EXHIBIT 4

EXPERT REPORT OF JANET BIXBY ARROWSMITH, M.D., F.A.C.P, F.A.C.E.

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April 22, 2021

***Himes, et al. v. Somatics, LLC*, Case No. 2:17-CV-06686-RGK- JCx**
(United States District Court, Central District of California)

A. Background and Experience

My name is Janet Bixby Arrowsmith. I am a physician licensed to practice medicine in the state of New Mexico. I received my M.D. degree in 1979 from the Tulane University School of Medicine. In 1982, I completed an internship and residency in internal medicine at the University of Alabama at Birmingham. I am Board Certified in Internal Medicine and an elected Fellow of the American College of Physicians. I am also an elected Fellow of the American College of Epidemiology.

In 1984 I was selected as an Epidemic Intelligence Service (EIS) officer. The EIS program is an elite, two-year training program in epidemiology sponsored by the federal Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. I was assigned to the U.S. Food and Drug Administration (FDA) and received both on-the-job and didactic experience in the science and practice of epidemiology over the course of those two years. When I joined CDC in 1984, I did so as a commissioned officer in the U.S. Public Health Service (USPHS). In 1986, after completing the EIS program, I was hired as a medical epidemiologist in the same organizational unit of FDA where I had worked for the preceding two years as a trainee—FDA's Center for Drug Evaluation

and Research (CDER). I continued to monitor, assess, and investigate adverse events reported in association with the use of approved pharmaceutical products marketed in the U.S. During my several years as an EIS officer and medical epidemiologist in the postmarket safety surveillance group at CDER, I published several articles in the peer-reviewed medical literature and co-authored a book chapter (*A View from a Regulatory Agency)* in the first edition of the textbook *Pharmacoepidemiology.* Similarly, I was co-author in the update and revision of that same chapter in the second edition of *Pharmacoepidemiology* and later sole author and co-author of another textbook chapter in the public health text entitled *Principles and Practices of Public Health Surveillance.*

I served as Deputy Director FDA's AIDS Coordination Staff (now known as the Office of Special Health Interests within the Office of the Commissioner of FDA) in 1988 and 1989. I was then assigned as Senior Medical Officer (HIV) in the Agency for Healthcare Policy and Research. In 1991, I moved back to the FDA as a medical review officer in the Division of Anti-Viral Drug Products where I was responsible for the review and assessment of Investigational New Drug exemption requests (INDs) and participated in the review and approval of the New Drug Application (NDA) for didanosine, the second anti-retroviral (anti-HIV) drug product approved for marketing in the U.S. I had additional responsibilities, as noted in my CV, and served as a consultant to the Center for Devices and Radiologic Health for medical devices promoted for use in treating HIV and HIV-related illness. I developed expertise in clinical trial design and evaluation, both as part of my training in the Division and through clinical trials course work through the CDER Staff College and at the Johns Hopkins University School of Public Health.

In 1993, I was selected as acting Director of the newly established Office of Surveillance and Biometrics (OSB) within FDA's Center for Devices and Radiological Health (CDRH). CDRH

is the review and management organization within FDA responsible for the regulation of all medical devices and radiation-emitting instruments marketed in the U.S. My office, OSB, employed approximately 120 staff whose training and background ranged from PhD statisticians, engineers, and physicians to clerical support personnel. I was responsible for developing the organizational structure of OSB, hiring, and assigning staff, and providing oversight and direction in the development and refinement of regulations establishing postmarket product surveillance and problem reporting requirements for medical device and radiologic product manufacturers, distributors, importers, and user facilities. Through my Office and staff, I assisted in drafting and review of regulations responsive to the Safe Medical Devices Amendments (SMDA) of 1990, as well as the 1992 amendments to SMDA, and met with regulated industry to discuss the proposed provisions of this new regulatory framework.

As OSB Office Director and a member of the CDRH Senior Staff, I was responsible for the assessment of problems reported to CDRH and for regulatory responses to device and patient problems reported to OSB/CDRH. At times, my assessments of some of the reported problems resulted in the suspension of marketing of medical devices potentially related to fatalities and serious injuries. My staff and I coordinated our activities with the premarket review divisions in the Office of Device Evaluation. We frequently worked with the Office of Compliance in CDRH to conduct formal health hazard evaluations, develop plans for addressing health hazards, and work with industry on corrective actions addressing postmarket problems identified by the two Offices. While at CDRH, I participated in closed circuit conferences with regulated industry, served on discussion panels for professional organizations serving regulated industry, and contributed papers to the scientific literature on specific device topics.

As Office Director in OSB, I supervised the statisticians and biostatisticians who reviewed and analyzed premarket and postmarket clinical study data related to medical devices either under review for marketing authorization or for postmarket evaluation. These scientists performed essential initial and review analyses related to both efficacy and safety of medical devices intended for or on the U.S. market. The statistical and biostatistical reviewers reported to their Division director who reported directly to me.

In 1995, after the arrival of my second child, I accepted a position with fewer management responsibilities, serving as a medical review officer in the Division of Blood and Blood Products, Office of Blood, Center for Biologics Evaluation and Review within FDA. In 1996, my family and I moved to New Mexico. I transferred to the Indian Health Service, another agency within the Department of Health and Human Services and the U.S. Public Health Service. I served for two years as a primary care provider and clinical specialty consultant in internal medicine at the Mescalero Apache Indian Health Service Hospital at Mescalero, New Mexico. In 1998, I left the USPHS after achieving the Navy rank of 0-6, Captain, and entered into private practice as a partner in the Internal Medicine Associates in Ruidoso, New Mexico.

In September 1999, I joined a small medical products consulting firm, Arrowsmith-Lowe Consulting, Inc., where I served as President of the company. Our company offered regulatory, medical, and epidemiological consultation services to companies regulated by FDA and to individuals affected by regulated medical products. Our clients included pharmaceutical companies, medical device companies, and biological product manufacturers. This firm offered a variety of services, including compliance audits, premarket assessments, postmarket data review and assessment, and medical product liability support. In 2008, I formed my own company, Arrowsmith Consulting LLC, and continued to provide the same types of regulatory consultation

I had offered while working with Arrowsmith-Lowe Consulting, including products liability consultation to plaintiffs claiming injuries related to the use of regulated medical products.

Over the course of my career at FDA and subsequently, I served as author or co-author of peer-reviewed journal articles and public health textbook chapters. The complete listing of my publications is included in my CV as Appendix A.

All of my opinions in this report and litigation are offered to a reasonable degree of certainty and probability within my fields of expertise, and those opinions are based on my education, experience, and materials that I have reviewed and relied on in this matter. This report is intended to provide an overview of my opinions, the bases for them, and the other information requested by the Court and the relevant rules. I reserve the right to offer additional opinions and support in response to the plaintiffs' experts and other evidence introduced after the date of this report.

I have been retained by plaintiffs' counsel and bill for my time at the rate of $750/hour for all activities related to issues in this litigation. A list of materials I reviewed for this case is attached as Appendix B.

B. Overview of The U.S. Food and Drug Administration's Regulation of Medical Devices

The FDA regulates medical products in the United States such as medical devices pharmaceutical products in an effort to protect the public health. Newly proposed medical devices are placed into one of three risk-based categories. ECT devices, among others, were "grandfathered" into Class 3 (the highest risk-based classification for devices) in 1976 by the Medical Devices Amendments.

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1. Premarket Evaluation of Medical Devices

Medical devices are regulated within the FDA's Center for Devices and Radiological Health (CDRH) and are approved through either the FDA's Premarket Approval Process or cleared for marketing through the FDA's Premarket Notification Process (510(k)). Medical devices comprise an enormous variation of products from those as simple as wooden tongue blades to medical devices with the electronic and materials complexity exemplified by implantable cardiac defibrillator devices and MRI machines.

Class I devices are simple devices and are considered to have a very low potential for negative health effects. As a result, Class I devices are required to comply with the lowest level of regulatory control. Elastic bandages are a common example of a Class I device.

Class II devices are devices for which "general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents..." and other requirements, potentially including submission of clinical data in premarket notification submissions in accordance with the so-called 510(k) provision of the FDCA. Examples of currently marketed Class II devices include surgical lasers for dermatology and nebulizers for respiratory conditions.

Class III devices are those devices for which premarket approval is required prior to their legal entry onto the U.S. market. A device is classified as Class III if there is insufficient information available to determine that general controls would provide "reasonable assurance of its safety and effectiveness" or if the device is subject to special controls and the device is "life-supporting or life-sustaining" or is for a use "which is of substantial importance in preventing

impairment of human health, or if the device presents a potential unreasonable risk of illness or injury." (21 C.F.R. §860.3(c)(3)).

Unlike Class I or II devices, Class III devices undergo premarket data development to establish safety and efficacy, including the conduct of clinical trials in humans. Class III devices are subject to premarket approval (PMA), which is the FDA's most stringent approval process for medical devices. FDA approval of a PMA application is necessary prior to marketing of a Class III device. Approval is based upon the FDA's finding that the device is safe and effective, in compliance with specific criteria. More specifically, "[i]n determining the safety and effectiveness of a device," the FDA considers "[t]he probable benefit to health from the use of the device weighed against any probable injury or illness from such use."[1] To make this determination, "the agency relies upon only scientific evidence."[2] Valid scientific evidence is defined as:

> evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is a reasonable assurance of the safety and effectiveness of a device under its conditions of use.[3]

A Class III device may only enter the market after the FDA reviews and approves the PMA application, including the medical device's design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness.

Until 2009, the FDA did not require premarket approval "to affirmatively demonstrate a reasonable assurance of safety and effectiveness" of grandfathered devices. Accordingly, ECT devices have been regulated through "the premarket notification [510(k)] regulatory pathway,

[1] 21 CFR § 860.7(b).
[2] 21 CFR § 860.7(c)(1).
[3] 21 CFR § 860.7(c)(2).

which requires a showing of substantial equivalence to a legally marketed device and is usually reserved for intermediate and low risk devices."

In 2009, the Government Accountability Office recommended that the FDA require that all such "grandfathered" devices be either reclassified into Class 1 or Class 2 or undergo premarket approval, which requires that controlled clinical trials be carried out prospectively.

2. Labeling for Medical Devices

Like other prescription medical products intended to diagnose, treat, prevent, or mitigate disease, medical devices are subject to regulations governing required labeling. Professional labeling for any prescription product is intended to provide the essential information a physician needs to know to safely and effectively use, recommend, or prescribe a prescription medical product.

3. Postmarket Surveillance for Medical Devices

The FDA is tasked with:…

> one of the most rigorous regulatory standards for protecting public health – reasonable assurance of safety and effectiveness. This bar can create disincentives for manufacturers to bring their technologies to the U.S. early, if at all, because to meet this standard often requires more evidence to bring a product to the U.S. marketplace, especially for high-risk devices and more innovative low-risk technologies than many other countries in the world.[4]

Postmarket surveillance for all medical devices is intended to provide additional safety information based on real world use of the product. Following market introduction of a newly marketed product, safety issues may arise. Postmarket surveillance is based on the review and evaluation of observational data in the form of adverse event case reports, post-approval studies if

[4] FDA, CDRH's 2018-2020 Strategic Priorities: Achieving Our Vision of Timely Patient Access to High-Quality, Safe and Effective Medical Devices.

required, published medical literature and safety information from other sources, such as complaint files.

Devices marketed in the U.S. are required to meet postmarket requirements. After marketing clearance or approval, the FDA continues to regulate medical devices, including monitoring their safety and effectiveness. This is done in a variety of ways, including requiring annual reports from the manufacturer on the safety, effectiveness, and other data on the device and conducting audits or inspections of medical device manufacturers. The postmarket reporting regulations are intended to provide a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner. If data from any source, including the medical and scientific literature, the MAUDE database and public dockets opened by FDA, suggest that a significant risk may be associated with the use of a medical device, the manufacturer may be required by FDA to make such information available through a number of potential sources including changes to the labeling or instructions for use so that users and patients can be informed of new risk information.

The FDA uses a variety of postmarket tools to monitor the safety and effectiveness of a device. This includes voluntary adverse reports submitted by consumers, patients, or treating physicians, as well as reports from user facilities about certain adverse events allegedly linked to devices. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as those from health care professionals, patients, and consumers or from other sources. While FDA cautions that there are limitations with MDR data,

companies are nonetheless obligated under regulation to investigate the potential relatedness of the adverse event report to the performance and use of their product.

In addition, complaint files, which are oral, written, electronic complaints provided to a device manufacturer that allege deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution must be evaluated for their potential relatedness to a reportable event – e.g., the potential for a reportable MDR arising from the complaint itself. 21 C.F.R. 820.3.

4. Medical Device Advisory Committees

Medical Device Advisory committees are panels of outside experts whom CDRH convenes "to provide independent, professional expertise and technical assistance on the development, safety and effectiveness, and regulation of medical devices…" Each committee consists of experts with recognized expertise and judgment in a specific field. Members have the training and experience necessary to evaluate information objectively and to interpret its significance." (www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm. Accessed March 18, 2019). Medical Device Advisory committee members are special government employees, screened for potentially disqualifying financial interests, and paid for the days during which they participate as members of a panel. The findings, recommendations and advice provided to FDA are carefully considered by FDA but are not binding upon the Agency.

There are five advisory committees including a Medical Devices Advisory Committee consisting of 18 panels covering various medical specialty areas, as well as the Medical Devices Dispute Resolution Panel.

In the specific case of ECT devices, FDA convened a panel of the Neurological Devices Advisory Committee on January 27-28, 2011. The meeting included FDA presentations of the

medical literature on ECT, presentations from industry, an open public hearing, and panel deliberations. Both the complete Advisory Committee transcript and FDA's summary of their findings are available for review on FDA's website.

5. Electroconvulsive Therapy

According to Weaver, Ravanus, Rush et. al. (1974) and as noted on page 17 of the January 17, 2011 Medical Device Advisory committee transcript, electroconvulsive therapy has been used for certain types of severe psychiatric illness since 1938. Convulsion-inciting devices have been legally marketed in the U.S. since before the enactment of the May 28, 1976 Medical Device Amendments. Thus, while there were no requirements for safety or effectiveness testing of such devices prior to the 1976 Amendments, ECT devices on the U.S. market before May 28, 1976 could serve as "predicate" devices for purposes of 510(k) clearance. Electroconvulsive devices were placed in Class III by the 1976 Amendments to the Food, Drug and Cosmetics Act, which means that such devices "will be required to undergo premarket approval at some time in the future." However, FDA has not required such clinical trials data and the Somatics Thymatron ECT device was found to be substantially equivalent to ECT devices on the U.S market prior to May 29, 1976. In a letter to Somatics Inc. and dated December 3, 1984, FDA does indicate that the device was cleared by CDRH as substantially equivalent to a legally marketed device and clearly states: "This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding." This statement is entirely consistent with 21 C.F.R. §807.97 (Misbranding by reference to premarket notification), which states: "Any representation that creates an impression

of official approval of a device because of complying with the prenotification regulations is misleading and constitutes misbranding."

As previously noted, there are no randomized, blinded, adequately controlled clinical trials data presented in the 510(k) application that provide human efficacy and safety data. The 510(k) assessment generally addresses such questions as: is the proposed new device similar in its technological design and functional components to the legally marketed predicate device and is the new device proposed for the same indications? The only discernible data generated by Somatics in support of "safety/efficacy" are two reports concerning application of the ECT device to two dalmatian dogs in whom were induced six instances of grand mal seizures, each lasting 15 to 30 seconds. Respiratory rate and heart rate/pulse rate were reported prior to induction of seizures, summarized as a range for each parameter following each seizure, and then reported two minutes following the final seizure. Efficacy or clinical responses for the first dog are summarized as follows: "Behavioral observations 24 hours later revealed the animal to be alert, lively, playful and energetic, and not different in any way from his untreated litter mate." The same treatment performed on the other previously untreated dalmatian indicated similar effects on the clinical parameters with the following reported as a clinical outcome in the dog: "Behavioral observations on a day following treatment were equally favorable as to the first dog treated."

None of the several studies submitted in support of the functional data for the Thymatron device provided any interpretable or statistically reliable clinical outcomes data. Thus, a review of the 501(k) submission revealed a marked absence of clinical trial or other data indicating or supporting efficacy claims in treating severe psychiatric illness. In fact, a 2019 review published in Ethical Human Psychology and Psychiatry, Vol. 21, no.2, pages 64-103 clearly indicates that clinical data supporting efficacy are of remarkably poor quality.

Reports of adverse events associated with the use of ECT for treatment of psychiatric illness were included in the 510(k) application as a 1968 article in the British Journal of Psychiatry. Whereas the authors conclude that unilateral electrode placement and the use of a pulsed current of "very low power," may be effective, I can discern no reliable outcome measurements subject to statistical analyses in the unblinded study involving 24 patients.

The Somatics Thymatron device was cleared for marketing via the 510(k) process as noted above. As a legally marketed medical device, Somatics became obligated to comply with all requirements under the FD&C Act as those requirements relate to marketed devices in the U.S.

6. 2011 Neurological Devices Advisory Committee Review of ECT Devices

In January 2011, the FDA conducted a review, with the help of an advisory committee, specifically intended to determine whether ECT could be reclassified into a Class other than Class III and whether to require ECT manufacturers to conduct double-blind controlled clinical trials to determine whether ECT is safe and effective. (Had the FDA required double-blind controlled trials, the manufacturers of ECT would not be allowed to market their ECT machines until those studies had been conducted and they had proven ECT's safety and efficacy, and the practice of ECT would have ended in the United States, unless and until such studies proved ECT to be safe and effective.)

As part of the FDA's review, the FDA invited public comment. The FDA received 3,045 public comments, many of which detailed brain damage, permanent memory loss, loss of cognitive function and other adverse events. *See* 2011 FDA Executive Summary (S 00585-00738). The public comments also included remarks from those who were strong advocates for ECT, urging the FDA to move ECT from Class III to a lower Class to avoid interruption of the availability of ECT in the U.S.

The Neurological Devices advisory committee was comprised of nine medical doctors, including the panel chair, of whom five were psychiatrists, one an anesthesiologist and two also identified themselves as neuropsychiatrists; the panel chair, Dr. Brott, is a neurologist. There were two biostatisticians, three doctoral level psychologists and a doctoral level neurological sciences specialist. There were also three non-scientist representatives, one from industry, one patient representative and one consumer representative among the panelists. In addition, FDA representatives were at the meeting and participated primarily as presenters. There were 24 individuals who spoke during the public comment part of the meeting as noted above, offering at times widely differing views of the safety and effectiveness of ECT in treating mental illness.

The questions posed to the members of the 2011 Advisory Committee generally addressed whether FDA should maintain the Class III designation of ECT devices overall and for specific possible indications or assign the devices or specific indications for use to Class II as well as questions about the need for a patient "check list" as part of the informed consent process for individuals for whom ECT is prescribed.

The FDA provided "An Executive Summary" of information it had compiled of the available safety and effectiveness data on ECT in treating various forms of severe psychiatric illness. In this summary, the initial listing of potential adverse events associated with ECT was cognitive dysfunction including memory loss (S 00590) and noted that memory loss including autobiographical memory loss was one of the "most concerning" adverse events associated with ECT. (S 00591).

The panel of advisory committee members would have a number of questions posed to them, including whether ECT devices should remain in Class III, requiring manufacturers to submit data on safety and effectiveness, or should be allowed to be reclassified as Class II devices

with special controls established to provide "reasonable assurance of safety and effectiveness for ECT treatment" of the following psychiatric conditions in lieu of submission of clinical trial and other data required for PMA approval:

a. Depression (unipolar and bipolar)

i. First-line treatment

ii. Treatment resistant

b. Bipolar manic (and mixed) states

c. Schizophrenia

d. Schizoaffective disorder

e. Schizophreniform disorder

f. Catatonia

In addition, FDA requested the advisory panel's suggestions for adverse events that might be included on a patient "check list" to use before the first ECT treatment that would serve to inform patients of potential adverse events associated with ECT. This checklist was titled by FDA as "Acceptance of Risk and Informed Decision Agreement." Among the major concerns to be addressed by this checklist were the "adverse cognitive and memory effects, especially with respect to anterograde and retrograde memory functioning." (Neurological Devices Panel; Electroconvulsive Therapy; January 27th and 28th, 2011; 24-Hour Summary; pages 1 and 2)

The advisory panel was provided with an overview of FDA's regulatory scheme for medical devices, with a brief history of the use of ECT and with an explanation of the regulatory history of ECT in the U.S. An open public hearing followed the ECT regulatory information in which patients, patient representatives, ECT-practitioners, psychologists, and psychiatric nurses offered their experiences and opinions. Among the 3045 respondents to the 2009 request for

written public comment, 79% supported maintaining ECT devices in Class III; 14% supported reclassifying these devices into Class II. (Georgiopoulos slides, Jan 28, PM slide #11, Public Docket). Dr. Anna Georgiopoulos, Psychiatric Medical Officer at the Center for Devices and Radiological Health, presented for the advisory committee. Dr. Georgiopoulos' Slide 11 of her presentation included the statement that "92 group (form) letters" had been submitted and reported that these 92 letters represented 6462 individuals who opposed reclassification to class II and 462 individuals who supported reclassification to Class II.

Dr. Georgiopoulos also presented a summary of the adverse events reported by patients and patient representatives:

> "Most respondents to the public docket reported an adverse event of ECT treatment. The most common type of adverse event reported in the public docket was some type of memory dysfunction with 529 such reports. This was followed by non-memory cognitive complaints with 357 reports, brain damage with 298 reports, and death or perceived shortened lifespan in those who had been previously treated with ECT with 126 reports."

Transcript, Day one, Page 140.

Continuing on page 140 and 141 of the first day's transcript, Dr. Georgiopoulos reported the following from comments submitted to the public docket:

> "The full list of reported adverse events is shown on this slide and the next slide in the order of frequency and includes worsening psychiatric condition, decreased functioning or quality of life, apathy, suicidality, seizures, physical trauma, cardiac problems, emotional trauma, incoordination or balance problems, motor symptoms, pain, headache, speech difficulty, dental or oral trauma, loss of creativity, stroke, vision problems, sleep disturbance, coma, nausea or vomiting, respiratory problems, substance abuse, hypertension, burns, falls, homicidality, nerve damage, fibromyalgia, hair loss, immune compromise, incontinence, ruptured aneurysm, sensory symptoms, tinnitus, and other or unspecified adverse events."

On day two of the Advisory Committee meeting, FDA posed five key questions to the panel, summarized as follows:

1. Did FDA identify the key risks associated with ECT in its review of medical/scientific literature, the MAUDE database, the public docket, and other sources?
2. Can the "key risks" of ECT be mitigated by special controls such as:
    a. use restricted to certain trained practitioners.
    b. specific information and instructions for use provided as physician labeling;
    c. patient labeling such as checklist of "all known risks" with the requirement that both the patient and the physician sign off on each element prior to initiating treatment.
    d. Require premarket clinical (meaning human) studies or preclinical (bench or animal) studies for changes in ECT technology or for changes in indications for use.
3. Are there potential regulatory controls that could mitigate the risks of adverse cognitive and memory effects? Among those the panel was asked to consider are:
    a. Physician labeling recommendations for pulse type, electrode positioning, frequency of treatment or monitoring cognitive status prior to and during the course of ECT treatment.
    b. Patient labeling requiring a checklist of all know ECT risks with sign-off on each item by the patient and physician.
    c. Requirement for further premarket studies for changes in ECT technology or new indications for use.
4. Discuss whether the current clinical data support the concept of brain damage as a potential risk of ECT and if it is a risk, how can this risk be mitigated.

5. The panel was asked for their overall recommendations for each of six current indications to remain in Class III or be moved into Class II regulatory schemes. Participants were asked for their recommendations for each of the following indications:
    a. Depression (unipolar and bipolar)
    b. Schizophrenia
    c. Bipolar manic (and mixed) states
    d. Schizoaffective disorder
    e. Schizophreniform disorder
    f. Catatonia

Discussion of the first question was relatively straightforward and resulted in the panel basically recommending that all 14 of the "key risks" identified by FDA be considered as associated with ECT for purposes of FDA's classification of ECT devices.

Discussion of part (a) of the second question prompted a comment by panel chair Brott that he was concerned about a recommendation to adopt the American Psychiatric Association's Guidelines restricting use of ECT devices to psychiatrists constituted a conflict of interest. The exact wording of how training and experience should be presented in labeling was left to FDA. The issue of requiring a checklist of all known risks of ECT as part of patient labeling with the requirement that patient and physician sign off on each element presented as (c) in question 2 was deferred until later during the discussion so that FDA could provide examples of similar types of check lists associated with the use of other devices. A similar proposal is included as part (b) of question 3.

Part (d) of question 2 was changed by panel consensus to a discussion of requirements for further premarket studies for significant changes in device technology that could potentially affect safety or efficacy (pages 343 - 436). The panel was in general agreement that FDA adopt that recommendation as a possible regulatory control which could be applied to ECT to mitigate the risks of ECT identified during the discussions.

The panel then turned to question 3, also intended to serve as regulatory controls that "FDA could apply to ECT to mitigate risks of adverse cognitive and memory effects (especially with respect to anterograde and retrograde memory functioning)." These physician labeling recommendations were discussed among the panelists and the consensus for section 3 (a)(i)-(v) was that specific recommendations or comments on the types of impulses used and the placement of electrodes were not recommended to be included as part of the physician labeling, in part because there is no clear consensus on the data that would support any recommendations for risk mitigation for these factors.

On item 3 (a)(vi), there was consensus that cognitive testing should be conducted prior to, during, and after ECT treatment and that this should be a formal assessment. (Transcript page 377). While there were no specifics agreed upon in terms of who should conduct the testing, what specific tests should be used and at exactly what intervals, there was general agreement that a baseline should be obtained prior to ECT and that testing should be conducted during the treatment interval and after treatment was completed. The panel suggested that FDA use adjectives to describe the testing such as "objective, standardized, formal" so that it is clear the assessments of cognition be more than a brief interview or an informal assessment. (Transcript page 384). The testing should be conducted by someone trained in the administration of such tests although that was not included as a specific recommendation for the physician labeling.

On Question 3(c) there was agreement on requiring further premarket studies, with the chair referring to the panel's responses and discussion of a similar proposal discussed as part of question 2, part (d). The panel then moved to Question 3 (b), addressing patient labeling requiring a checklist of "all know risks of ECT, with each item to be singed off by both patient and physician prior to initiating treatment." After much discussion, FDA clarified that this would be a document in addition to informed consent and entitled it "Acceptance of Risk and Informed Decision Agreement," offering an example of such a document included as part of patient labeling for an ophthalmologic device. The panel recommended that FDA redraft the list to identify adverse events that were related to the procedure and those that affected cognitive functioning in an effort to simplify the list and aid in patient understanding about the adverse events that were clearly so distressing to patients during the public comment period. (Transcript page 412).

In discussing question 4, concerning the association of "brain damage" with ECT, the advisory committee offered very mixed views of the available data, risks, and potential benefits of ECT. There appeared to be consensus that no specific evidence of "brain damage" had been evidenced by the public docket comments or the literature review presented by FDA. However, as was noted during this discussion, the research was old, the studies were troubling and there were no definitive answers. Dr. Good, a neurologist, indicated that he felt this was "an area for rich research going forward." Dr. Goodman, a psychiatrist on the panel, agreed, saying there was evidence for brain changes following ECT, perhaps not brain damage.

Dr. Duff, a neuropsychologist, felt that the reported changes in cognition "have to represent something." Dr. Brott, a neurologist and the panel chairperson stated that "I would have done something different from what we've seen." Brott challenged psychiatry as a specialty "to do more to answer the questions that have been raised in the public docket, in the literature review

and by this panel with regard to structural and electrical changes in the brain." Dr. Gordon, one of the two biostatisticians on the panel, was concerned that "we have virtually no data on memory deficits, other cognitive function at more than 6 months and a year" indicating the paucity of data available on the long-term adverse cognitive and memory effects of ECT.

While there was discussion about the cerebrospinal fluid and blood/serum markers of potential brain and neuronal tissue damage, concerns persisted about some of the MRI and CT changes seen after ECT and how to interpret those changes in the context of ECT and other, pharmacological- or talk-therapy- related changes using the same technologies. The issue remained unresolved but was identified as an area rich in potential for further exploration and investigation.

A total of 17 panel members provided recommendations for classification of the devices with respect to each indication. Dr. Brott, the panel chair, did not specifically offer his recommendations on classification. The panel members were asked to provide their recommendations for class assignment for each of the six clinical diagnostic categories listed above.

The recommendations for Class assignment are as follows:

Major depression – 8 panel members recommended Class II assignment: 9 recommended Class III.

Schizophrenia – 4 panel members recommended Class II; 13 recommended Class III.

Bipolar mania– 5 panel members recommended Class II; 12 panel members recommended Class III.

Schizoaffective disorder – 3 panel member recommended Class II; 14 panel members recommended Class III.

Schizophreniform disorder – only the industry representative recommended Class II assignment; the remaining 16 panel members recommended Class III.

Catatonia - a majority of panel members – 9 in all – recommended Class II; the remaining 8 panel members recommended Class III.

Thus, a majority of the FDA advisory panel members advised keeping ECT devices in Class III for all the indications for use except catatonia, for which it advised Class II. In every case, the two biostatisticians recommended Class III assignment as did the doctoral level psychologists and neuropsychologists. In every case, the industry representative recommended Class II. (Transcript pages 431-476).

Only 11 clinical trials were conducted starting in the late 1950s that could arguably be considered controlled trials. In these trials, while there was some indication of efficacy during acute treatment, there was no difference after one month. By today's standards, these trials were methodologically primitive. *See* Read, J. et al. (2019). Electroconvulsive therapy for depression: A review of the quality of ECT versus sham ECT trials and meta-analyses. ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY, 21, 64-100; 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; Read, J. & Bentall, R. (2010). The effectiveness of electroconvulsive therapy: A literature review. EPIDEMIOLOGY AND PSYCHIATRIC SCIENCES, 19, 333-7.

Notwithstanding the controversy concerning the lack of controlled studies demonstrating ECT's efficacy and safety, the multitude of reports of brain damage, permanent memory loss and other safety issues raised during these proceedings, and the panel's concerns, Somatics took no

action to alert practitioners of the potential harm caused by ECT, nor did the company do anything to investigate the alleged lack of efficacy and risks.

After seven years of inaction by both Somatics and the FDA, the FDA finally issued a final order on the classification of ECT devices in December 2018. *See* below and Food and Drug Administration Neurological Devices; Reclassification of Electroconvulsive Therapy Devices; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses. Final order. Fed Reg. 2018; 83:66103-66124.

Again, until then, ECT devices had been "grandfathered" into Class III for all indications, and the list of "cleared indications" for ECT had been depression (unipolar and bipolar), schizophrenia, bipolar manic (and mixed) states, schizoaffective disorder, schizophreniform disorder, and catatonia. FDA's apparent disregard for the recommendations of its own expert advisory committee panel is curious.

In its final order, the FDA moved two of ECT's indications into Class II, with "special controls." As noted in the discussion above, "special controls" are a series of requirements regarding technical parameters of the devices, labeling about adverse effects, practitioner training, and a few aspects of clinical practice. The two indications moved from Class III to Class II were catatonia and "a severe major depressive episode associated with major depressive disorder or bipolar disorder in patients aged 13 years and older who have treatment resistance or who require a rapid response due to the severity of their psychiatric or medical condition."

The FDA chose to leave less severe depression, schizophrenia, schizoaffective disorder, and mania in Class III. For all other indications, ECT manufacturers are required to conduct the necessary PMA studies to determine the safety and efficacy of ECT if they choose to market the devices for these patients. To my knowledge, the companies have not conducted such studies and,

in my estimation, are unlikely to do so because ECT practitioners are allowed to prescribe and use devices as they choose so long as these devices are approved or cleared for use and legally marketed for any indication. Use in treating patients with diagnoses not specifically cited in the labeling as within the cleared indications for use is considered the practice of medicine, which FDA has steadfastly maintained that it does not regulate. While there are an estimated 49,000 psychiatrists in clinical practice in the U.S., only about 2% of psychiatrists (approximately 1,000) perform ECT procedures on patients.

In the Federal Register Volume 83 number 246 pages 66103 through 66124, FDA issued its Final Order on Reclassification of Electroconvulsive Devices. In this Federal Register Notice, FDA reclassified ECT devices into Class II for the treatment of catatonia or a severe major depressive episode associated with major depressive disorder or bipolar disorder in patients ages 13 years and older who are treatment resistant or require a rapid response due the severity of their medical or psychiatric illness. 83 F.R. 66103-66124. The notice stated that all other indications would be considered Class III and would require submission of a PMA. This FR notice also included as Table 1, the risks to health associated with ECT and the mitigation measures for those risks. Among those listed were cognitive and memory impairment with the mitigation factors of labeling, technical factors, non-clinical test data and labeling. (83 F.R. at 66111).

In the Final Order (83 F.R. at 66119), under Response 26, FDA stated that labeling for ECT devices will be required to include the following: "ECT treatment may be associated with disorientation, confusion, and memory loss, including short-term (anterograde) and long-term (autobiographical) memory loss following treatment. These side effects tend to go away within a few days to a few months after the last treatment with ECT. However, some patients have reported a permanent loss of memories of personal life events (i.e., autobiographical memory)." The order

further sates that "because of the complexity of memory loss, cognitive status monitoring prior to beginning ECT and during the course of treatment via formal neuropsychological assessment for evaluating specific cognitive functions (e.g., orientation, attention, memory, executive function) is included as a special control.

Somatics' Adverse Event Reporting

In all the years Somatics' ECT machine has been on the market, Somatics had not reported a single adverse event (until March 2019) despite numerous reports in the medical literature, and the extensive complaints of memory and cognitive deficits submitted to the public docket and offered verbally during the public comment portion of the 2011 Advisory Committee meeting.

As a device manufacturer, Somatics was obligated by regulation and had a public health duty to monitor the medical literature for reports of adverse events as well as investigate the reports provided as part of the 2011 Advisory Committee meeting. For decades, there have been many reports in the literature and concerns raised about ECT causing permanent memory loss and brain damage, yet Somatics failed to investigate or warn of these risks. Clearly, Somatics was aware of these risks as evidenced by one of the company's owners downplaying the risk in a book and in letters to the editor appearing in the published literature. *See, e.g.*, Electroconvulsive Therapy, Fourth Edition, published in 2002, p. 200; Abrams, Re: Cognitive effects of ECT in Community Settings, Journal of ECT, Vol. 23, June 2007.

It is a device manufacturer's duty to keep apprised of safety issues related to their devices, to investigate claims of harm and to report and warn of said harms. Somatics utterly failed its duties as a prudent manufacturer in this regard. My review of the deposition testimony of the three founders and current managers of Somatics, David L. Mirkovich, Conrad Swartz, M.D., and Richard Abrams, M.D., none of whom is an ECT practitioner, indicates a startling lack of interest

in the FDA regulatory framework and requirements with which regulated industries are expected to comply. (e.g., Abrams Depo., page 19 lines 2-12, page 81 lines 1 -14, Page 81 line 15 – page 82 line 17, pages 98 – page 100; Swartz Depo., page 43, page 67 line24 – page 68 line 2, pages 74 – 86, page 121 lines 19 – 122 line 6; Mirkovich Depo., page 52 line 3 – 25, pages 98 line 13 – page 99 line 3, pages 153 line 10 – page 154 line 25).

Allegations of adverse events from any source, including public dockets, medical and scientific literature, user facility reports in the MAUDE database, or oral or written allegations and reports of injury or death all trigger a manufacturer's obligation to investigate, as established in 21 C.F.R §§ 803.17, 803.18 and 820.198. A report or an allegation of injury such as an infection or burn that necessitates medical or surgical care obligates the manufacturer to investigate the circumstances of the injury and its relatedness to their device independent of corroboration by a health care provider.

This regulatory obligation requires that the manufacturer collect all "reasonably known" information including information from a user facility, other reporter or any additional information that can be obtained by investigation, analysis, testing, or other evaluation of the manufacturer's device. If the investigation cannot determine that there is no association between the use of the device and a serious injury, the manufacturer is required to file a Medical Device Report (MDR) with the FDA.

All MDRs and problem reports, such as reports of a device malfunction or misuse that may result in a serious injury or death, are included in the FDA's Medical and User Facility Device Experience (MAUDE) database. Clinical, scientific, and regulatory personnel at FDA as well as clinicians and other researchers outside of FDA may use the MAUDE database to conduct signal analyses, evaluate trends and assess risks potentially associated with the use of medical devices.

If manufacturers appropriately provide the required information to FDA, these data can be analyzed by researchers inside and outside of FDA and be presented in the scientific and medical literature, in meetings and conferences and otherwise disseminated within the medical and scientific professions.

If the data available via MAUDE indicate that a significant risk may be associated with the use of a device, that information can then be provided to health care providers who can communicate such risks to their patients. A manufacturer that fails to meet these postmarket regulatory obligations deprives the scientific and medical community of information essential to proper evaluation of risks and appropriate communication of risk to his or her patients.

If, as appears to be evident in this instance concerning ECT and the Somatics corporation, a manufacturer becomes aware of skin burn, reports of death, brain damage and permanent or persistent memory loss and fails to investigate and report all such serious adverse events, that manufacturer has failed to meet its public health and regulatory obligations under the FD&C Act and the attendant medical device reporting regulations. As noted in 21 C.F.R § 803, Subpart B:

> (c) "What kind of information reasonably suggests that a reportable event has occurred?"
>
> > (1) "Any information, including professional, scientific, or medical facts, observations or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

A serious injury is defined in the regulations as "an injury that is [1] life threatening, [2] results in permanent impairment of a body function or permanent damage to a body structure, or

[3] necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function; excluding trivial impairment or damage." 21 C.F.R. § 803.3(w).

User Manuals for Northridge Hospital, Sharp Hospital and the 2019 User Manual for the Thymatron IV

A review of the user instruction manuals for the Thymatron IV available at the Northridge Hospital (dated September 20, 2000) and that available at Sharp Hospital (dated October 8, 2001) revealed minimal information on patient safety. The Northridge document attributed to Drs. Abrams and Swartz offers information on the contribution of sine wave technology to memory and cognitive impairment and addresses the potential for skin burns (page 22) whereas the Sharp manual describes the wave form for inducing convulsions as "Bipolar brief pulse square wave" and recommends review of the patient's hydration status and sedative-hypnotic drug use prior to subsequent treatment days in the event of difficulty in inducing seizures.

There are no specific warnings or lists of potential adverse events potentially related to the Somatics Thymatron device provided to physicians in the Sharp manual of October 2001 and minimal information in the Northridge manual. In his deposition, when questioned about the absence of specific warnings in the Sharp document from October 2001, Dr. Swartz stated that it is not the job of Somatics to determine if users were aware of the risks of ECT (page 54) and states that the only reason the company updated its instructions for use in 2018 was to avoid litigation. (page 55) and to comply with FDA's regulatory requirements (page 56).

In contrast, the more recent user manual, dated in 2019, provides significant additional information on the potential adverse effects of ECT, advises that only physicians or healthcare

workers trained in ECT and who have had supervised experience with ECT administer the procedure. It both excerpts safety information related to memory and cognitive impairment (S 01789) and also provides the FDA mandated safety warnings concerning physical and cognitive/memory effects. Safety information is found in several places in the user manual, including pages S 0195-99, safety and efficacy on pages S 01801-03; safety on S 01830-07, S 01812, S 1831-32, and in Addendum III titled "Instructions to Patient" on pages S 01864-65.

It is important to note, however, that the reference in the manual to The American Psychiatric Association's 2001 Task Force report "The Practice of Electroconvulsive Therapy" does not relieve Somatics of its regulatory responsibility to provide full and complete instructions for use, information on the indications for use, and adequate warnings about known and potential risks and adverse events in the labeling for their device.

The "Instructions to Patients" addendum does not seem to be written in accordance with FDA's Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers in that the language used in the patient instructions is still more technical than I would expect for a document that the guidance instructs be written at an eighth-grade reading level. For example, page 76 (S 01864) of the 2019 Instruction Manual states: "Although the incidence of permanent cognitive memory loss was not supported by the clinical literature…." Again, rather than informing patients that this is a potential risk of ECT, which had been reported in the medical literature for decades, Somatics downplays the risk directly to patients.

FDA Inspections of Somatics, January 2012 and April 2016

In January 2012, an FDA compliance investigator named Rafael Padilla spent approximately three days during the week of January 18-25, 2012 at the Somatics facility in Lake Bluff, IL. David Mirkovich, general manager and sales manager, was the Somatics representative

who worked with the FDA inspector. Somatics was and is described as "a specifications developer, repackager, relabeler, and own label distributor of class II/III medical devices" further explaining that "[t]he firm designs and distributes an electroconvulsive device, cutaneous electrodes and bite block." (2012 Establishment Inspection Report (EIR), page 1).

During the several days' inspection of the manufacturing facility and records, there were eleven observations of objectional conditions and findings. The 11 observations were provided to Mr. Mirkovich at the conclusion of the inspection and covered a number of areas.

Observation 1 indicated that the firm had failed to adequately establish procedures to validate design features of the devices and to ensure that any changes in the device design are validated and meet the needs of the end user. Similarly, observation 2 indicated that results of design validation were not documented in the design history file, including the method(s), the dates and the individual or individuals preforming design validation. Specifically, the firm had not documented the results of any design validation for the Thymapad™ stimulus electrode to include the methods, the date, and the individual or individuals performing the validation. The example cited was that, since January 2008, the firm had made changes to some element inside the Thymapad™ and there was no documentation in the design history file of design validation to ensure the device conforms to the defined user needs and intended uses.

Observation 3 Noted that the firm's written MDR procedure did not include an internal system providing for "the timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements." The inspector further explained that the "firm's MDR Procedure SOP-1403 Vigilance and Recall does not include an internal system which provides for the timely and effective

identification, communication and evaluation of events that may be subject to medical device reporting requirements." (2012 Form FDA-483, page 2) Of note, at this time the Somatics Thymatron ECT device had been cleared for marketing in the U.S. since October 1984 and the company had filed not a single MDR with FDA.

Observation 4 stated that "Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established." Specifically, the inspector noted "Your firm's SOP-1402 Post-Marketing Communication and Changes is not adequately established so that complaints are processed in a uniform and timely manner, oral complaints are documented upon receipt, and that complaints are evaluated for MDR reportability." This is a regulatory requirement established in 21 C.F.R. 802.3, as noted above, apart from the public health obligation inherent in the manufacture and marketing of a cleared and presumed therapeutic medical device in the U.S.

Observation 5 similarly addressed deficiencies in the complaint investigation process, noting that "[r]ecords of complaint investigations do not include required information." More specifically, the inspector noted that "Your firm's complaint investigations do not include the nature and details of the complaint or any reply to the complainant" and provides four redacted examples of complaints the investigations of which "do not provide nature and details of the complaints and whether the device was being used to treat a patient." A redacted comment addressing the source or nature of most of the complaints, according to Mr. Mirkovich, was provided in the Form 483 but is not available for review due to the redactions. The final comment from the inspector concerning Observation 5 is: "Additionally, your firm does not document any reply to the complainant." (2012 Form FDA-483, page 3)

Observation 6 indicates that "[p]rocedures for acceptance of incoming product have not been adequately established. Specifically, [y]our firm has not adequately established procedures for the acceptance of incoming product to include the documented acceptance or rejection activities of incoming product." This implies that should any incoming components be judged inadequate or failing to function as required, there is no adequate procedure for identifying and rejecting sub-standard, defective, or otherwise unacceptable device component.

Observation 7 indicated that Somatics had "no agreement with suppliers to notify you of changes in the product or services." The inspector further specified that the "firm does not have an agreement with suppliers of the Thymapad® stimulus electrode and the EEDS snap recording electrodes to notify you of any changes in the product or service so that your firm may determine whether the changes may affect the quality of the finished device."

Observation 8 further noted that "[a]cceptance activities were not adequately documented" and specified that records "for the acceptance activities of the Thymatron®, EEDS recording electrodes, and the Thymapad™ stimulus electrodes are not adequately documented to include the acceptance activities performed and the signature of the individual(s) conducting the acceptance activities and where appropriate the equipment." (2012 Form FDA-483, page 3).

Similar to Observation 8, Observations 9 -11 address Somatics' quality acceptance and documentation procedures. Observation 9 states that "[p]rocedures have not been adequately established to control product that does not conform to specified requirements" and further specifies that the "firm's Nonconforming Materials procedure SOP-1301 does

not include how nonconformances will be handled to address the documentation and evaluation of the nonconformance to include a determination of the need for an investigation of the nonconformance." (2012 Form FDA-483, page 3). Observation 10 states that procedures "to ensure sampling methods are adequate for their intended use have not been established" explaining that the firms' s sampling activities for the Thymapad and EEDS recording electrodes are not supported by the firm's SOP-2001 Statistical Techniques to ensure that the sampling methods are adequate. (2012 Form FDA-483, page 4).

Observation 11 states that the procedures "for identifying valid [Statistical] techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics have not been adequately established." Specifically, the inspector notes that SOP-2001 (identified under Observation 10 as the SOP for Statistical Techniques) "does not [identify] a valid [redacted] technique for controlling and verifying product characteristics of incoming product and supplies as well as your firm's use of [redacted] to evaluate complaints associated [with] a product line or lot of product." In addition to the 11 Observations identified above, the inspector noted that the firm did not list its cutaneous electrodes and bite blocks on the firm's registration and listing. (2012 EIR, page 2).

A second inspection of the Somatics facility, which later relocated to Venice, FL, took place in April 2016. While the inspector noted that the firm had made corrections based on the previous inspection, he also noted six additional objectional conditions.

Under the History/Interstate Commerce/Jurisdiction discussion (2016 EIR, page 2), the inspector was informed that the contract manufacturer for the Thymatron IV device is not

registered with FDA. The inspector informed Mr. Mirkovich, Somatics' representative during this second inspection, who claimed that Somatics had been informed that such contract manufacturers were not required to register with FDA unless they shipped finished product directly to customers. The inspector clarified that, while that was true "up until a few years ago," all contract manufacturers of finished devices are required to register with FDA whether they deliver devices to customers or not. *See* 21 C.F.R. 807.40. Somatics was also instructed that the electrodes, recording electrodes, and mouthguards needed to be added to Somatics' medical device listing as they were not listed at the time of the inspection. The observations listed on Form-FDA 483 were summarized in the 2016 EIR.

> As to Observation 1, the Supplier and Monitoring QSP 7.4-1 was inadequate because there was no requirement for the firm to obtain documented evidence that its critical suppliers have proper controls for critical operations touching several areas including software development/software validation. (2016 EIR, page 9).
>
> Observation 2 noted that the firm's final acceptance of the Thymatron devices does not include testing of the alarms, heart rate monitoring or EEG/seizure monitoring.
>
> Observation 3 documented that Somatics added a pulse width feature to their software in 2001 and an EEG Frequency feature to the software in 2002 but did not have a Design History File for those changes, including an assessment for the need to meet 510(k) regulatory requirements.
>
> Observation 4 relates to deficiencies in documentation of design changes, risk analyses, test equipment calibration and compliance of design changes with the Quality System regulation. Specifically, the inspector indicated that a Risk Analysis Report from March 29, 2016 was inadequate in that it lacks risk of burns and memory loss; it lacks risks related

to heart rate monitoring or EEG (seizure) monitoring; and it lacks process related risks. (2016 EIR, page 10).

Observation 5 noted that the calibration of test equipment used during the final acceptance testing of Thymatron devices is done by the firm's contractor but not documented.

Observation 6 was concerned with the fact that Somatics does not require all design changes to be done in accordance with the design control section of the Quality System regulation. (21 C.F.R. 820.30(i))

The inspector also noted that, on the firm's website, there was a statement in the Frequently Asked Questions section that stated ECT can help with mania and schizophrenia. (2016 EIR, page 8). The inspector informed Mr. Mirkovich that the firm needed to be aware that, making representations that ECT's intended uses included schizophrenia and certain other mental health conditions would require the company to submit a PMA within 90 days after publication of the Final Order by FDA for intended uses such as treating schizophrenia, mania and other mental health conditions.

Of note, and despite the clear statement by FDA included in the original 510(k) clearance letter, as well as the regulatory prohibition (21 C.F.R. §807.97) against claiming FDA approval, as recently as March 2020, Somatics claimed FDA approval on its website. (https://thyrmatron.com/catalog_thymatron.asp). *See* Swartz Depo. 155-157. That statement is no longer present on the website but its inclusion in such promotional materials demonstrates either ignorance or utter disrespect for FDA's regulations and regulatory authority.

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Summary of my Opinions concerning Electroconvulsive Therapy in general and the Somatics Thymatron Device:

1. Despite more than 80 years of use worldwide, there are no blinded, appropriately powered, adequate, and well-controlled studies published in the medical literature or submitted by ECT device manufacturers supporting the efficacy or safety of electroconvulsive therapy in psychiatric patients.
2. While the Thymatron device received 510(k) market clearance by CDRH, Somatics has failed to provide any meaningful clinical trials data on the safety and effectiveness of the device in treating severe psychiatric illnesses, e.g. treatment of "catatonia or a severe major depressive episode associated with major depressive or bipolar disorder in patients age [sic]13 years and older who are treatment-resistant or who require a rapid treatment response." (www.thymatron.com/main_home.asp)
3. Somatics repeatedly has failed to investigate, evaluate, and report to FDA, as required by 21 CFR 803, potentially significant adverse events associated with the use of its devices in treating psychiatric illness.
4. Somatics failed to establish design validation, failed to document design validation, failed to establish procedures for acceptance of incoming products, failed to establish procedures for identifying and controlling nonconforming products, and failed to establish and follow procedures to ensure that sampling of certain products and supplies required for the use of the device which are purchased from and supplied by manufacturers other than Somatics are verified as acceptable.

5. Somatics failed to abide by its duty to monitor the medical literature for reports of adverse events concerning permanent memory loss and brain damage and provide warnings of such known risks to the medical community.

I hold these opinions to a reasonable degree of medical, scientific, and regulatory certainty.

Janet B. Arrowsmith, M.D.

Janet B. Arrowsmith, M.D.

Corrales, NM

April 22, 2021

Date

APPENDIX A

CURRICULUM VITAE
JANET B. ARROWSMITH, M.D., F.A.C.P, F.A.C.E.
April 2021

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Education:

Bachelor of Arts, Zoology	Duke University	1972
Doctor of Medicine	Tulane University	1979

Internship and Residency:
Internal Medicine — University of Alabama at Birmingham
1979 through 1982

Additional Training:
Epidemic Intelligence Service — National Centers for Disease Control and Prevention, 1984 through 1986

Licensure:

Federal Licensing Exam	June 1979
New Mexico	Nov. 1996 to July 2012; January 2016 reinstatement, current

Specialty Board Certification:
American Board of Internal Medicine — September 1986

Professional Associations:

Member, American College of Physicians	Elected 1987
Fellow, American College of Physicians	Elected April 1994
Member, American College of Epidemiology	Elected April 2002
Fellow, American College of Epidemiology	Elected October 2008

Member, American Association for the Advancement of Science
Member, International Society of Pharmacoepidemiology
Member, Drug Information Association
Member, American Medical Association
Member, NM Medical Society

Professional Experience:

Arrowsmith Consulting, LLC 2008 to present
*President and sole proprietor of medical, epidemiological, and regulatory consulting firm
Corrales, New Mexico
* Clinical assistant professor, University of NM School of Medicine 2019- present
* Chair, Special Emphasis Panel NIAID, NIH May 2016
* Special Emphasis Panel NIAID, NIH November 2009

1999 to 2008
Arrowsmith-Lowe Consulting, Inc.

* President of drug, biologic, and device consulting firm
* Consultant, NIDA Division of Research and Development, National Institutes of Health;
* Member, Special Emphasis Panel, National Institute of Allergy and Infectious Diseases, NIH 1999 to 2009
* Primary Care provider, Family Practice Associates of Ruidoso, NM

1998 to 1999
Internal Medicine Associates, Ruidoso, NM

*Full time internal medicine practice with ICU privileges
*Member, Critical Care / Cardiorespiratory Committee
*Physician member, Infection Control Committee
*Physician Board member, Headstart of Lincoln County
*Ryan White provider, University of New Mexico Health Sciences Center

1996-1998:
Clinical Specialty Consultant, Mescalero PHS Indian Health Service
Hospital, Mescalero, NM

* Full time clinician in a family practice inpatient and outpatient setting
* Consultant on Internal Medicine specialty problems
* Member of the Quality Assurance special team
* Co-chair of the Hospital Infection Control Committee
* Mescalero Service Unit member of the Albuquerque Area Diabetes Team
*Acting Clinical Director, June 1997 – November 1997

1995-1996:
Medical Review Officer, Division of Blood Applications, Office of Blood Research and Review, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Rockville, MD

* Internal medicine clinical specialist with expertise in clinical trial design and xenograft transplantation
* Primary care provider for HIV-infected persons, Whitman-Walker Clinic, Washington, DC

1993 - 1995
Acting Director, Office of Surveillance and Biometrics, Center for Devices and Radiological Health. U.S. Food and Drug Administration, Rockville, MD

* Supervised staff of 113 professional and support personnel with an annual budget of $2.5 million
* Responsible for monitoring safety and effectiveness of all medical devices marketed in the U.S.
* Primary care provider for HIV-infected persons, Whitman-Walker Clinic, Washington, DC

1991-1993:
Medical Review Officer, Division of Antiviral Drug Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Rockville, MD

* Reviewer for initial clinical trials of new drugs developed to treat HIV, Herpes, Varicella-Zoster and other human viral pathogens
* Clinical consultant to the Division's laboratory for pre- and post-exposure prophylaxis to reduce risk for Hepatitis B and HIV infections
* Field reviewer for CDC's community-based programs in HIV prevention
* Primary care provider for HIV-infected persons, Whitman-Walker Clinic, Washington, DC

1990-1991:

Senior Medical Officer (HIV), Office of the Forum on Quality in Health Care, Agency for Health Care Policy and Research, Rockville, MD

* Senior Agency clinical consultant HIV-related policies
* Established and convened panel of clinical and community experts for the development of clinical care and treatment guidelines for HIV infection, published in 1993.
* Primary care provider for HIV-infected persons, Whitman-Walker Clinic, Washington, DC

1988-1990

Deputy Director, Office of AIDS and Special Health Concerns, Office of the Commissioner, U.S. Food and Drug Administration, Rockville, MD

*Directed the FDA activities for the AIDS Clinical Trials Information Service, a publicly accessible database of all clinical trials to treat HIV infection
*National and international representative for FDA policies on regulation of HIV-related products for diagnosis and treatment
* Primary care provider for HIV-infected persons, Whitman-Walker Clinic, Washington, DC

1986 to 1996
Clinical Instructor
Department of Medicine
Georgetown University Medical Center
Washington, DC

1986-1988
Staff Epidemiologist, Office of Epidemiology and Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

* Monitored postmarket safety and effectiveness of marketed drugs
* Consultant to Centers for Drug and Biologics Evaluation and Research on epidemiologic issues and problems
* Special consultant to the U.S. Department of Justice
* Primary care, Department of Medicine, Georgetown University Medical Center, Washington, DC.

1984-1986
Epidemic Intelligence Service Officer, National Centers for Disease Control and Prevention, Atlanta, GA

* First EIS officer assigned to the FDA
* Participated in CDC and FDA epidemiologic investigations of problems of national and regional interest, see bibliography and abstract listings
* Assigned as editor *pro tempore* Morbidity and Mortality Weekly Report,

1982-1984
Staff Physician, Cooper Green Hospital, Birmingham AL

* Internal Medicine attending physician with student, resident and intern teaching responsibilities
* Quality Assurance review responsibilities and Chair, medical-nursing quality assurance program

Other Professional Activities

- Member, UNM School of Medicine Community Faculty Advisory Board
- Facilitator, Clinical Reasoning courses, UNM Medical School, Albuquerque NM August 2019 - present
- Guest Lecturer, Temple University School of Pharmacy, December 8 2016
- Santa Fe County representative, New Mexico Medical Society 2016
- Abstract reviewer, American College of Epidemiology 2013, 2014
- Consultant, Special Emphasis Panel, NIAID, NIH November 2009, August 2016
- Chair, Membership Committee, American College of Epidemiology, 2008-2009
- Medical specialist, Managed Health Care Bureau, N M Public Regulation Commission 2007
- Vice Chair, Membership Committee American College of Epidemiology 2006 - 2008
- Reviewer, 2006 Congress of Epidemiology abstracts
- Lincoln County Councilor, New Mexico Medical Society Council of Governors, 2005 -2007
- Editorial Consultant, ACP's PIER program 2005 - 2006
- Reviewer, American College of Physicians' (ACP)'s Physician Information and Education Resource (PIER) modules 2004-2006
- President, Lincoln County Medical Society, 2004-2005
- Hoofbeats Therapeutic Riding Program Board of Directors, Alto NM, 2004 to 2006
- Membership Committee, American College of Epidemiology, 2002
- Volunteer physician, Bishop Stoney Camp, Episcopal Dioceses of the Rio Grande, 2004, 2005
- Reviewer, Scientific Program Committee, International Society for Pharmacoepidemiology, 2004, 2005, 2007, 2008, 2012, 2016, 2020
- Secretary/treasurer, Lincoln County Medical Society, elected December 2003-2004
- Medical Director, Ruidoso Home Care, September 2000 to 2013
- Professional Advisory Group, Ruidoso Home Care and Hospice, September 2000 to 2013
- Medical Advisor, Hoofbeats Therapeutic Riding Program, Alto, NM 2001 to 2006
- Representative, NM Council of the American College of Physicians, 1998 - 2000
- Moderator, Pharmacoepidemiology session, Annual EIS Conference, CDC, Atlanta, GA; 4/97
- Physician Representative DC Branch of the Commissioned Officers' Association 7/95-4/96.
- Member, PHS Medical Review Board July 1991 to 1998
- Member, PHS Co-Step Board Panel January 1991 to 1998.
- FDA Representative, PHS working Group on management of occupational exposure to HIV, 2/89.
- FDA Representative, AIDS Information Service Panel, US PHS Executive Task Force on AIDS; September 1989 - September 1990.
- Editorial Board, *Journal of Pharmacoepidemiology*, April 1988.
- Reviewer, *Annals of Internal Medicine*, 1988 to present
- Visiting Professor, International School of Pharmacoepidemiology, Erice Italy, September 1987

Uniformed Services

- US PHS 1984 – 1998: Highest rank achieved Captain (0-6); Honorable discharge February, 1998 at Commander (0-5) grade.

Bibliography

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Abstracts

- Arrowsmith-Lowe, Janet. How Do Drugs Get onto the US Market and What Happens Next? Annual Meeting NM Chapter American College of Physicians November 3 – 5, 2005 Albuquerque, NM (poster presentation, second prize in presentation)
- Arrowsmith-Lowe J, Gogel HK, Lynn R, et al. Serendipitous overdose of octreotide acetate used for variceal hemorrhage. Annual meeting NM Chapter ACP-ACIM, Albuquerque NM, 1999.
- Arrowsmith JB and Kennedy DL. National patterns of aspirin use and Reye syndrome reporting APHA Annual Meeting; New Orleans, LA. 1987
- Arrowsmith JB. Guillian-Barre Syndrome following Streptokinase Exposure : A case study in Pharmacoepidemiology, APHA Annual Meeting Washington DC 1986.
- Arrowsmith JB, Kuritsky JN, Faich GA, Hsu JP. Morbidity and mortality associated with the use of an intravenous vitamin E preparation, Eferol. EIS Conference, CDC Atlanta, GA 1986.

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Letters

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- Arrowsmith JB, Kuritsky JN, Milstein JB, Murano G. Streptokinase and the Guillian-Barre syndrome. Ann Int Med 1985; 103: 302.
- Arrowsmith JB, Gams R. Dystonia with Droperidol therapy. N Engl J Med 1981; 305: 227.

Book Chapters

- Seligman P, Braun M, Gross T, Arrowsmith J "Postmarket Surveillance of Medical Products in the United States" In: Principles and Practices of Public Health Surveillance. 3rd edition Teutsch SM, St. Louis M, et al eds. Oxford University Press, 2010.
- Arrowsmith-Lowe J "Post-Market Safety Surveillance for Pharmaceuticals" In: Principles and Practice of Public Health Surveillance, 2nd edition Teutsch SM and Churchill RE, eds. Oxford University Press, 2000.
- Arrowsmith JB, Anello C. Postmarketing Surveillance: A view from a regulatory agency. In: Pharmacoepidemiology Strom BL, ed. Churchill Livingstone, New York, 1989; revised 1994.

Other Publications

- Arrowsmith-Lowe J. Summertime and the "stomach flu". *Apache Scout*; Mescalero NM, August 1996.
- Arrowsmith-Lowe J and Simmons D "Recognizing Sexual Abuse in Children" *Apache Scout*, Mescalero, NM, September 1997.
- Arrowsmith J and de laHoussaye MK. Flow of Federal Health Funds, State of Louisiana. Prepared for the Office of the Commissioner, Division of Administration, State of Louisiana, Baton Rouge LA, 1975.

Representative Presentations:

- "Human Trafficking" 2014 National Women's Heritage Month Event, Celebrating Women of Character, Courage and Commitment" USDA Forest Service, Albuquerque NM March 26, 2014. • "How FDA Works: Drugs and Medical Devices" Staff and Fellow Grand Rounds, Department of Gastroenterology, University of New Mexico, Albuquerque, NM January 10, 2013. • "Dealing With Menopause" Mescalero Apache Women's Wellness Conference, Inn of the Mountain Gods. Mescalero, NM May 15, 2012
- "Cardiovascular Safety of Prescription Drugs" John L. Wilson Cardiology lectureship, Presbyterian Healthcare Services, Albuquerque, NM October 1, 2010.
- "How drugs get to market in the US" Sacramento Mountain Village, Ruidoso NM May 2008
- "How FDA Works" Lincoln County Medical Society, Ruidoso NM March 13, 2008
- "Medication Errors in Children" Pediatric Research Roundtable, Consumer Healthcare Products Association, Washington DC, June 28, 2007
- Arrowsmith-Lowe J, Gogel HK, Lynn R, et al. "Serendipitous overdose of octreotide acetate used for variceal hemorrhage". Annual meeting NM Chapter ACP-ACIM, Albuquerque NM, 1999. • Medical Issues for Women Living with HIV. Positive Women's Retreat, sponsored by Camino de Vida of New Mexico. Las Cruces NM, May 12, 2000

- Sexually Transmitted Diseases: Prevention and treatment. Camp Sierra Blanca Juvenile Detention Center, Capitan, NM December, 1999.
- Antibiotic Resistance and Misuse of Antibiotics, Artesia, NM and Portales NM March, 1998
- Moderator, Postmarketing Surveillance Panel, Annual EIS Convention, CDC, April 1997.
- "Recognizing sexual abuse in a child" Mescalero Headstart Program continuing education series. September, 1996; Mescalero, NM.
- "Menopause" Federal Women's Association monthly meeting, Mescalero NM; August 1996.
- "CDRH Executive Roundtable" at the Regulatory Affairs Professional Society Annual Meeting Washington, DC; September 1994.
- "Medical Device Reporting " Medical Devices Update 1994, The Food and Drug Law Institute, Washington, DC; June 1994.
- "Epidemiology of Blood Borne Pathogens, Including HIV" University of Texas University of Health Sciences School of Dentistry, October 1993.

Awards

- PHS Citation- 1987 epidemiology of aspirin and Reye syndrome and of the E-Ferol syndrome.
- American Medical Association's Physicians Recognition Award, July 1985 through June 1988, July 1988 through June 1991, July 1991 through June 1994, July 1994 through June 1997, July 1998 through June 2001, June 2001 through June 2003, June 2003 through June 2006.
- PHS Citation-1989 for outstanding effort in coordination of AIDS activities for the Food and Drug Administration.
- PHS Unit Commendation-1990 for extraordinary achievements in developing a toll-free accessible AIDS clinical trials database.
- PHS Unit Commendation-1991 for exemplary service in clinical guideline development.
- Whitman-Walker Clinic volunteer of the month, April 1992.
- PHS Outstanding Unit Commendation -1992 for contributions to the review and approval of ddI.
- Center for Devices and Radiological Health Certificate of Appreciation-1995 for outstanding leadership and exceptional achievement.
- US Food and Drug Administration Certificate of Appreciation-1995 for support and contribution of the FDA MedWatch Program.
- PHS Unit Commendation -1995 as a member of the corporate wide injunctions group.
- PHS Unit Commendation -1995 as a member of the Ad Hoc Committee on Total Parenteral Nutrition Issues.
- PHS Unit commendation -1995 as a member of the MedWatch Coordinating Council.
- PHS Unit Commendation -1995 as a member of the Cables and Leads Working Group.
- DHHS Secretary's Award and PHS Unit Commendation -1996 for outstanding performance addressing the problems of electrodes and patient cables and leads
- Letters of appreciation,1996, David A. Kessler, Commissioner, U.S. Food and Drug Administration; and Mary Pendergast, Deputy Commissioner, US FDA
- Certificate of Appreciation for eight years of volunteer service, presented March 1996, Whitman-Walker Medical Center, Washington, DC.
- PHS Isolated Hardship Ribbon, 1996.
- Outstanding Alumna, Louise McGhee School, New Orleans, LA March 1997.
- “Angel of Adoption” Congressional Coalition on Adoption, Washington DC, September 11, 2001
- Letter of recognition for “exceptionally fine quality” peer reviews, *Annals of Internal Medicine,* 2004, 2011
- State Champion, Long Stirrup Division, NM Hunter Jumper Association, 2005
- Community Service Award, 2012, New Mexico Medical Society
- Honored as “A Woman of Character, Courage and Commitment” 2014 National Women’s Heritage Month 2014, Washington Civil Rights Office, USFS, USDA March 26, 2014.
- 50th Anniversary Keynote Speaker, Louise S. McGehee School Founder’s Day, March 24, 2017.

Other Activities and Associations

- Board of Directors, Trinity House Catholic Worker September 2020 - present
- Faculty facilitator, Clinical Reasoning Course, UNM School of Medicine, 2019, 2020
- 40th Reunion Organizing Committee, Tulane University School of Medicine, 2018-2019
- Graduate, Living School, Center for Action and Contemplation, Albuquerque NM 2017-2019
- Vice President, Board of Directors, Toscana at Cabezon Homeowners Association Nov 2016 – December 2019
- Reviewer for Thacker Award, EIS Alumni Association, 2018, 2019
- Committee for Art and Remembrance/Stitching Our Stories, Santa Fe NM, April 2016-2018
- Peer reviewer, Division of AIDS, NIAID, NIH, August, 2016.
- Peer reviewer and Panel Chair, National Institute of Allergy and Infection Diseases, National Institutes of Health, May 2016
- Santa Fe County Representative, New Mexico Medical Society Annual Meeting, May 2016
- Community Outreach Council Episcopal Church in Lincoln County, NM September 2012
- Host family, *Up With People* advance team, January - February 2012
- FBI Human Trafficking Working Group in NM 2010 - present
- President, Board of Directors, NM Organized Against Trafficking Humans (NM OATH), 2010 to 2012.
- Volunteer, Spay and Neuter Clinic, Humane Society of Lincoln County, 2010 to 2012
- Lector, Episcopal Church in Lincoln County, NM 2008
- State Champion 2005, Long Stirrup Division, NM Hunter Jumper Association
- Hoofbeats Therapeutic Riding Program Medical Director and Member, Board of Directors, 2004 - 2006
- Vice President, PAC, White Mountain Elementary School, 2002-2003
- Parent Advisory Council (PAC) Representative, SVP 2001-2002
- Participant, *Volunteer in Public Schools Program*, Ruidoso Municipal Schools, 1998,1999,2000,2001,2002, 2003, 2004, 2005, 2006
- Homeroom Parent and Parents' Council member, Nob Hill Early Childhood Center, Ruidoso, NM, 1999-2000
- Physician Consultant, Headstart Program of Lincoln County, NM, 1998-1999
- Lector, St. Thomas' Episcopal Parish, Washington DC 1992 -1996.
- Alumnae Advisor, Duke University Students' Career Counseling Program, 1992 to present.
- Member, Education Committee, St. Thomas' Episcopal Parish, Washington DC 1990 to 1993.
- Member, Latin American Parents' Association, Washington Metropolitan Area, 1989 to 1996.

Continuing Medical Education Activities

- Poster Presentation, Annual Meeting American College of Physicians, NM Chapter, Nov. 2005 Massachusetts Medical Society's Journal Watch Program, 25 to 50 credit hours/year 1997 to present
- Drug Information Association Annual Meeting, 2003, 2004, 2006, 2008, 2010
- American College of Epidemiology Annual meeting 2002, 2006, 2008
- American College of Physicians Annual Meetings 1985, 1987, 1995, 1999, 2001
- ACP Regional Meeting, Albuquerque, NM1996, 1998, 1999, 2004, 2005
- IHS Course on Gynecology, Prenatal and Obstetrical Care, September 1996, Denver CO
- Basic CPR Lincoln County Medical Center, 1996, 1997, 1998, 2000, 2002, 2003, 2004, 2005, 2006
- Basic CPR, Safety Ireland, Dublin Ireland, March 2016
- Advanced Cardiac Life Support, Lincoln County Medical Center 1996, 1998, 2000, 2002
- Medical Response to Public Health Emergencies, Albuquerque NM, May 2005

APPENDIX B

List of Materials Relied on by Dr. Janet Arrowsmith:

1. Deposition transcript of Richard Abrams
2. Deposition transcripts of Conrad Swartz (Aug. 10, 2018 & Apr. 1, 2021)
3. Deposition transcript of Somatics, LLC's Person Most Knowledgeable, David Mirkovich
4. Somatics' Thymatron System IV Instructor's Manuals (2000, 2001, and 2019 Editions)
5. Nov. 15, 2006 Email between Richard Abrams and Conrad Swartz
6. 2018 Addendum to Somatics' Manual and Cover Letter to Addendum
7. 2018 Regulatory Update Notice Posted on Somatics' Website
8. Somatics' Adverse Event Reports to FDA Maude Database
9. Declaration of Nancy A. Pressly re. Manufacturer-Submitted Adverse Event Reports to FDA
10. 2012 and 2016 FDA Inspection of Somatics Reports
11. Somatics' Standard Operating Procedures
12. FDA Executive Summary of the 2011 Neurological Devices Advisory Committee Review of ECT Devices
13. FDA Advisory Committee Transcripts of the 2011 Neurological Devices Advisory Committee Review of ECT Devices
14. Somatics' Submissions for 2011 FDA Neurological Devices Advisory Committee Review of ECT Devices Hearing
15. 2018 FDA Reclassification Order on ECT devices (83 F.R. 66103-66124).
16. Somatics' 1984 Submission to FDA for 510(k) Clearance
17. Somatics' 1985 Clearance Letter
18. Somatics' 1995 Clearance Letter
19. Nov. 25, 2020 Email to FDA Acknowledging No Double-Blind studies of ECT in Modern Era
20. "Efficacy of ECT" by Richard Abrams, June 24, 2004 (S00739-744)
21. "Efficacy and Safety of the Thymatron System IV ECT device, a Comprehensive Review" Dec. 26, 2018 (S00747-756)
22. Somatics' Webpage Claiming FDA Approval
23. Somatics' Promotional Material Claiming Proven Safety and Efficacy
24. 21 C.F.R. § 807.97

25. 21 C.F.R. § 807.40
26. 21 C.F.R. § 803
27. 21 C.F.R. § 803.3
28. 21 C.F.R. § 802.3
29. 21 C.F.R § 803.17
30. 21 C.F.R § 803.18
31. 21 C.F.R. § 807.97
32. 21 C.F.R. § 807.40
33. 21 C.F.R. § 820.30
34. 21 C.F.R § 820.198
35. Read, J. et al. (2019). Electroconvulsive therapy for depression: A review of the quality of ECT versus sham ECT trials and meta-analyses. ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY, 21, 64-100.
36. 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.
37. Read, J. & Bentall, R. (2010). The effectiveness of electroconvulsive therapy: A literature review. EPIDEMIOLOGY AND PSYCHIATRIC SCIENCES, 19, 333-7.