road
Thousand Oaks, CA 91320
Tel: (805) 498-1212
Fax: (805) 498-3030

Attorneys for Plaintiffs JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN; DANIEL BENJAMIN

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN and DANIEL BENJAMIN, individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MECTA CORPORATION; SOMATICS, LLC; and DOES 1 through 10, inclusive,

Defendants.

Case No.: **2:17-cv-06686 RGK(PJWx)**

PLAINTIFF MARCIA BENJAMIN'S RESPONSE TO INTERROGATORIES FROM SOMATICS, LLC, SET ONE

PROPOUNDING PARTY: **SOMATICS, LLC**

RESPONDING PARTY: **MARCIA BENJAMIN**

SET NO.: **ONE (1)**

subject to medical device reporting requirements. They also lacked risk evaluations for burns and memory loss.

- Richard K Vogel, Investigator
- Rafael Padilla, Investigator

The following response is based on discovery and investigations that are ongoing and not yet complete. This response is made without prejudice to Responding Party's right to utilize subsequently discovered evidence at trial or in connection with pretrial proceedings, or to amend these responses in the event that any information is subsequently acquired or learned by Responding Party or inadvertently omitted in this response.

INTERROGATORY NO. 6

If YOU contend that YOU received treatment with a SOMATICS ECT device, for each treatment session:

a. State the date of treatment;

b. State the model of the ECT device used to treat YOU;

c. State the address where treatment was administered;

d. State the IDENTITY of the HEALTH CARE PROVIDER(S) who administered treatment to YOU; and

e. State all warnings YOU received, including whether the warnings were verbal or written, as well as the IDENTITY of any person providing such warnings, prior to receiving treatment.

RESPONSE TO INTERROGATORY NO. 6

Objection. As phrased, this request is vague, ambiguous, overly broad, oppressive, burdensome, harassing, seeks documents protected from disclosure by the attorney-client privilege or confidential attorney work product and premature disclosure of expert information, including that it relies on the terms "treatment" and "warnings" which are not defined and the term "YOU" which as defined violates privileges. Additionally, propounding party does not limit this request in time or scope and it is irrelevant in that the request seeks documents that are not relevant to the party's claims or defenses in this action nor likely to lead to discovery of admissible

Without waiving any objections, but subject to them, and to the extent this interrogatory is understood to be requesting "treatment" Responding Party received from HEALTH CARE PROVIDERS while admitted to their facilities for ECT sessions and is only seeking material facts and persons that do not fall under a protected privilege and/or attorney work product, RESPONDING PARTY answers as follows:

(a-d): To the extent Responding Party has been able to discover, Responding party received "treatment" with a Thymatron System IV ECT device at Northridge Hospital Medical Center, located at 16300 Roscoe Boulevard, Northridge, CA 91328, on the following dates: September 28, 2012; October 1, 2012; October 10, 2012; October 12, 2012; October 15, 2012; October 17, 2012; October 24, 2012; October 26, 2012; October 29, 2012; October 31, 2012; November 2, 2012; November 5, 2012; December 3, 2012; December 5, 2012; December 7, 2012; December 14, 2012; December 21, 2012; February 6, 2013, March 4, 2013.

e: Documents served concurrently herewith may evidence "warnings" received by Responding Party prior to receiving "treatments" by HEALTH CARE PROVIDERS at Northridge Hospital Medical Center. No "warnings," other than those provided in Responding Party's production, are recalled by Responding Party. Responding party was not informed before ECT treatment that ECT may cause permanent brain damage, long-term retrograde and anterograde amnesia, severe cognitive impairment, acute organic brain syndrome, or death. Instead, Responding Party was informed that ECT would end or reduce depression, agitation and disturbing thoughts.

Responding Party may have received additional "treatment" which Responding Party has not yet been able to identify. The following response is based on discovery and investigations that are ongoing and not yet complete. This response is made without prejudice to Responding Party's right to utilize subsequently discovered evidence at trial or in connection with pretrial proceedings, or to amend these

VERIFICATION
Riera, et al. v. Mecta Corp., et al.
Case No.: **2:17-cv-06686-RGK (PJWx)**

I, the undersigned hereby declare, as follows:

I have read the foregoing document entitled: **PLAINTIFF MARCIA BENJAMIN'S RESPONSES TO INTERROGATORIES FROM SOMATICS, LLC, SET ONE**, and know its contents.

I am the Plaintiff in this matter and, as to the matters stated herein, they are true of my own knowledge except as to those matters which are stated on information and belief and, as to those matters, I believe them to be true. Certain requests seek legal conclusions and, as to those matters, I have relied on my counsel.

I declare under penalty of perjury under the law of the United States of America that the above is true and correct. Executed on this 1st day of May 2018, at THOUSAND OAKS, California.

MARCIA BENJAMIN, Declarant

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC,

Defendant.

Case No. 2:17-CV-06686-RGK-PJW

VIDEOTAPED DEPOSITION OF MICHAEL FRANKEL, M.D.

TAKEN FEBRUARY 19, 2021

REPORTED REMOTELY BY:

BEVERLY A. BENJAMIN, CSR No. 710

Notary Public

you?

A. No, that's fine. Let's just proceed.

Q. Understood.

So as I indicated, I represent a company called Somatics, LLC. Have you ever heard of that company before, Doctor?

A. Yes, I have.

Q. How have you heard of them?

A. They're the manufacturer of the equipment that we use when we perform ECT.

Q. Do you know the name of the equipment that you're referring to?

A. Yes, it's known as the Thymatron IV series.

Q. Have you ever had any conversations with anybody at Somatics, LLC?

A. I don't believe so, not for quite a while if I did, but I don't recall. No, I don't recall any conversations.

Q. Can you give us kind of a brief statement of your educational background, starting with medical school?

A. My medical school, which I attended, was the State University of New York, Downstate Medical Center, College of Medicine. I then went on to do a medical internship, internal medicine internship, at an

publication available for other doctors to read or patients to read?

A. I don't think so, no.

Q. Now, Doctor, can you tell me what sources that you rely on to inform or educate yourself on the risks of ECT?

A. Not specifically, but again, over the years I've attended conferences and read various literature from newsletters and such. Not one particular publication specifically. Plus I have a number of books in my office here that I use for information regarding ECT.

Q. Do you rely on your clinical observations to assess the risks of ECT?

A. Very much so.

Q. In terms of your review of literature, do you subscribe to any scholarly journals that discuss the risks of ECT?

A. Well, not specifically for ECT, but a number of different journals, one of which is the Carlat Report, AudioDigest, Annals of Psychiatry, I also subscribe to the Journal of the American Psychiatric Association.

Q. Have you ever heard of the Journal of ECT?

A. Yes, I have.

Q. Do you subscribe to that publication?
A. No, I don't.
Q. Is there any reason why you don't?
A. Just never thought about it.
Q. Have you relied on any disclosure from Somatics, LLC, to inform you of the risks of ECT?
A. No.
MR. ESFANDIARI: Objection to form.
Q. (BY MR. BENKNER) How often would you attend conferences that discussed ECT?
A. Maybe once every year or two.
Q. How frequently do you review literature that discusses ECT?
A. Infrequently, perhaps once every several months, once a year.
Q. So if you had to identify the primary source that you rely on in terms of how to inform or educate yourself on the risks of ECT, what would you say that is?
MR. ESFANDIARI: Objection to form.
THE WITNESS: I would say basically the publications that I mentioned.
Q. (BY MR. BENKNER) Even more so than your clinical observations?
MR. ESFANDIARI: Objection to form.

Q. So when you were referring to memory disturbances, are you referring to loss of autobiographical memories, things that you might have learned in the past?

A. Yes.

Q. Doctor, do you know whether ECT can cause movement disorders, anything that affects your ability to produce or control the movement of the body?

A. I've never seen that.

Q. How about sensory disorder, something that affects your ability to hear or smell?

A. Haven't had that, haven't seen it.

Q. Have you ever seen ECT cause brain damage in any of your patients?

A. No.

Q. Have any of your patients ever claimed that ECT caused brain damage to them?

MR. ESFANDIARI: Objection to form.

THE WITNESS: Not in those specific words but I have had patients who do complain of different cognitive disturbances over the years, who they may attribute to ECT treatments.

Q. (BY MR. BENKNER) And has that ever caused concern to you that ECT was causing long-term cognitive impairment?

A. Not really, because almost every case we are very careful to make sure that every other treatment option has been exhausted before we do ECT. And by giving the patient informed consent, we feel that the patients almost exclusively will choose to have the treatment despite the possibility of a number of side effects that can occur.

Q. Doctor, can you think of any other -- strike that.

Are there any other risks of treatment that you're aware of that can be caused by ECT?

A. Well, we've had, in 35 years we've had one patient have a myocardial infarction; in 35 years we've had one patient have a stroke but they were found to have a malignant brain tumor which caused the stroke and the ECT just brought it out. So I'd say that one instance and the one myocardial infarction over the years have been our only very serious complications. We've had two patients who developed atrial fibrillation, both for very short periods of time.

And those are the only significant side effects over several decades that we've seen in treating thousands of patients.

Q. Doctor, I'm going to switch gears for a second here and share my screen with you. Give me one second.

A. Okay.

Q. I should ask you, do you have your clinical notes for Ms. Benjamin with you?

A. Yes, I do.

Q. Great. Let's make this a little easier.

A. Okay.

MR. BENKNER: Madam Court Reporter, can you allow me access to screen share?

(Exhibit 1 marked.)

Q. (BY MR. BENKNER) Doctor, do you see a document in front of you on your screen?

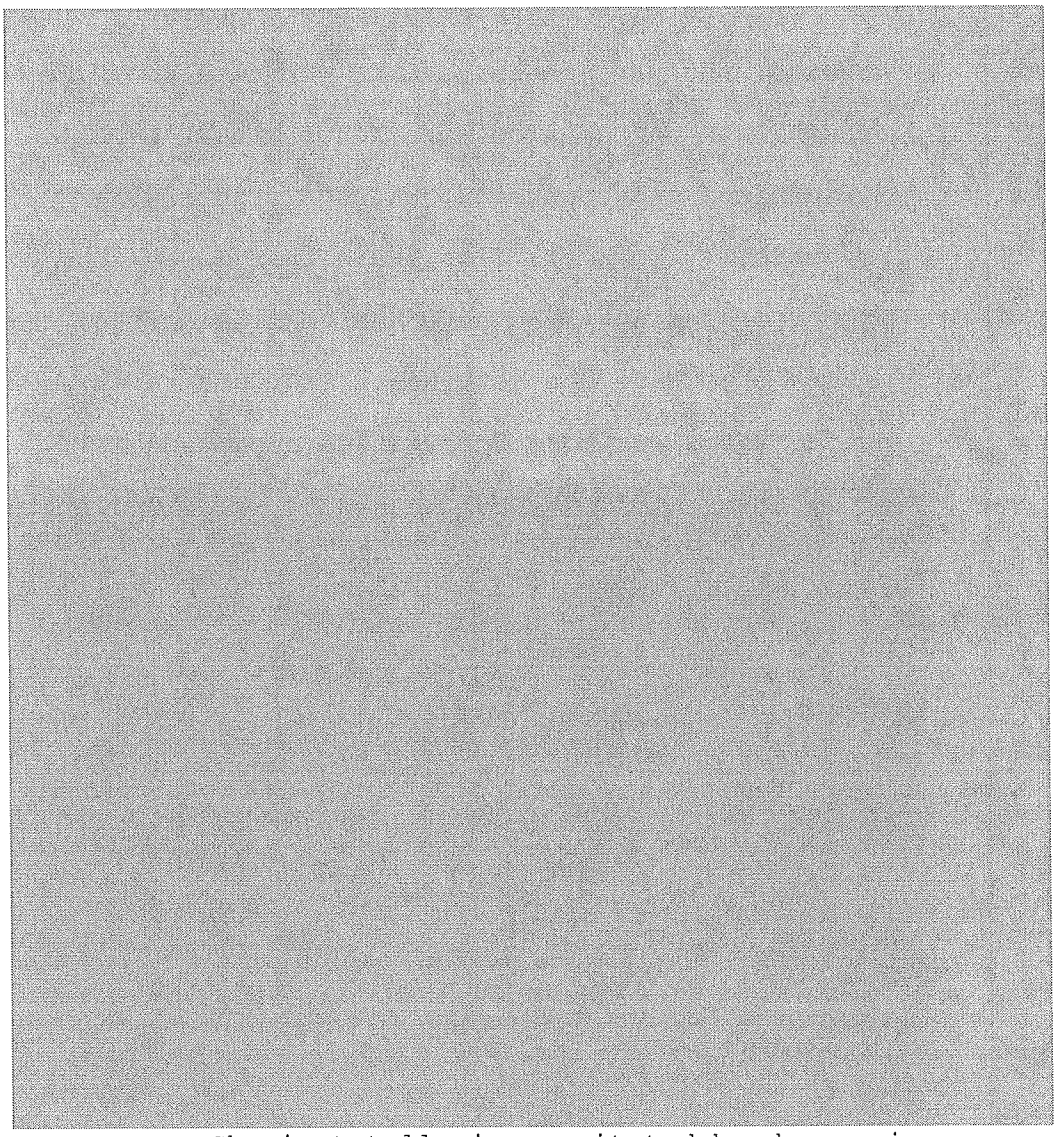
A. Yes, I do.

Q. I'll represent that this is a five-page document that we received from your office in response to a --

A. Correct. Yeah. Back 8 years ago we were doing handwritten consultation notes, which we've since changed to actual dictations. So this is an old way we were doing consultations back in 2012. But that is my initial consultation report on this patient.

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

And as you said, it is handwritten. So your handwriting is really not as bad as other doctors that I've seen. But I am wondering if you could help us out

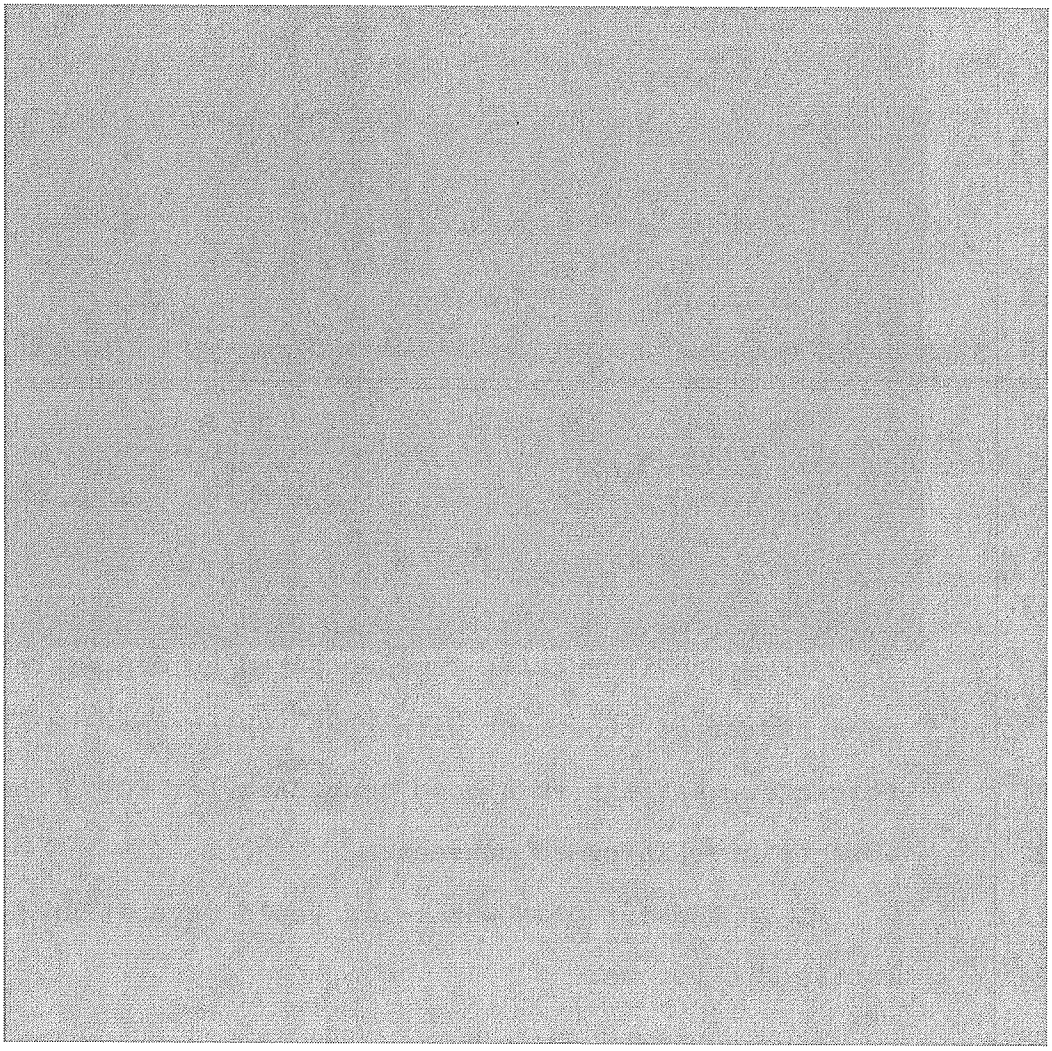


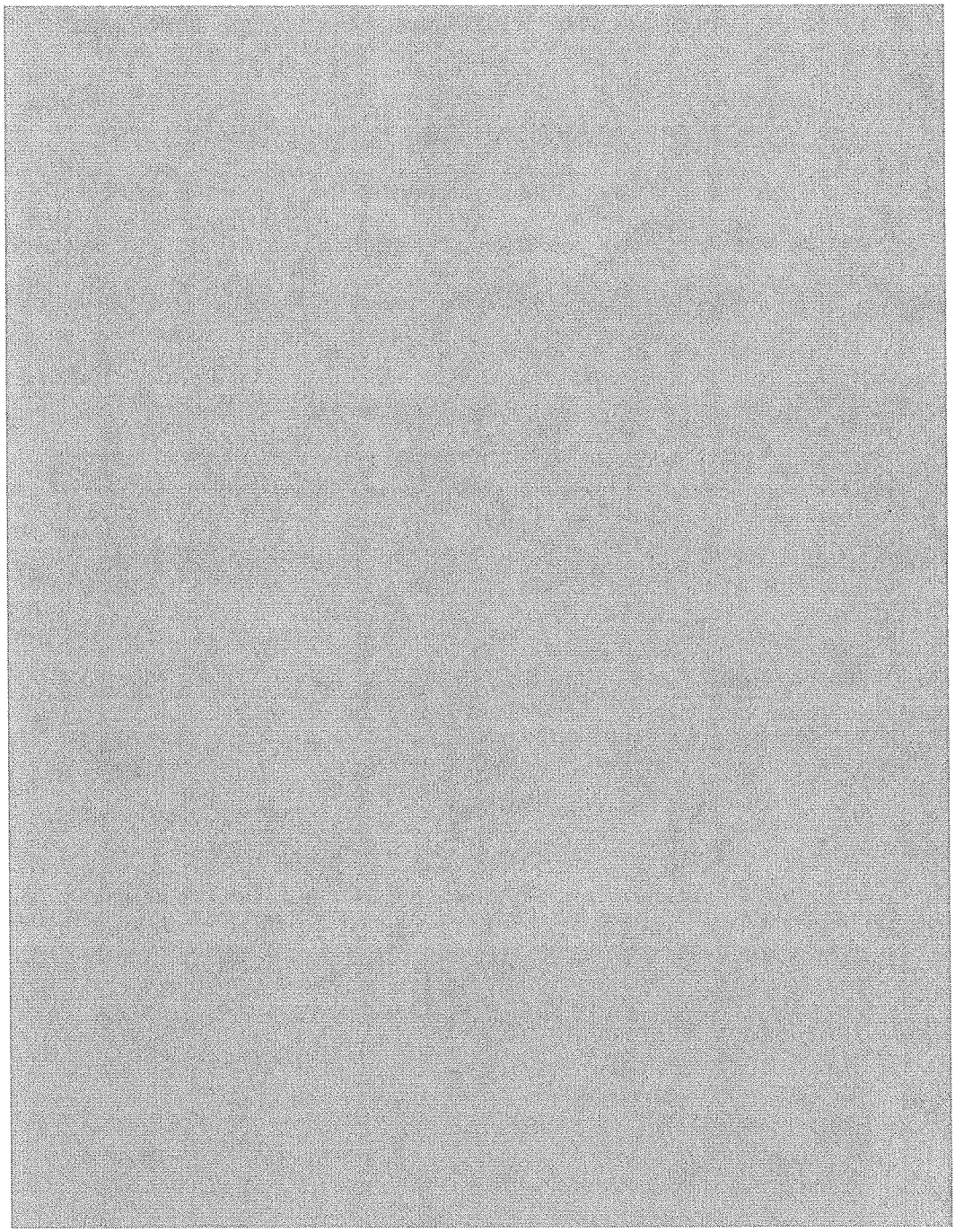
She is totally incapacitated by depression, even had brief treatment with rTMS, which she did not tolerate. Patient is a good candidate for ECT. She is able to give informed consent.

And our plan was -- if you'd move it up a little bit for me.

Q. Sure.

A. Details of ECT explained to patient then her husband, who was present at the consultation. We concentrate on the side effects of recent memory disturbance and confusion, which are generally reversible. However, I do share that I have had a small number of patients who have had small pieces of remote memory that have not returned. They are referred to online sites for more information regarding ECT.





Q. I'm going to show you a new document identified as Exhibit No. 5.

(Exhibit 5 marked.)

Q. (BY MR. BENKNER) Do you see that?

A. Yes, I do.

Q. Do you know what this document is?

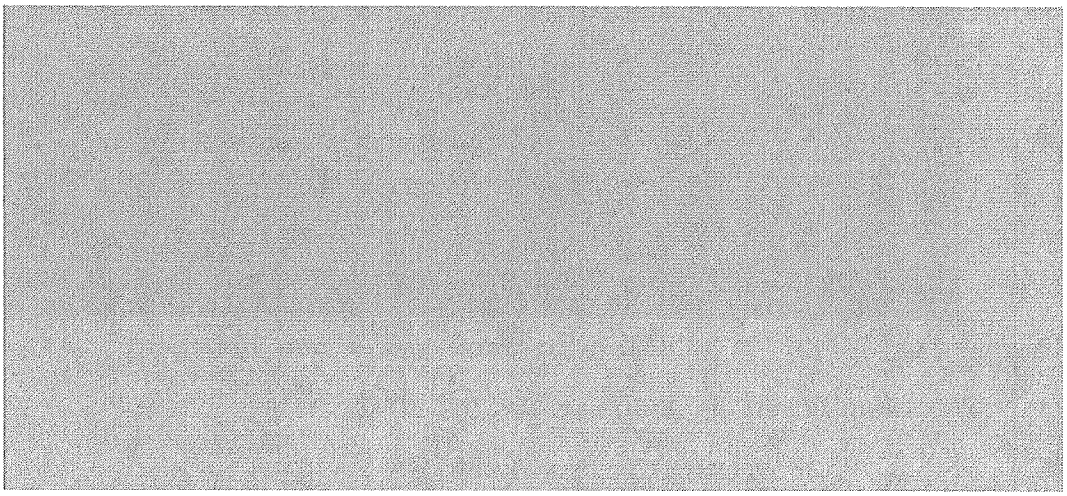
A. Yes, it's a summary of the actual ECT treatment that we dictate each time we do a treatment.

Q. And I will represent to you I got this from Northridge Hospital pursuant to a subpoena request. And the date of procedure on this is March 4, 2013. Do you see that there?

A. Yes, I do.

Q. And based on the records that were produced by the hospital, this is the last date that we have showing that Mrs. Benjamin underwent ECT treatment under your care. Do you have any information that she underwent treatment at any point after March 4, 2013?

A. No, that was the last treatment I have as well.



from any medical device companies?

A. No, I have not.

Q. In addition to ECT, do you also prescribe medications for the treatment of mental issues?

A. Yes, I do.

Q. From time to time do you ever receive literature from a manufacturer informing you of updated safety information associated with their drug or device?

A. We receive a good deal of literature from various drug companies, for example, but I don't pay terribly much attention to them.

Q. Have you ever in the past received what's sometimes referred to as a "dear doctor" letter where the company may inform the medical community about new risks that have come to light concerning either their drug or their device?

A. You know, I don't recall specifically receiving a letter like that. But again, we're pretty much well informed about various side effects and problems through the literature. But I don't recall specifically receiving a letter from a particular company dealing with a particular side effect or risk.

Q. In your practice, medicine evolves; correct?

A. Correct.

Q. And as time goes on, new risks may be

REPORTER'S CERTIFICATE

I, BEVERLY A. BENJAMIN, CSR No. 710, Certified Shorthand Reporter, certify:

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony and all objections made were recorded stenographically by me and transcribed by me or under my direction;

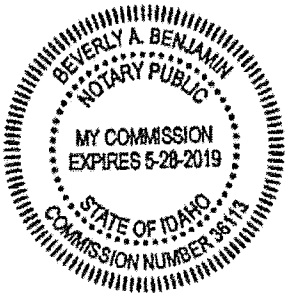
That the foregoing is a true and correct record of all testimony given, to the best of my ability;

I further certify that I am not a relative or employee of any attorney or party, nor am I financially interested in the action.

IN WITNESS WHEREOF, I set my hand and seal this _____ day of _____ _____.

Beverly A Benjamin

BEVERLY A. BENJAMIN, CSR
Notary Public
P.O. Box 2636
Boise, Idaho 83701-2636



UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC,

Defendant.

Case No. 2:17-CV-06686-RGK-PJW

CONFIDENTIAL

VIDEOTAPED DEPOSITION OF MARCIA BENJAMIN

TAKEN FEBRUARY 17, 2021

Job No. CS4463472

REPORTED REMOTELY BY:

BEVERLY A. BENJAMIN, CSR No. 710

Notary Public

any risks to your health?

A. No, there was no -- the operation itself was a risk because once you are weaning off, you have to go very slowly.

Q. So kind of going back to this Exhibit No. 2 here, March 4, 2013, as the last date of treatment. Do you recall why you stopped receiving ECT?

A. Why I stopped using ECT?

Q. Yeah. Do you know why?

A. Because there was no need for it.

Q. Why do you say that?

A. There was no further need for it; so it's...

Q. When you say "there was no further need," did Dr. Frankel tell you that your course of ECT treatment was concluded?

A. No, he did not. I'm a bit confused.

Q. Sure. Let me reask it.

Since your last treatment of ECT was on March 4, 2013, was there any reason why you didn't undergo any further ECT after that date?

A. I don't remember why I stopped, but I believe it wasn't working and -- yeah.

Q. What makes you think it wasn't working?

A. Because -- I don't remember, but I think that there were side effects that I was not able to endure.

It just wasn't worth it to go through that.

Q. Can you recall any of the side effects you were experiencing?

A. Memory loss, lots of pain in my body, bleeding, just pain all over. It was just like, having difficulty walking, having complete confusion of where I was or which city I was in, what time and date it was. It was just a nightmare.

Q. Did you tell Dr. Frankel you were experiencing any of these problems?

A. Yes, I did.

Q. What did he say?

A. That it would be temporary. It would last about a month and a half to 2 months.

Q. Did you experience any of these symptoms after --

A. Sorry?

Q. I interrupted you. Go ahead, Mrs. Benjamin.

A. I couldn't remember holidays or anything. I lost a lot of memories and it just wasn't worth it.

Q. Did you experience these problems, memory loss, pain in your body, bleeding, and difficulty walking beyond a month and a half after you completed ECT treatment?

A. Yes, I did.

Q. Did you tell Dr. Frankel that you were still experiencing those problems?

A. Yes, I did. I called them.

Q. What did he tell you?

A. That it could go up to 6 months. When he said that, then I knew then and then that he was just not honest.

Q. So you no longer believed him when you had a conversation with him and he told you now it would be 6 months?

A. No, I did not. Not only that, he decided to -- started to suggest other medications, which was just not -- hmm-um. It seemed to me like he was doing trial and error. He wasn't sure himself.

Q. Did you ever seek -- strike that.

After you completed your ECT treatment with Dr. Frankel, when did you next see a doctor?

A. I went back to Dr. Gudeman, and I remember him being shocked to see that Dr. Frankel had given me 20 sessions when he had only asked for 6.

MS. ALARCON: Is this an okay time to take a 5-minute break?

MR. BENKNER: Yeah, sure, that's fine.

MS. ALARCON: Thank you.

THE VIDEOGRAPHER: This marks the end of media

A. Yes, I do.

Q. There's a date on this document, September 23, 2016. Do you believe that's the date that you mailed this to Dr. Frankel?

A. Yes, that is what it says there.

Q. Okay. Now, why were you requesting your medical records from Dr. Frankel?

A. I'm sorry?

Q. Why were you requesting your medical records from Dr. Frankel?

A. I wanted to understand what had been done to me. I have a right to have my records.

Q. Again, I was just trying to understand why you were requesting them.

A. Um-hmm.

Q. Did he respond to this request?

A. No.

MR. BENKNER: So I want to show you another document on your screen. It should appear. Mark this as Exhibit No. 8.

(Exhibit 8 marked.)

Q. (BY MR. BENKNER) Have you seen this document before?

A. Yes, I addressed that document to Dr. Frankel.

Q. So again, there's a signature on there. Do

you recognize that as yours?

A. Um-hmm.

Q. Is that "yes"?

A. Yes, that is a "yes."

Q. And the date here is July 16, 2015. Do you believe that's the date you mailed this request to Dr. Frankel?

A. Yes.

Q. And did Dr. Frankel respond to this request?

A. No. That was the reason why I sent the subsequent one to him.

Q. In between July 16, 2015, and the date identified on Exhibit 7, September 23, 2016, did you make any other efforts to try to get your records from him?

A. Well, other than what it states there, no.

Q. I'll show you a new document, Exhibit No. 9.

(Exhibit 9 marked.)

Q. (BY MR. BENKNER) Do you see that in front of you?

A. Yes, I do.

Q. And obviously let me know if you need me to blow it up if you need to read something or --

A. It would be nice if you could make it a little bigger.

different. It sounds like from this letter that you believe Mr. Iannaccone received copies of your medical records from Dr. Frankel. Is that accurate?

A. Yes, he did, without my permission.

Q. So what I want to know is, did Mr. Iannaccone ever give you copies of the medical records that were given to him by Dr. Frankel?

A. When I informed him that the release of my medical records were illegally done to Dr. Frankel, he put a copy in the mail and had it sent to me.

Q. Perfect.

A. But it was not because I had requested them.

Q. A new document in front of you. This one is kind of far back. Let me scroll up. Can you read that?

A. Yes.

(Exhibit 10 marked.)

Q. (BY MR. BENKNER) This is Exhibit No. 10, it has a date of September 22, 2016.

A. Um-hmm.

Q. Have you ever seen this document before?

A. Yep.

Q. Do you know what it is?

A. It's a letter to Dr. Hirt.

Q. Did you draft the letter?

A. I believe so, yes.

Q. And do you know what the purpose of this letter was?

MS. ALARCON: Objection; vague and ambiguous.

Q. (BY MR. BENKNER) Let me rephrase.

Why did you draft the letter to Dr. Hirt in September 2016?

A. I believe I was thanking him for helping me with my treatment.

Q. I'm going to show you a new document now, Exhibit No. 11.

(Exhibit 11 marked.)

Q. (BY MR. BENKNER) Do you see a new document on your screen?

A. Yes.

Q. Do you recognize this document?

A. Yes, I do.

Q. What is it?

A. This is a letter from me to Dr. Gaines.

Q. And is this a critique of the neurological report that Dr. Gaines drafted for you?

A. Yes, it is.

Q. Did Dr. Gaines alter or change her report based on the criticisms in Exhibit No. 11?

A. I don't know.

Q. Did Dr. Gaines respond -- sorry. I

Felicio is my mom's last name; Stefanon is my father's last name; and Benjamin is Daniel's last name. I can write it in the chat box if you want.

THE REPORTER: Please.

Q. (BY MR. BENKNER) Ms. Benjamin, do you have a Facebook page?

A. I do.

Q. And do you have that under your name Marcia HF Stefanon Benjamin?

A. I do.

Q. I'll show you a new document.

MR. BENKNER: What are we on, 14?

(Exhibit 14 marked.)

Q. (BY MR. BENKNER) Do you see that on your screen?

A. Yes, um-hmm.

Q. Do you recognize this as a post that you made on your Facebook page?

A. Yes.

Q. Do you know who Dr. Peter Breggin is?

A. He's a psychiatrist.

Q. How are you familiar with him?

A. Just read a few of his things, saw a few of his videos.

Q. So it's my understanding that this is, what

you posted here is a link to another page that pops up. Does that sound right?

A. Correct. Um-hmm.

Q. So I'm going to show you what came up when I clicked on it, Exhibit No. 15, is an article. Do you see that on your screen?

A. I do.

Q. Have you ever seen this article before?

A. Yes, I have.

Q. Is this the article that you linked to your Facebook page on --

A. I'm not sure because he has so many articles.

Q. Okay. But you do recognize Exhibit 14 -- let me go back to it. Sorry. I'm having computer problems.

A. I do. I'm interested in reading about psychiatry and different types of treatments. Yes, I do.

Q. This one it says, the name of it is: "A Prescription for Love: An introduction to Toxic Psychiatry." Do you see that?

A. Yeah, I do.

Q. For the record, I'm referring to Exhibit No. 14. And then I want to go back -- strike that. Hold on one second.

MS. ALARCON: I'm freezing, just FYI.

MR. BENKNER: I see the problem. Monique, let me know when you're ready to go.

MS. ALARCON: I'm not ready. Hold on.

I'm ready.

Q. (BY MR. BENKNER) I'm going to share my screen with you again. I apologize, Mrs. Benjamin, it looks like I was looking at the wrong post. I'm now going to mark as Exhibit No. 15 another Facebook post. Do you recognize this as one of your Facebook posts?

(Exhibit 15 marked.)

THE WITNESS: I do.

Q. (BY MR. BENKNER) So the article that we just saw in Exhibit 14, "A Prescription for Love: An Introduction to Toxic Psychiatry," do you now recognize that as linked to your Facebook page here on Exhibit 15?

A. I'm seeing it. I don't remember exactly what it was about. But like I said to you, I'm interested in reading about psychiatry, especially given what I underwent, it was of my interest.

Q. It's my understanding that on Facebook when they put the date here, the date on Exhibit No. 15 is September 26, 2014, that that's the date that you would have posted this. Is that your understanding as well?

A. Yes.

MR. BENKNER: I have no further questions.

MS. ALARCON: I think we need to clear up the exhibit numbers just now. I don't know if the court reporter is following, but I don't -- I believe when you started showing these Facebook posts you were at 14.

MR. BENKNER: Sure. I'll put it on the record and clarify what they are.

MS. ALARCON: That would be great.

MR. BENKNER: So No. 15, which we're looking at right now is a Facebook post, confirmed by the witness, posted on September 26, 2014.

THE WITNESS: I was undergoing --

MS. ALARCON: Marcia, there's no question pending. We just have to clarify the dates and the exhibit numbers. Thank you.

MR. BENKNER: Exhibit No. 13 is Marcia's Facebook post from September 14, 2014.

And then Exhibit 14 was the article linked to Exhibit 15 called "A Prescription for Love: An Introduction to Toxic Psychiatry."

MS. ALARCON: Okay. Thank you.

So I just have a few follow-up questions.

Jason, if you wouldn't mind, stop the screen share.

EXAMINATION

REPORTER'S CERTIFICATE

I, BEVERLY A. BENJAMIN, CSR No. 710, Certified Shorthand Reporter, certify:

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

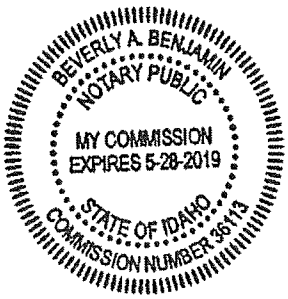
That the testimony and all objections made were recorded stenographically by me and transcribed by me or under my direction;

That the foregoing is a true and correct record of all testimony given, to the best of my ability;

I further certify that I am not a relative or employee of any attorney or party, nor am I financially interested in the action.

IN WITNESS WHEREOF, I set my hand and seal this _____ day of _____ _____.

BEVERLY A. BENJAMIN, CSR
Notary Public
P.O. Box 2636
Boise, Idaho 83701-2636



Marcia Stefanon Benjamin, CID, CCIDC
[redacted]

July 16, 2015

Michael Frankel, MD
[redacted]

Dear Dr. Frankel,

This is a personal formal request for the release and full disclosure of all electronic convulsive treatments given to me from September 2012 through March 2013. Please incorporate all specifics including all medications, anesthetics, muscle paralyzing agents, machine model, voltage used, the number of seizures per treatment, seizure length, and post ECT recovery details. In addition, please include any audio-visual materials from the procedures.

Thank you very much for your time and attention.

Sincerely,

Marcia Stefanon Benjamin

EXHIBIT
8

Benkner Dec Ex H- 0001

Michael Frankel, M.D. Inc.

[redacted]

Authorization For Release of Information

By signing this document, I (name of patient) MARCIA STEFANON BENJAMIN (hereinafter "Patient") hereby authorize Michael Frankel, M.D. (hereinafter "Provider") to disclose mental health treatment information and records obtained in the course of Provider's treatment of patient, including, but not limited to, Provider's diagnosis of Patient, to (name and functions of the person or entity to whom disclosure is made) MARCIA STEFANON BENJAMIN, CID, CCIDC # 6424 ENVIRONMENTAL DESIGNER AND ARCHITECT PROFESSIONAL

I understand that I have a right to receive a copy of this authorization. I understand that any cancellation or modification of this authorization must be in writing. I understand that I have the right to revoke this authorization at any time unless Provider has taken action in reliance upon it. And, I also understand that such revocation must be in writing and received by Provider at 22144 Clarendon Street #300, Woodland Hills, CA 91367 to be effective.

This disclosure of information and records authorized by Patient is required for the following purpose: PERSONAL INFORMATION

The specific uses and limitations on the types of medical information to be discussed are as follows: NONE

Such disclosure shall be limited to the following specific types of information: FULL DISCLOSURE OF ELECTRIC CONVULSIVE TREATMENTS (ECTS) INCLUDING ALL SPECIFICS (MEDS., MACHINE USED, VOLTAGE, SEIZURE LENGTH, ETC)

Provider shall not condition treatment upon Patient signing this authorization.

Patient has the right to refuse to sign this form.

Patient understands that information used or disclosed pursuant to this authorization may be subject to re-disclosure by the recipient and may no longer be protected by the Federal Privacy Rule, although applicable California law may protect such information.

This authorization shall remain valid until: PERMANENT

Patient MARCIA STEFANON BENJAMIN Signature [signature]

Date 07/16/2015

September 22, 2016

Dear Dr. Hirt,

Let me begin by thanking you for from the bottom of my heart. Simple words cannot express my profound gratitude for what you have done and does for my recovery. All treatments received at your office since day one have not only rescued me from a severe iatrogenic condition but introduce me to real medicine responsibly applied, putting me in a healthier functioning mode that gradually helps me regain my health and my life back. Despite having to push through daily post iatrogenic brain injury symptoms, I feel better and more confident than I ever felt since all this nightmare happened from 2011 until 2014. Right now I am in the process of relocating and reopening my architectural design office, trying to engage in working at least part time for now, I am more involved in social family and friends' activities, I joined my Temple's Choir and will be singing during the High Holidays, I am walking 30 minutes daily while will participate in the 5K Ventura Heart Walk in October, I'm trying my best to attend beginning Yoga twice a week, and I'm volunteering as Head Volleyball Coach at the USYVL supporting the city of Agoura Hills youth teams. I am fully aware that I could not have done this without your treatments. You literally saved my life, Dr. Hirt.

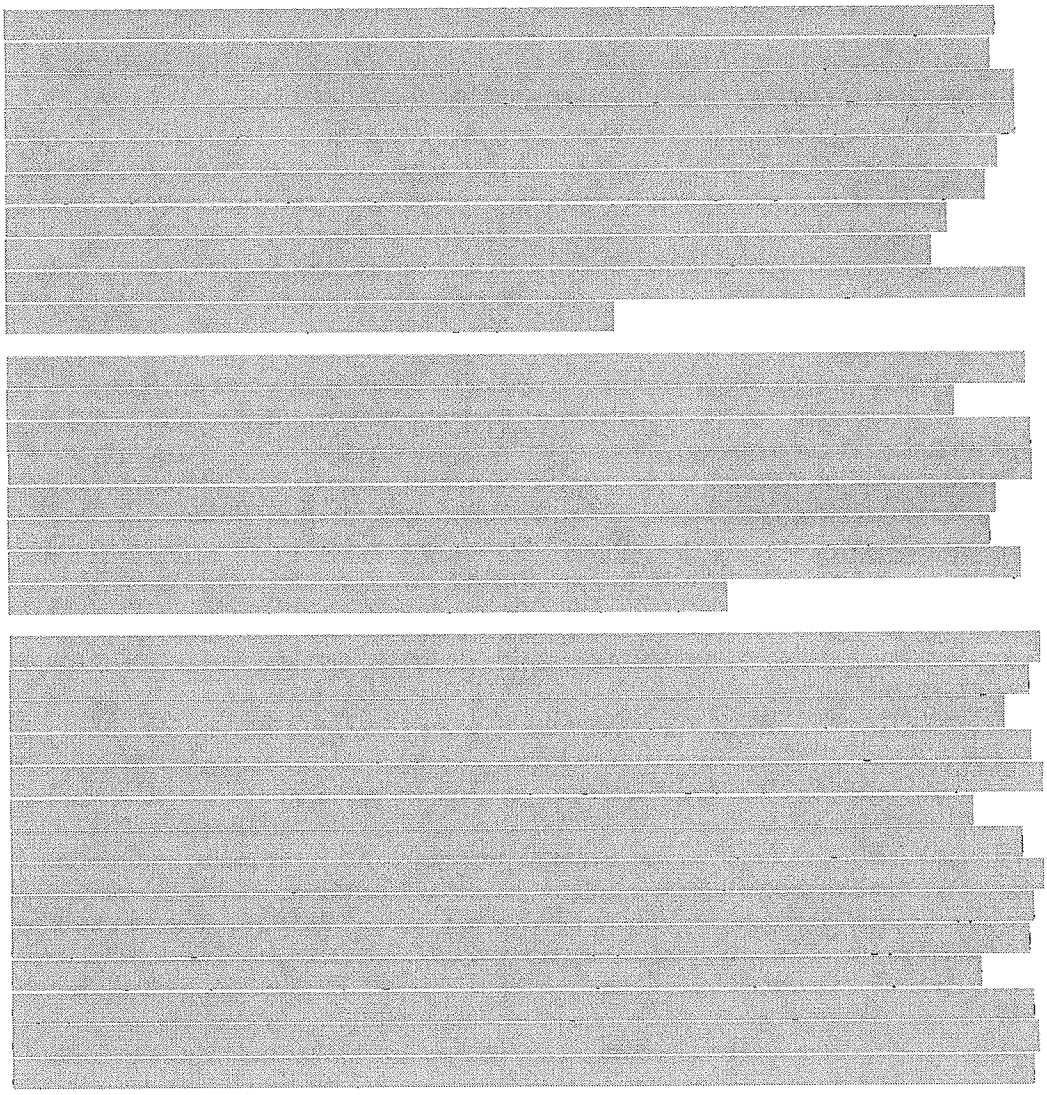
As I became more and more cognizant of the level of iatrogenic injury that I have endured prior to becoming your patient, I understood that I indeed had undergone inhumane torture. I do acknowledge that there may be a necessity for using strict allopathic medical treatments in order to address severe symptoms during a health crisis moment to save someone's life; however, I was never a mentally ill patient nor ever imposed any risk of harm to myself nor to others – I had and still have a thyroid condition which was incorrectly addressed, misdiagnosed as anxiety, and then as anxiety with depression which was in fact chemically induced by a serious over prescription of depressants [redacted] The side effects [redacted] prompt this negligent doctor, Dr. David Gudeman, to misdiagnose me once again only now as "severely depressed with resistance to most medicines", and to suggest the use of electric shock as a solution to "bring me back" from the nightmare that he himself had created in the first place. The electric shock doctor, Dr. Michael Frankel, although well recognized in his field, also misdiagnosed me with severe depression, completely neglecting the over prescription by Dr. Gudeman, suggesting a series of 6 shocks, which later unfolded into 20 sessions of horrific invasive electric shocks applied at a higher voltage [redacted] When I begged him to stop, the shock doctor said that I had to have continue with maintenance sessions for ever, and that I should start taking Lithium! By then, my husband and I knew then that I had been a victim of iatrogenic medicine – March 2013. We went back to Dr. Gudeman to recap what had happened, and agreed to his suggestion of Transcranial Magnetic Stimulation maintenance sessions in lieu of the latter; however, my husband and I were still inoculated into believing that this so called reputable UCLA doctor actually knew what he was doing. Therefore, in addition to shocks, I underwent 36 very painful and expensive unnecessary TMS sessions, wrongly

EXHIBIT 10

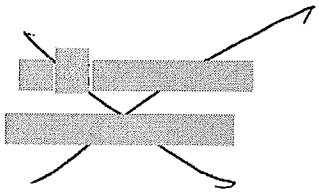
Benkner Dec Ex I- 0001

applied on the right side of my brain, as I informed by the recent TMS technician who did my lasted MRI, which subsequently caused further brain damage.

As soon as I begged Dr. Gudeman to stop with all of it, I got a call from his office that same week stating that his medical licenses had been revoked. My family and I were horrified by what had happened and became concerned for my wellbeing after all that I had gone through. We had no idea of which doctor to see and what to do following that reality, and while trying to make sense of what had happened, we further learned that two of Dr. Gudeman's patients had died from over prescription which caused the Medical Board to revoke his licenses. This happened in late October 2013, about 20 months prior to meeting you, Dr. Hirt. My family and I were revolted, specially from having trusted and believed in these two highly referred doctors.



[redacted]



With profound gratitude,

Marcia

Marcia S. Benjamin, CID, AIA Associate

[redacted]

www.aiedesignstudio.com

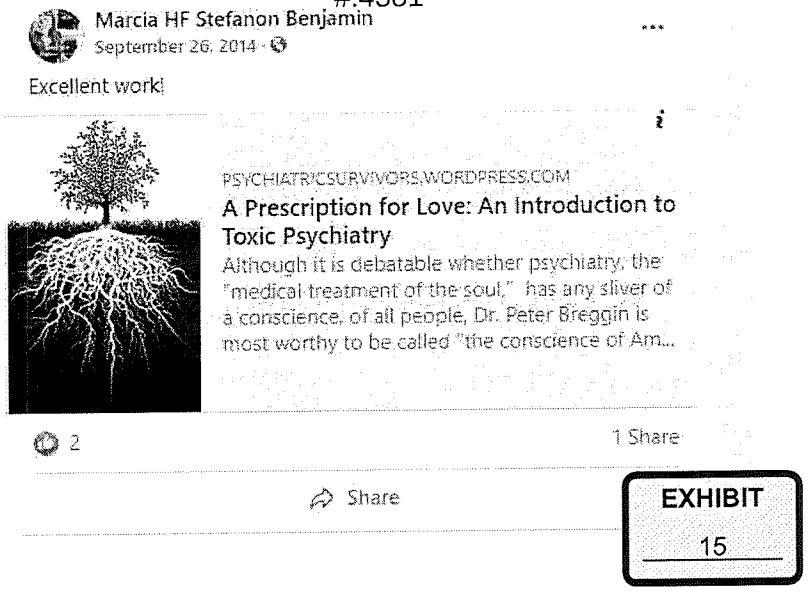
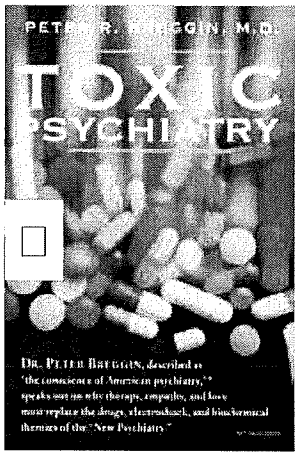


EXHIBIT
15

Benkner Dec Ex J- 0001

Psychiatric Survivors

A Prescription for Love: An Introduction to Toxic Psychiatry

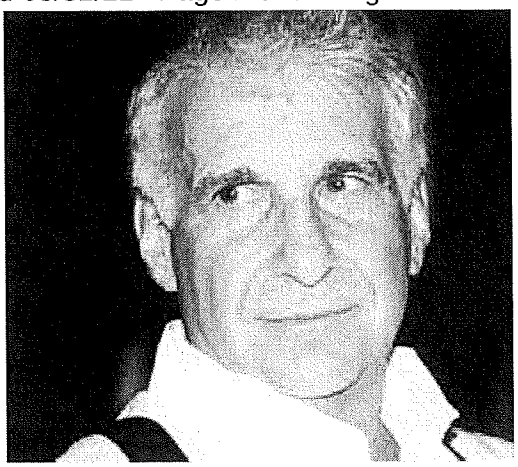


(https://psychiatricsurvivors.files.wordpress.com/2014/04/toxic_psychiatry.jpg)Although it is debatable whether psychiatry (http://en.wikipedia.org/wiki/Psychiatry), the "medical treatment of the soul," has any sliver of a conscience, of all people, Dr. Peter Breggin (http://www.breggin.com/) is most worthy to be called "the conscience of American psychiatry." He (http://en.wikipedia.org/wiki/Peter_Breggin) began his career by offering love and support to those who were suffering under atrocious conditions in mental hospitals, and he has continued to demonstrate throughout his career, in the words of the subtitle of his book *Toxic Psychiatry* (http://www.amazon.com/Toxic-Psychiatry-Electroshock-Biochemical-Theories/dp/0312113668), "why therapy, empathy, and love must replace the drugs, electroshock and biochemical theories of the 'New Psychiatry.'"

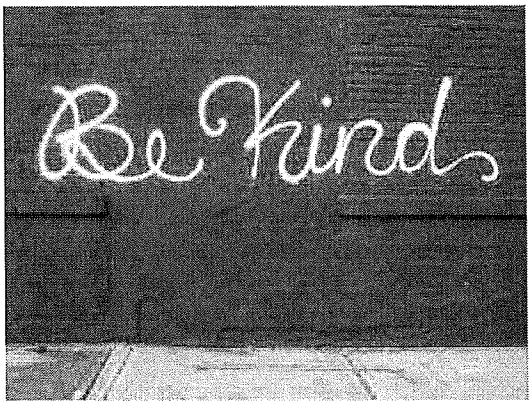
(https://psychiatricsurvivors.files.wordpress.com/2014/04/breggin.jpg)Why does this matter? In the introduction to *Toxic Psychiatry*, Breggin recognizes that "Psychiatry sets the tone and direction for the field of mental health and has been rapidly pushing it toward a more biological or medical viewpoint." This push toward "a more biological or medical viewpoint" is simultaneously a push away from the "therapy, empathy, and love" for which Breggin so adamantly advocates. In the first chapter of *Toxic*

EXHIBIT
14

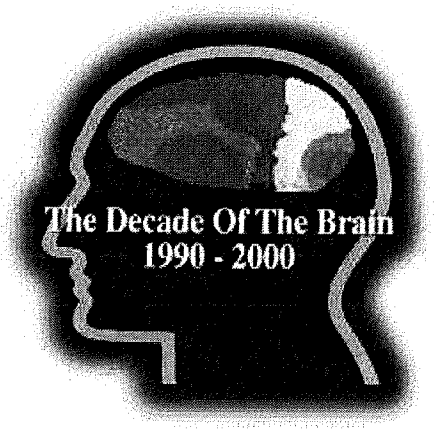
Benkner Dec Ex K- 0001



Psychiatry, Breggin recalls his introduction to the field of mental health, noting how psychiatry has grown progressively out of control. He keenly observed that psychiatric treatments "had caused or worsened many of the patients' problems," and that "much of the patients' upset and suffering was induced by the hospital environment itself." Breggin quickly came to realize that doctors were not just abusing patients in the hospitals, but they were devising chemical and psychological methods to dominate them and to intimidate them into submission.



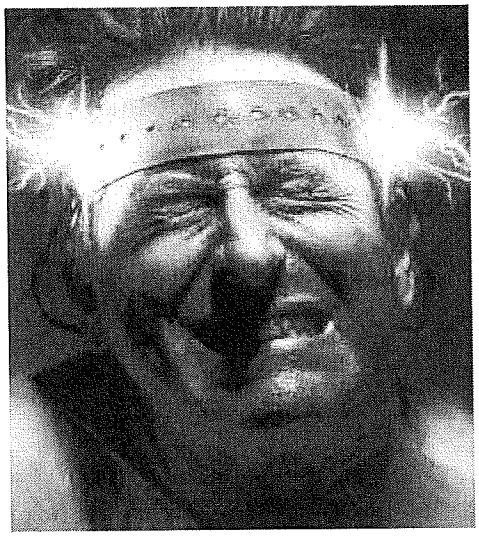
(https://psychiatricsurvivors.files.wordpress.com/2014/04/be_kind.jpg)In contrast to such hostility, Breggin and his associates lovingly helped several people recover from their afflictions. Rather than ging and demeaning the patients, Breggins' crew accomplished a "miracle" by "showing [our] nts care and attention; by talking with them and taking them for walks, by helping them get erly fitted with eyeglasses, false teeth, or clothing, by reacquainting them with their forgotten families, or by connecting them with more humane supervised facilities outside the hospital." Unfortunately, Breggins' prescriptions for kindness encountered the opposing currents of the psychiatric revolution of the 1960s. In 1966, when Breggin became a full-time consultant at the National Institute of Mental Health (NIMH), psychiatry was "well on the way toward its wholesale conversion to biochemical and genetic theories and to technological interventions, such as drugs and electroshock."



(https://psychiatricsurvivors.files.wordpress.com/2014/04/decade_of_brain.gif)Ironically, as the media turned up the volume of the biopsychiatric message, the only "biochemical imbalances" that could be identified with certainty were the ones that were being produced by psychiatric treatment itself. President George Bush declared 1990 to be the first year in the Decade of the Brain, but sadistic psychiatry made sure that it was not the first year in the Decade of the Heart. In *Toxic Psychiatry,* Breggin contrasts the compassion of students who have been educated in the humanities with the ruthlessness of psychiatric education: "Your psychiatrist will have more power than you. He or she can prescribe drugs or shock, lock you up against your will, talk behind your back with your husband, wife, or parents and make plans for your future without consulting you. As a medical expert in malpractice and patients' rights suits, I have dealt with numerous cases of individuals who sought psychiatric help for routine problems in living, such as sadness over the loss of a loved one, only to find themselves swept along the path of biopsychiatry, ending up with permanent brain dysfunction and damage from [redacted] and shock treatment."

Even though Breggin published *Toxic Psychiatry* in 1991, he predicted several of the harmful results that psychiatry has since produced, including increasing numbers of parents surrendering responsibility for their children to mental health professionals, millions of children subdued by "legal" drugs or the authority of psychiatric workers, patients suffering under the stigma of false diagnoses, patients suffering from prescription drug induced brain damage, and health care professions being dominated by the multi-billion-dollar pharmaceutical industry. As Breggin observes early on in his book, "All of the major psychiatric treatments work by producing brain dysfunction, and too often they result in lobotomylike effects and permanent damage. I discovered that biopsychiatry resists criticism of any one of its theories and physical interventions because all of them rest upon the same flawed principles and harmful practices."

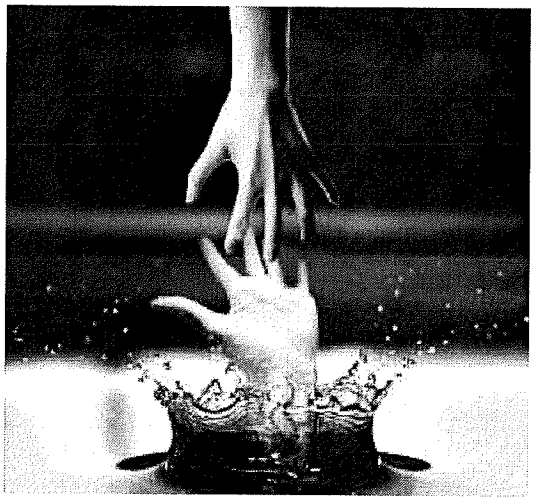
(https://psychiatricsurvivors.files.wordpress.com/2014/04/electroshock.jpg)Breggin then systematically addresses various harmful aspects of the psychopharmacological enterprise, beginning with "'Schizophrenic' Overwhelm and Neuroleptic Drugs" and concluding with a chapter on "Women, Children, the Homeless, and the Psycho-Pharmaceutical Complex." Along the way, the author confronts the problems of "'Depressive' and 'Manic Depressive' Overwhelm, Antidepressants, Lithium, and Electroshock," and "'Anxiety' Overwhelm and the Minor Tranquilizers." Finally, Breggin presents his suggestions for "Psychosocial Alternatives" along with a list of "Groups to Join," "Periodicals to Subscribe to," and "Sources of Legal and Psychotherpeutic Help." Throughout the book, the crux of Breggins' thesis is simply that psychiatry is toxic. The evidence that he gives to support his thesis is enough to persuade the most skeptical mind.



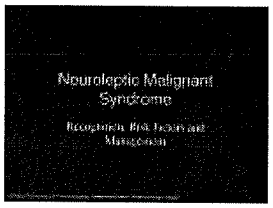
(https://psychiatricsurvivors.files.wordpress.com/2014/04/roots.jpg)Breggins' command of the psychiatric literature, history and data is remarkable, but his insights into the root causes of human suffering are equally convincing. For example, Breggin posits, "If we are beings rather than devices, then our most severe emotional and spiritual crises originate within ourselves, our families, and our society. Our crises can be understood as conflicts or confusion about our identities, values, and aspirations rather than as biological aberrations. And as self-determining human beings, we can work toward overcoming those feelings of helplessness generated by our past spiritual and social defeats." Furthermore, Breggin notes that, "Parents of disturbed offspring commonly observe, 'She was different from the others from the beginning- too sensitive. That's what she was, overly sensitive.' Another nent frequently expressed by these parents: "Oh, she was different from the start. She didn't seem pond to us. She wasn't willing to be held. She was always less social than her brothers and sisters.' withdrawal response represents a normal sensitivity to the anxieties, tensions, lovelessness, bad feelings, negative vibrations, fears, and so on emanating from the parents."

(https://psychiatricsurvivors.files.wordpress.com/2014/04/cinderelladisney.jpg)Why is this? Breggin points out that "Envious feelings often motivate the hostility directed toward the wounded member of the family. The story of Cinderella expresses how the most beautiful, sensitive, and spiritually shining child can become the butt of ridicule and abuse. It is difficult for a mother, father, or older brother or

sister to accept that someone has arrived in their circle with unique sensitivity, passion, or awareness. They feel put to shame by the new member. In turn, they shame him or her." Once the family rejects such a child, rest assured that psychiatrists will only exacerbate the trauma with "drugs, restraints, and isolation rooms, reenacting and reinforcing the original humiliations experienced in the family."



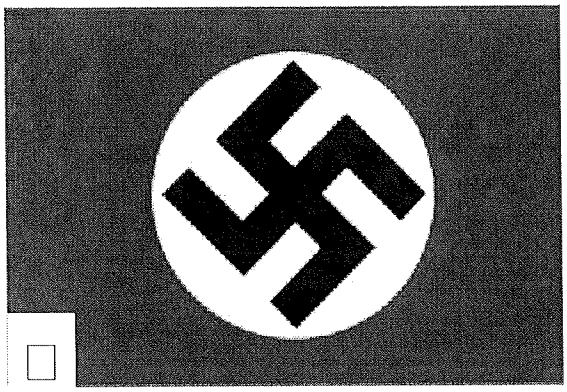
(https://psychiatricsurvivors.files.wordpress.com/2014/02/cropped-survive_11.jpg)However, Breggin is careful to remind the reader about individual responsibility: "Ultimately, every individual must choose whether or not to overcome any hardship or oppression inflicted by the family, society, or psychiatry. Human beings retain a measure of free will as long as they remain conscious. Indeed, without the exercise of a flickering will, there is no hope for people; and it is the helper's role to encourage every hint of self-determination." At this point, Breggin introduces the embodiment of such an ethos, the brave leaders of the psychiatric survivor movement, many of whom "lead interesting, exciting, productive and satisfying lives."



(https://psychiatricsurvivors.files.wordpress.com/2014/04/neuroleptic_malignant_syndrome2.png)In subsequent chapters, Breggin delves into great detail about the effects of neuroleptic drugs, such as chemical lobotomy and iatrogenic (treatment-caused) harm. He demonstrates how so-called "miracle drugs" actually cause a variety of impairments such as Tardive Dyskinesia, Tardive Dementia, Lethargic Encephalitis, mental deterioration, permanent neurological damage, and in some cases the fatal effect of Neuroleptic Malignant Syndrome. In addition to warning of the great dangers of neuroleptic drugs, Breggin also shows that such drugs are just as dangerous to withdraw from. He recognizes that psychiatry has quite literally produced its own epidemic: "Organized psychiatry is fond of producing half-cocked statistics on how many so-called schizophrenics or depressives there are in the country, because it helps business. But it is loathe to estimate how many patients it is permanently damaging." Patients are rarely alerted to the negative short and long-term effects of psychotropic drugs.

(https://psychiatricsurvivors.files.wordpress.com/2014/04/trust_me_im_a_doctor.jpg)One of the most troubling trends in modern psychiatry is the tendency to reduce suffering to simplistic genetic and biological theories while recklessly attaching sweeping labels like "schizophrenia" and "bipolar

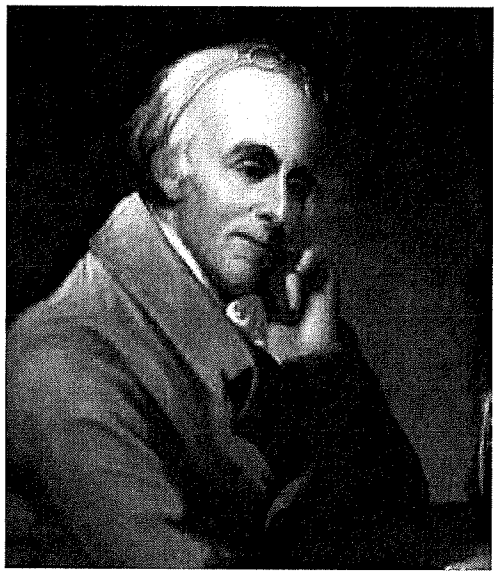
disorder" to unsuspecting patients. Ironically, as psychiatry inclines more and more toward genetic and biological models for diagnosing suffering, the actual scientific and statistical evidence tends in the opposite direction. In other words, as psychiatry gropes for genetic and biological causes of "diseases," more and more facts confirm that the root causes of "mental illness" are psychological and environmental in nature, except for the biological damage that is inflicted directly by psychotropic drugs. Nevertheless, the media continues to lull the public into adopting the genetic and biological framework that is so prevalent within the field of psychiatry. As Breggin chides, "In psychiatry, biological research is guided, indeed driven, by the profession's need to justify its existence as a medical specialty."



(https://psychiatricsurvivors.files.wordpress.com/2014/04/naziflag.gif)Surprisingly, such tendencies are not unique to modern psychiatry. In the 1930s, with the support of the Rockefeller Foundation, Ernst Rudin became the head of the Nazi eugenics program and chief champion of racial hygiene. Not coincidentally, Rudin was also the "single most important psychiatric researcher in the field of genetics during the highly active period of the 1930s." Rudin's American counterpart, Franz Kallmann, praised Hitler's genocidal rampage while lamenting that such a "final solution" could not be enacted to such an extent in America. During the time that Breggin was writing *Toxic Psychiatry*, Rudin and Kallmann had been reinstated by biopsychiatrists as "legitimate scientists."

(https://psychiatricsurvivors.files.wordpress.com/2014/04/genain_quadruplets.jpg)Breggin also draws attention to one of the most infamous episodes of modern biopsychiatry, namely the "Genain Quadruplets." Geneticists Paul Wender and David Rosenthal conducted a study of four young women, identical quadruplets, who had apparently gone mad. Rosenthal assumed that "schizophrenia in four genetically identical females was prima facie evidence of a genetic cause," while completely glossing over the fact that each of these children was subjected to horrific emotional, psychological, physical and sexual abuse. Breggin promptly reproves so severe an oversight, "For Rosenthal to suggest that the study supports a genetic theory of schizophrenia itself constitutes a form of child abuse."

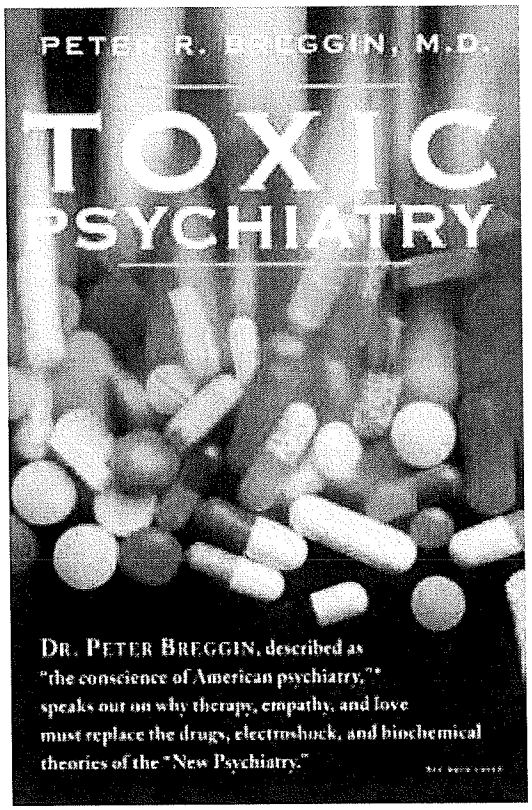
(https://psychiatricsurvivors.files.wordpress.com/2014/04/benjamin_rush_painting_by_peale.jpg)Breggin traces the fanatical search for biological and genetic causes for mental illnesses back to 18th century, when Benjamin Rush, one of the signers of the Declaration of Independence, believed that "the source of madness resides in the blood vessels of the brain," a belief that led him to bleed his patients. Rush was

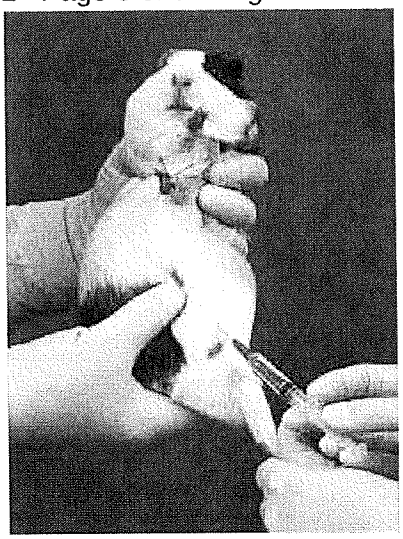


the inventor of a torture device called the "tranquilizer chair," and he even committed his own son to his mental institution. As Breggin records, "Rush is also notorious for having bled George Washington to death. Does it mean something that the Father of Psychiatry killed the Father of the Country?"

When it comes to theories of "Depressive" and "Manic-Depressive" illness, Breggin is even more perceptive concerning non-biological and non-genetic factors: "Guilt-provoking parents often take more notice of their children than do shaming parents. They make them feel as if they have a significant but negative impact on the family. Typically the parents blame their own suffering on the child. Their classic axioms include 'Children aren't worth the pain they cause' and 'Wait until you have children and see the pain they cause you.' The children may be called 'bad' or 'burdensome' and be taught that they caused pain and travail from the pregnancy throughout their teenage years and even into adulthood. As they grow up, these children become dominated by duty and obligations-often felt as guilt- in their ons with others." Breggin takes into consideration other environmental and cultural influences e unraveling the biological theories of "Depressive" and "Manic-Depressive" overwhelm. The biology of depression," writes Breggin, "is based less on science than on politics- the wish of psychiatry to maintain a medical image, to uphold its dictatorial authority, to garner federal funds, and to convince patients to seek psychiatric help." Sadly, psychiatry's wish has in large measure been granted, with increased numbers of patients subjected to lithium, antidepressants and electroshock. As with the neuroleptic drugs, Breggins describes the terrible effects of antidepressants, and the even more terrible effects that can be experienced while attempting to withdraw from the drugs.

The story of lithium, in particular, is one worth remembering. Breggin recounts the history of John Cade who "accidentally discovered the effect of lithium while injecting it into guinea pigs in his laboratory in Australia." Cade discovered that the lithium rendered the poor animals flaccid and sedated, lethargic and unresponsive to stimuli. Then he promptly decided to experiment on human beings. "He quickly discovered that he could subdue hospital inmates as easily as he did the guinea pigs, making them into more docile inmates," and that his "pioneering efforts" made the patients "quiet and amenable." Breggin concludes the chapter with this summary: "In the world of modern psychiatry, claims can become truth, hopes can become achievements, and propaganda is taken as science. Nowhere is this more obvious than in psychiatric pretensions concerning the genetics, biology, and physical treatment of depression and mania. As we also found in regard to neuroleptics and so-called schizophrenia, biopsychiatric is based too often on distortions, incomplete information, and sometimes outright fraud- at the expense of reason and science."





(https://psychiatricsurvivors.files.wordpress.com/2014/04/toxic_psychiatry1.jpg)The rest of Breggin's
rch is as accurate as it is stimulating to study. He leaves no stones unturned in his quest to expose
ue nature of psychiatry, and he invites the reader to consider not only the hard science, but also the
ching accounts of personal suffering. It may well be true that Dr. Peter Breggin is the "conscience of American psychiatry." His book *Toxic Psychiatry* contains enough truth to stir up even the most apathetic conscience. Moreover, his simple plea for greater empathy and love toward those who suffer contains more common sense then all the journals of psychiatry combined. For the sickness that is psychiatry, I prescribe an ample dose of Dr. Breggin's book to everyone, whether psychiatrist, victim of psychiatry, or otherwise.

April 24, 2014 Horatius Cocles

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

-vs-

SOMATICS, LLC,

Defendant.

CASE NO. 2:17-CV-06686-RGK-PJW

VIDEOTAPED DEPOSITION OF
DANIEL BENJAMIN
TAKEN ON BEHALF OF THE DEFENDANT
VIA VIDEOCONFERENCE
ON MARCH 4, 2021

Job No. CS4482811

REPORTED BY: TRENA K. BLOYE, CSR

Q (By Mr. Benkner) Yeah. Go ahead and let me know when you're ready.

A I'm ready.

Q Okay. So going back to my question, then, she indicated that prior to undergoing ECT she would engage in sexual relations with you approximately three to four times a week. Is that accurate?

A That's accurate.

Q Okay. And then a little bit further down this sentence says, "It took approximately three years after ECT before conjugal relations returned to the same frequency as they existed prior." Is that an accurate statement?

A That is accurate.

Q Do you know exactly when your -- the sexual relationship you had with your wife changed from three to four times to less?

A I cannot pinpoint exactly, but I have to say -- yeah, I can't pinpoint exactly. But I think -- I think in terms of a block of time before and after it's easier for me to see.

Q Sure. Were you having any problems with sexual relations while she was treating with Dr. Gudeman, first treating with Dr. Gudeman before undergoing ECT?

A No. I can expand on that if you like.

Q Sure.

A She had ups and downs in her -- with the medication Gudeman was giving her, so there were some ups where the relationship was quasi normal.

Q And in thinking -- thinking about the period of time after she underwent ECT, how did it change? It went from three to four times a week to approximately how often?

A There wasn't a lot of conjugal interaction during that time. If there was --

Q Can you give me any estimate?

A No. If there was a window here or there where things were, you know, relatively peaceful, maybe. But twice a year. I don't know. I really can't venture a guess.

Q Okay. And at any point did you seek the advice of a therapist or other healthcare provider to try to fix that problem?

A No. The problem of conjugal visits is what you are referring to?

Q This specific issue, yes.

A I don't really care for that question because the goal was to get her well. It was not -- to get the conjugal visits re-established was not the point.

Q Okay. So other than the conjugal relations

Page 51

C E R T I F I C A T E

STATE OF OKLAHOMA)
) SS:
COUNTY OF OKLAHOMA)

I, Trena K. Bloye, Certified Shorthand Reporter within and for the State of Oklahoma, certify that DANIEL BENJAMIN was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth, in the case aforesaid; that the witness chooses to read and sign the deposition; that the above and foregoing videotaped deposition was taken by me in shorthand and thereafter transcribed; that the same was taken on March 4, 2021, at 10:00 a.m. PST, via videoconference; that I am not an attorney for, nor a relative of any of said parties or otherwise interested in the event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 8th day of March, 2021.

Trena K. Bloye, CSR
State of Oklahoma CSR No. 1522

POOLE & SHAFFERY, LLP
David S. Poole (SBN 94690)
dpoole@pooleshaffery.com
Jason A. Benkner (SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway
Suite 250
Telephone: 661.290.2991
Facsimile: 661.290.3338

Attorneys for Defendant
SOMATICS LLC

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN, Plaintiffs, v. SOMATICS, LLC, Defendant.	Case No.: Judge: Complaint filed: **DECLARATION OF CONRAD SWARTZ, M.D., PH.D., IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT** [Filed concurrently with: ; and [Proposed] Order] Date: Time: Location: Judge:

COMES NOW, Defendant SOMATICS LLC ("Somatics"), and submits this Declaration from Conrad Swartz, M.D., Ph.D., in support of its Motion for Summary Judgment, as follows:

DECLARATION OF CONRAD SWARTZ, M.D., PH.D.

I, Conrad Swartz, M.D., Ph.D., declare:

1. I am a Member-Manager of Defendant, SOMATICS LLC ("Somatics"), which is a party to this lawsuit.

2. Somatics, as a business, was initially formed in 1983 and began operations in 1984 for the purpose of selling electroconvulsive therapy ("ECT") devices to hospitals for use in treatment of certain types of mental illnesses.

3. At all times during its existence, Somatics has operated with permission from the Food and Drug Administration ("FDA"), through Section 510(k) FDA clearance. The FDA has never precluded Somatics from marketing or selling its ECT devices.

4. I have been informed that Plaintiff MICHELLE HIMES ("Ms. Himes") underwent ECT treatment at Sharp Mesa Vista Hospital between April 13, 2011 and January 9, 2012.

5. I have been informed that Plaintiff MARCIA BENJAMIN ("Ms. Benjamin"), underwent ECT treatment at Northridge Hospital between September 28, 2012 and March 4, 2013.

6. Up through the dates that these two Plaintiffs underwent ECT, Somatics' warnings regarding the risks of ECT treatment were published in two sources: (1) the operator's/instruction manual provided with the device upon purchase; and (2) a patient information pamphlet. As a Member-Manager, I was involved in the creation and publication of such warnings.

///

///

///

///

///

The foregoing is within my personal knowledge, and if called as a witness, I could and would competently testify thereto. I declaration under penalty of perjury that the foregoing is true and correct. This declaration was executed on the 30th day of March, 2021, at Vancouver, Washington.

Conrad Swartz, M.D., Ph.D. 3/30/21 10:52 AM

POOLE SHAFFERY

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **March 31, 2021**, I served the foregoing document described as: **DECLARATION OF CONRAD SWARTZ, M.D., PH.D., IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **March 31, 2021**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

Nicole Lyons, Declarant

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SECOND FLOOR, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

SERVICE LIST

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

Bijan Esfandiari, Esq.
Monique Alarcon, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
T: 310-207-3233
F: 310-820-7444
For e-service:
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
CHall@BaumHedlundLaw.com
vadlivankina@baumhedlundlaw.com
jjoseph@baumhedlundlaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Second Floor, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY & KOEGLE, LLP
David S. Poole (SBN 94690)
dpoole@pooleshaffery.com
Jason A. Benkner (SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway, Suite 250
Santa Clarita, CA 91355
(661) 290-2991 Tel.
(661) 290-3338 Fax

Attorneys for Defendant
SOMATICS, LLC

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC;

Defendant.

Case No.: 2:17-CV-06686-RGK-PJW

ANSWER OF DEFENDANT SOMATICS, LLC TO PLAINTIFF'S FIFTH AMENDED COMPLAINT

Pursuant to Rule 8 of the Federal Rules of Civil Procedure ("Fed. R. Civ. P."), Defendant, SOMATICS, LLC ("Somatics"), hereby answers and responds to the allegations contained in the Fifth Amended Complaint filed by MICHELLE HIMES, DIANE SCURRAH, MARCIA BENJAMIN and DANIEL BENJAMIN (collectively "Plaintiffs"). Somatics responds to the paragraphs of the Fifth Amended Complaint as follows:

SUMMARY OF THE ACTION

1. Somatics denies that its conduct resulted in injuries to Plaintiffs.

2. Somatics objects to the use of the terms "ECT shock device" and "shock treatment" as ambiguous and derogatory.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

3. Somatics is without sufficient knowledge or information to form a belief as to the truth of the allegations contained this paragraph, and on that basis, denies.

4. Somatics admits that ECT may be administered by healthcare providers to treat a variety of patients suffering from certain psychological disorders. To the extent any factual allegation contained in this paragraph requires a further response, they are denied.

5. Somatics is without sufficient knowledge or information to form a belief as to the truth of the allegations contained this paragraph, and on that basis, denies.

6. Somatics denies the allegations in this paragraph.

7. Somatics denies the allegations in this paragraph.

8. Somatics denies the allegations in this paragraph.

9. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

10. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

11. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

12. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

13. Somatics denies the allegations in this paragraph.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

14. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

15. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

16. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

17. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any allegations are directed to Somatics, they are denied.

PARTIES

18. Somatics is without sufficient knowledge or information to form a belief as to the truth of the allegations contained this paragraph, and on that basis, denies.

19. Somatics is without sufficient knowledge or information to form a belief as to the truth of the allegations contained this paragraph, and on that basis, denies.

20. Somatics is without sufficient knowledge or information to form a belief as to the truth of the allegations contained this paragraph, and on that basis, denies.

21. Somatics is without sufficient knowledge or information to form a belief as to the truth of the allegations contained this paragraph, and on that basis, denies.

22. Somatics denies that it was formed in the State of Florida in 1984. Somatics admits the remaining allegations contained in this paragraph.

///

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

23. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

24. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

JURISDICTION AND VENUE

25. Somatics does not contest this Court's jurisdiction.

26. Somatics does not contest this Court's jurisdiction.

27. Somatics does not contest this Court's jurisdiction.

PLAINTIFF-SPECIFIC ALLEGATIONS

28. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

29. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

30. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

31. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

32. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies.

33. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use

of the term "shock treatment" as vague, ambiguous and derogatory. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

34. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

35. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory.

36. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

37. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

38. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

39. Somatics lacks specific information and belief to respond to the allegations in this paragraph, and on that basis, denies. Somatics objects to the use of the terms "ECT shock device" and "shock treatment" as vague, ambiguous and derogatory.

SUBSTANTIVE ALLEGATIONS

40. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

41. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

42. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

43. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

44. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

45. Somatics admits that it has been a manufacturer of ECT devices since at least 1985, that it did not submit a PMA application, that its devices did not obtain approval through the PMA process, but denies that it was required to do so.

46. Somatics denies failing to report as required by the FDA.

47. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

48. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

49. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

50. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

51. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

52. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

53. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

54. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

55. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

56. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

57. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

58. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

59. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the

term "shock treatment" as vague, ambiguous and derogatory. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

60. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory. Somatics objects to the use of the term "brain damage" as vague, ambiguous and overbroad.

61. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the term "brain injury" as vague, ambiguous and overbroad.

62. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

63. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

64. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

65. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory.

66. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

67. Somatics denies that it failed to comply with any relevant requirements imposed upon it under FDA regulations.

68. Somatics denies that it failed to comply with any relevant requirements imposed upon it under FDA regulations. The remaining allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

69. Somatics denies that it failed to comply with any relevant requirements imposed upon it under FDA regulations. The remaining allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

70. Somatics denies that it failed to comply with any relevant requirements imposed upon it under FDA regulations. The remaining allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

71. Somatics denies that Elektrika, Inc. is the legal manufacturer of its products. Somatics denies that it failed to comply with any requirements imposed upon it under FDA regulations.

72. Somatics denies the implied allegations in this paragraph that healthcare professionals could have only discovered the risks of ECT through information disclosed to the FDA. The remaining allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any additional factual allegations were intended, they are denied.

73. Somatics denies the implied allegations in this paragraph that healthcare professionals could have only discovered the risks of ECT through information disclosed to the FDA. The remaining allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

respond. To the extent that any additional factual allegations were intended, they are denied.

74. Somatics denies the implied allegations in this paragraph that healthcare professionals could have only discovered the risks of ECT through information disclosed to the FDA. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the term "shock treatment" as vague, ambiguous and derogatory.

75. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the term "ECT shock devices" as vague, ambiguous and derogatory.

76. Somatics denies concealing any facts relevant to this lawsuit. The remaining allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any additional factual allegations were intended, they are denied.

77. Somatics denies the allegation that it improperly influenced any research into the safety and efficacy of ECT. The remaining allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any additional factual allegations were intended, they are denied.

78. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the use of the term "ECT shock devices" as vague, ambiguous and derogatory.

79. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

FIRST CLAIM OF RELIEF

Negligence/Negligence Per Se (Adulteration and Misbranding)

80. Somatics realleges its responses set forth in all preceding paragraphs of this answer as if fully set forth herein.

81. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

82. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

83. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

84. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

85. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

86. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

87. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the terms "shock treatment" and "ECT shock devices" as vague, ambiguous and derogatory.

88. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any

factual allegations were intended, they are denied. Somatics objects to the term "brain injury" as vague, ambiguous and overbroad. Somatics objects to the term "shock treatment" as vague, ambiguous and derogatory.

89. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

90. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

SECOND CLAIM FOR RELIEF

Negligence/Negligence Per Se (Failure to Warn, Timely Investigate, Evaluate, and Report Adverse Events)

91. Somatics realleges its responses set forth in all preceding paragraphs of this answer as if fully set forth herein.

92. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

93. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

94. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

95. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

///

///

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

THIRD CLAIM FOR RELIEF

Strict Products Liability – Failure to Warn

96. Somatics realleges its responses set forth in all preceding paragraphs of this answer as if fully set forth herein.

97. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

98. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the term "brain damage" as vague, ambiguous and overbroad.

99. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

100. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

101. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

102. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the term "brain damage" as vague, ambiguous and overbroad.

103. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the terms "ECT shock devices" and "shock treatment" as vague, ambiguous and derogatory.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

104. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

FOURTH CLAIM FOR RELIEF

Strict Product Liability – Adulteration and Misbranding

105. Somatics realleges its responses set forth in all preceding paragraphs of this answer as if fully set forth herein.

106. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the term "ECT shock devices" as vague, ambiguous and derogatory.

107. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the term "ECT shock devices" as vague, ambiguous and derogatory.

108. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

FIFTH CLAIM FOR RELIEF

Loss of Consortium

109. Somatics realleges its responses set forth in all preceding paragraphs of this answer as if fully set forth herein.

110. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the term "shock treatment" as vague, ambiguous and derogatory.

111. Somatics lack sufficient information and belief to respond to this allegation, and on that basis, denies.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

112. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the term "shock treatment" as vague, ambiguous and derogatory.

113. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied. Somatics objects to the term "shock treatment" as vague, ambiguous and derogatory.

114. The allegations in this paragraph constitute legal argument or conclusion and therefore Somatics is not required to respond. To the extent that any factual allegations were intended, they are denied.

PRAYER FOR RELIEF

115. Somatics denies that Plaintiffs are entitled to any relief sought under the fifth amended complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

Each of the Plaintiffs' recovery against Somatics is barred, diminished, or reduced in that the First Amended Complaint fails to state facts sufficient to constitute a cause of action against Somatics.

SECOND AFFIRMATIVE DEFENSE

(Statute of Limitations)

Each of the Plaintiffs' recovery against Somatics is barred by the applicable statute of limitations.

THIRD AFFIRMATIVE DEFENSE

(Comparative Fault)

Each of the Plaintiffs' recovery against Somatics is barred, diminished, or reduced in that other persons, whose names and/or capacities are currently unknown

to Somatics, are in some matter responsible for or at fault in approximately causing the damage purportedly sustained by Plaintiffs.

FOURTH AFFIRMATIVE DEFENSE

(Failure to Mitigate)

Each of the Plaintiffs' recovery against Somatics is barred, diminished or reduced to the extent that each of the Plaintiffs failed to take reasonable actions to avoid or mitigate their purported damages.

FIFTH AFFIRMATIVE DEFENSE

(Laches)

Each of the Plaintiffs' recovery against Somatics is barred, diminished or reduced by the doctrine of laches in that each of the Plaintiffs waited an unreasonable period of time in which to file this action and that the prejudicial delay has worked to the detrimental effect of Somatics.

SIXTH AFFIRMATIVE DEFENSE

(Consent)

Each of the Plaintiffs' recovery against Somatics is barred, diminished or reduced to the extent that each of the Plaintiffs consented to the acts or omissions allegedly resulting in the purported harm they each experienced.

SEVENTH AFFIRMATIVE DEFENSE

(Sophisticated Intermediary)

Each of the Plaintiffs' recovery against Somatics is barred, diminished or reduced because at all times relevant to this complaint, each of the Plaintiffs' treating physicians who administered and/or recommended ECT were sophisticated, within the meaning of the sophisticated intermediary doctrine, and each had an independent duty to know and warn of the risks of ECT.

///

///

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

EIGHTH AFFIRMATIVE DEFENSE

(Sophisticated User)

Each of the Plaintiffs' recovery against Somatics is barred, diminished or reduced in that the users of Somatics' devices were sophisticated, within the meaning of the sophisticated user doctrine, and had an independent duty to know and warn of the risks of ECT.

NINTH AFFIRMATIVE DEFENSE

(Preemption)

Somatics is informed and believes that if Plaintiffs were injured by any products of Somatics, such product(s) when they left the custody possession and control of Somatics were accepted, approved, and mandated by and under the laws and regulations of the United States and its duly constituent agencies. Therefore, the causes of action asserted in the Fifth Amended Complaint are barred under the doctrine of federal preemption. Granting the relief sought would infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

TENTH AFFIRMATIVE DEFENSE

(Reservation of Rights to Amend)

Somatics reserves its right to amend this answer to assert additional affirmative defenses in the future, and to supplement those asserted herein upon completion of further investigation and discovery.

WHEREFORE, Somatics prays that:

1. Plaintiffs receive nothing by the Fifth Amended Complaint;
2. For cost of suit;
3. Attorney fees according to contract or law;
4. For such other and further relief as this Court may deem just and proper.

DATED: June 26, 2020

POOLE SHAFFERY & KOEGLE, LLP

By: /S/ Jason Benkner
David S. Poole
Jason A. Benkner
Attorneys for Defendant,
SOMATICS, LLC

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-PJW

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **June 29, 2020**, I served the foregoing document described as: **ANSWER OF DEFENDANT SOMATICS, LLC TO PLAINTIFF'S FIFTH AMENDED COMPLAINT** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **June 29, 2020**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

/s/ Nicole Lyons
Nicole Lyons, Declarant

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

SERVICE LIST

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-PJW

Bijan Esfandiari, Esq.
BAUM HEDLUND ARISTEI & GOLDMAN, PC
10940 Wilshire Blvd, 17th Floor
Los Angeles, CA 90024
T: (310) 207-3233
F: (310) 820-7444
E: BEsfandiari@BaumHedlundLaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Bijan Esfandiari, Esq. (SBN 223216)
besfandiari@baumhedlundlaw.com
Monique Alarcon, Esq. (SBN 311650)
malarcon@baumhedlundlaw.com
BAUM HEDLUND ARISTEI & GOLDMAN P.C.
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
(310) 207-3233 Tel
(310) 820-7444 Fax

David M. Karen, Esq. (SBN 117883)
dk@dk4law.com
DK LAW GROUP, LLP
3155 Old Conejo Road
Thousand Oaks, CA 91320
Tel: (805) 498-1212
Fax: (805) 498-3030

Attorneys for Plaintiffs
MICHELLE HIMES; DIANE SCURRAH;
MARCIA BENJAMIN;
AND DANIEL BENJAMIN

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

v.

SOMATICS, LLC,

Defendant.

Case No.: **2:17-cv-06686 RGK-PJW**

FIFTH AMENDED COMPLAINT FOR:

1. NEGLIGENCE/NEGLIGENCE *PER SE* (Adulteration & Misbranding);
2. NEGLIGENCE/NEGLIGENCE *PER SE* (Failure to Warn, Failure to Timely Investigate, Evaluate, and Report Adverse Events);
3. STRICT LIABILITY—FAILURE TO WARN;
4. STRICT LIABILITY (Adulteration & Misbranding); and
5. LOSS OF CONSORTIUM.

DEMAND FOR JURY TRIAL

Plaintiffs MICHELLE HIMES, DIANE SCURRAH, MARCIA BENJAMIN and DANIEL BENJAMIN, (collectively "Plaintiffs"), individually and on behalf of all other similarly situated individuals, hereby complain against Defendant SOMATICS, LLC ("Defendant") and, on information and belief, allege as follows:

SUMMARY OF THE ACTION

1. This is a products liability action brought by Plaintiffs, who sustained personal injuries after undergoing multiple rounds of electroconvulsive therapy ("ECT"), utilizing ECT devices designed, manufactured, and sold by SOMATICS, LLC. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 & 1332.

2. An ECT shock device is "a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head." 21 C.F.R. § 882.5940(a). An ECT shock device, in lay terms, is used to administer 'shock treatment.'

3. The California Department of Mental Health reported 3,302 patients given ECT in 2001 alone. The number of patients given ECT shock treatment in California per year is likely to have increased since that time.

4. The primary demographic for ECT shock treatment is comprised of patients suffering from bipolar disorder ("BPD") and/or severe depression. ECT shock treatment is liberally prescribed for a variety of psychological disorders including, but not limited to schizophrenia and catatonia. ECT shock treatment is used on patients of all ages, including children and the elderly.

5. Plaintiffs are individuals suffering from ECT-induced brain trauma and varying degrees of ensuing physiological, psychological and emotional injury including, but not limited to permanent brain dysfunction, severe permanent cognitive and memory impairment, lasting short-term memory difficulties, acute

and/or chronic organic brain syndrome, and complete neurological collapse secondary to ECT shock treatment.

6. Despite statutory duties under the Food, Drug and Cosmetic Act ("FDCA") and directives by the Food & Drug Administration ("FDA") that ECT device manufacturers report information concerning safety and effectiveness testing for their devices to the FDA, SOMATICS, LLC, has not complied with these statutory obligations. Defendant has not responded to the FDA's order requiring submission of a summary of, and a citation to, all safety and effectiveness data known or available concerning the use of their devices by August 14, 1997.

7. Prior to the filing of the Complaint in this action, the only order by the FDA to which Defendant responded was one mandated by the Safe Medical Devices Act of 1990 ("SMDA") requiring Defendant's submission of a summary of, and citation to, any information known or otherwise available about the safety and effectiveness of its ECT devices by August 7, 2009. Defendant's responses failed to include nearly all adverse safety and effectiveness information relating to use of ECT shock devices. Defendant also grossly understated the incidence of death resulting from ECT. Such a response by Defendant failed to comply with its statutory reporting requirements under the MDA and SMDA.

8. As a direct and proximate result of Defendant's refusal to comply with multiple orders by the FDA and satisfy its state duties running parallel to its federal statutory duties, as of the time of the original filing of this action, Defendant had not provided the FDA with the information it had requested in order to determine whether submission of a PMA should be required, as is typical for Class III medical devices. To this day, ECT devices have never satisfied the stringent premarket approval standards that Class III medical devices are required to meet.

9. Because of the lack of testing rigor, the mechanism of action by which ECT may provide any benefit to patients, if indeed it does, remains unascertained

and unknown. Testing over the years has not shown any conclusive benefit to those receiving ECT shock treatment beyond those that may be associated with a brief bout of mania in the short-term. Conversely, the risks of ECT use remain apparent and include but are not limited to concussive brain injury and debilitating electrical brain trauma, resulting in permanent long-term memory loss, lasting cognitive impairment, seizures, acute and/or chronic organic brain syndrome, complete neurological collapse, and death.

10. But for Defendant's failure to comply with the FDCA, MDA, and SMDA, Plaintiffs would not have suffered the injuries alleged in this complaint. Compliance required Defendant to investigate, solicit, and report information upon learning that its ECT devices may have contributed to a death or serious injury and specifically report all "reasonably known" information to the FDA. The FDA makes all such information public in order to warn patients, medical providers and the general public of risks inherent in certain medical devices.

11. Defendant's failure to submit to the FDA all safety and effectiveness data reasonably known and/or available relating to use of its ECT devices by certain effective dates for premarket approval rendered its devices "misbranded" under the FDCA.

12. Defendant's failure to investigate, evaluate, and file adverse event reports pertaining to occasions on which its devices may have caused or contributed to a death or serious injury also rendered its devices "misbranded" under the FDCA.

13. Somatics, LLC has utilized a contract manufacturer unregistered with the FDA to manufacture all of its "Thymatron" devices for decades. A device manufactured by an unregistered contract manufacturer is "misbranded" under the FDCA.

14. Moreover, all modern ECT devices are marketed as "substantially equivalent" to pre-1976 "predicate" devices, but the predicate devices were not

legally marketed for failure to timely investigate and report adverse events. According to Defendant's contention, modern ECT devices have different intended uses than predicate devices and differ in design and function. Although the contention is unestablished, if it were proven true the "different" modern devices would not meet the requirement that they be "substantially equivalent" to its predicate devices, and the 510(k) clearance for all modern ECT devices is invalid. To the extent Class III devices are not substantially equivalent to a predicate, a PMA would be required for modern ECT device, as the modern device would raise new questions of safety and effectiveness. As Defendant has submitted no PMA application relative to the allegedly different, modern ECT devices, these devices are "adulterated" and are being manufactured and marketed in violation of the FDCA.

15. The manufacture, introduction, or receipt of an adulterated or misbranded medical device through interstate commerce is prohibited under the FDCA.[1]

16. Defendant'sfailure to comply with federal medical device regulations by investigating, evaluating, and reporting information reasonably suggesting death or serious injury with which their devices may have been associated resulted in a lack of knowledge among Plaintiffs' medical providers and the public in general about the risk of craniocerebral trauma inherent in administration of ECT shock treatment, but SOMATICS, LLC nevertheless continued to market its adulterated, misbranded, and defective ECT shock devices in the United States. Because some form of physiological, psychological, or emotional injury results universally from ECT shock treatment, Defendant's conduct directly and proximately caused injuries to the Plaintiffs.

17. This action seeks to remedy the damages caused by Defendant's conduct: violating the state law reporting duties running parallel to the Food, Drug

[1] 21 U.S.C. § 331.

& Cosmetic Act and causing harm by placing an adulterated, misbranded, and defective product into the stream of commerce. Defendant's violation of federal statutory duties, as demonstrated by (1) Defendant's failure to comply with all administrative orders by the FDA requiring Defendant to submit to the FDA all safety and effectiveness data reasonably known and/or available for its ECT shock devices by certain effective dates and (2) failure to maintain systems for the timely investigation, evaluation, and reporting of adverse events to the FDA, resulted in the decades-long circulation of misbranded and adulterated medical devices in the stream of commerce as well as a lack of knowledge among Plaintiffs' medical providers and the public in general about craniocerebral trauma caused by ECT shock treatment.

PARTIES

18. Plaintiff MARCIA BENJAMIN ("M. BENJAMIN") is a citizen of the State of California.

19. Plaintiff DANIEL BENJAMIN ("D. BENJAMIN") is a citizen of the State of California.

20. Plaintiff MICHELLE HIMES ("HIMES") at the time of the filing of her original complaint was a citizen of the State of California.

21. Plaintiff DIANE SCURRAH ("SCURRAH") is a citizen of the State of California.

22. Plaintiffs are informed and believe and based thereon allege that, at all relevant times, starting with its founding in 1984, Defendant SOMATICS, LLC ("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. Plaintiffs are further informed and believe and based thereon allege that SOMATICS is an ECT manufacturer and provider and, in that regard is authorized to conduct business in the State of California and does conduct business in the State of California.

23. Plaintiffs are further informed and believe, and based upon such information and belief allege, that Defendant, actively condoned, encouraged, participated in, and/or instigated the conduct described herein below in furtherance of its common scheme, plan and design which entailed, among other things: (a) aiding and abetting the common course of conduct complained of herein; (b) participating in and/or knowing and acquiescing in the acts complained of herein; and (c) taking and/or ratifying conduct to enrich themselves at the expense of Plaintiffs.

24. Plaintiffs are informed and believe that Defendant , is in some manner legally responsible for the events alleged in this Complaint.

JURISDICTION AND VENUE

25. This Court has subject matter jurisdiction over the lawsuit under 28 U.S.C. § 1332(a), because Plaintiffs and Defendant are citizens of different states to the extent required by statute and the amount in controversy exceeds $75,000, exclusive of interest and costs.

26. This Court has personal jurisdiction over Defendant SOMATICS because it has sufficient minimum contact in California to render the exercise of jurisdiction by this Court proper.

27. Venue is proper in the Central District of California under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims, , occurred in this District.

PLAINTIFF-SPECIFIC ALLEGATIONS

28. Plaintiff M. BENJAMIN, in seeking an effective treatment for symptoms relating to withdrawal from psychotropic medication, underwent a series of 22 separate rounds of ECT shock treatment between about January 2011 to September 2014. ECT did not improve M. BENJAMIN's symptoms relating to psychotropic medication withdrawal. Instead, ECT caused severe physiological, psychological, and emotional injury, including dental trauma and brain injury.

29. Following treatment, M. BENJAMIN did not know and had no reason to know that she had sustained a concussive brain injury from ECT use or that the symptoms she was experiencing post-treatment were the result of a concussive brain injury, or would be long-term or permanent. M. BENJAMIN incorrectly but reasonably believed that she was experiencing only minor short-term side effects from ECT use that would improve over time as no information to the contrary was given to her by her medical providers. Following treatment, M. BENJAMIN also did not know and had no reason to know or suspect that wrongful conduct had caused her to suffer concussive brain injury, or was attributable to ECT device manufacturers' violation of the FDCA, causing ECT device to be available and recommended for use on her, without warning of the true risks of brain trauma and therefore without adequate informed consent.

30. Towards the end of 2016, in the course of having conferred with counsel, M. BENJAMIN learned for the first time that Defendant had failed to comply with multiple administrative orders by the FDA, had never obtained FDA approval for their ECT devices, and had never maintained a system for the timely investigation, evaluation, and reporting of adverse events, and that this wrongful conduct on the part of Defendant had caused ECT to be available as a recommended treatment, caused her to be a recommended candidate and caused her to undergo ECT treatment and to sustain the concussive brain injury.

31. Prior to the end of 2016, when the Citizen Petition for reclassification and/or banning of ECT devices became public, she had no reason to suspect, or inquire as to, the wrongful conduct or the nature of her injuries caused by that conduct. However, even if she had inquired earlier, no amount of inquiry would have revealed the danger of concussive brain injury likely to result from ECT shock treatment or the wrongful conduct of Defendant in having failed to comply with regulatory requirements. This information was unavailable to the medical community at large and to these plaintiffs in particular, specifically because of

Defendant's noncompliance with regulations, including failure to report adverse events attributable to ECT use in the MAUDE database at any time prior to filing the within litigation.

32. Plaintiff D. BENJAMIN is and has been, at all times relevant to the allegations herein, lawfully married to Plaintiff M. BENJAMIN. D. BENJAMIN suffers a loss of consortium that M. BENJAMIN offered during the course of their marriage as a result of ECT shock treatment. D. BENJAMIN had no reason to know or inquire as to whether his wife had sustained injuries a result of wrongful conduct until the end of 2016, in privileged consultation with counsel. As her husband, D. BENJAMIN's delayed discovery of his wife's injury and its wrongful cause followed the same course as his wife's as set forth in the preceding Paragraph above.

33. Plaintiff HIMES obtained over twenty rounds of ECT shock treatment between about April 2011 and about July 2012 at Sharp Mesa Vista Hospital in San Diego, California. As a result of receiving ECT shock treatment, HIMES suffers severe physiological, psychological, and emotional injury, including brain injury. Plaintiff HIMES's husband suffers a loss of the consortium that HIMES offered during the course of their marriage as a result of HIMES's receipt of ECT shock treatment. Following treatment, HIMES did not know and had no reason to know that she had sustained a concussive brain injury from ECT use, or that the symptoms she was experiencing post-treatment were the result of a concussive brain injury, or that they would be long term or permanent. HIMES incorrectly but reasonably believed that she was experiencing only minor short-term side effects from ECT use that would improve over time, as no information to the contrary was given to her by her medical providers. Following treatment, HIMES also did not know and had no reason to know or suspect that wrongful conduct had caused her concussive brain injury, or that it was attributable to ECT manufacturer's violation of FDA regulations, causing ECT device to be available and recommended for use

on her, without warning of the true risks of brain trauma without adequate consent.

34. Towards the very end of 2016 or the beginning of 2017, in the course of having conferred with counsel, HIMES learned for the first time that Defendant had failed to comply with multiple administrative orders by the FDA, had never obtained FDA approval for their ECT devices, and had never maintained a system for the timely investigation, evaluation, and reporting of adverse events and that this wrongful conduct on the part of Defendant had caused ECT to be available as a recommended treatment, caused her to be a recommended candidate and caused her to undergo ECT treatment and to sustain the concussive brain injury.

35. Prior to the end of 2016, when the Citizen Petition for reclassification and/or banning of ECT devices became public, she had no reason to suspect, or inquire as to, the wrongful conduct or the nature of her injuries caused by that conduct. However, even if she had inquired earlier, no amount of inquiry would have revealed the danger of concussive brain injury likely to result from ECT shock treatment or the wrongful conduct of Defendant in having failed to comply with regulatory requirements. This information was unavailable to the medical community at large, and to these plaintiffs in particular, specifically because of Defendant's noncompliance with regulations, including failure to report adverse events attributable to ECT use in the MAUDE data base at any time prior to filing the within litigation.

36. Plaintiff SCURRAH underwent over fifty-eight rounds of ECT shock treatment in seeking to treat her bipolar disorder, beginning on March 28, 2012 and continuing for about nine months. ECT shock treatment caused SCURRAH severe physiological, psychological, and emotional injury, including brain injury. Following treatment, SCURRAH did not know and had no reason to know that she had sustained a concussive brain injury from ECT use or that the symptoms she was experiencing post-treatment were the result of a concussive brain injury, or that it would be long term or permanent. SCURRAH incorrectly but reasonably

believed that she was experiencing only minor short-term side effects from ECT use that would improve over time, as no information to the contrary was given to her by her medical providers. Following treatment, SCURRAH also did not know and had no reason to know or suspect that wrongful conduct had caused her concussive brain injury, or that it was attributable to ECT manufacturer's violations of federal regulations, which caused ECT device to be available and recommended for use on her, without warning of the true risks of brain trauma and therefore without adequate informed consent.

37. Towards the end of 2016 or during the early part of 2017, in the course of having conferred with counsel, SCURRAH learned for the first time that Defendant had failed to comply with multiple administrative orders by the FDA, had never obtained FDA approval for their ECT devices, and had never maintained a system for the timely investigation, evaluation, and reporting of adverse events and that this wrongful conduct on the part of Defendant had caused ECT to be available as a recommended treatment, caused her to be a recommended candidate and caused her to undergo ECT treatment and to sustain the concussive brain injury.

38. Prior to the end of 2016, when the Citizen Petition for reclassification and/or banning of ECT devices became public, she had no reason to suspect, or inquire as to, the wrongful conduct or the nature of her injuries caused by that conduct. However, even if she had inquired earlier, no amount of inquiry would have revealed the danger of concussive brain injury likely to result from ECT shock treatment or the wrongful conduct of Defendant in having failed to comply with regulatory requirements. This information was unavailable to the medical community at large and to these plaintiffs in particular, specifically because of Defendant's noncompliance with regulations, including failure to report adverse events that may be attributable to ECT use in the MAUDE data base at any time prior to filing the within litigation.

39. Plaintiffs underwent ECT shock treatment using an ECT shock device manufactured, sold and/or distributed by Defendant. Plaintiffs would not have been injured in the absence of Defendant's noncompliance and wrongful conduct. Plaintiffs were denied access to critical information and appropriate recommendations from and through their medical providers which providers would have acted, treated, and recommended differently had Defendant complied with statutory requirements, and had Defendant disseminated critical information and warnings to the medical community. Plaintiffs would not have been recommended candidates for ECT shock treatment and would not have undergone ECT shock treatment. Additionally, the ECT devices, it is alleged and believed, would not have been marketed, manufactured, sold and/or distributed, or available within the stream of commerce, but for Defendant's noncompliance with regulatory requirements as these devices are adulterated, misbranded, and defective.

SUBSTANTIVE ALLEGATIONS

40. The regulation of devices, including ECT devices, is relatively new. The United States Congress enacted the Medical Device Amendments of 1976 (the "MDA"), effective May 28, 1976, amending the FDCA "to provide for the safety and effectiveness of medical devices intended for human use."

41. Pursuant to the MDA, the FDA was required to review all existing medical devices and, by regulation, divide each into one of three classes of devices established to control access to the market depending on the intended use, the indications for use, and the risks that the particular device posed to the user. A Class I ("General Controls"), device was subject to general post-market or after-sale controls including good manufacturing practices. A Class II ("Performance Standards") device was to be subject to FDA established regulations for performance standards as well as post-market controls. A Class III ("Premarket Approval") device required a premarket approval application ("PMA") and approval before sale, or a product development protocol, and adherence to post-

market controls. By way of contrast, a wheelchair is an example of a Class I device while an implantable pacemaker is an example of a Class III device.

42. On September 4, 1979, the FDA published an Order in the Federal Register (the "1979 FDA Order") presenting its "final ruling" that ECT devices are Class III "Premarket Approval" devices under the MDA and specifically ordered manufacturers such as Defendants to prepare and submit a PMA for approval. The FDA's ruling stated in relevant part:

> "The Food and Drug Administration (FDA) is issuing a final ruling classifying electroconvulsive therapy devices into Class III (premarket approval). The effect of classifying a device into Class III is to require each manufacturer of the device to submit to FDA a premarket approval application ["PMA"] that includes information concerning safety and effectiveness tests for the device."[3]

43. The FDA's Order followed the recommendation of the Neurological Section of the Respiratory and Nervous System Devices empaneled by the FDA, due to the lack of available information regarding the safety of ECT devices and following public comment. The FDA concluded that Class III placement was required as "there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the ECT device."[4]

44. As of September 4, 1979, Congress intended that Defendant herein, as a manufacturer of ECT devices, submit a PMA application to the FDA for approval of this Class III device as a prerequisite to continued access to the market. The PMA application was to contain "safety and effectiveness" information derived from testing, e.g., from clinical trials. Moreover, PMA applications are required to include "specimens of the labeling proposed to be used for such device,"[5] to be submitted for FDA approval.

45. Defendant, along with another manufacturer who is no longer a party

[3] *See* 44 Fed. Reg. 172, at 51776-77 (Sept. 4, 1979) (reporting 21 C.F.R. § 882 [Docket No. 78N-1103]).
[4] *See* 21 C.F.R. § 882.5940.
[5] 21 U.S.C. § 360e(c)(1)(F).

to this action, have been the sole ECT device manufacturers in the United States market since at least 1985, and have held 100% of the US market share since that time. Defendant has never submitted a premarket approval application, nor have ECT devices ever been granted premarket approval, which is the FDA's official (and only) determination of "safety and effectiveness" for Class III medical devices.

46. Plaintiffs are informed and believe and based thereon allege that Defendant has never conducted human trials in order to support its continued claims of their devices' "safety and effectiveness." Defendant continued to manufacture, sell and distribute its ECT devices in the United States, and otherwise enabled their continued use, despite a lack clinical proof of safety or effectiveness and Congress's intent that they prove such to the FDA.

47. Plaintiffs are informed and believe and based thereon allege that prior to the filing of the Complaint in this action, Defendant failed to investigate, evaluate injury, and submit reports to the FDA whenever the Defendant received or otherwise became aware of information that reasonably suggested that one of its marketed ECT devices may have caused or contributed to a death or serious injury, as required by federal law. Failure to submit such adverse event reports resulted in Defendant's ECT devices being "misbranded" under federal law.[6] Defendant continued to manufacture, sell, and distribute its ECT devices in the United States, and otherwise enabled their continued use, despite being "misbranded" under federal law.

48. The United States Congress enacted the Safe Medical Devices Act of 1990 ("SMDA"), effective November 28, 1990, amending the FDCA "to make improvements in the regulation of medical devices." Thereafter, the FDA published an Order in the Federal Register (the "1995 FDA Order") pursuant to the SMDA requiring that the manufacturers of ECT devices, including Defendants,

[6] 21 U.S.C. § 352(t).

submit a summary of, and a citation to, all information known or available about the safety and effectiveness of their respective ECT devices to the FDA by August 14, 1997.[7]

49. Plaintiffs are informed and believe and based thereon allege that Defendant violated the SMDA, and the 1995 FDA Order, by failing to submit a summary of, and a citation to, all information known or available about the safety and effectiveness of its respective ECT devices to the FDA by August 14, 1997. Defendant continued to manufacture, sell and distribute its respective devices in the United States, and otherwise enable their continued use. This rendered all of Defendant's ECT devices misbranded on separate legal grounds.

50. On April 9, 2009, the FDA published a third Order in the Federal Register (the "2009 FDA Order") again requiring the manufacturers of ECT devices, including Defendant, to comply with the SMDA by submitting all information known or available about the safety and effectiveness of ECT devices to the FDA by the deadline of August 7, 2009.[8] Defendant responded to this order, but withheld a significant amount of information relating to adverse events from the FDA. None of the information provided directly or adequately addressed the known issues of permanent memory loss, cognitive impairment, or the certainty of electrically-induced brain injury and other intracranial insults resulting from ECT. Thus, Defendant rendered its devices misbranded on yet another ground.

51. The FDCA's implementing regulations provide that manufacturers of medical devices must report to the FDA within 30 calendar days after the day that the manufacturer receives, or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer: "(1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that [the manufacturer has

[7] 60 Fed. Reg. 156, at 41986-89 (Aug. 14, 1995).
[8] 74 Fed. Reg. 67, at 16214-17 (Apr. 9, 2009).

marketed] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."[9]

52. The regulations provide that manufacturers must submit all information "reasonably known." "Reasonably known" information is "(i) [a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) any information in your possession; or (iii) any information that you can obtain by analysis, testing, or other evaluation of the device."[10]

53. Defendant continued to violate the SMDA, and related orders, by failing to produce reasonably known information and by withholding data from the FDA relating to the safety and effectiveness of its respective ECT devices, including data relating to the devices' collective propensity to cause harm. In response to each and every one of the thousands of instances of Defendant becoming aware of information reasonably suggesting death or serious injury with which its devices may be associated, Defendant conducted no investigation and reflexively rationalized, with no scientific justification at all, any alleged harm as resulting from an "underlying psychiatric condition" rather than the true obvious cause: the inducement of a major motor seizure through application of electricity to the crania of patients.[11] All devices designed to cause a major motor seizure through application of electricity to the cranium, regardless of design or technical specifications, present an unavoidable risk of serious trauma to the brain.

54. Plaintiffs are informed and believe and based thereon allege that the overwhelming weight of scientific evidence relating to ECT shock treatment suggests that there is no long-term benefit to receiving ECT shock treatment at all, that the alleged short-term benefits are transient and are little more than a bout of mania following brain damage, that ECT shock treatment inherently damages the

[9] 21 C.F.R. § 803.50(a).
[10] 21 C.F.R. § 803.50(b).
[11] 21 C.F.R. § 882.5940 (regulatory definition for electroconvulsive therapy devices, the predicate device type for all modern ECT devices).

brain, and that any mechanism of action by which it is said to 'treat' depression or mental illness is hypothetical.

55. As a result of the Defendant's conduct in violating statutory requirements and selective withholding and manipulation of the data surrounding ECT devices, and the duties under state law running parallel to such requirements, the devices have continued to be manufactured, sold, distributed and have remained in use without testing, public dissemination of reliable information and data as to safety and effectiveness, warnings of inherent dangers, and without the requisite premarket FDA approval.

56. As evidenced by the warnings and consent forms that patients encounter prior to ECT, all or nearly all psychiatrists that administer ECT in the United States are under the impression that they have found a way to induce a major motor seizure in patients through application of electricity to the cranium with no risk of causing craniocerebral trauma at all. Proper compliance by Defendant with the pre-market screening and post-market surveillance obligations imposed on medical device manufacturers by the FDCA would have corrected this misperception among the psychiatric community and ensured conveyance of an adequate warning to patients, potentially ultimately resulting in a drastic curtailment or even non-use of Defendant's ECT devices on all or virtually all classes of patients.

57. Defendant continues to manufacture, sell and distribute adulterated, misbranded, and defective ECT devices to this day. Doing so violates both a duty established under federal statute and parallel duties under state tort law. Had Defendant refrained from marketing adulterated and/or misbranded medical devices as was required by the FDCA, it would have stopped manufacturing and/or distributing their devices when the FDCA begun to prohibit the introduction into interstate commerce of adulterated and/or misbranded medical devices, or the introduction into interstate commerce of devices without a system in place for the

timely investigation, evaluation, and reporting of adverse events.

58. The FDA's guidance document pertaining to medical device reporting states that "a publicly disclosable version of the medical device reports that we have received is available on the CDRH webpage at http://www.accessdata.fda.gov/ scripts/cdrh/cfdocs/cfMAUDE/search.CFM."[12] At the time of the original filing of this action, of the 49 reports that were posted on the MAUDE database pertaining to ECT devices, the majority were voluntarily submitted by patients, and none were submitted by device manufacturers under their mandatory reporting duties. Had Defendant complied with its federal and parallel state duties to report to the FDA all safety and effectiveness data reasonably known or available for ECT, the FDA's MAUDE database would have, for decades, reflected the multitude of adverse events that routinely result from administration of ECT shock treatment.

59. 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 FDCA's obligation to investigate and report these events to the FDA. For example, from the 1940s to the 1980s, 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 2010 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, and therefore invoking its statutory duty to investigate, evaluate, and report the complaints to the FDA. However, at the time of the filing of the original complaint, there were no manufacturer-submitted

[12] MEDICAL DEVICE REPORTING FOR MANUFACTURERS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF DOCUMENT 26 (2016).

adverse event reports in FDA's MAUDE database corresponding to those adverse event allegations, illustrating Defendant's continuous and intentional failure to investigate and/or report adverse events to the FDA.

60. "The Electroshock Quotationary" was published in 2006.[13] 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 advocate 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 went investigated and reported by Defendant.

61. 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.[14]

62. A brain scan study confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.[15]

63. A study relating MRI scans of patients demonstrated a strong correlation between the numbers of previous ECT treatments to loss of brain tissue.[16]

64. 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.[17]

---

[13] LEONARD ROY FRANK, THE ELECTROSHOCK QUOTATIONARY (2006), http://www.endofshock.com/102C_ECT.PDF.
[14] Weinberger et al., *Structural Abnormalities in the Cerebral Cortex of Chronic Schizophrenic Patients*, 36 ARCHIVES GEN. PSYCHIATRY, 935-39 (1979).
[15] Calloway et al., *ECT and Cerebral Atrophy: A CT Study*, 64 ACTA PSYCHIATRICA SCANDINAVICA 442-45 (1981).
[16] Andreasen et al., *MRI of the Brain in Schizophrenia*, 47 ARCHIVES GEN. PSYCHIATRY, 35-41 (1990).
[17] R.J. Dolan et al., *The Cerebral Appearance in Depressed Subjects*, 16 PSYCHOL. MED., 775-79 (1986).

65. Finally, a particularly graphic study documented intra-cranial bleeding resulting from ECT shock treatment administered using current ECT devices.[18] Defendant remained willfully ignorant of the adverse events in these and other reasonably known studies in an attempt to evade its FDCA reporting duties.

66. Shock treatment is covered by numerous federal programs including Medicare and is sufficiently remunerative to keep entire psychiatric facilities in business.

67. Defendant conducted no investigation corresponding to the allegations in the original Complaint in this action, or the medical literature cited herein, within thirty days of its filing on September 11, 2017.

68. The FDA brought specific reportable events to the attention of Defendant during facility inspections. Defendant did not timely investigate and/or report those specific events.

69. In SOMATICS, LLC's 2009 response to the FDA's third Order, the manufacturer states: "[t]he Somatics Thymatron ECT device has already been in functional class II during its entire lifetime of 25 years . . . ." Since ECT devices are officially classified into Class III based on their potential risk to human health and safety, and because Class II devices are generally safer than Class III devices, such a statement is misleading to health care providers and to patients, who may be led to believe that ECT is safer than it actually is. The only sense in which ECT devices are "functionally in Class II" is in that ECT devices have managed to reach the market without the submission of a premarket approval application. Premarket approval is a safeguard applied only to Class III devices by virtue of their unreasonable risk of causing injury, and the only reason ECT devices have managed to stay on the market without submission of premarket approval applications is because Defendants failed to submit them when due. Accordingly,

[18] Kulkarni & Melkundi, *Subdural Hematoma: An Adverse Event of Electroconvulsive Therapy – Case Report and Literature Review*, CASE REPORTS IN PSYCHIATRY (2012).

in attempting to demonstrate the safety of SOMATICS' ECT devices, SOMATICS instead draws attention to their regulatory noncompliance.

70. Also, in their 2009 submission to the FDA, SOMATICS states: "[i]n the ensuing 25 years [since clearance of the Thymatron] there has been no occurrence of a reported adverse event." Given the multitude of adverse events that regularly result, and have resulted, from ECT shock treatment, this statement is an admission that SOMATICS, LLC has not reported any of the adverse events that have occurred as a result of use of their Thymatron devices in 25 years. In the same submission to the FDA, SOMATICS, LLC claimed a lack of evidence of any ECT-induced permanent memory loss in patients past the six-month mark after the procedure.

71. SOMATICS, LLC has used a contract manufacturer unregistered by the FDA, Elektrika, Inc., to manufacture its devices for decades.

72. Had the FDA's MAUDE database accurately reflected the multitude of adverse events that result routinely from ECT treatment, those adverse events would have been noticed by professionals in the psychiatric field, addressed in academic and medical literature, discussed at meetings and conferences attended by psychiatrists within California and the United States generally, and altogether well-known by the general public.

73. Had Defendant satisfied its reporting duties, ECT patients' medical providers would have been properly informed by the FDA's MAUDE database, by medical and academic literature discussing the adverse events in the MAUDE database, by meetings they attended at which the adverse events resulting from ECT would have been discussed, by general public discussion, and thereafter by direct warning from the FDA as to the inherent risks associated with ECT. ECT is inherently harmful to the human brain, but this fact is not publicly known because of Defendants' breach of their FDCA reporting duties and all state common law duties running parallel to those FDCA reporting requirements.

74. But for Defendant's breach of its federal and state reporting duties that arose out of the requirements imposed by the FDCA and the FDA's multiple orders, Plaintiffs' medical providers would have had knowledge of the risk inherent in ECT shock treatment in time to prevent Plaintiffs' injuries. Plaintiffs' medical providers, with knowledge that modern ECT devices actually have not managed to mitigate the risk of brain trauma resulting from induced seizures through application of electricity to the cranium, would have conveyed a warning to patients, as common law principles of informed consent require such warning of unavoidable risks of serious harm. Plaintiffs would then have been in a position to either give informed consent or refuse the treatment entirely. Moreover, medical providers would have acted different, including severely limiting recommendations, or ceasing to recommend ECT shock treatment altogether for all or virtually all patients.

75. But for Defendant's marketing of adulterated, misbranded, and defective medical devices, plaintiffs would not have had access to ECT shock treatment, and would not have suffered the injuries alleged herein. Accordingly, but for Defendants' conduct in manufacturing and marketing their devices, ECT shock devices would not exist in their current form, if at all.

76. Defendant concealed the facts such that no plaintiff reasonably would have known of facts giving rise to this suit: namely, that SOMATICS, LLC comprehensively failed to investigate adverse events, conduct human clinical trials, and report all safety and effectiveness data known or available relating to the use of their ECT devices to the FDA, as was required by multiple FDA orders and the state medical device warning duties running parallel thereto. Whenever Defendant encountered adverse safety information, it reflexively attributed it to "severe depression," "bipolar" or any other psychiatric condition without acknowledgement of the fact that seizures, grand mal or otherwise, are to be assiduously avoided according to the rest of the medical profession. To this day,

Defendant seemingly attributes it to coincidence that the "side effects" of ECT are identical to the symptoms of trauma to the brain.

77. Medical literature and studies purporting to prove that ECT does not cause brain injury is methodologically flawed. Researchers seeking to study the adverse safety risks presented by ECT have difficulty obtaining funding in the United States. Defendant, holding a strong interest in preventing public revelation of the unavoidable risk of intracranial insult and/or craniocerebral trauma presented by ECT, has maintained improper ties and provided kickbacks and/or honoraria to opinion leaders and those responsible for determining who gets funding for research into ECT's safety and effectiveness in an attempt to prevent public revelation of ECT's adverse safety risks. Plaintiffs believe the primary motive behind this behavior is to ensure that funds from federal programs keep numerous psychiatric units financially afloat.

78. Because of Defendant's fraudulent concealment of facts, no Plaintiff knew or should have known that Defendants failed to comply with federal statutory requirements or of the dangers inherent in use of ECT shock devices that gave rise to their claims asserted herein.

79. Plaintiffs diligently filed this suit in a timely fashion upon discovering the facts giving rise to the claims asserted herein, namely that Defendants failed to satisfy the reporting requirements imposed by the FDCA, MDA and SMDA.

FIRST CLAIM FOR RELIEF

Negligence/Negligence *Per Se* (Adulteration and Misbranding)

(By Plaintiffs against SOMATICS)

80. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, all preceding paragraphs of this Complaint.

81. SOMATICS failed to respond to the FDA's Order requiring submission of a summary of, and a citation to, all data known or available concerning the safety and effectiveness of their ECT devices by August 14, 1997,

and August 7, 2009, respectively. Failure to furnish such information rendered all of their devices misbranded.

82. SOMATICS, according to its own contentions, manufacture and introduce into interstate commerce devices that have different intended uses, and different technical characteristics that raise new questions of safety and effectiveness when compared to their predicate devices. Moreover, its predicate devices were not legally marketed. This renders all of Defendant's devices adulterated.

83. SOMATICS has never had in place a system for the timely investigation, evaluation, and reporting of adverse event complaints to the FDA, and has never reported an adverse event despite countless instances of becoming aware of information reasonably suggesting death or serious injury associated with its devices.

84. SOMATICS utilizes an unregistered contract manufacturer to manufacture all of their devices. This renders SOMATICS' devices misbranded.

85. Defendant has had and continues to have a duty of reasonable care under California state common law to refrain from the manufacture, delivery, or introduction into interstate commerce of adulterated and/or misbranded devices. Such devices are legally defective.

86. SOMATICS breached those state common law duties owed to Plaintiffs when it continued to market their adulterated and misbranded medical devices for decades.

87. M. BENJAMIN, , HIMES, and SCURRAH underwent ECT shock treatment delivered by ECT shock devices placed into the stream of commerce by the Defendant, and during the time that adulterated and misbranded ECT devices were being manufactured, sold and distributed.

88. M. BENJAMIN, HIMES, and SCURRAH have suffered, and/or continue to suffer concussive brain injury and ensuing cognitive impairment,

severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome and related injuries following and as a proximate result of ECT shock treatment and Defendant's breach of duty owed to plaintiffs. This harm is of the type sought to be prevented by the passage of the FDCA, MDA, and SMDA, and Plaintiffs, as recipients of Class III medical devices, are of the class of plaintiffs the applicable statutes and regulations are intended to protect.

89. Had Defendant complied with its state law duties requiring them to refrain from manufacturing, delivering, or introducing into interstate commerce their misbranded and adulterated devices, those devices would never have reached or injured the putative class. Accordingly, compensatory damages are appropriate.

90. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

SECOND CLAIM FOR RELIEF

Negligence/Negligence *Per Se* (Failure to Warn, Failure to Timely Investigate, Evaluate, and Report Adverse Events)

(By Plaintiffs against SOMATICS)

91. Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully set forth herein.

92. Defendant has and has had a continuous duty since the early 1980s to investigate, evaluate, and report information reasonably suggesting death or serious injury associated with its devices to the FDA within 30 days of discovering such information.

93. In breach of said duty, Defendant encountered countless adverse event complaints and other information reasonably suggesting death or serious injury resulting from ECT, but never maintained a system for the timely reporting of adverse safety information and never submitted a single adverse event report to the FDA prior to the filing of this action.

94. Had Defendant complied with its state law duties to report to the FDA

all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), this information would have appeared prominently and accessibly in the FDA's MAUDE database and in medical journals, and would have been discussed at conferences attended by the psychiatric profession at large. The FDA and/or Defendant also would have or should have promulgated a warning to the end users of ECT shock devices within the medical profession, who would have been on constructive notice of the latent dangers inherent in providing ECT shock treatment to Plaintiffs and patients in time to alter their conduct and their recommendations, and to convey a warning of craniocerebral trauma, thereby preventing a deprivation of informed consent and associated injuries as claimed. Accordingly, the negligent conduct of SOMATICS actually caused, proximately caused, and was a substantial factor in causing the harm suffered by Plaintiffs. Accordingly, compensatory damages are appropriate

95. Defendant acted with oppression, fraud, and malice. Accordingly, punitive damages are appropriate.

THIRD CLAIM FOR RELIEF

Strict Product Liability– Failure to Warn

(By Plaintiffs against SOMATICS)

96. Plaintiff hereby re-allege, and incorporate by reference as though fully set forth herein, all preceding paragraphs of this Complaint.

97. Defendant SOMATICS manufactured, distributed, and sold its ECT devices in the stream of commerce within the United States, knowing that they would be used without inspection for defect.

98. The ECT devices, at all times relevant to the causes of action alleged in this Complaint, caused and continue to cause permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome, and these facts were both known and knowable in light of the

scientific and medical knowledge available in the medical and scientific communities. Defendant's failure, at the time of manufacture and distribution, to adequately warn plaintiffs and medical providers of these latent dangers and risks renders the devices adulterated, misbranded, and defective with respect to the marketing and information provided to Plaintiffs.

99. Craniocerebral trauma and ensuing cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome present a substantial danger to patients when ECT devices are used as intended or misused in a foreseeable way.

100. Ordinary consumers would not recognize these potential risks inherent to ECT devices, especially in light of Defendant's aggressive marketing and promotion campaigns.

101. SOMATICS failed to investigate and provide adequate warnings of these risks.

102. M. BENJAMIN, HIMES, and SCURRAH suffer permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome as a direct result of administration of ECT shock treatment. Plaintiffs, had they been properly warned about the true nature of ECT shock devices, would not have received ECT treatment.

103. In addition, had Defendant complied with its state law duties to give a post-sale warning to the FDA of all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), this information would have appeared prominently in the FDA's MAUDE database and in medical journals and the FDA and/or Defendant would have promulgated a warning to the end users of ECT shock devices within the medical profession, who would have been on constructive notice of the unavoidable risk of intracranial insult to patients in providing ECT shock treatment Plaintiffs and would have conveyed a warning

of craniocerebral trauma in time to prevent their injuries. Accordingly, the conduct of SOMATICS actually caused, proximately caused, and was a substantial factor in causing the harm suffered by Plaintiffs. Therefore, compensatory damages are appropriate.

104. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

FOURTH CLAIM FOR RELIEF

Strict Product Liability (Adulteration and Misbranding)

(By Plaintiffs Against SOMATICS)

105. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

106. All of Defendant's ECT shock devices have been adulterated and/or misbranded for their entire life on the market. This regulatory noncompliance rendered all ECT defective for purposes of strict liability under California common law.

107. But for Defendant's introduction of defective medical devices into interstate commerce, ECT shock devices would never have reached Plaintiffs who therefore would not have suffered unwarned craniocerebral trauma secondary to shock treatment.

108. Defendant acted with oppression, fraud and malice. As such, punitive damages are appropriate.

FIFTH CLAIM FOR RELIEF

Loss of Consortium

(By D. BENJAMIN Against SOMATIC)

109. Plaintiff, D. BENJAMIN hereby re-alleges, and incorporates by reference as though fully set forth herein, all preceding paragraphs of this Complaint.

110. D. BENJAMIN is a spouse of M. BENJAMIN who underwent ECT

shock treatment, and as a result has suffered a loss of consortium.

111. D. BENJAMIN is and has at all times relevant to this Complaint been lawfully married to M. BENJAMIN.

112. Those injured by ECT shock treatment suffered tortious injuries as a result of Defendant's actions.

113. D. BENJAMIN who is married to a spouse that has suffered injury resulting from ECT shock treatment has suffered a loss of consortium.

114. That loss of consortium was a direct and proximate result of the Defendant's acts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

1. For compensatory damages in light of the pain and suffering, inconvenience, emotional distress, loss of consortium, loss of earnings, and lost earning capacity suffered by Plaintiffs;

2. For punitive damages in light of Defendant's oppression, fraud, and malice;

3. For costs of suit and expenses incurred herein, including expert fees;

4. For reasonable attorney's fees and such other nontaxable costs;

5. For injunctive relief; and

6. For all such other and further relief that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for all claims so triable.

Dated: June 15, 2020 Respectfully submitted,

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

By: */s/ Bijan Esfandiari*
Bijan Esfandiari
besfandiari@baumhedlundlaw.com

Monique Alarcon
malarcon@baumhedlundlaw.com
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
(310) 207-3233 Tel
(310) 820-7444 Fax

David M. Karen
DK LAW GROUP, LLP
3155 Old Conejo Road
Thousand Oaks, CA 91320
Telephone: (805) 498-1212
Facsimile: (805) 498-3030
dk@dk4law.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Himes, et al. v. Mecta Corporation, et al.
United States District Court Case No. 2:17-CV-06686-RGK-PJW

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 10940 Wilshire Blvd.,17th Floor, Los Angeles, CA 90024.

On June 15, 2020, I served the foregoing documents described as: **FIFTH AMENDED COMPLAINT** on the interested parties in said action as follows:

David S. Poole, Esq.
Jason A. Benkner, Esq.
POOLE & SHAFFERY, LLP
400 South Hope Street, Suite 720
Los Angeles, California 90071
(213) 439-5390
(213) 439-0183 Facsimile
E: dpoole@pooleshaffery.com
jbenkner@pooleshaffery.com

Attorneys for Defendant
SOMATICS, LLC

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Los Angeles, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below.

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on June 15, 2020, at Los Angeles, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

/s/ Bijan Esfandiari
Bijan Esfandiari

NOT FOR PUBLICATION

FILED

APR 7 2020

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

JOSE RIERA; et al., Plaintiffs-Appellants, v. SOMATICS, LLC, Defendant-Appellee.	No. 18-56470 D.C. No. 2:17-cv-06686-RGK-PJW MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
R. Gary Klausner, District Judge, Presiding

Submitted April 2, 2020**
Pasadena, California

Before: BEA and BADE, Circuit Judges, and DRAIN,*** District Judge.

Plaintiffs Michelle Himes, Diane Scurrah, Marcia Benjamin, and Daniel Benjamin (collectively, "Plaintiffs") appeal the district court's dismissal of their

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

*** The Honorable Gershwin A. Drain, United States District Judge for the Eastern District of Michigan, sitting by designation.

Third Amended Complaint ("TAC") against Somatics, LLC under Federal Rule of Civil Procedure 12(b)(6) on statute of limitations grounds. The district court had diversity jurisdiction pursuant to 28 U.S.C. § 1332, and we have jurisdiction pursuant to 28 U.S.C. § 1291. "A federal court sitting in diversity applies the substantive law of the state, including the state's statute of limitations." *Albano v. Shea Homes Ltd. P'ship*, 634 F.3d 524, 530 (9th Cir. 2011) (citation omitted). We review de novo the district court's grant of a motion to dismiss under Rule 12(b)(6). *Skilstaf, Inc. v. CVS Caremark Corp.*, 669 F.3d 1005, 1014 (9th Cir. 2012). We reverse and remand to the district court for further proceedings.

1. To the extent the district court erred by failing to construe Somatics's Rule 12(b)(6) motion to dismiss as a Rule 12(c) motion for judgment on the pleadings, the error is harmless because the same standard applies to Rule 12(b)(6) and Rule 12(c) motions. *See United States ex. rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054 n.4 (9th Cir. 2011).

2. The district court erred by dismissing Plaintiffs' TAC on statute of limitations grounds. Under California law, the district court could dismiss Plaintiffs' TAC on statute of limitations grounds only if the TAC stated dates that "clearly and affirmatively appear on the face of the complaint; it is not enough that the complaint shows that the action may be barred." *Geneva Towers Ltd. P'Ship v. City of San Francisco*, 60 P.3d 692, 700 (Cal. 2003) (citation omitted). "Where a complaint

does not reveal on its face that it is barred by the statute of limitations, a plaintiff has no obligation to plead around the defense." *JPMorgan Chase Bank, N.A. v. Ward*, 245 Cal. Rptr. 3d 303, 312 (Ct. App. 2019) (citations omitted).

The TAC alleges the dates of Plaintiffs' final electroconvulsive therapy ("ECT") treatments but does not allege when Plaintiffs became injured. The district court improperly inferred that Plaintiffs were injured, and Plaintiffs' causes of action accrued, on the date of their final ECT treatments. Because the TAC alleges the dates of Plaintiffs' final ECT treatments and not the dates of Plaintiffs' injuries, the TAC "does not reveal on its face" that Plaintiffs' claims were barred by the statute of limitations.[1] *Id.* The district court therefore erred by dismissing Plaintiffs' TAC as time barred.

REVERSED and REMANDED.

---

[1] Plaintiffs argued that the statute of limitations does not apply because "their claims were not time-barred on the face of the complaint" for the first time on appeal. Although we generally do not consider arguments that are raised for the first time on appeal, *see In re Mercury Interactive Corp. Sec. Litig.*, 618 F.3d 988, 992 (9th Cir. 2010), Somatics waived any argument regarding Plaintiffs' waiver by failing to assert it in its answering brief, *see Norwood v. Vance*, 591 F.3d 1062, 1068 (9th Cir. 2010).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK (PJW)	Date	September 14, 2018
Title	***Jose Riera and Deborah Chase v. Somatics, LLC***		

Present: The Honorable	R. GARY KLAUSNER, UNITED STATES DISTRICT JUDGE	
Sharon L. Williams	Not Reported	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiff:	Attorneys Present for Defendant:	
Not Present	Not Present	

Proceedings: **(IN CHAMBERS) Order Re: Plaintiffs' Motion for Partial Summary Judgment and Defendant's Motion for Summary Judgment (DE 79, 80)**

I. INTRODUCTION

On September 11, 2017, Marcia Benjamin ("M. Benjamin"), Daniel Benjamin ("D. Benjamin"), Jose Riera ("Riera"), Michelle Himes ("Himes"), Diane Scurrah ("Scurrah"), and Deborah Chase ("Chase"), individually and on behalf of all others similarly situated, filed a Complaint against Mecta Corporation ("Mecta") and Somatics, LLC ("Somatics") (collectively, "Defendants"). The six Plaintiffs filed a Third Amended Complaint ("TAC") on April 19, 2018. On June 19, 2018, pursuant to a Motion to Dismiss under Federal Rule of Civil Procedure ("Rule") 12(b)(6), the Court dismissed the claims of M. Benjamin, D. Benjamin, Himes, and Scurrah as barred by the statute of limitations, dismissed all claims against Mecta, and dismissed Riera's and Chase's claims against Somatics with leave to amend.

Plaintiffs Riera and Chase (collectively, "Plaintiffs") filed a Fourth Amended Complaint ("FAC") against Somatics on June 26, 2018. The FAC alleges six causes of action for negligence, product liability, and strict liability.

On July 29, 2018, Plaintiffs filed the instant Motion for Partial Summary Judgment on Presumption of Failure to Exercise Due Care on Elements (1) and (4) of California Evidence Code 699, requesting summary adjudication as to two elements of the negligence per se claims. On July 30, 2018, Defendants filed the instant Motion for Summary Judgment as to all claims. For the following reasons, the Court **DENIES** Plaintiffs' Motion in part, **GRANTS** Plaintiffs' Motion in part, **DENIES** Defendant's Motion in part, and **GRANTS** Defendant's Motion in part.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title *Jose Riera and Deborah Chase v. Somatics, LLC*

II. FACTUAL BACKGROUND

Somatics is a developer[1] of an electroconvulsive therapy ("ECT") device called the Thymatron System IV ("Thymatron"), which is used to treat severe psychiatric disturbances by inducing in the patient a major motor seizure by applying a brief but intense electrical current to the patient's head. Somatics is one of only two U.S. manufacturers of ECT devices. Plaintiffs are patients who received ECT from Somatics' devices and now allege that they suffer ECT-induced concussive brain trauma and ensuing physiological, psychological, and emotional injuries including permanent brain dysfunction and memory loss. Riera was first given ECT at Huntington Hospital between April and May 2016, and Chase received ECT at Kaiser Permanente beginning on April 3, 2015 to Spring of 2016.

Specifically, Riera contends that he cannot recall new information, has forgotten past knowledge and skills, and is unable to remember people, events, daily routines, or to process information. Chase contends that she suffers from permanent memory loss and cannot remember significant life events from her children's childhoods or recognize faces and that she experiences anxiety, embarrassment, and distress as a result.

Before receiving ECT, Riera was hospitalized for expressing suicidal ideations and becoming "nonfunctional." He has a history of alcoholism and mild psychomotor retardation. Prior to her ECT treatments, Chase was also hospitalized for symptoms of severe recurrent depression and has a long history of using medications, having difficulty concentrating, and suffering from memory problems.

Plaintiffs seek recovery for injuries resulting from Somatics' alleged negligence in failing to comply with medical device reporting, adulteration, and misbranding obligations of the Food, Drug and Cosmetic Act ("FDCA") and from Somatics' failure to warn consumers of ECT's risks. The FDCA requires medical device manufacturers to report instances of death or serious injury ("adverse events") caused by their devices and to maintain internal controls sufficient to investigate, evaluate, and report potential adverse event complaints.

In relevant part, Plaintiffs allege that Somatics' failure to comply with the FDCA and give adequate warnings caused Plaintiffs to suffer brain injuries from ECT. Had they or their psychiatrists known the risks of "craniocerebral trauma," Plaintiffs would either not have been given or not have agreed to the treatment. (Pl.s' Compl. ¶ 87.) In the alternative, Plaintiffs argue that the Thymatron

[1] Although the parties disagree about whether Somatics manufactures its devices on its own, Somatics acknowledges that Elektrika, Inc. ("Elektrika") fabricates the Thymatron device, which is then sent to Somatics for the final steps in the repackaging process. Mirkovich Decl. ¶ 21 (ECF No. 81-1).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

product would not have been sold to their respective hospitals in the first place. Huntington Hospital purchased a Thymatron in 2006 and Kaiser bought one in 2011.

A. Adverse Event Reports and Complaints

Somatics does not dispute that it has never reported an adverse event to the FDA. However, Somatics maintains that it has investigated complaints regarding potential adverse events but has not yet received a complaint sufficiently serious or credible to report. (Mirkovich Decl. ¶¶ 7–9, ECF No. 81-1.) Plaintiffs, on the other hand, contend that Somatics had notice of adverse events and failed to report them in violation of the FDCA.

Specifically, Somatics did not report adverse events from the publicly-accessible Manufacturer and User Facility Device Experience ("MAUDE") database. Somatics maintains that it monitors the database and has not received information necessitating a report. (Mirkovich Decl. ¶¶ 8–10, Ex. B, ECF No. 81-3.)

1. 1995 Order

An FDA Order in 1995 required Somatics to submit information related to the safety and efficacy of its ECT device by August 1997. Although Plaintiffs contend that Somatics did not respond to this Order based on the absence of a record of a response, *see* Karen Decl. Ex. G (ECF No. 79-12), Somatics presents evidence that they did respond to the Order, *see* Abrams Decl. ¶ 3 (ECF 81-4). Regardless, the FDA did not contact Somatics seeking further information. (*Id.* ¶ 6.)

2. 2009 Public Docket

In 2009, the FDA opened a public docket to collect comments on the classification of ECT devices.[2] *See* 74 Fed. Reg. 46607 (Sep. 10, 2009). By 2010, the docket had yielded over 3,000 comments about ECT containing reports of death, brain damage, and memory loss. The FDA issued an Executive Summary of the complaints in 2011. Somatics reviewed the comments but contends that it did not have sufficient information to investigate further or file a report. (Mirkovich Decl. ¶¶ 15–18, ECF No. 81-1.)

[2] The FDA classifies the Thymatron as a "Class III" device. At the time of the 2009 docket, the FDA was considering reclassifying it from a Class III to a Class II device but did not ultimately choose to do so. *See* 80 Fed. Reg. 81226 (Dec. 29, 2015).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK (PJW)	Date	September 14, 2018
Title	***Jose Riera and Deborah Chase v. Somatics, LLC***		

The parties disagree about whether the complaints in the public docket were severe enough to require adverse event reports. (*Compare* Makowski Decl. ¶ 14, ECF No. 81-5, *with* Mirkovich Decl. ¶¶ 14–17, ECF No. 81-1.) Somatics believes that the complaints were politically motivated "anti-ECT propaganda aimed at defeating the FDA's recommendation to declassify ECT devices" and thus unreliable. (Mirkovich Decl. ¶ 14, ECF No. 81-1.) Plaintiffs, on the other hand, argue that Somatics had sufficient information to investigate and that the complaints were reportable. (*See* Arrowsmith Decl. ¶¶ 6–13. ECF No. 79-3.) Somatics admits that it did not investigate any of the complaints.

B. 2012 and 2016 Facility Inspections

In 2012, the FDA inspected the Somatics facility and observed that Somatics' written Medical Device Reporting ("MDR") procedures were inadequate with respect to the timely and effective identification and evaluation of adverse events. At the end of the inspection, the FDA official issued Somatics an FDA Form 483 with a list of "objectionable observations."[3] (Makowski Decl., Ex. B, 0012. ECF No. 81-7.)

An FDA inspector returned in 2016 for a facility inspection and determined that "the firm had made corrections" and no further action was required. (Makowski Decl., Ex. C 0039, ECF No. 81-8.) However, the inspector flagged a patient skin burn complaint that was caused by a Thymatron in 2013 that Somatics should have documented and submitted as an MDR. Although Somatics had responded to the complaint in a letter to the FDA, the event constituted a serious injury and thus required an official report. (Makowski Decl., Ex. C 0043, ECF No. 81-8.) Notably, however, the inspector "did not include this deviation on the FDA-483 since the FDA had been made aware of this event" through Somatics' letter and did not need more information on the specific skin burn. *Id.*

Somatics has not received a regulatory sanction from the FDA. At the end of the 2016 inspection, the FDA inspector warned Somatics that if it did not take corrective action to address objectionable observations, the "FDA *can* take such actions as issuance of Warning Letter or seizure of product." (Makowski Decl., Ex. C 0049, ECF No. 81-8 (emphasis added).) It has not yet chosen to do so. Plaintiffs only offer evidence that a manufacturer who fails to report adverse events "*should* be found in violation of its reporting and investigatory responsibilities" under the FDCA. (Arrowsmith Decl., ¶ 14, ECF No. 79-3.)

[3] The FDA Form 483 lists objectionable observations and indicates that the produce or manufacturer may be in violation of the FDCA. *See* U.S. Food and Drug Administration, *Inspections, Compliance, Enforcement, and Criminal Investigations: Inspection Observations*, https://www fda.gov/iceci/inspections/ucm250720.htm (last accessed September 4, 2018).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title *Jose Riera and Deborah Chase v. Somatics, LLC*

III. JUDICIAL STANDARD

Pursuant to Federal Rule of Civil Procedure 56(a), a court may grant summary judgment where "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Rule 56(a) also provides for summary judgment on "part of each claim or defense." *Id.* To prevail on a summary judgment motion, the moving party must show that there are no triable issues of material fact as to matters upon which it has the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

To defeat a summary judgment motion, the non-moving party may not merely rely on its pleadings or on conclusory statements. *Id.* at 324. Nor may the non-moving party merely attack or discredit the moving party's evidence. *See Nat'l Union Fire Ins. Co. v. Argonaut Ins. Co.*, 701 F.2d 95, 97 (9th Cir. 1983). The non-moving party must affirmatively present specific admissible evidence sufficient to create a genuine issue of material fact for trial. *Celotex*, 477 U.S. at 324.

The materiality of a fact is determined by whether it might influence the outcome of the case based on the contours of the underlying substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over such facts amount to genuine issues if a reasonable jury could resolve them in favor of the nonmoving party. *Id.*

IV. DISCUSSION

C. Plaintiffs' Motion for Summary Judgment

Plaintiffs move for summary adjudication on two elements of their negligence per se claims on the following issues: (1) Somatics failed to maintain an internal system for evaluation, investigation, and reporting of adverse events as required by 21 C.F.R. § 820.198; (2) Somatics misbranded its "Thymatron" device in violation of 21 U.S.C. § 352(t) and 21 U.S.C. § 352(o); (3) Somatics breached its duty of care under California law by failing to comply with 21 C.F.R. § 820.198; (4) Somatics breached its duty of care by misbranding its devices under 21 U.S.C. § 352(t) and 21 U.S.C. § 352(o); and (5) Somatics breached its duty of care by introducing its misbranded "Thymatron" device in violation of 21 U.S.C. § 331.

California Evidence Code § 669 establishes a presumption that a party failed to exercise due care if: (1) he "violated a statute, ordinance, or regulation of a public entity"; (2) the "violation proximately caused death or injury to the person or property"; (3) the "death or injury resulted from an occurrence of the nature which the statute, ordinance, or regulation was designed to prevent"; and (4) the "person suffering the death or the injury to his person was one of the class of persons for whose protection the

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

statute, ordinance, or regulation was adopted." Cal. Evid. Code § 669(a). With reference to the five issues above, Plaintiffs seek summary adjudication on elements (1) and (4).

1. Element One – Violation of a Statute, Ordinance, or Regulation of a Public Entity

The first issue is whether Somatics violated a statute, ordinance, or regulation of a public entity and as such breached its duty of care. Both parties agree that the Somatics is subject to the provisions of the FDCA applicable to medical devices. Relevant here are the Medical Device Reporting ("MDR") regulations in Title 21 of the Code of Federal Regulations, authorized by the FDCA.

a. California Duty of Care

Plaintiffs maintain that Somatics' alleged violations of the FDCA constitute a breach of the standard of care in California because the FDCA establishes the applicable standard for medical device manufacturers. *See* Cal. Evid. Code § 669. California's duty of care under California Evidence Code 669 parallels the FDA regulations. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *DiRosa v. Showa Denko K.K.*, 44 Cal. App. 4th 799, 808 (Cal. Ct. App. 1996) ("the FDCA has been adopted as the standard of care in a negligence action"). Therefore, if Somatics violated the FDCA as alleged, then Somatics also breached the standard of care in California under element (1) of California Evidence Code 669. Cal. Evid. Code § 669(a).

b. Internal Procedures of 21 C.F.R. § 820.198 and 21 C.F.R. §§ 803.17(a)–(b)

Plaintiffs first argue that Somatics violated the FDCA regulations on maintaining internal procedures to record, investigate, and evaluate medical device reports. Manufacturers are required to maintain complaint files and establish written, standardized procedures for "receiving, reviewing, and evaluating complaints" to determine "whether the complaint represents an event which is required to be reported to FDA." 21 C.F.R. § 820.198(a)–(b); 21 C.F.R. § 803.17. In addition, manufacturers must evaluate all complaints to determine whether further investigation is warranted, and if not, the manufacturer "shall maintain a record that includes the reason no investigation was made" as well as the manufacturer's responses. *Id.* at § 820.198(b); 21 C.F.R. § 803.18.

The parties disagree as to whether Somatics has ever maintained an internal system for the investigation, evaluation, and reporting of adverse events. Somatics insists that it had a system prior to 2012 and simply improved its written system after the 2012 inspection, *see* Mirkovich Decl. ¶¶ 3–6 (ECF No. 81-1) ("At all times during my employment, Somatics has maintained an internal procedure for evaluating, investigation, and reporting adverse events to the FDA."), while Plaintiffs maintain that Somatics has never had an internal system, Karen Decl. Ex. A 0036 (ECF No. 79-6). Between the first

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

FDA inspection in 2012 and the second in 2016, Somatics hired the consulting firm Emergo to help update its procedures. (Mirkovich Decl. ¶ 4, ECF No. 81-1.) Those changes have been adopted by Somatics and are still in effect today. (*Id.*; *see also* Mirkovich Decl., Ex. A, ECF No. 81-1.)

Plaintiffs rely largely on the 2012 FDA investigation of the Somatics facility in which the inspector noted that Somatics' written internal procedures were inadequate. However, as discussed in the 2016 inspection report, Somatics implemented the requested changes and now has a detailed procedure in place. Somatics also presented evidence that before 2012 they had internal systems for evaluating and logging complaints; these were just not as detailed as the inspector in 2012 preferred.

More importantly, the observational objections in 2012 do not conclusively show a violation of the FDCA provisions above. The FDA issued no Warning Letters or regulatory sanctions, and while the absence of an official sanction is not dispositive on whether Somatics was in violation of the law, there is a genuine issue as to material fact about whether Somatics' procedures rose to the level of a violation of 21 CFR § 820.198 or 21 CFR §§ 803.17(a)-(b).

c. Reporting Requirements under 21 C.F.R. § 803.50 and 21 C.F.R. § 803.20

Plaintiffs also allege that Somatics breached its reporting requirements under 21 C.F.R. §§ 803.20–803.50. In general, manufacturers must file a report within thirty days of receiving information, from any source, that "reasonably suggests that a device that [they] market . . . [m]ay have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). Information "reasonably suggests" that an adverse event has occurred when it includes "professional, scientific, or medical facts, observations, or opinions that would cause [a manufacturer] to come to a reasonable conclusion that the device has caused or may have caused or contributed to an MDR reportable event." 21 C.F.R. § 803.20(c). Serious injuries are those that are life threatening, result in permanent impairment of a body function or structure, or necessitate medical intervention to preclude irreversible damage to a body structure, excluding "trivial impairment or damage." 21 C.F.R. § 803.3(w).

After receiving a complaint, the manufacturer is "responsible for conducting an investigation of each event and evaluating the cause of the event" to report it as needed. 21 C.F.R. § 803.50(b)(3). Adverse events do not have to be reported when the manufacturer reasonably concludes that the device did not cause the death or serious injury, that it was not the manufacturer of the device in question, or that the information is erroneous. 21 C.F.R. § 803.22(b). However, even if the manufacturer determines that an adverse event was not reportable, it must retain documentation of the complaint, the information on which the finding of non-reportability is based, and an explanation of the conclusion that it was not reportable. 21 C.F.R. § 820.198; 21 C.F.R. § 803.18.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK (PJW)	Date	September 14, 2018
Title	***Jose Riera and Deborah Chase v. Somatics, LLC***		

Somatics has never filed an adverse event report with the FDA. However, there is genuine disagreement about whether there have been adverse events to report, and thus whether Somatics has violated its reporting requirements. Plaintiffs cite five pieces of evidence to prove that Somatics violated its reporting requirements. The Court will address each in turn.

1. 2013 Skin Burn

Somatics did not report the skin burn discussed in the 2016 FDA Inspection, but Somatics and Plaintiffs offer conflicting evidence about whether this burn qualified as a reportable adverse event. This disagreement does not need to be resolved, however, because this evidence is not material.

Even if the evidence indisputably proved that the skin burn was a reportable event, and Somatics violated the law by failing to report, Plaintiffs present no evidence indicating that this violation proximately caused their injuries as required under the second element of California Evidence Code 669. Cal. Evid. Code § 669(a)(2). Plaintiffs do not allege that they suffer from skin burns or that had they known about incidences of skin burns prior to receiving ECT treatment, they would not have agreed to undergo this treatment. (*See* Pl.s' Compl. ¶ 87.) Instead, they specifically allege that had Somatics reported or warned of adverse events of "craniocerebral trauma" and permanent memory loss, they would have been less likely to agree to ECT. As a result, Somatics' alleged failure to report the skin burn is immaterial and cannot form the basis of granting summary judgment on this issue.

2. 3,000 Docket Reports

The second piece of evidence that Plaintiffs cite is the 2011 FDA Summary of the 3,000 complaints of ECT-related injuries, including death, memory loss, and brain damage. Somatics believed the comments were unreliable and that they did not have enough information to investigate. Plaintiffs, however, offer evidence that the events were reportable and thus Somatics is in violation of the FDCA. The FDA inspector in 2012 and 2016 made no mention of these complaints, despite discussing the skin burn above. As such, there is a genuine dispute as to material fact about whether Somatics was in breach of its obligation to report these events.

3. 1995 FDA Order and Response

Similarly, Plaintiffs cite the 1995 FDA Order and the apparent lack of a response as evidence that Somatics violated reporting requirements, but Somatics has presented sufficient evidence to raise a genuine dispute as to whether they responded.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

4. MAUDE Database Reports

There is a genuine dispute as to whether Somatics reviews and reports adverse events discovered through the MAUDE database, and a such this Court cannot find that Somatics has violated its statutory duties on this ground.

d. Misbranding under 21 USC §§ 352(o), 352(t), § 331(a), § 360(i), and § 360(t)

Plaintiffs also allege that the violations listed above caused the Thymatron devices to be "misbranded" and introduced into interstate commerce in violation of 21 U.S.C. § 331(a). A device is misbranded if there has been "a failure or refusal to give required notification or to furnish required material information" under the FDCA. 21 U.S.C. § 352(t). Because there is a genuine dispute as to material fact about whether Somatics was in violation of the regulations above, this Court cannot find that the Thymatron device was misbranded on this ground.

A device is also misbranded if it was "manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered" with the FDA. 21 U.S.C. § 352(o); 21 U.S.C. § 360(i); 21 C.F.R. § 807.20(a). However, prior to October 1, 2012, contract manufacturers were not required to register with the FDA if they manufactured the device according to another's specifications and did not distribute the device to consumers directly. 21 C.F.R. § 807.20(a)(2) (2012), *amended by* 21 C.F.R. § 807.20 (2018). Now, they must register. 21 C.F.R. § 807.20(a)(2).

The parties dispute whether Elektrika is a contract manufacturer that must register within the meaning of 21 C.F.R. § 807.20(a). If Elektrika manufacturers the final product that Somatics distributes, it is now required to register with the FDA. If it failed to do so, the Thymatron device is likely misbranded. However, the law that requires Elektrika to register was enacted in 2012, which is one year after the Thymatron device was sold to Plaintiff Chase's treating hospital and six years after the other Thymatron was sold to Plaintiff Riera's treating hospital. Prior to 2012, Somatics did not need to register Elektrika. Therefore, the timeline makes it impossible for Plaintiffs to show that the failure to register Elektrika after 2012 proximately caused their injuries, and as such the alleged misbranding of Elektrika is immaterial.

e. Conclusion

Based on the evidence above, there is a genuine dispute about whether Somatics violated its requirements for internal procedures under 21 CFR § 820.198 and 21 CFR §§ 803.17(a)-(b), reporting under 21 CFR § 803.50 and 21 CFR § 803.20, or misbranding under 21 USC §§ 352(o), 352(t), §

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

331(a), § 360(i), and § 360(t). A reasonable juror could conclude that Somatics did not violate a statute, ordinance, or regulation of a public entity. Cal. Evid. Code § 669(a).

As a result, the Court must **DENY** summary judgment on the first element of California Evidence Code § 669(a).

2. Element Four – The Class of Persons for Whose Protection the Statutes, Ordinances, or Regulations were Adopted

The FDCA's medical device reporting regulations provide a mechanism by which the FDA and device manufacturers can identify and monitor adverse events to "detect and correct problems in a timely manner." Medical Device Reporting for Manufacturers Guidance for Industry and Food and Drug Administration Staff, 2016 WL 6903478, at *6 (Nov. 8, 2016) ("Guidelines"). Moreover, the Guidelines assist the FDA to "protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use." 21 C.F.R. § 803.1(a).

Plaintiffs request summary judgment on the issue of whether Plaintiffs are among the class of persons for whose protection the regulations at issue here were adopted, satisfying the fourth element of negligence per se under California Evidence Code § 669. Cal. Evid. Code §669 (the "person suffering the death or the injury to his person was one of the class of persons for whose protection the statute, ordinance, or regulation was adopted.") Plaintiffs are patients who received ECT from their treating doctors using Somatics' Thymatron devices. Somatics does not offer evidence to the contrary. Therefore, Plaintiffs are among the class protected by the FDCA regulations.

Accordingly, this Court **GRANTS** summary judgment on element four of California Evidence Code § 669(a).

D. Defendant's Motion for Summary Judgment

Somatics moves for summary judgment on all six of Plaintiffs' claims. The Court will examine each claim in turn.

1. Claim 1: Negligence – Adulteration and Misbranding

Plaintiffs' first claim is for negligence and negligence per se based on the misbranding and adulteration of the Thymatron. To prevail on the negligence claim, Plaintiffs must show: (1) a legal duty to use due care; (2) a breach of that duty; and (3) the breach proximately and legally caused the resulting injury to Plaintiff. *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 433 (Cal. Ct. App. 2014). When applicable, the FDCA "has been adopted as the standard of care in a negligence action." *DiRosa v.*

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

Showa Denko K.K., 44 Cal. App. 4th 799, 808 (Cal. Ct. App. 1996). This claim is premised on Somatics' alleged violations of the FDCA.

To prevail on the negligence per se claim, Plaintiff must show that Somatics (1) violated the statute or regulation; (2) which proximately caused Plaintiffs' injuries; (3) from an occurrence of the nature which the statute or regulation was designed to prevent; and (4) Plaintiffs were of the class of persons for whose protection the statute or regulation was enacted. Cal. Evid. Code § 669(a). Plaintiffs have met the burden of showing the fourth element.

As discussed above, there is a genuine dispute as to material fact regarding whether the Thymatron device was misbranded in violation of the FDCA. Therefore, summary judgment is not appropriate with respect to whether Somatics breached its duty.

With respect to causation, Plaintiffs allege that had the devices not been misbranded, they would not have been sold to Plaintiffs' respective treating hospitals, and therefore Plaintiffs would not have received ECT. However, Plaintiffs do not provide evidence to support this contention. There is a genuine dispute as to whether the devices were misbranded, but assuming they were, it is still not clear how Plaintiffs would prove that but for the misbranding, the Thymatron devices would not have been sold into the stream of commerce. For example, even if the adverse events that Plaintiff describes from the 2009 Public Docket had been reported separately by Somatics to the FDA, there is nothing to suggest that the FDA would have taken the Thymatron device off the market – especially since the FDA knew about the complaints in the Docket and took no action. Moreover, there is no evidence that the information would have gotten to Plaintiffs' hospitals prior to purchasing their respective Thymatron devices. Therefore, Plaintiffs have not presented evidence sufficient to create a genuine issue of fact on this issue.

Because Plaintiffs failed to meet their burden to create a factual contention on causation, summary judgment is appropriate in favor of Somatics on this claim.

2. Claim 2: Negligence – Failure to Investigate, Evaluate, and Report

Plaintiffs' second claim is for negligence and negligence per se based on Somatics' failure to investigate, evaluate, and report adverse events. The elements Plaintiffs must prove are the same as claim one. Once again, there is a genuine dispute as to whether Somatics breached its statutory duty to investigate, evaluate, and report adverse events, and whether there is causation.

The question of causation in negligence or products liability cases is often "peculiarly for the jury." *Campbell v. General Motors Corp.*, 32 Cal. 3d 112, 120 (Cal. 1982) (citations omitted).

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK (PJW)	Date	September 14, 2018
Title	***Jose Riera and Deborah Chase v. Somatics, LLC***		

Moreover, Plaintiffs have the burden of establishing causation. *Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 968 (Cal. 1997).

To show causation, Plaintiffs contend that had Somatics reported adverse events, the doctors would have warned Plaintiffs of the dangers of brain trauma, memory loss, and cognitive defects, and Plaintiffs would not have agreed to receive ECT. Plaintiffs present evidence from two doctors stating that had they known that there was a risk of permanent memory loss or brain damage, they would have warned Plaintiffs. (*See* Depo. of Navin Adatia, ECF No. 84-4; Depo. of Viguen Movsesian, ECF No. 84-4.) Plaintiffs further allege that had a single adverse event been reported to the FDA, it would have reached Plaintiffs' doctors, and the doctors would have either passed the warnings along to Plaintiffs, who would have declined treatment, or they would not have recommended that Plaintiffs get ECT in the first place. Somatics contends that the chain of causation is tenuous; there is no evidence that the FDA would have made the adverse reports public, or that Plaintiffs or their doctors would have received the information, or that Plaintiffs would have declined ECT had they known. (*See* Arrowsmith Decl. ¶ 15, ECF No. 84-17.) As such, there is a genuine issue of fact on this element.

Additionally, there is a genuine dispute as to whether ECT caused Plaintiffs' injuries at all. Somatics presents evidence that Plaintiffs cannot establish that their cognitive impairment and memory loss were caused by ECT, given Plaintiffs' prior experiences of memory issues, chronic depression, Chase's past medication use, and Riera's past alcohol use. Moreover, Somatics' expert argues that "there is no empirical way to test whether the ECT administered to [Plaintiffs] had any adverse effect on them specifically." (Kellner Decl. ¶¶ 29–32, ECF No. 80-2.) On the other hand, Plaintiffs present evidence that "to a reasonable scientific certainty," Plaintiffs have suffered structural brain damage "consistent with the patterns found in the literature on ECT." (Perillo Decl. ¶ 16, ECF No. 84-23.) Plaintiffs' expert "completely disagree[s]" with Somatics' expert regarding the issue of causation, and as such, there is a genuine dispute as to material fact on the question of whether the ECT device caused Plaintiffs' injury.

Accordingly, the Court denies summary judgment on this claim.

3. Claim 3: Negligence – Failure to Warn

Plaintiffs' third claim for negligence is based on the failure to warn. To prevail on this claim, Plaintiffs must show that (1) Somatics sold the product; (2) Somatics knew or reasonably should have known that it was dangerous; (3) Somatics knew or should have known that users would not have realized the danger; (4) Somatics failed to adequately warn of the danger or instruct users on the safe use; (5) a reasonable manufacturer would have warned of this danger; (6) Plaintiffs were harmed; and (7) Somatics' failure to warn was a substantial factor in causing Plaintiffs' harm. *Motus v. Pfizer, Inc.*,

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

196 F. Supp. 2d 984, 990–91 (C.D. Cal. Dec. 20, 2001); *Putensen v. Clay Adams, Inc.*, 12 Cal. App. 3d 1062, 1076–77 (Cal. Ct. App. 1970).

The parties present conflicting evidence about whether Somatics knew or should have known of the risk of brain damage and whether the existing warnings for memory loss and brain damage were adequate. Somatics presents evidence that while amnesia is a well-known and scientifically acknowledged risk of ECT, brain damage is not. (*See* Kellner Decl. ¶¶ 12, 14, 17, ECF No. 80-2; Benkner Decl., Ex. A, SOM 281-83, ECF No. 105-2.) Plaintiffs' experts, however, argue that scientific literature suggests that brain trauma from ECT causes both cognitive defects and memory loss in patients, and therefore that all are well-known. (*See* Dolan Decl. ¶ 62, ECF No. 84-19; Castleman Decl. ¶ 18, ECF No. 84-12; Perillo Decl. ¶¶ 15–17, ECF No. 84-23.) Therefore, there is a genuine dispute as to whether the risk of brain damage is well-known or scientifically-accepted. If brain damage is a known risk of ECT, Somatics would have a duty to warn, and Plaintiffs would then need to show that Somatics' warnings were inadequate.

Somatics' Thymatron device comes with both a Patient Information Pamphlet and an Operator's Manual. The Operator's Manual is given to the facilities that administer ECT, and it provides instructions and warnings and directs the operators to follow the American Psychiatric Association's Task Force Report ("Task Force Report"). This Task Force Report summarizes current scientific knowledge regarding the proper use and risks of ECT.

Somatics presents evidence that the Task Force Report is the most thorough and authoritative report on ECT and indicates the widely-known risks of ECT, including cognitive side effects. The Report indicates that amnesia may sometimes result from ECT, and that although it is usually short-term, in rare circumstances it lasts longer. (*See* Kellner Decl. ¶ 11, ECF No. 80-2.) Moreover, the Report indicates that "[a] small minority of patients treated with ECT later report devastating cognitive consequences," although it goes on to say that these reports are rare and that "[m]ultiple factors likely contribute." (*Id; see also* Kellner Decl., Ex. F, 70–71, ECF No. 80-8. The Patient Information Pamphlet indicates that the main side effects of ECT include confusion and short-term memory loss that "occasionally continues in a mild form for a period of months, or longer." (Kellner Decl., Ex. D, SOM 06095, ECF No. 80-6. When asked if ECT causes brain damage, the pamphlet says that "[t]he available evidence speaks against this possibility" and the animal studies "have shown no evidence of brain damage." *Id.* Finally, the pamphlet indicates that ECT does not cause permanent memory loss "in most people." *Id.* Somatics argues that for the well-known risk of permanent memory loss, their warnings were adequate, and that because the risk of brain damage is not scientifically established, no warning was necessary.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

Plaintiffs, however, present evidence that these warnings were inadequate and that the Task Force Report is unreliable. (*See* Dolan Decl. ¶ 62, ECF No. 84-19; Castleman Decl. ¶¶ 15–18, ECF No. 84-12.) Riera and Chase both declare that they would not have gotten ECT had they known the risk of permanent memory loss or brain damage. (Riera Decl. ¶ 3, PA 182–83, ECF No. 26-2; Chase Decl. ¶ 4, PA 179, ECF No. 26-2.) Whether the warnings were adequate and whether Plaintiffs would have agreed to receive ECT had the warnings been more detailed is a question of fact about which there is a genuine dispute.

Accordingly, summary judgment on this claim is not appropriate.

4. *Claim 4: Strict Products Liability – Failure to Warn Because of Failure to Investigate, Evaluate, and Report*

Plaintiffs' fourth claim is for strict products liability based on the failure to warn through the investigation, evaluation, and reporting of adverse events. Plaintiffs allege that had Somatics filed the adverse event reports as required by the FDCA, Plaintiffs or their doctors would have seen the reports and been effectively warned against receiving ECT.

To prevail, Plaintiffs must prove that (1) Somatics manufactured the product; (2) the Thymatron had known or knowable risks in light of generally-accepted scientific and medical knowledge; (3) the potential risks presented a substantial danger when the Thymatron is used in a reasonably foreseeable way; (4) that ordinary consumers would not recognize; (5) Somatics failed to adequately warn of this risk; (6) Plaintiffs were harmed; and (7) the lack of warnings was a substantial factor in causing Plaintiffs' harm. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 995–96 (Cal. 1991). The adequacy of warnings is generally a question of fact for the jury. *Jackson v. Deft, Inc.*, 223 Cal. App. 3d 1305, 1320 (Cal. 1990).

As discussed above, there is a genuine dispute as to whether there is a known and substantial risk of brain injury about which Somatics failed to adequately warn consumers. Moreover, there is a genuine dispute about whether Somatics failed to investigate, evaluate, or report adverse events, or whether this failure caused Plaintiffs' injuries. Therefore, summary judgment cannot be granted on this claim.

5. *Claim 5: Strict Products Liability – Adulteration and Misbranding*

Plaintiffs also allege that because Somatics failed to comply with the regulatory duties described above, a misbranded product was introduced on the market, which eventually caused Plaintiffs' injuries. Had the product not been misbranded, it may not have been sold to Plaintiffs' treating hospitals and Plaintiffs would not have been given ECT.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

To prevail, Plaintiffs must show that they were harmed by the product that contained a manufacturing defect. *Johnson v. United States Steel Corp.*, 240 Cal. App. 4th 22, 30 (Cal. Ct. App. 2015). Here, Plaintiffs argue that the Thymatron is misbranded under the FDCA, and thus defective. But for Somatics' introduction of a defective medical device into interstate commerce, the Plaintiffs would never have been injured by ECT. More specifically, Plaintiffs contend that regulatory compliance would have forced Somatics to address "epistemological difficulties" in the research on the risks of ECT, and this has caused a "paucity of evidence" on whether brain damage is caused by ECT. (Arrowsmith Decl. ¶¶ 7–13, ECF No. 79-3.) Plaintiffs present no evidence to support this chain of causation. Accordingly, as discussed with respect to claim one above, Plaintiffs have not met their burden to affirmatively present specific admissible evidence sufficient to create a genuine issue of material fact for trial. Summary judgment is granted for Somatics on this claim.

6. Claim 6: Strict Products Liability – Failure to Warn Doctors Directly

Finally, Plaintiff's sixth claim is for strict products liability based on the failure to warn doctors directly. The elements of this claim are the same as the fourth claim, above. The warning at issue in this claim would have been given to Plaintiffs' physicians. *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (Cal. Ct. App. 1999).

As discussed above, the parties present conflicting evidence about whether there is a known or substantial risk of brain injury and permanent memory loss, whether ordinary consumers would be aware of these risks, whether the warnings were adequate, and whether this failure to warn caused Plaintiffs' injuries.

Somatics contends that Plaintiffs cannot show that the doctors would have read the public docket reports, but the Court assumes that the doctors would have performed their legal duties and passed along warnings about which they were aware. *See* Welf. & Inst. Code § 5326.2. Moreover, Plaintiffs present evidence that had doctors known of the risk of permanent memory loss or brain damage, they would have told their patients. Therefore, there is a genuine dispute of fact on this issue, and summary judgment is not appropriate.

Accordingly, summary judgment is not appropriate on this claim.

V. EVIDENTIARY OBJECTIONS

To the extent the parties have objected to any of the evidence relied upon by the Court, those objections are overruled for purposes of this Order.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK (PJW) Date September 14, 2018

Title ***Jose Riera and Deborah Chase v. Somatics, LLC***

VI. CONCLUSION

For the foregoing reasons, this Court:

DENIES Plaintiff's Motion for Partial Summary Judgment as to Presumption of Failure to Exercise Due Care on Element (1) of the California Evidence Code 669; and

GRANTS Plaintiff's Motion for Partial Summary Judgment as to Presumption of Failure to Exercise Due Care on Element (4) of California Evidence Code 669;

GRANTS Defendant's Motion for Summary Judgment as to Claims One and Five; and

DENIES Defendant's Motion for Summary Judgment as to Claims Two, Three, Four, and Six.

IT IS SO ORDERED.

_____ : _____

Initials of Preparer _____

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK-PJW	Date	June 19, 2018
Title	***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***		

Present: The Honorable	R. GARY KLAUSNER, UNITED STATES DISTRICT JUDGE	
Sharon L. Williams (Not Present)	Not Reported	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiff:	Attorneys Present for Defendant:	
Not Present	Not Present	

Proceedings: **(IN CHAMBERS)** Order Re: Defendant's Motion to Dismiss Based on Statute of Limitations (DE 55); Defendant's Motion to Dismiss for Lack of Causation and Duty to Warn (DE 56)

I. INTRODUCTION

On September 11, 2017, Marcia Benjamin ("M. Benjamin"), Daniel Benjamin ("D. Benjamin"), Jose Riera ("Riera"), Michelle Himes ("Himes"), Diane Scurrah ("Scurrah"), and Deborah Chase ("Chase") (collectively, "Plaintiffs"), individually and on behalf of all others similarly situated, filed a Complaint against Mecta Corporation ("Mecta") and Somatics LLC ("Somatics") (collectively, "Defendants"). Plaintiffs' Third Amended Complaint ("TAC"), filed April 19, 2018, is now the operative complaint. The TAC alleges (1) negligence/negligence per se—adulteration and misbranding; (2) negligence/negligence per se—failure to timely investigate, evaluate, and report adverse events; (3) strict liability—failure to warn; (4) strict liability—adulteration and misbranding; and (5) loss of consortium.

On May 10, 2018, Defendants filed two motions to dismiss pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). The first argues the claims of M. Benjamin, D. Benjamin, Himes, and Scurrah should be dismissed as barred by the statute of limitations. The second argues the entire TAC should be dismissed because Plaintiffs cannot allege facts sufficient to establish the necessary elements of causation or duty to warn. The Court addresses both motions in this order.

For the following reasons, the Court **GRANTS** Defendant's motions to dismiss.

II. FACTUAL BACKGROUND

Plaintiffs allege the following facts relevant to the present motions:

Defendants have been the only U.S. manufacturers of electroconvulsive therapy ("ECT") devices since at least 1985. ECT devices are used to treat patients with severe psychiatric disturbances by applying a brief intense electrical current to the patient's head to induce a major motor seizure. ECT treatment caused patients varying degrees of physical, psychological, and emotional injuries, including

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK-PJW Date June 19, 2018

Title ***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***

concussive brain injury and debilitating electrical brain trauma.

Plaintiffs received ECT treatment between approximately the following dates: Riera received treatment between April 22, 2016 and May 4, 2016, Chase between April 2015 and spring of 2016, M. Benjamin between January 2011 and September 2014, Himes between April 2011 and July 2012, and Scurrah between March 28, 2012, and December 2012. All Plaintiffs who received ECT treatment now suffer brain injuries and trauma. Plaintiff D. Benjamin is married to M. Benjamin and suffers a loss of consortium related to M. Benjamin's claims.

Plaintiffs believed their symptoms were minor short-term side effects of ECT treatment. They had no reason to suspect that they had incurred permanent brain injury until a Citizen Petition to reclassify or ban ECT devices was released in August 2016. Information on the safety risks of ECT devices was unavailable because Defendants failed to comply with statutory obligations to investigate, evaluate, and submit reports to the FDA on the safety and effectiveness of the ECT devices. When presented with adverse event allegations regarding their ECT devices, Defendants rationalized, without scientific justification, that any alleged harm resulted from "underlying psychiatric condition[s]," rather than from ECT treatment. Further, Defendants provided kickbacks or honoraria to opinion leaders to prevent public discovery of the risks of ECT therapy. As a result of Defendant's statutory noncompliance, the ECT devices have never satisfied premarket approval standards required of such medical devices. Defendants' fraudulent concealment of the ECT devices' risks of brain injury and trauma left the public, including medical providers, patients receiving ECT treatment, and their spouses, without information about the devices' dangers.

III. JUDICIAL STANDARD

To survive a motion under Rule 12(b)(6), a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible if the plaintiff alleges enough facts to permit a reasonable inference that the defendant is liable for the alleged misconduct. *Id.* A plaintiff need not provide "detailed factual allegations" but must provide more than mere legal conclusions. *Twombly*, 550 U.S. at 555. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

When ruling on a Rule 12(b)(6) motion, the court must "accept all factual allegations in the complaint as true." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). The court must also "construe the pleadings in the light most favorable to the nonmoving party." *Davis v. HSBC Bank Nev., N.A.*, 691 F.3d 1152, 1159 (9th Cir. 2012). However, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK-PJW Date June 19, 2018

Title ***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***

IV. DISCUSSION

A. Statute of Limitations

Defendants argue that Plaintiffs M. Benjamin, D. Benjamin, Himes, and Scurrah failed to state a claim upon which relief can be granted because the statute of limitations expired on their claims. Plaintiffs counter that Defendants are equitably estopped from asserting the statute of limitations as a defense. Alternatively, Plaintiffs argue the doctrine of fraudulent concealment and the discovery rule tolled the statute of limitations.

It is undisputed that the two year statute of limitations under California Civil Procedure Code § 335.1 applies to Plaintiffs' claims. *See* Cal. Civ. Proc. Code § 335.1; *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 809 n.3 (2005) (discussing products liability claim); *Viramontes v. Pfizer, Inc.*, No. 2:15-cv-1754 TLN AC (PS), 2015 U.S. Dist. LEXIS 171695 (E.D. Cal. Dec. 23, 2015) (discussing loss of consortium claim). The statute of limitations typically begins to run when all the elements of the claim have occurred. *Soliman v. Philip Morris Inc.*, 311 F.3d 966, 971 (9th Cir. 2002).

As Defendants argue, Plaintiffs' claims started to accrue after each Plaintiff's last round of ECT treatment, the latest of which occurred in September 2014. Thus, unless one of Plaintiffs' counterarguments prevail, these four Plaintiffs' claims are time-barred because their claims accrued more than two years before they were filed in September 2017. Each of Plaintiffs' counterarguments is addressed below.

1. Equitable Estoppel

Plaintiffs first argue that Defendants' statute of limitations defense is unavailable under the doctrine of equitable estoppel.

A defendant is estopped from asserting the statute of limitations as a defense if the defendant made a misrepresentation while the statute of limitations was still running that reasonably induced the plaintiff into refraining from bringing a timely suit. *Lantzy v. Centex Homes,* 31 Cal. 4th 363, 383–84 (2003). The plaintiff also must have proceeded diligently once the truth was discovered. *See id.* at 384. There is no requirement that the defendant have intent to mislead. *See Vu v. Prudential Prop. & Cas. Ins. Co.*, 26 Cal. 4th 1142, 1152 (2001). However, the defendant's statement or conduct must amount to a misrepresentation of fact that bears on the necessity of bringing a timely suit. *Lantzy*, 31 Cal. 4th at 384 n.18. A mere denial of liability is insufficient. *Id.*

Here, Plaintiffs allege the following facts are sufficient to establish equitable estoppel: (1) in response to the FDA's 2009 Order, Defendants concealed their regulatory noncompliance by downplaying and discrediting adverse allegations; (2) when Defendants became aware of prior patients' alleged harm, Defendants rationalized, without scientific justification, evaluation, or investigation, that

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-CV-06686-RGK-PJW	Date	June 19, 2018
Title	***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***		

the alleged harm resulted from an "underlying psychiatric condition" and not from ECT treatment; and (3) prior to Plaintiffs' treatments and alleged injuries, Defendants attempted to prevent public revelation of the risks of ECT therapy by providing kickbacks or honoraria to the research community. (TAC ¶¶ 35–51, 77, 105.)

Defendants contend that Plaintiffs failed to allege that they relied on any specific representation made by either Defendant which caused Plaintiffs to delay bringing suit. The Court agrees.

Plaintiffs do not allege that Defendants made any specific factual misrepresentations to them after learning of Plaintiffs' alleged injuries. Instead, Plaintiffs essentially argue that Defendants have either denied or refused to acknowledge the risks of ECT devices in their reports to the FDA. This more closely resembles a blanket denial of liability to the public, rather than a misrepresentation of fact bearing on the necessity of bringing a timely suit in Plaintiffs' particular case.

2. Fraudulent Concealment

Plaintiffs also argue that the theory of fraudulent concealment tolled the statute of limitations on their claims.

If a defendant fraudulently conceals a claim against a plaintiff, the statute of limitations will toll for as long as the plaintiff reasonably relies on the misrepresentation. *Grisham v. Philip Morris U.S.A., Inc.*, 40 Cal. 4th 623, 637 (2007). A plaintiff must plead facts to support the theory of fraudulent concealment with particularity. *Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117, 1132–33 (C.D. Cal. 2010).

Absent a fiduciary relationship, the defendant must have engaged in affirmative fraud to prevent the plaintiff from discovering his or her claim within the statute of limitations. *Id.* at 1131. The defendant's alleged fraud must also be "above and beyond the wrongdoing upon which the plaintiff's claim is filed." *Lukovsky v. City & Cty. of S.F.*, 535 F.3d 1044, 1052 (9th Cir. 2008). A plaintiff's alleged basis for fraudulent concealment cannot be the same as the basis for his or her claim. *Id.* Otherwise, the substantive wrong will merge with the tolling doctrine, ultimately eliminating the statute of limitations. *Id.* (citing *Cada v. Baxter Healthcare Corp.*, 920 F.2d 446, 451 (7th Cir. 1990)).

The complaint must show when and how the fraud was discovered. *Baker v. Beech Aircraft Corp.*, 39 Cal. App. 3d 315, 321 (1974). In addition, the complaint must show that, despite the plaintiff's reasonable diligence, the facts giving rise to the claim were not discoverable at an earlier date because of the defendant's fraudulent concealment. *Id.* at 321–22.

Defendants contend fraudulent concealment did not toll the statute of limitations because Plaintiffs failed to adequately plead: (1) affirmative fraud (2) above and beyond the alleged wrongdoing on which Plaintiffs base their claims (3) that prevented Plaintiffs from discovering their claims despite

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK-PJW Date June 19, 2018

Title ***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***

their exercise of reasonable diligence.

Plaintiffs argue that the following allegations constitute affirmative fraud above and beyond the wrongdoing that forms the basis of their claims: Defendants rationalized harm to past ECT patients as resulting from "underlying psychiatric condition[s]" and Defendants attempted to prevent public revelation of the risks of ECT therapy by paying off the research community.

These actions describe Defendants' alleged methods of nondisclosure and their failure to report the safety and effectiveness of ECT devices, which also form the basis of Plaintiffs' claims.[1] Therefore, even if Plaintiffs' allegations are considered affirmative actions, they are not misrepresentations above and beyond the wrongdoings on which Plaintiffs ground their claims.

Further, Defendants' alleged misrepresentations did not hinder Plaintiffs' ability to bring suit before the statute of limitations expired. As explained further below, Plaintiffs could have discovered the facts giving rise to their claims before the statute of limitations expired if they had exercised reasonable diligence. However, Plaintiffs also failed to plead facts to show they exercised this diligence.

3. Discovery Rule

Plaintiffs also argue that the discovery rule tolled the statute of limitations.

The discovery rule "postpones accrual of a cause of action until the plaintiff discovers, or has reason to discover, the cause of action." *Fox*, 35 Cal. 4th at 807. Discovery occurs when the plaintiff has reason to suspect the factual basis for his or her claim. *Id.*; *Gutierrez v. Mofid*, 39 Cal. 3d 892, 897 (1985). The plaintiff does not need to know the specific facts necessary to establish the claim, but must have notice of the circumstances that would put a reasonable person on inquiry of the wrong. *Gutierrez*, 39 Cal. 3d at 896–97 (citing *Sanchez v. S. Hoover Hosp.*, 18 Cal. 3d 93, 101 (1976)). A plaintiff relying on the discovery rule must plead facts to show: "(1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Fox*, 35 Cal. 4th at 808.

Plaintiffs do not allege that they made any investigation into the cause of their injuries before 2016. Instead, Plaintiffs allege that no amount of inquiry would have revealed ECT's risk of brain injury or Defendants' failure to comply with regulations because that information was unavailable to the medical community. (Pls.' TAC ¶¶ 38, 45, 48.) Further, Plaintiffs allege that Plaintiffs had no reason to suspect or inquire about this information until the Citizen Petition for the reclassification or banning of ECT devices was released in August 2016. (*Id.*) These conclusory allegations are untenable in light of other facts pled in the TAC.

Plaintiffs allege that they believed they were experiencing minor short-term side effects of ECT use that would improve over time. But Plaintiffs' side effects lasted for two or more years before the

[1] *Compare, e.g.* Pls.' TAC ¶ 77 *with* ¶ 104.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK-PJW Date June 19, 2018

Title ***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***

Citizen Petition was released. Given the duration of the injuries and Plaintiffs' belief that these injuries were linked to ECT treatment, a reasonable person would have inquired into their nature and cause much sooner. Had Plaintiffs made a reasonable inquiry, the alleged facts suggest they could have discovered the factual basis of their claims.

For example, Plaintiffs contend that other ECT patients have reported adverse reactions since 1938, including thousands of complaints at FDA hearings in 2009 and 2010; Mecta was sued in the 1990s for serious injuries resulting from ECT treatment; and several studies published since the 1980s have suggested or documented reasonably known brain injury resulting from ECT treatment. (Pls.' TAC ¶¶ 83–90.) A reasonably diligent investigation could have uncovered these facts before the Citizen Petition was released and before the statute of the limitations on Plaintiffs' claims expired.

Under the facts alleged, Plaintiffs had both inquiry notice and the ability to make earlier discovery through reasonable diligence.

4. In Summary

For the foregoing reasons, the Court **GRANTS** Defendants' Motion to Dismiss M. Benjamin's, D. Benjamin's, Himes', and Scurrah's claims as time barred under the applicable statute of limitations. Even if the statute of limitations did not bar these Plaintiffs' claims, the allegations supporting Plaintiffs' claims are insufficient for reasons explained below.

B. Lack of Causation and Duty to Warn

Causation is an element of both Plaintiffs' negligence and strict products liability claims. *See Huitt v. S. Cal. Gas Co.*, 188 Cal. App. 4th 1586, 1603–04 (2010) (explaining that the plaintiff must prove causation to establish claims that a defendant was negligent or strictly liable in failing to issue a warning). Defendants argue that Plaintiffs fail to establish causation because Plaintiffs do not allege that Defendants manufactured or sold the ECT machines used in each of the Plaintiffs' ECT treatments. Generally, a plaintiff asserting the claims at issue must allege exposure to a product manufactured or sold by the defendant to establish causation. *See Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 982 (1997). Moreover, a manufacturer generally has no duty to warn of hazards in another manufacturer's product. *See O'Neil v. Crane Co.*, 53 Cal. 4th 335, 344–46 (2012). Thus, absent allegations that Defendants manufactured the specific devices used on Plaintiffs, Defendants argue that Plaintiffs also cannot establish a duty to warn. Plaintiffs insist they either have pled or can plead facts sufficient to establish that Defendants manufactured the ECT devices at issue. Alternatively, Plainitffs argue that the facts support a theory of cross-manufacturer liability.

The TAC does not specifically allege which Defendant manufactured the devices used on each Plaintiff. In fact, the TAC admits that many Plaintiffs "are unable to ascertain which of the Defendants manufactured the particular device that contributed to their injuries." (TAC ¶ 103, ECF No. 52.)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK-PJW Date June 19, 2018

Title ***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***

Nevertheless, Plaintiffs argue the Court can infer causation from their allegations that Defendants have controlled the entire U.S. market for such devices since 1985. (*Id.* ¶¶ 69, 103.) At most, this allegation creates a reasonable inference that one, but not necessarily both, of the Defendants manufactured the ECT devices at issue. It is possible Plaintiffs were treated with devices manufactured only by Somatics, or devices manufactured only by Mecta. The Court cannot discern which.

Plaintiffs argue that it does not matter which Defendant manufactured the ECT devices at issue because the theory of cross-manufacturer liability established in *T.H. v. Novartis Pharmaceuticals Corporation* ("*Novartis*"), 4 Cal. 5th 145, 163 (2017), applies under the facts alleged.

As mentioned above, a manufacturer generally has no duty to warn of injuries caused by another manufacturer's products. *Id.* at 180; *O'Neil*, 53 Cal. 4th at 344–46. But the California Supreme Court in *Novartis* carved out a narrow exception for cross-manufacturer liability in certain unique circumstances. *Novartis*, 4 Cal. 5th at 180. Based on consideration of the foreseeability of the relevant injury and considerations of public policy,[2] the Court held a brand-name manufacturer could be held liable based on its deficient warning label even though the plaintiff's injuries were caused by a generic manufacturer's drug. *Id.* at 164–69.

For foreseeability, the Court reasoned that it was legally certain a defective brand-name label would injure patients who took the generic bioequivalent, because federal regulations mandated that the manufacturer of the generic drug use a label identical to that of its brand-name predecessor. *Id.* at 166. The brand-name manufacturer's duty to maintain an updated safety label combined with the generic manufacturer's preexisting duty to copy that label created a legal certainty that the brand-name manufacturer's warning defects would impact users of the generic bioequivalent. *Id.* The Court also concluded that public policy favored cross-manufacturer liability under the circumstances because "only the brand-name drug manufacturer has unilateral authority to modify the drug's label by adding to or strengthening a warning." *Id.* at 155. The brand-name manufacturer's control over the generic manufacturer's warning label was key to the Court's decision to impose cross-manufacturer liability. *Id.* at 165, 174. That control created "the unusual situation where one entity's misrepresentations about its own product foreseeably and legally 'contributed substantially to the harm' caused by another entity's product." *Id.* at 180 (quoting *O'Neil*, 53 Cal. 4th at 362).

Plaintiffs allege this case presents similar circumstances because the FDA requires ECT manufacturers to report adverse events to the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. According to Plaintiffs, if either Defendant had reported adverse events brought to its attention, this would have raised alarm in the medical community about ECT, thus creating a de facto warning about the dangers of any ECT manufacturers' products. (TAC ¶¶ 79–81.) But as

[2] These considerations, called "the *Rowland* factors," are applied when deciding whether to carve out a new legal duty of care. *Novartis*, 4 Cal. 5th at 164-65; *Rowland v. Christian*, 69 Cal. 2d 108, 113 (1968). Three factors bear on foreseeability: the foreseeability of injury to the plaintiff, the certainty the plaintiff suffered injury, and the connection between the defendant's actions and the injury. Four bear on policy: moral blame, the prevention of future harm, the burden on the defendant and the general public, and the availability of insurance. *Novartis*, 4 Cal. 5th at 165.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK-PJW Date June 19, 2018

Title ***JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.***

Defendants argue, these FDA reporting requirements do not mirror the pharmaceutical industry's explicit labeling requirements. The duty to report adverse events does not give individual ECT manufacturers the explicit duty or the power to control each other's warnings. Absent this control, neither foreseeability nor policy weighs strongly enough in favor of imposing a duty to warn of hazards in another manufacturer's ECT device. Therefore, the narrow cross-manufacturer liability exception created in *Novartis* does not apply here.

In sum, Plaintiffs have not presented factual or legal arguments that compel the Court to create a new cross-manufacturer duty exception for the ECT device industry. Therefore, Plaintiffs must have pled exposure to a specific ECT device manufacturer's product to impose liability under the general rule that manufacturers are liable only for injuries caused by their own products. The TAC, in its current form, fails in this regard. As such, Plaintiffs' pleadings do not state plausible negligence or strict products liability claims. Plaintiffs' loss of consortium claim is dependent on those claims, and so it too fails. The Court accordingly **GRANTS** Defendants' Motion to Dismiss Plaintiffs' claims for failure to adequately allege causation or a duty to warn.

C. Leave to Amend

Plaintiffs argue that recently acquired medical records establish that Somatics manufactured the ECT machines used on Plaintiffs. They request leave to amend their complaint with this new information.

These facts cannot overcome the statute of limitations. For the reasons stated above, the facts alleged in the complaint foreclose the possibility that Plaintiffs M. Benjamin, D. Benjamin, Himes, and Scurrah were unable to discover the basis for their claims through reasonable diligence within the limitations period. As such, their claims are **dismissed with prejudice**. *See Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir. 1995) (stating that dismissal with prejudice is proper if amendment would be futile).

However, these facts could partly cure the deficiencies in Riera's and Chase's claims, as they brought their claims within the statute of limitations. If Somatics manufactured the ECT devices at issue, the Court can infer that Plaintiffs were exposed to their devices and that Somatics had a duty to warn of the risks inherent in those devices. *See O'Neil*, 53 Cal. 4th at 351. Thus, these proposed allegations would likely be sufficient to cure the deficiencies in Riera's and Chase's claims against Somatics. The Court therefore **dismisses** Riera's and Chase's claims against Somatics **with leave to amend within seven days of this order**. Plaintiffs present no facts to suggest they can amend the TAC to assert that Mecta manufactured the ECT devices at issue. The Court therefore **dismisses** Riera's and Chase's claims against Mecta **with prejudice.**

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. 2:17-CV-06686-RGK-PJW Date June 19, 2018

Title *JOSE RIERA ET AL. v. MECTA CORPORATION ET AL.*

VI. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' Motions to Dismiss.

The Court **dismisses with prejudice** Plaintiffs' M. Benjamin's, D. Benjamin's, Himes', and Scurrah's claims as barred by the statute of limitations.

The Court **dismisses** the claims of the remaining Plaintiffs Riera and Chase as insufficiently pled. Riera and Chase **may amend** their claims against Somatics **within seven days** in accordance with this order; their claims against Mecta are **dismissed with prejudice.**

IT IS SO ORDERED.

Initials of Preparer

David M. Karen, Esq.
State Bar No. 117883
dk@dk4law.com
Kimberly Offenbacher, Esq.
State Bar No. 166318
ko@dk4law.com
A. Scott Brown, Esq.
State Bar No. 221786
asb@dk4law.com

DK LAW GROUP, LLP
3155 Old Conejo Road
Thousand Oaks, CA 91320
Tel: (805) 498-1212
Fax: (805) 498-3030

Attorneys for Plaintiffs MARCIA BENJAMIN; DANIEL BENJAMIN; JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; & DEBORAH CHASE

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MARCIA BENJAMIN; DANIEL BENJAMIN; JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MECTA CORPORATION; SOMATICS, LLC; and DOES 1 through 10, inclusive,

Defendants.

Case No.: 2:17-cv-06686 RGK-PJW

FIRST AMENDED COMPLAINT FOR:

1. NEGLIGENCE/NEGLIGENCE *PER SE*;
2. STRICT PRODUCT LIABILITY—MARKETING AND INFORMATION DEFECT—FAILURE TO WARN; and
3. LOSS OF CONSORTIUM.

CLASS ACTION

DEMAND FOR JURY TRIAL

//

Plaintiffs MARCIA BENJAMIN, DANIEL BENJAMIN, JOSE RIERA, MICHELLE HIMES, DIANE SCURRAH, and DEBORAH CHASE (collectively "Plaintiffs"), individually and on behalf of all other similarly situated individuals, hereby complain against Defendants MECTA CORPORATION, SOMATICS, LLC and DOES 1 through 10, inclusive (collectively "Defendants") and, on information and belief, allege as follows:

SUMMARY OF THE ACTION

1. This is a class action brought by Plaintiffs, on behalf of themselves and other similarly situated electroconvulsive therapy ("ECT")[1] patients, who have sustained injuries resulting from Defendants' conduct. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 & 1332.

2. An ECT shock device is "a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head." 21 C.F.R. § 882.5940(a). An ECT shock device, in lay terms, is used to administer 'shock treatment.'

3. The California Department of Mental Health reported 3,302 patients given ECT in 2001 alone. The number of patients given ECT shock treatment in California per year is likely to have increased since that time.

4. The primary demographic for ECT shock treatment is comprised of patients suffering from bipolar disorder ("BPD") and/or severe depression. ECT shock treatment is liberally prescribed for a variety of psychological disorders including, but not limited to schizophrenia and catatonia. ECT shock treatment is used on patients of all ages, including children and the elderly.

//

//

[1] Also referred to as "shock therapy" or "shock treatment."

5. Plaintiffs and members of the putative class are individuals suffering from various degrees of physiological, psychological and emotional trauma including, but not limited to skin burns, permanent brain damage, severe permanent cognitive and memory impairment, broken teeth, prolonged seizures, myocardial infarction, ruptured bowels, acute and/or chronic organic brain syndrome, complete neurological collapse, and sometimes death, secondary to ECT shock treatment.

6. Despite statutory duties under the Food, Drug and Cosmetic Act ("FDCA") and directives by the FDA, pursuant to the Medical Device Amendments of 1976 ("MDA") that ECT device manufacturers report information concerning safety and effectiveness testing for their devices to the FDA,[2] no ECT device manufacturer, including MECTA CORPORATION or SOMATICS, LLC, complied with these statutory obligations. No ECT manufacturer, including either Defendant, responded to the FDA's first two orders requiring them to submit safety and effectiveness data by May 28, 1982 and August 14, 1997, respectively. Defendants only responded to a third FDA order, mandated by the Safe Medical Devices Act of 1990 ("SMDA") requiring Defendants to submit "any information known or otherwise available" about the safety and effectiveness of the device, *including adverse safety or effectiveness information*. Defendants' responses failed to include information relating to the majority of physiological, psychological, and emotional injuries frequently suffered by those who receive ECT shock treatment. Defendants also grossly understated the incidence of death resulting from ECT. Such a response by Defendants failed to comply with their statutory reporting requirements under the MDA and SMDA.

//

//

//

[2] 44 Fed. Reg. 172, at 51776-51777 (Sept. 4, 1979) ("This action is being taken under the Medical Device Amendments of 1976."); *see* Medical Device Amendments of 1976, 21 U.S.C. § 351 *et seq.*

7. As a direct and proximate result of Defendants' refusal to comply with multiple orders by the FDA and satisfy their state duties running parallel to their statutory duties, as of the time of this filing, ECT devices have never satisfied the stringent premarket approval standards that Class III medical devices are required to meet.

8. Because of the lack of testing rigor, the mechanism of action by which ECT yields any alleged benefit to patients remains unascertained and unknown. Testing over the years has not shown any conclusive benefit to receiving ECT shock treatment past a brief bout of mania in the short-term, but the risks remain apparent, and include but are not limited to permanent long-term memory loss, cognitive impairment, debilitating electrical brain trauma, seizures, acute and/or chronic organic brain syndrome, complete neurological collapse, and death.

9. But for Defendants' failure to comply with the FDCA, MDA, and SMDA, the putative class members would not have suffered the serious injuries alleged in this complaint, since compliance would require that the Defendants investigate, solicit, and report information when they learn that their ECT devices may have contributed to a death or serious injury and specifically warn the FDA of adverse safety and effectiveness information.

10. Defendants' failure to submit to the FDA all safety and effectiveness data reasonably known and/or available relating to use of their ECT devices by certain effective dates for premarket approval rendered their devices "adulterated" under the FDCA.

11. Defendants' failure to furnish statutorily mandated material or information pertaining to occasions on which their devices may have contributed to a death or serious injury rendered their devices "misbranded" under the FDCA.

//

//

//

12. The manufacture, introduction, or receipt of an adulterated or misbranded medical device through interstate commerce is prohibited under the FDCA.[3]

13. Defendants' failure to warn the FDA of the latent dangers inherent in ECT through satisfying its adverse event reporting obligations resulted in a lack of knowledge among the medical providers of members of the putative class and the public in general about the latent dangers inherent in administration of ECT shock treatment, but they nevertheless continued to market their adulterated, misbranded, and defective ECT shock devices in the United States. Because some form of physiological, psychological, or emotional injury results universally from ECT shock treatment, Defendants' conduct directly and proximately caused injuries to the putative class.

14. This class action seeks to remedy the damages caused by Defendants' conduct: violating the state warning duties running parallel to the Food, Drug & Cosmetic Act and causing harm by placing a defective product into the stream of commerce. Defendants' violation of federal statutory duties, as demonstrated by Defendants' failure to comply with three separate administrative orders by the United States Food and Drug Administration ("FDA"), which required Defendants to submit to the FDA all safety and effectiveness data reasonably known and/or available for their ECT shock devices by certain effective dates, resulted in a lack of knowledge among the medical providers of members of the putative class and the public in general about the latent dangers inherent in ECT shock treatment.

PARTIES

15. Plaintiff MARCIA BENJAMIN ("M. BENJAMIN") is a citizen of the State of California.

16. Plaintiff DANIEL BENJAMIN ("D. BENJAMIN") is a citizen of the

[3] 21 U.S.C. § 331.

State of California.

17. Plaintiff JOSE RIERA ("RIERA") is a citizen of the State of California.

18. Plaintiff MICHELLE HIMES ("HIMES") is a citizen of the State of California.

19. Plaintiff DIANE SCURRAH ("SCURRAH") is a citizen of the State of California.

20. Plaintiff DEBORAH CHASE ("CHASE") is a citizen of the State of California.

21. Plaintiffs are informed and believe and based thereon allege that, at all relevant times, Defendant MECTA CORPORATION ("MECTA") is and was a corporation formed and existing under the laws of the State of Oregon with its principal place of business at 19799 SW 95th Place B, Tualatin, Oregon. Plaintiffs are further informed and believe and based thereon allege that MECTA is an ECT manufacturer and provider and, in that regard is authorized to conduct business in the State of California and does conduct business in the State of California.

22. Plaintiffs are informed and believe and based thereon allege that, at all relevant times, starting with its founding in 1984, Defendant SOMATICS, LLC ("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. Plaintiffs are further informed and believe and based thereon allege that SOMATICS is an ECT manufacturer and provider and, in that regard is authorized to conduct business in the State of California and does conduct business in the State of California.

23. Plaintiffs are not presently aware of the true names and capacities, whether individual, corporate, associate or otherwise, of Defendants named in this action as DOES 1 through 10, and each of them, and therefore sue such Defendants, and each of them, by such fictitious names. Plaintiffs are informed and believe, and

on the basis of such information and belief allege, that each fictitiously named Defendant is legally responsible for the acts alleged herein, and/or is liable to Plaintiffs as hereinafter alleged. Plaintiffs are informed and believe, and on the basis of such information and belief allege, that at all times mentioned herein, that such fictitiously named Defendants, and each of them, were participants in the stream of commerce and/or necessary marketing agents that played a role in delivering ECT shock devices to their end users.

24. Plaintiffs are informed and believe, and, based upon such information and belief allege that the Defendants named in this action as DOES 1 through 10, and each of them, herein knowingly conspired together in various combinations, and agreed amongst themselves to act in concert and in furtherance of a common scheme, plan and design to commit, aid, abet and/or render substantial assistance in the wrongs complained of herein below. Plaintiffs are further informed and believe, and based upon such information and belief allege that Defendants knew as they were conducting themselves that they were substantially assisting in the accomplishment of wrongdoing, and had the right and ability to control the actions of the remaining Defendants but did nothing to curb the activities described herein below, or prevent others from engaging in such conduct. Plaintiffs are further informed and believe, and based upon such information and belief allege, that Defendants, and each of them, actively condoned, encouraged, participated in, and/or instigated the conduct described herein below in furtherance of their common scheme, plan and design which entailed, among other things: (a) aiding and abetting the conspiracy and common course of conduct complained of herein; (b) participating in and/or knowing and acquiescing in the acts complained of herein, sufficient to categorize such conduct as conspiratorial; and (c) taking and/or ratifying conduct to enrich themselves or their co-conspirators, at the expense of Plaintiffs.

//

25. Plaintiffs are informed and believe that Defendants, and each of them, are in some manner legally responsible for the events alleged in this Complaint. Plaintiffs are further informed and believe that each of the Defendants acted in all respects pertinent to this action as the agent of the other Defendants, carried out a joint scheme, business plan, policy, or enterprise, or aided and abetted the acts and omissions alleged herein, and that the acts and omissions of each Defendant are legally attributable to the other Defendants.

26. Plaintiffs are informed and believe that Defendants are the only manufacturers of ECT devices within the United States.

JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction over the lawsuit under the Class Action Fairness Act, 28 U.S.C. § 1332, because this is a proposed class action in which: (1) there are at least 100 Class members; (2) the combined claims of Class members exceed $5,000,000, exclusive of interest, attorney's fees, and costs; and (3) Plaintiffs and Defendants are citizens of different states to the extent required by statute.

28. This Court has subject matter jurisdiction over the lawsuit under 28 U.S.C. § 1331 because the vindication of Plaintiffs' rights under state law substantially and necessarily turn on a construction of federal law, specifically 21 U.S.C. § 360e with respect to premarket approval applications, 21 U.S.C. § 360i with respect to medical device manufacturer reporting requirements, and 21 U.S.C. § 351 with respect to the illegality of marketing adulterated or misbranded medical devices.

29. This Court has personal jurisdiction over Defendant MECTA because it has sufficient minimum contacts in California to render the exercise of jurisdiction by this Court proper.

//

30. This Court has personal jurisdiction over Defendant SOMATICS because it has sufficient minimum contact in California to render the exercise of jurisdiction by this Court proper.

31. Venue is proper in the Central District of California under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims, including ECT shock treatment received by representative Class members, occurred in this District.

PLAINTIFF-SPECIFIC ALLEGATIONS

32. Plaintiff M. BENJAMIN, in seeking an effective treatment for symptoms relating to withdrawal from psychotropic medication, underwent a series of 22 separate rounds of ECT shock treatment between about January 2011 to September 2014. ECT did not improve M. Benjamin's symptoms relating to psychotropic medication withdrawal. Instead, it caused severe physiological, psychological, and emotional injury, including dental trauma and brain injury.

33. Plaintiff D. BENJAMIN is and has been at all times relevant to the allegations herein lawfully married to Plaintiff M. BENJAMIN. D. BENJAMIN suffers a loss of consortium that M. BENJAMIN offered during the course of their marriage as a result of ECT shock treatment.

34. Plaintiff RIERA, in seeking an effective treatment for severe depression, underwent a series of six separate rounds of ECT shock treatment on April 22, 2016, April 25, 2016, April 27, 2016, April 29, 2016, May 2, 2016, and May 4, 2016 at Huntington Memorial Hospital in Pasadena, California. ECT did not generate any improvement in RIERA's severe depression. Instead, it caused severe physiological, psychological, and emotional injury, including brain injury.

35. Plaintiff HIMES obtained over twenty rounds of ECT shock treatment between about April 2011 and about July 2012 at Sharp Mesa Vista Hospital in San Diego, California. As a result of receiving ECT shock treatment, HIMES suffers severe physiological, psychological, and emotional injury, including brain injury.

Plaintiff HIMES's husband suffers a loss of the consortium that HIMES offered during the course of their marriage as a result of HIMES's receipt of ECT shock treatment.

36. Plaintiff SCURRAH underwent over fifty-eight rounds of ECT shock treatment in seeking to treat her bipolar disorder, beginning on March 28, 2012 and continuing for about nine months. ECT shock treatment caused SCURRAH severe physiological, psychological, and emotional injury, including brain injury.

37. Plaintiff CHASE underwent ECT shock treatment at least seven times in seeking to treat her major depressive disorder and severe anxiety, between April of 2015 and Spring of 2016. ECT shock treatment caused CHASE severe physiological, psychological, and emotional injury, including brain injury.

CLASS ACTION ALLEGATIONS

38. Plaintiffs bring this action on behalf of themselves and all others similarly situated as this action satisfies the requirements of numerosity, commonality, typicality, adequacy of representation, and predominance and superiority[4] requirements of Federal Rules of Civil Procedure, Rule 23.

39. The proposed Class is defined as follows:

CLASS

> All individuals and spouses of individuals in the United States who received ECT shock treatment in California after May 28, 1982, administered by an ECT shock device that was manufactured, sold and/or distributed by Defendants after May 28, 1982, and who suffered an injury as a result thereof, with the exception of paragraph 40 below.

//

//

[4] Fed. R. Civ. P. 23(b)(3).

40. Excluded from the Class are government entities, and all judges assigned to hear any aspect of this litigation, as well as their immediate family members.

41. The members of the Class are so numerous that joinder is impractical. The Class consists of thousands of individuals, as ECT shock treatment has been available and administered to the described Class for more than 30 years, with the annual estimate of ECT shock patients per year in California numbering in the thousands. Although the exact number and identity of the class members is not presently known, the class can be defined and ascertained by means of the objective criteria, through strategic publication, and through coordinated discovery of the identities of all purchasers of ECT shock devices as sold by and obtained from MECTA and SOMATICS since the beginning of the class period.

42. There are questions of law and fact that are common to the Class, and these common questions predominate over any questions affecting only individual Class members. Among the questions common to the Class are:

a. Defendants' statutory obligation not to market an adulterated or misbranded medical device and/or reporting requirements imposed by the FDCA;

b. Whether the FDCA gives rise to a duty to warn;

c. Whether Defendants violated statutory obligations and/or reporting requirements and/or breached their duty to warn;

d. The dates of said violations and/or breaches;

e. Whether, had Defendants complied with their statutory duties, their ECT devices would have been on the market;

f. Defendants' efforts to comply and/or justifications for non-compliance with the reporting requirements and/or duty to avoid marketing an adulterated or misbranded medical device as may be offered by Defendants in their defense;

g. Whether Defendants' violations and/or breaches can give rise to liability under the state laws running parallel to the federal laws;

h. Information as to the safety and effectiveness, or lack thereof, for the use of ECT shock devices;

i. The inherent dangers of the use of ECT shock devices;

j. Information known or knowable to Defendants regarding the safety and effectiveness, or lack thereof, of the use of ECT shock devices;

k. Whether Defendants' culpable state of mind in in failing to comply with federal statutory duties and their parallel state counterparts subjects Defendants to punitive damages.

43. Common questions of fact and law predominate over any questions affecting only individual Class members with respect to liability, and damages may be properly bifurcated for separate determination.

44. The claims of Plaintiffs are typical of the claims of Class in that they underwent ECT shock treatment using an ECT shock device manufactured, sold and/or distributed by Defendants that, like the Class members, they would not have undergone had Defendants not violated the FDCA or had not manufactured, sold and/or distributed an adulterated, misbranded, and defective ECT shock device within the stream of commerce, and would therefore not have been injured by ECT shock treatment.

45. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have no interests antagonistic to the interest of any of the other Class members.

46. Plaintiffs are committed to the vigorous pursuit of this action and have retained competent counsel with the necessary experience and skill to prosecute this action on behalf of the Class.

//

47. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The issues that may be jointly tried, when compared to those requiring separate adjudication, are so numerous and substantial that the maintenance of a class action would be advantageous to the judicial process and to the litigants. In light of the allegations made, individual litigation to resolve the whole of this matter would be unnecessarily costly and burdensome and would deter individual claims.

48. To attempt to resolve the entirety of this claim by processing individual cases would increase both the expenses and the delay, not only to class members, but also to Defendants and the Court. In contrast, a class action will avoid case management difficulties and provide multiple benefits to the litigating parties, including efficiency, economy of scale, unitary adjudication with consistent results and equal protection of the rights of each class member, all by way of the comprehensive and efficient supervision of the litigation by a single court.

49. Without class certification, the prosecution of separate actions by individual members of the class would create a risk of inconsistent or varying adjudications with respect to individual members of the proposed class that would establish incompatible standards of conduct for Defendants.

SUBSTANTIVE ALLEGATIONS

50. The regulation of devices, including ECT devices, is relatively new. The United States Congress enacted the Medical Device Amendments of 1976 (the "MDA"), effective May 28, 1976, amending the FDCA "to provide for the safety and effectiveness of medical devices intended for human use."

51. Pursuant to the MDA, the FDA was required to review all existing medical devices and, by regulation, divide each into one of three classes of devices established to control access to the market depending on the intended use, the indications for use, and the risks that the particular device posed to the user. A

Class I ("General Controls"), device was subject to general post-market or after-sale controls including good manufacturing practices. A Class II ("Performance Standards") device was to be subject to FDA established regulations for performance standards as well as post-market controls. A Class III ("Premarket Approval") device required a premarket approval application ("PMA") and approval before sale, or a product development protocol, and adherence to post-market controls. By way of contrast, a wheelchair is an example of a Class I device while an implantable pacemaker is an example of a Class III device.

52. On September 4, 1979, the FDA published an Order in the Federal Register (the "1979 FDA Order") presenting its "final ruling" that ECT devices are Class III "Premarket Approval" devices under the MDA and specifically ordered manufacturers such as Defendants to prepare and submit a PMA for approval. The FDA's ruling stated in relevant part:

> The Food and Drug Administration (FDA) is issuing a final ruling classifying electroconvulsive therapy devices into Class III (premarket approval). The effect of classifying a device into Class III is to require each manufacturer of the device to submit to FDA a premarket approval application ["PMA"] that includes information concerning safety and effectiveness tests for the device."[5]

53. The FDA's Order followed the recommendation of the Neurological Section of the Respiratory and Nervous System Devices empaneled by the FDA due to the lack of available information regarding ECT devices and following public comment. The FDA concluded that Class III placement was required as "there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the ECT device."[6]

[5] *See* 44 Fed. Reg. 172, at 51776-77 (Sept. 4, 1979) (reporting 21 C.F.R. § 882 [Docket No. 78N-1103]).
[6] *See* 21 C.F.R. § 882.5940.

54. As of September 4, 1979, Defendants herein, as manufacturers of ECT devices, were specifically ordered to submit a PMA application to the FDA for approval of this Class III device as a prerequisite to continued access to the market. The PMA application was to contain "safety and effectiveness" information derived from testing, e.g., from clinical trials. Moreover, PMA applications must include "specimens of the labeling proposed to be used for such device,"[7] to be submitted for FDA approval.

55. Defendants, as manufacturers of ECT devices, were required to perform clinical trials and submit their respective PMA applications by May 28, 1982.

56. Plaintiffs are informed and believe and based thereon allege that Defendants thereafter violated the MDA, and the 1979 FDA Order, and specifically failed to conduct human trials and/or submit PMA applications with safety and effectiveness information then available to date to the FDA by May 1982, or at all. Failure to timely submit PMAs resulted in Defendants' ECT devices being "adulterated" under federal law. Defendants continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enabled their continued use, despite being "adulterated" under federal law.[8]

57. Plaintiffs are informed and believe and based thereon allege that Defendants failed to submit reports to the FDA whenever the Defendants received or otherwise became aware of information that reasonably suggested that one of their marketed devices may have caused or contributed to a death or serious injury, as required by federal law. Failure to submit such adverse event reports resulted in Defendants' ECT devices being "misbranded" under federal law.[9] Defendants continued to manufacture, sell, and distribute their respective devices in the United

[7] 21 U.S.C. § 360e(c)(1)(F).
[8] 21 U.S.C. § 351; *see id.* § 331 (prohibiting "introduction," "receipt," or "delivery" of adulterated or misbranded devices into interstate commerce).
[9] 21 U.S.C. § 352(t).

States, and otherwise enabled their continued use, despite being "misbranded" under federal law.

58. The United States Congress enacted the Safe Medical Devices Act of 1990 ("SMDA"), effective November 28, 1990, amending the FDCA "to make improvements in the regulation of medical devices." Thereafter, the FDA published an Order in the Federal Register (the "1995 FDA Order") pursuant to the SMDA requiring that the manufacturers of ECT devices, including Defendants, submit a summary of, and a citation to, all information known or available about the safety and effectiveness of their respective ECT devices to the FDA by August 14, 1997.[10]

59. Plaintiffs are informed and believe and based thereon allege that Defendants violated the SMDA, and the 1995 FDA Order, by failing to submit a summary of, and a citation to, all information known or available about the safety and effectiveness of their respective ECT devices to the FDA by August 14, 1997. Defendants continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enable their continued use.

60. On April 9, 2009, the FDA published a third Order in the Federal Register (the "2009 FDA Order") again requiring the manufacturers of ECT devices, including Defendants, to comply with the SMDA by submitting all information known or available about the safety and effectiveness of ECT devices to the FDA by the deadline of August 7, 2009.[11] Defendants responded to this order, but withheld a significant amount of information relating to adverse events from the FDA. None of the information provided directly addressed the known issues of permanent memory loss, cognitive impairment, or the certainty of brain damage resulting from ECT.

//

//

[10] 60 Fed. Reg. 156, at 41986-89 (Aug. 14, 1995).
[11] 74 Fed. Reg. 67, at 16214-17 (Apr. 9, 2009).

61. The FDCA's implementing regulations provide that manufacturers of medical devices must report to the FDA within 30 calendar days after the day that the manufacturer receives, or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer: "(1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that [the manufacturer has marketed] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."[12]

62. The regulations provide that manufacturers must submit all information "reasonably known." "Reasonably known" information is "(i) [a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) any information in your possession; or (iii) any information that you can obtain by analysis, testing, or other evaluation of the device."[13]

63. Defendants continued to violate the SMDA, and related orders, by failing to produce reasonably known information and by withholding data from the FDA relating to the safety and effectiveness of their respective ECT devices, including data relating to the devices' collective propensity to cause harm.

64. Plaintiffs are informed and believe and based thereon allege that the overwhelming weight of scientific evidence relating to ECT shock treatment suggests that there is no long-term benefit to receiving ECT shock treatment at all, that the alleged short-term benefits are transient and are little more than a bout of mania following brain damage, that ECT shock treatment inherently damages the brain, and that any mechanism of action by which it is said to 'treat' depression or mental illness is hypothetical.

//

//

[12] 21 C.F.R. § 803.50(a).
[13] 21 C.F.R. § 803.50(b).

65. As a result of the Defendants' conduct in violating statutory requirements and selective withholding and manipulation of the data surrounding ECT devices, and the duties under state law running parallel to such requirements, the devices have continued to be manufactured, sold, distributed and have remained in use without testing, public dissemination of reliable information and data as to safety and effectiveness, warnings of inherent dangers, and without the requisite premarket FDA approval.

66. Defendants continue to manufacture, sell and distribute adulterated, misbranded, and defective ECT devices to this day. Doing so violates both a duty established under federal statute and parallel duties under state tort law.

67. The FDA's guidance document pertaining to medical device reporting states that "a publicly disclosable version of the medical device reports that we have received is available on the CDRH webpage at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM."[14] Of the 49 reports posted on the MAUDE database pertaining to ECT devices, the majority appear to have been voluntarily submitted by patients, and none appear to have been submitted by device manufacturers under their mandatory reporting duties. Had Defendants complied with their federal and parallel state duties to report to the FDA all safety and effectiveness data reasonably known or available for ECT, the FDA's MAUDE database would have reflected the multitude of adverse events that routinely result from administration of ECT shock treatment.

68. 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 FDCA's obligation to investigate and report these events to the FDA. For example, from the 1940s to the 1980s, various psychiatric experts have documented brain damage correlated with

[14] MEDICAL DEVICE REPORTING FOR MANUFACTURERS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF DOCUMENT 26 (2016).

ECT. These adverse events were "reasonably known" to both MECTA and SOMATICS, and therefore created a statutory duty to investigate and report them to the FDA. However, there are no manufacturer-submitted adverse event reports in FDA's MAUDE database, illustrating Defendants' continuous and intentional failure to report adverse events to the FDA.

69. Multiple lawsuits were filed against MECTA corporation in the 1990s. These lawsuits alleged serious injuries, including but not limited to brain damage, permanent cognitive impairment, and ruptured bowels resulting from ECT shock treatment. The CEO of MECTA, Ms. Robin Nicol, admits that these lawsuits alleged that MECTA's devices caused brain damage to the patients. She testified that she was not even curious why multiple people had sued her company for causing them brain damage, assuming the lawsuits to be "frivolous." Defendants intentionally evaded their duty to investigate these adverse events or submit any adverse event reports to the FDA.

70. "The Electroshock Quotationary" was published in 2006.[15] 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 advocate 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 went investigated or reported by Defendants.

71. Many studies during the class period 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.[16]

[15] LEONARD ROY FRANK, THE ELECTROSHOCK QUOTATIONARY (2006), http://www.endofshock.com/102C_ECT.PDF.
[16] Weinberger et al., *Structural Abnormalities in the Cerebral Cortex of Chronic Schizophrenic*

72. A brain scan study confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.[17]

73. A study relating MRI scans of patients demonstrated a strong correlation between the numbers of previous ECT treatments to loss of brain tissue.[18]

74. 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.[19]

75. Finally, a particularly graphic study documented intra-cranial bleeding resulting from ECT shock treatment administered using current ECT devices.[20] Defendants remained willfully ignorant of the adverse events in these and other studies in an attempt to evade their reporting duties under the FDCA.

76. In sworn deposition testimony in 2004, in an unrelated suit, the CEO of MECTA, Robin Nicol, was asked if she or anyone from her company had "made any effort to solicit information from persons who have received ECT to see whether or not they have been harmed." She responded "no . . . that is not in the purview of our company's responsibilities."

//

//

//

//

//

Patients, 36 ARCHIVES GEN. PSYCHIATRY, 935-39 (1979).

[17] Calloway et al., *ECT and Cerebral Atrophy: A CT Study*, 64 ACTA PSYCHIATRICA SCANDINAVICA 442-45 (1981).

[18] Andreasen et al., *MRI of the Brain in Schizophrenia*, 47 ARCHIVES GEN. PSYCHIATRY, 35-41 (1990).

[19] R.J. Dolan et al., *The Cerebral Appearance in Depressed Subjects*, 16 PSYCHOL. MED., 775-79 (1986).

[20] Kulkarni & Melkundi, *Subdural Hematoma: An Adverse Event of Electroconvulsive Therapy – Case Report and Literature Review*, CASE REPORTS IN PSYCHIATRY (2012).

77. In SOMATICS, LLC's 2009 response to the FDA's third Order, the manufacturer states: "[t]he Somatics Thymatron ECT device has already been in functional class II during its entire lifetime of 25 years . . . ." Since ECT devices are officially classified into Class III based on their potential risk to human health and safety, and because Class II devices are generally safer than Class III devices, such a statement is misleading to health care providers and to patients, who may be led to believe that ECT is safer than it actually is. The only sense in which ECT devices are "functionally in Class II" is in that ECT devices have managed to reach the market without the submission of a premarket approval application. Premarket approval is a safeguard applied only to Class III devices by virtue of their unreasonable risk of causing injury, and the only reason ECT devices have managed to stay on the market without submission of premarket approval applications is because Defendants failed to submit them when due. Accordingly, in attempting to demonstrate the safety of SOMATICS' ECT devices, SOMATICS instead draws attention to their regulatory noncompliance.

78. Also, in their 2009 submission to the FDA, SOMATICS states: "[i]n the ensuing 25 years [since clearance of the Thymatron] there has been no occurrence of a reported adverse event." Given the multitude of adverse events that regularly result, and have resulted, from ECT shock treatment, this statement is an admission that SOMATICS, LLC has not reported any of the adverse events that have occurred as a result of use of their Thymatron devices in 25 years.

79. Had the FDA's MAUDE database accurately reflected the multitude of adverse events that result routinely from ECT treatment, those adverse events would have been noticed by professionals in the psychiatric field, addressed in academic and medical literature, discussed at meetings and conferences attended by psychiatrists within California and the United States generally, and altogether well-known by the general public.

//

80. Had Defendants satisfied their reporting duties, ECT patients' medical providers would have been properly informed by the FDA's MAUDE database, by medical and academic literature discussing the adverse events in the MAUDE database, by meetings they attended at which the adverse events resulting from ECT would have been discussed, by general public discussion, and thereafter by direct warning from the FDA as to the inherent risks associated with ECT. ECT is inherently harmful to the human brain, but this fact is not publicly known because of Defendants' breach of their FDCA reporting duties and all state common law duties running parallel to those FDCA reporting requirements.

81. But for Defendants' breach of their federal and state reporting duties that arose out of the requirements imposed by the Food, Drug, and Cosmetic Act and the FDA's three orders, the putative class's medical providers would have had knowledge of the risk inherent in ECT shock treatment in time to prevent the putative class's injuries. Members of the putative class would then have been in a position to either give informed consent or refuse the treatment entirely.

82. But for Defendants' marketing of adulterated, misbranded, and defective medical devices, plaintiffs would not have had access to ECT shock treatment, and would not have suffered the injuries alleged herein. Accordingly, but for Defendants' conduct, ECT shock devices would not exist in their current form, if at all.

83. ECT shock devices are defined in the FDA's regulations without reference to particular manufacturers. Thus, any warning of adverse events by one manufacturer would have been reported under the same category of "Device, Electroconvulsive Therapy" on the FDA's MAUDE database. The same warning and testing requirements applied to all manufacturers, and warnings submitted by one manufacturer would have by definition alerted all healthcare providers of the dangers posed by any manufacturer's ECT devices. Accordingly, by failing to report adverse events to the FDA and failing to furnish other required safety and

effectiveness information to the FDA, each Defendant actually and proximately caused the injuries suffered by every member of the putative class without regard to which Defendant manufactured the particular device that caused the particular injury.

84. Many putative class members are unable to ascertain which of the Defendants manufactured the particular device that contributed to their injuries.

85. Defendants concealed the facts such that no plaintiff reasonably would have known of facts giving rise to this suit: namely, that MECTA CORPORATION, SOMATICS, LLC and DOES 1-10 comprehensively failed to investigate adverse events, conduct human clinical trials, and report all safety and effectiveness data known or available relating to the use of their ECT devices to the FDA, as was required by the three FDA orders and the state medical device warning duties running parallel thereto.

86. Because of Defendants' fraudulent concealment of facts, no member of the putative class knew or should have known that Defendants failed to comply with federal statutory requirements or of the dangers inherent in use of ECT shock devices that gave rise to their claims asserted herein.

87. Plaintiffs diligently filed this suit in a timely fashion upon discovering the facts giving rise to the claims asserted herein, namely that Defendants failed to satisfy the reporting requirements imposed by the FDCA, MDA and SMDA.

FIRST CLAIM FOR RELIEF

Negligence/Negligence *Per Se*

(By Plaintiffs against all Defendants)

88. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 87 of this Complaint.

//

//

89. MECTA, SOMATICS and DOES 1-10 were the manufacturers of ECT devices, classified as Class III medical devices, and as such owed a duty of care to the putative class and to public at large to use that degree of care in the manufacturing of such Class III medical devices as would be used in similar circumstances to avoid exposing others to a foreseeable risk of harm. Congress enacted the MDA and the SMDA to protect individuals in the United States with respect to risks posed by medical devices, including Class III medical devices, and specifically required premarket approval, testing, investigation, solicitation of information relative to injuries, and submission of any and all safety and effectiveness data reasonably known or available to the FDA for the purpose of ensuring the safety of psychiatric and medical patients from products and medical devices that have not been adequately tested and screened for dangers.

90. MECTA, SOMATICS, and DOES 1-10 breached those duties owed to the putative class and to the public at large by continuously failing to contact user facilities, conduct testing, and report safety and effectiveness data to the FDA from May 28, 1982 to the present.

91. MECTA, SOMATICS, and DOES 1-10 breached additional statutory duties and corresponding parallel state duties owed to the putative class when they continued to market their adulterated and misbranded medical devices after failing to submit premarket approval applications by the deadline of May 28, 1982.

92. M. BENJAMIN, RIERA, HIMES, SCURRAH, and CHASE, as well as all other members of the putative class, underwent ECT shock treatment delivered by ECT shock devices placed into the stream of commerce by one of the Defendants after May 28, 1982.

93. M. BENJAMIN, RIERA, HIMES, SCURRAH, and CHASE, as well as all other members of the putative class, have suffered, and/or continue to suffer permanent brain damage, cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome and related

injuries following ECT shock treatment. This harm is of the type sought to be prevented by the passage of the FDCA, MDA, and SMDA.

94. Had Defendants complied with their state law duties to give a post-sale warning to the FDA of all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), ECT in its current form would not have been marketed to the medical providers of members of the putative class. Accordingly, the negligent conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

95. Alternatively, had Defendants complied with their state law duties to give a post-sale warning to the FDA of all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), this information would have appeared prominently and accessibly in the FDA's MAUDE database and in medical journals and the FDA would have promulgated a warning to the end users of ECT shock devices within the medical profession, who would have been on constructive notice of the latent dangers inherent in providing ECT shock treatment to members of the putative class in time to prevent their injuries. Accordingly, the negligent conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

96. Alternatively, Defendants had a duty not to market their defective, adulterated, and misbranded devices after failing to comply with their reporting requirements.

//

97. Defendants acted with oppression, fraud and malice. As such, punitive damages are appropriate.

SECOND CLAIM FOR RELIEF

Strict Product Liability

Marketing and Information Defect– Failure to Warn

(By Plaintiffs against all Defendants)

98. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 97 of this Complaint.

99. Defendants MECTA, SOMATICS, and DOES 1-10 manufactured, distributed, and sold their ECT devices in the stream of commerce within the United States, knowing that it was to be used without inspection for defect.

100. The ECT devices, at all times relevant to the causes of action alleged in this Complaint, caused and continue to cause permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome, and these facts were both known and knowable in light of the scientific and medical knowledge available in the scientific community. Defendants' failure to adequately warn plaintiffs and medical providers by warning the FDA of these latent dangers renders the devices adulterated, misbranded, and defective with respect to the marketing and information provided to the members of the putative class alleged herein.

101. Permanent brain damage, cognitive impairment, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome present a substantial danger to patients when ECT devices are used as intended or misused in a foreseeable way.

102. Ordinary consumers would not recognize these potential risks inherent to ECT devices.

103. MECTA, SOMATICS, and DOES 1-10 failed to investigate and provide adequate warnings of these risks.

104. M. BENJAMIN, RIERA, HIMES, SCURRAH, and CHASE, as well as all other members of the putative class, suffer permanent brain damage, severe permanent retrograde and anterograde amnesia, and acute and/or chronic organic brain syndrome as a direct result of administration of ECT shock treatment. Plaintiffs and members of the putative class, had they been properly warned about the true nature of ECT shock devices, would not have received ECT shock treatment.

105. Had Defendants complied with their state law duties to give a post-sale warning to the FDA of all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), ECT shock devices in their current form would not have been marketed to the medical providers of members of the putative class. Accordingly, the conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

106. Alternatively, had Defendants complied with their state law duties to give a post-sale warning to the FDA of all information the manufacturer becomes aware of, from any source, that reasonably suggests that its device may have caused or contributed to a serious injury (as was required by the FDCA), this information would have appeared prominently in the FDA's MAUDE database and in medical journals and the FDA would have promulgated a warning to the end users of ECT shock devices within the medical profession, who would have been on constructive notice of the latent dangers inherent in providing ECT shock treatment to members of the putative class in time to prevent their injuries. Accordingly, the conduct of MECTA, SOMATICS, and DOES 1-10 actually caused, proximately caused, and was a substantial factor in causing the harm suffered by members of the putative class. Accordingly, compensatory damages are appropriate.

107. Alternatively, Defendants had a duty not to market their defective devices after failing to comply with their reporting requirements.

108. Defendants acted with oppression, fraud and malice. As such, punitive damages are appropriate.

FOURTH CLAIM FOR RELIEF

Loss of Consortium

109. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 108 of this Complaint.

110. D. BENJAMIN and other members of the putative class are spouses of patients who underwent ECT shock treatment, and as a result have suffered a loss of consortium.

111. D. BENJAMIN is and has at all times relevant to this Complaint been lawfully married to M. BENJAMIN. Other members of the putative class were in valid and lawful marriages to persons injured by ECT shock treatment.

112. Those injured by ECT shock treatment suffered tortious injuries as a result of Defendant's actions.

113. D. BENJAMIN and those members of the putative class in marriages to those that have suffered injury resulting from ECT shock treatment have suffered a loss of consortium.

114. That loss of consortium was a direct and proximate result of the Defendant's acts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

1. For compensatory damages in light of the pain and suffering, emotional distress, loss of consortium, wrongful deaths, and other damages suffered by members of the putative class;

2. For punitive damages in light of Defendants' oppression, fraud, and

malice;

3. For costs of suit and expenses incurred herein, including expert fees;

4. For reasonable attorney's fees and such other nontaxable costs, subject to court approval, as provided by Rule 23(h) of the Federal Rules of Civil Procedure;

5. For all such other and further relief that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for all claims so triable.

Dated: November 7, 2017

Respectfully submitted,

DK LAW GROUP, LLP

By: /s/_____
David M. Karen, Esq.
Attorneys for Plaintiffs

David M. Karen, Esq.
State Bar No. 117883
dk@dk4law.com
Kimberly Offenbacher, Esq.
State Bar No. 166318
ko@dk4law.com
A. Scott Brown, Esq.
State Bar No. 221786
asb@dk4law.com

DK LAW GROUP, LLP
3155 Old Conejo Road
Thousand Oaks, CA 91320
Tel: (805) 498-1212
Fax: (805) 498-3030

Attorneys for Plaintiffs JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; & DEBORAH CHASE

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MECTA CORPORATION; SOMATICS, LLC; and DOES 1 through 10, inclusive,

Defendants.

Case No.:

COMPLAINT FOR:

1. NEGLIGENCE/NEGLIGENCE *PER SE*;
2. STRICT PRODUCT LIABILITY—MARKETING AND INFORMATION DEFECT—FAILURE TO WARN; and
3. LOSS OF CONSORTIUM.

CLASS ACTION

DEMAND FOR JURY TRIAL

Plaintiffs JOSE RIERA, MICHELLE HIMES, DIANE SCURRAH, and DEBORAH CHASE (collectively "Plaintiffs"), individually and on behalf of all other similarly situated individuals, hereby complain against Defendants MECTA

CORPORATION, SOMATICS, LLC and DOES 1 through 10, inclusive (collectively "Defendants") and, on information and belief, allege as follows:

SUMMARY OF THE ACTION

1. This is a class action brought by Plaintiffs, on behalf of themselves and other similarly situated electroconvulsive therapy ("ECT")[1] patients, who have sustained injuries resulting from Defendants' conduct. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 & 1332.

2. An ECT shock device is "a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head." 21 C.F.R. § 882.5940(a). An ECT shock device, in lay terms, is used to administer 'shock treatment.'

3. The California Department of Mental Health reported 3,302 patients given ECT in 2001 alone. The number of patients given ECT shock treatment in California per year is likely to have increased since that time.

4. The primary demographic for ECT shock treatment is comprised of patients suffering from bipolar disorder ("BPD") and/or severe depression. ECT shock treatment is liberally prescribed for a variety of psychological disorders including, but not limited to schizophrenia and catatonia. ECT shock treatment is used on patients of all ages, including children and the elderly.

5. Plaintiffs and members of the putative class are individuals suffering from various degrees of physiological, psychological and emotional trauma including, but not limited to skin burns, permanent brain damage, severe permanent cognitive and memory impairment, broken teeth, prolonged seizures, myocardial infarction, ruptured bowels, acute and/or chronic organic brain syndrome, complete neurological collapse, and sometimes death, secondary to ECT shock treatment.

///

[1] Also referred to as "shock therapy" or "shock treatment."

6. Despite statutory duties under the Food, Drug and Cosmetic Act ("FDCA") and directives by the FDA, pursuant to the Medical Device Amendments of 1976 ("MDA") that ECT device manufacturers report information concerning safety and effectiveness testing for their devices to the FDA,[2] no ECT device manufacturer, including MECTA CORPORATION or SOMATICS, LLC, complied with these statutory obligations. No ECT manufacturer, including either Defendant, responded to the FDA's first two orders requiring them to submit safety and effectiveness data by May 28, 1982 and August 14, 1997, respectively. Defendants only responded to a third FDA order, mandated by the Safe Medical Devices Act of 1990 ("SMDA") requiring Defendants to submit "any information known or otherwise available" about the safety and effectiveness of the device, *including adverse safety or effectiveness information.* Defendants' responses failed to include *any* information relating to the majority of physiological, psychological, and emotional injuries frequently suffered by those who receive ECT shock treatment. Defendants also grossly understated the incidence of death resulting from ECT. Such a response by Defendants failed to comply with their statutory reporting requirements under the MDA and SMDA.

7. As a direct and proximate result of Defendants' refusal to comply with multiple orders by the FDA and satisfy their state duties running parallel to their statutory duties, as of the time of this filing, ECT devices have never satisfied the stringent premarket approval standards that Class III medical devices are required to meet.

8. Because of the lack of testing rigor, the mechanism of action by which ECT yields any alleged benefit to patients remains unascertained and unknown. Testing over the years has not shown any conclusive benefit to receiving ECT shock treatment past a brief bout of mania in the short-term, but the risks remain

[2] 44 Fed. Reg. 172, at 51776-51777 (Sept.4, 1979) ("This action is being taken under the Medical Device Amendments of 1976."); *see* Medical Device Amendments of 1976, 21 U.S.C. § 351 *et. seq.*

apparent, and include but are not limited to permanent long-term memory loss, cognitive impairment, debilitating electrical brain trauma, seizures, acute and/or chronic organic brain syndrome, complete neurological collapse, and death.

9. But for Defendants' failure to comply with the FDCA, MDA, and SMDA, the putative class members would not have suffered the serious injuries alleged in this complaint, since compliance would require that the Defendants investigate, solicit, and report information when they learn that their ECT devices may have contributed to a death or serious injury and specifically warn the FDA of adverse safety and effectiveness information.

10. Defendants' failure to submit to the FDA all safety and effectiveness data reasonably known and/or available relating to use of their ECT devices by certain effective dates for premarket approval rendered their devices "adulterated" under the FDCA.

11. Defendants' failure to furnish statutorily mandated material or information pertaining to occasions on which their devices may have contributed to a death or serious injury rendered their devices "misbranded" under the FDCA.

12. The manufacture, introduction, or receipt of an adulterated or misbranded medical device through interstate commerce is prohibited under the FDCA.[3]

13. Defendants' failure to warn the FDA of the latent dangers inherent in ECT resulted in a lack of knowledge among the medical providers of members of the putative class and the public in general about the latent dangers inherent in administration of ECT shock treatment, but they nevertheless continued to market their adulterated, misbranded, and defective ECT shock devices in the United States. Because some form of physiological, psychological, or emotional injury results universally from ECT shock treatment, Defendants' conduct directly and proximately caused injuries to the putative class.

[3] 21 U.S.C. § 331.

14. This class action seeks to remedy the damages caused by Defendants' conduct: violating the state warning duties running parallel to the Food, Drug & Cosmetic Act and causing harm by placing a defective product into the stream of commerce. Defendants' violation of federal statutory duties, as demonstrated by Defendants' failure to comply with three separate administrative orders by the United States Food and Drug Administration ("FDA"), which required Defendants to submit to the FDA all safety and effectiveness data reasonably known and/or available for their ECT shock devices by certain effective dates, resulted in a lack of knowledge among the medical providers of members of the putative class and the public in general about the latent dangers inherent in ECT shock treatment.

PARTIES

15. Plaintiff JOSE RIERA ("RIERA") is a citizen of the State of California.

16. Plaintiff MICHELLE HIMES ("HIMES") is a citizen of the State of California.

17. Plaintiff DIANE SCURRAH ("SCURRAH") is a citizen of the State of California.

18. Plaintiff DEBORAH CHASE ("CHASE") is a citizen of the State of California.

19. Plaintiffs are informed and believe and based thereon allege that, at all relevant times, Defendant MECTA CORPORATION ("MECTA") is and was a corporation formed and existing under the laws of the State of Oregon with its principal place of business at 19799 SW 95th Place B, Tualatin, Oregon. Plaintiffs are further informed and believe and based thereon allege that MECTA is an ECT manufacturer and provider and, in that regard is authorized to conduct business in the State of California and does conduct business in the State of California.

///

20. Plaintiffs are informed and believe and based thereon allege that, at all relevant times, starting with its founding in 1984, Defendant SOMATICS, LLC ("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. Plaintiffs are further informed and believe and based thereon allege that SOMATICS is an ECT manufacturer and provider and, in that regard is authorized to conduct business in the State of California and does conduct business in the State of California.

21. Plaintiffs are not presently aware of the true names and capacities, whether individual, corporate, associate or otherwise, of Defendants named in this action as DOES 1 through 10, and each of them, and therefore sue such Defendants, and each of them, by such fictitious names. Plaintiffs are informed and believe, and on the basis of such information and belief allege, that each fictitiously named Defendant is legally responsible for the acts alleged herein, and/or is liable to Plaintiffs as hereinafter alleged. Plaintiffs are informed and believe, and on the basis of such information and belief allege, that at all times mentioned herein, that such fictitiously named Defendants, and each of them, were participants in the stream of commerce and/or necessary marketing agents that played a role in delivering ECT shock devices to their end users.

22. Plaintiffs are informed and believe, and, based upon such information and belief allege that the Defendants named in this action as DOES 1 through 10, and each of them, herein knowingly conspired together in various combinations, and agreed amongst themselves to act in concert and in furtherance of a common scheme, plan and design to commit, aid, abet and/or render substantial assistance in the wrongs complained of herein below. Plaintiffs are further informed and believe, and based upon such information and belief allege that Defendants knew as they were conducting themselves that they were substantially assisting in the accomplishment of wrongdoing, and had the right and ability to control the actions

of the remaining Defendants but did nothing to curb the activities described herein below, or prevent others from engaging in such conduct. Plaintiffs are further informed and believe, and based upon such information and belief allege, that Defendants, and each of them, actively condoned, encouraged, participated in, and/or instigated the conduct described herein below in furtherance of their common scheme, plan and design which entailed, among other things: (a) aiding and abetting the conspiracy and common course of conduct complained of herein; (b) participating in and/or knowing and acquiescing in the acts complained of herein, sufficient to categorize such conduct as conspiratorial; and (c) taking and/or ratifying conduct to enrich themselves or their co-conspirators, at the expense of Plaintiffs.

23. Plaintiffs are informed and believe that Defendants, and each of them, are in some manner legally responsible for the events alleged in this Complaint. Plaintiffs are further informed and believe that each of the Defendants acted in all respects pertinent to this action as the agent of the other Defendants, carried out a joint scheme, business plan, policy, or enterprise, or aided and abetted the acts and omissions alleged herein, and that the acts and omissions of each Defendant are legally attributable to the other Defendants.

JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction over the lawsuit under the Class Action Fairness Act, 28 U.S.C. § 1332, because this is a proposed class action in which: (1) there are at least 100 Class members; (2) the combined claims of Class members exceed $5,000,000, exclusive of interest, attorney's fees, and costs; and (3) Plaintiffs and Defendants are citizens of different states to the extent required by statute.

25. This Court has subject matter jurisdiction over the lawsuit under 28 U.S.C. § 1331 because the vindication of Plaintiffs' rights under state law substantially and necessarily turn on a construction of federal law, specifically

21 U.S.C. § 360e with respect to premarket approval applications, 21 U.S.C. § 360i with respect to medical device manufacturer reporting requirements, and 21 U.S.C. § 351 with respect to the illegality of marketing adulterated or misbranded medical devices.

26. This Court has personal jurisdiction over Defendant MECTA because it has sufficient minimum contacts in California to render the exercise of jurisdiction by this Court proper.

27. This Court has personal jurisdiction over Defendant SOMATICS because it has sufficient minimum contact in California to render the exercise of jurisdiction by this Court proper.

28. Venue is proper in the Central District of California under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims, including ECT shock treatment received by representative Class members, occurred in this District.

PLAINTIFF-SPECIFIC ALLEGATIONS

29. Plaintiff RIERA, in seeking an effective treatment for severe depression, underwent a series of six separate rounds of ECT shock treatment on April 22, 2016, April 25, 2016, April 27, 2016, April 29, 2016, May 2, 2016, and May 4, 2016 at Huntington Memorial Hospital in Pasadena, California. ECT did not generate any improvement in RIERA's severe depression. Instead, it caused severe physiological, psychological, and emotional injury.

30. Plaintiff HIMES obtained over twenty rounds of ECT shock treatment between about April 2011 and about July 2012 at Sharp Mesa Vista Hospital in San Diego, California. As a result of receiving ECT shock treatment, HIMES suffers severe physiological, psychological, and emotional injury. Plaintiff HIMES's husband suffers a loss of the consortium that HIMES offered during the course of their marriage as a result of HIMES's receipt of ECT shock treatment.

///

31. Plaintiff SCURRAH underwent over fifty-eight rounds of ECT shock treatment in seeking to treat her bipolar disorder, beginning on March 28, 2012 and continuing for about nine months. ECT shock treatment caused SCURRAH severe physiological, psychological, and emotional injury.

32. Plaintiff CHASE underwent ECT shock treatment at least seven times in seeking to treat her major depressive disorder and severe anxiety, between April of 2015 and Spring of 2016. ECT shock treatment caused CHASE severe physiological, psychological, and emotional injury.

CLASS ACTION ALLEGATIONS

33. Plaintiffs bring this action on behalf of themselves and all others similarly situated as this action satisfies the requirements of numerosity, commonality, typicality, adequacy of representation, and predominance and superiority[4] requirements of Federal Rules of Civil Procedure, Rule 23.

34. The proposed Class is defined as follows:

CLASS

All individuals in the United States who received ECT shock treatment in California after May 28, 1982, administered by an ECT shock device that was manufactured, sold and/or distributed by Defendants after May 28, 1982, and who suffered an injury as a result thereof, with the exception of paragraph 35 below.

35. Excluded from the Class are government entities, and all judges assigned to hear any aspect of this litigation, as well as their immediate family members.

36. The members of the Class are so numerous that joinder is impractical. The Class consists of thousands of individuals, as ECT shock treatment has been available and administered to the described Class for more than 30 years, with the

[4] Fed. R. Civ. P. 23(b)(3).

annual estimate of ECT shock patients per year in California numbering in the thousands. Although the exact number and identity of the class members is not presently known, the class can be defined and ascertained by means of the objective criteria, through strategic publication, and through coordinated discovery of the identities of all purchasers of ECT shock devices as sold by and obtained from MECTA and SOMATICS since the beginning of the class period.

37. There are questions of law and fact that are common to the Class, and these common questions predominate over any questions affecting only individual Class members. Among the questions common to the Class are:

a. Defendants' statutory obligation not to market an adulterated or misbranded medical device and/or reporting requirements imposed by the FDCA;

b. Whether the FDCA gives rise to a duty to warn;

c. Whether Defendants violated statutory obligations and/or reporting requirements and/or breached their duty to warn;

d. The dates of said violations and/or breaches;

e. Whether, had Defendants complied with their statutory duties, their ECT devices would have been on the market;

f. Defendants' efforts to comply and/or justifications for non-compliance with the reporting requirements and/or duty to avoid marketing an adulterated or misbranded medical device as may be offered by Defendants in their defense;

g. Whether Defendants' violations and/or breaches can give rise to liability under the state laws running parallel to the federal laws;

h. Information as to the safety and effectiveness, or lack thereof, for the use of ECT shock devices;

i. The inherent dangers of the use of ECT shock devices;

j. Information known or knowable to Defendants regarding the

safety and effectiveness, or lack thereof, of the use of ECT shock devices;

k. Whether Defendants' culpable state of mind in in failing to comply with federal statutory duties and their parallel state counterparts subjects Defendants to punitive damages.

38. Common questions of fact and law predominate over any questions affecting only individual Class members with respect to liability, and damages may be properly bifurcated for separate determination.

39. The claims of Plaintiffs are typical of the claims of Class in that they underwent ECT shock treatment using an ECT shock device manufactured, sold and/or distributed by Defendants that, like the Class members, they would not have undergone had Defendants not violated the FDCA or had not manufactured, sold and/or distributed an adulterated, misbranded, and defective ECT shock device within the stream of commerce, and would therefore not have been injured by ECT shock treatment.

40. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have no interests antagonistic to the interest of any of the other Class members.

41. Plaintiffs are committed to the vigorous pursuit of this action and have retained competent counsel with the necessary experience and skill to prosecute this action on behalf of the Class.

42. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The issues that may be jointly tried, when compared to those requiring separate adjudication, are so numerous and substantial that the maintenance of a class action would be advantageous to the judicial process and to the litigants. In light of the allegations made, individual litigation to resolve the whole of this matter would be unnecessarily costly and burdensome and would deter individual claims.

43. To attempt to resolve the entirety of this claim by processing individual cases would increase both the expenses and the delay, not only to class members, but also to Defendants and the Court. In contrast, a class action will avoid case management difficulties and provide multiple benefits to the litigating parties, including efficiency, economy of scale, unitary adjudication with consistent results and equal protection of the rights of each class member, all by way of the comprehensive and efficient supervision of the litigation by a single court.

44. Without class certification, the prosecution of separate actions by individual members of the class would create a risk of inconsistent or varying adjudications with respect to individual members of the proposed class that would establish incompatible standards of conduct for Defendants.

SUBSTANTIVE ALLEGATIONS

45. The regulation of devices, including ECT devices, is relatively new. The United States Congress enacted the Medical Device Amendments of 1976 (the "MDA"), effective May 28, 1976, amending the FDCA "to provide for the safety and effectiveness of medical devices intended for human use."

46. Pursuant to the MDA, the FDA was required to review all existing medical devices and, by regulation, divide each into one of three classes of devices established to control access to the market depending on the intended use, the indications for use, and the risks that the particular device posed to the user. A Class I ("General Controls"), device was subject to general post-market or after-sale controls including good manufacturing practices. A Class II ("Performance Standards") device was to be subject to FDA established regulations for performance standards as well as post-market controls. A Class III ("Premarket Approval") device required a premarket approval application ("PMA") and approval before sale, or a product development protocol, and adherence to post-market controls. By way of contrast, a wheelchair is an example of a Class I device while an implantable pacemaker is an example of a Class III device.

47. On September 4, 1979, the FDA published an Order in the Federal Register (the "1979 FDA Order") presenting its "final ruling" that ECT devices are Class III "Premarket Approval" devices under the MDA and specifically ordered manufacturers such as Defendants to prepare and submit a PMA for approval. The FDA's ruling stated in relevant part:

> The Food and Drug Administration (FDA) is issuing a final ruling classifying electroconvulsive therapy devices into Class III (premarket approval). The effect of classifying a device into Class III is to require each manufacturer of the device to submit to FDA a premarket approval application ["PMA"] that includes information concerning safety and effectiveness tests for the device."[5]

48. The FDA's Order followed the recommendation of the Neurological Section of the Respiratory and Nervous System Devices empaneled by the FDA due to the lack of available information regarding ECT devices and following public comment. The FDA concluded that Class III placement was required as "there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the ECT device."[6]

49. As of September 4, 1979, Defendants herein, as manufacturers of ECT devices, were specifically ordered to submit a PMA application to the FDA for approval of this Class III device as a prerequisite to continued access to the market. The PMA application was to contain "safety and effectiveness" information derived from testing, e.g., from clinical trials. Moreover, PMA applications must include "specimens of the labeling proposed to be used for such device,"[7] to be submitted for FDA approval.

---

[5] *See* 44 Fed. Reg. 172, at 51776-77 (Sept. 4, 1979) (reporting 21 C.F.R. § 882 [Docket No. 78N-1103]).
[6] *See* 21 C.F.R. § 882.5940.
[7] 21 U.S.C. § 360e(c)(1)(F).

50. Defendants, as manufacturers of ECT devices, were required to perform clinical trials and submit their respective PMA applications by May 28, 1982.

51. Plaintiffs are informed and believe and based thereon allege that Defendants thereafter violated the MDA, and the 1979 FDA Order, and specifically failed to conduct human trials and/or submit PMA applications with safety and effectiveness information then available to date to the FDA by May 1982, or at all. Failure to timely submit PMAs resulted in Defendants' ECT devices being "adulterated" under federal law. Defendants continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enabled their continued use, despite being "adulterated" under federal law.[8]

52. Plaintiffs are informed and believe and based thereon allege that Defendants failed to submit reports to the FDA whenever the Defendants received or otherwise became aware of information that reasonably suggested that one of their marketed devices may have caused or contributed to a death or serious injury, as required by federal law. Failure to submit such adverse event reports resulted in Defendants' ECT devices being "misbranded" under federal law.[9] Defendants continued to manufacture, sell, and distribute their respective devices in the United States, and otherwise enabled their continued use, despite being "misbranded" under federal law.

53. The United States Congress enacted the Safe Medical Devices Act of 1990 ("SMDA"), effective November 28, 1990, amending the FDCA "to make improvements in the regulation of medical devices." Thereafter, the FDA published an Order in the Federal Register (the "1995 FDA Order") pursuant to the SMDA requiring that the manufacturers of ECT devices, including Defendants, submit a summary of, and a citation to, all information known or available about the safety

[8] 21 U.S.C. § 351; *see id.* § 331 (prohibiting "introduction," "receipt," or "delivery" of adulterated or misbranded devices into interstate commerce).
[9] 21 U.S.C. § 352(t).

and effectiveness of their respective ECT devices to the FDA by August 14, 1997.[10]

54. Plaintiffs are informed and believe and based thereon allege that Defendants violated the SMDA, and the 1995 FDA Order, by failing to submit a summary of, and a citation to, all information known or available about the safety and effectiveness of their respective ECT devices to the FDA by August 14, 1997. Defendants continued to manufacture, sell and distribute their respective devices in the United States, and otherwise enable their continued use.

55. On April 9, 2009, the FDA published a third Order in the Federal Register (the "2009 FDA Order") again requiring the manufacturers of ECT devices, including Defendants, to comply with the SMDA by submitting all information known or available about the safety and effectiveness of ECT devices to the FDA by the deadline of August 7, 2009.[11] Defendants responded to this order, but withheld a significant amount of information relating to adverse events from the FDA. None of the information provided directly addressed the known issues of permanent memory loss, cognitive impairment, or the certainty of brain damage resulting from ECT.

56. The FDCA's implementing regulations provide that manufacturers of medical devices must report to the FDA within 30 calendar days after the day that the manufacturer receives, or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer: "(1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that [the manufacturer has marketed] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."[12]

57. The regulations provide that manufacturers must submit all information "reasonably known." "Reasonably known" information is "(i) [a]ny

[10] 60 Fed. Reg. 156, at 41986-89 (Aug. 14, 1995).
[11] 74 Fed. Reg. 67, at 16214-17 (Apr. 9, 2009).
[12] 21 C.F.R. § 803.50(a).

information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) any information in your possession; or (iii) any information that you can obtain by analysis, testing, or other evaluation of the device."[13]

58. Defendants continued to violate the SMDA, and related orders, by failing to produce reasonably known information and by withholding a large quantity of data from the FDA relating to the safety and effectiveness of their respective ECT devices, including data relating to the devices' collective propensity to cause harm.

59. Plaintiffs are informed and believe and based thereon allege that when the FDA, pursuant to statutory duty, scheduled hearings before its Neurological Devices Panel in 2011 to discuss the safety and effectiveness of ECT shock treatment, Defendants hired numerous psychiatrists with conflicts of interest to perform a skewed culling of data points (from about 60 studies out of 1,200) so as to suggest that ECT shock treatment posed minimal risks and had significant short-term benefits, and had a death rate hundreds of times lower than the actual death rate of those who undergo ECT shock treatment.

60. Plaintiffs are informed and believe and based thereon allege that the overwhelming weight of scientific evidence relating to ECT shock treatment suggests that there is no long-term benefit to receiving ECT shock treatment at all, that the alleged short-term benefits are transient and are little more than a bout of mania following brain damage, that ECT shock treatment inherently damages the brain, and that any mechanism of action by which it is said to 'treat' depression or mental illness is hypothetical.

61. As a result of the Defendants' conduct in violating statutory requirements and selective withholding and manipulation of the data surrounding ECT devices, and the duties under state law running parallel to such requirements, the devices have continued to be manufactured, sold, distributed and have remained

[13] 21 C.F.R. § 803.50(b).

in use without testing, public dissemination of reliable information and data as to safety and effectiveness, warnings of inherent dangers, and without the requisite premarket FDA approval.

62. Defendants continue to manufacture, sell and distribute adulterated, misbranded, and defective ECT devices to this day. Doing so violates both a duty established under federal statute and parallel duties under state tort law.

63. The FDA's guidance document pertaining to medical device reporting states that "a publicly disclosable version of the medical device reports that we have received is available on the CDRH webpage at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM."[14] Of the 49 reports posted on the MAUDE database pertaining to ECT devices, the majority appear to have been voluntarily submitted by patients, and none appear to have been submitted by device manufacturers under their mandatory reporting duties. Had Defendants complied with their federal and parallel state duties to report to the FDA all safety and effectiveness data reasonably known or available for ECT, the FDA's MAUDE database would have reflected the multitude of adverse events that routinely result from administration of ECT shock treatment.

64. 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 FDCA's obligation to investigate and report these events to the FDA. For example, from the 1940s to the 1980s, various psychiatric experts have documented brain damage correlated with ECT. These adverse events were "reasonably known" to both MECTA and SOMATICS, and therefore created a statutory duty to investigate and report them to the FDA. However, there are no manufacturer-submitted adverse event reports in FDA's MAUDE database, illustrating Defendants' continuous and intentional

[14] MEDICAL DEVICE REPORTING FOR MANUFACTURERS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF DOCUMENT 26 (2016).

failure to report adverse events to the FDA.

65. Multiple lawsuits were filed against MECTA corporation in the 1990s. These lawsuits alleged serious injuries, including but not limited to brain damage, permanent cognitive impairment, and ruptured bowels resulting from ECT shock treatment. The CEO of MECTA, Ms. Robin Nicol, admits that these lawsuits alleged that MECTA's devices caused brain damage to the patients. She testified that she was not even curious why multiple people had sued her company for causing them brain damage, assuming the lawsuits to be "frivolous." Defendants intentionally evaded their duty to investigate these adverse events or submit any adverse event reports to the FDA.

66. In sworn deposition testimony in 2004, in an unrelated suit, Robin Nicol, was asked if she or anyone from her company had "made any effort to solicit information from persons who have received ECT to see whether or not they have been harmed." She responded "no . . . that is not in the purview of our company's responsibilities."

67. Had Defendants satisfied their reporting duties, ECT patients' medical providers would have been properly informed by the FDA's MAUDE database, by medical journals, and thereafter by direct warning from the FDA as to the inherent risks associated with ECT. ECT is inherently harmful to the human brain, but this fact is not publicly known because of Defendants' breach of their FDCA reporting duties and all state common law duties running parallel to those FDCA reporting requirements.

68. If the medical providers for members of the putative class or general public had knowledge of the devices' inherent risk of permanent injury, members of the putative class would not have undergone ECT shock treatment, but for Defendants' breach of their federal and state reporting duties that arose out of the requirements imposed by the Food, Drug, and Cosmetic Act and the FDA's three orders.

69. But for Defendants' marketing of adulterated, misbranded, and defective medical devices, plaintiffs would not have had access to ECT shock treatment, and would not have suffered the injuries alleged herein. Accordingly, but for Defendants' conduct, ECT shock devices would not exist in their current form, if at all.

70. ECT shock devices are defined in the FDA's regulations without reference to particular manufacturers. Thus, any warning of adverse events by one manufacturer would have been reported under the same category of "Device, Electroconvulsive Therapy" on the FDA's MAUDE database. The same warning and testing requirements applied to all manufacturers, and warnings submitted by one manufacturer would have by definition alerted all healthcare providers of the dangers posed by any manufacturer's ECT devices. Accordingly, by failing to report adverse events to the FDA and failing to furnish other required safety and effectiveness information to the FDA, each Defendant actually and proximately caused the injuries suffered by every member of the putative class without regard to which Defendant manufactured the particular device that caused the particular injury.

71. Defendants concealed the facts such that no plaintiff reasonably would have known of facts giving rise to this suit: namely, that MECTA CORPORATION, SOMATICS, LLC and DOES 1-10 comprehensively failed to investigate adverse events, conduct human clinical trials, and report all safety and effectiveness data known or available relating to the use of their ECT devices to the FDA, as was required by the three FDA orders and the state medical device warning duties running parallel thereto.

72. Because of Defendants' fraudulent concealment of facts, no member of the putative class knew or should have known that Defendants failed to comply with federal statutory requirements or of the dangers inherent in use of ECT shock devices that gave rise to their claims asserted herein.

73. Plaintiffs diligently filed this suit in a timely fashion upon discovering the facts giving rise to the claims asserted herein, namely that Defendants failed to satisfy the reporting requirements imposed by the FDCA, MDA and SMDA.

FIRST CLAIM FOR RELIEF

Negligence/Negligence *Per Se*

(By Plaintiffs against all Defendants)

74. Plaintiffs hereby re-allege, and incorporate by reference as though fully set forth herein, paragraphs 1 through 73 of this Complaint.

75. MECTA, SOMATICS and DOES 1-10 were the manufacturers of ECT devices, classified as Class III medical devices, and as such owed a duty of care to the putative class and to public at large to use that degree of care in the manufacturing of such Class III medical devices as would be used in similar circumstances to avoid exposing others to a foreseeable risk of harm. Congress enacted the MDA and the SMDA to protect individuals in the United States with respect to risks posed by medical devices, including Class III medical devices, and specifically required premarket approval, testing, investigation, solicitation of information relative to injuries, and submission of any and all safety and effectiveness data reasonably known or available to the FDA for the purpose of ensuring the safety of psychiatric and medical patients from products and medical devices that have not been adequately tested and screened for dangers.

76. MECTA, SOMATICS, and DOES 1-10 breached those duties owed to the putative class and to the public at large by continuously failing to contact user facilities, conduct testing, and report safety and effectiveness data to the FDA from May 28, 1982 to the present.

77. MECTA, SOMATICS, and DOES 1-10 breached additional statutory duties and corresponding parallel state duties owed to the putative class when they continued to market their adulterated and misbranded medical devices after failing to submit premarket approval applications by the deadline of May 28, 1982.