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Dear Ms. Kotler,

I write to appeal your denial of Request number: 2020-7319 for the expedited processing of the Electronic Freedom of Information Act request submitted on 9 October 2020.

The FOI #2020-7319 requested the following:

- ECT manufacturers' premarket approval applications (PMA) for all uses not presently classified as class II (i.e., schizoaffective disorder, parkinsonism, dementia, bipolar manic state, OCD, autism, etc)
- Notices of completed product development protocols (PDP) submitted to the FDA before March 27, 2019 for any electroconvulsive therapy device with an intended "use to treat catatonia or a severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients age 13 years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition" (21CFR882.5940).

As you stated in your email, "The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."”

Imminent threat to the life or physical safety for ECT recipients

The following threats are based on present guidelines in community settings[1–3]:

- All-cause mortality during ECT treatment is 0.42 [0.11 – 1.52] deaths per 1,000 patients. 29% of ECT deaths are Cardiac related."[4]
- 1:50 ECT patients experience Major Adverse Cardiac Events (MACE). 1:250-500 treatments result in MACE. (MACE is defined as "myocardial infarction, arrhythmia, pulmonary edema, pulmonary embolism, acute heart failure, and cardiac arrest.")[4]
- People receiving ECT are 4.8 times more likely to complete suicide within first week after discharge.
- ECT's "severe stress-exposure or trauma"[5] causes pervasive microstructural damages (petechial hemorrhaging, gliosis, astrocytosis, myelin sheath damage, cerebrovascular vascular) most

concentrated in the current's path [2,6–13], increased immunoreactivity[14–17], metabolic abnormalities[16,18–23] including acquired channelopathies[24–32], and loss of astrocytes effects tight junctions of the blood-brain-barrier integrity increasing potential for neurodegenerative disorders[33]. These microstructural damages, only visible in neuropathological animal and human studies, identify injuries throughout the brain consistent with electrical injury from sources of electricity other than ECT all of which have long-lasting neurological consequences.[25,26,29,34–63]

- Though microstructural damage occurs through the entire brain, the brain stem and anterior of the frontal lobes carries the brunt of up to 450 volts, 900 mA current, 576 mC Charge (1200 mC in the UK) electricity because it is the focal point of the electrical path. [1,2,8]
- Electroconvulsive therapy is not a singular event. Index courses are 8-12 treatments, typically given three times a week. Like all repetitive brain injuries, the greater the amount of time between insults, the fewer cognitive and neurological side effects. Acute treatment calls for ECT to be given as often as three times a week—and if a seizure doesn't last at least 25 seconds, the APA recommends repeating the procedure at a higher electrical dose within moments of the first attempt.[3] Further, maintenance ECT is recommended for patients who routinely relapse. There are is are no PMA or PDP on record to establish safety limits on "maintenance ECT," Research demonstrates that spacing treatments at least 38.6 days apart will avoid a "cumulative effect."

  Unscrupulous psychiatrists give patients repeat "index courses" as evident by the woman in Connecticut with an active court case to end her ECT treatments after having received more than 500 in five years—which "likely happens more often than people realize."[64] Repeated use of ECT must be understood in the contest of both repetitive brain injury and repetitive electrical trauma.[65] Modern understanding of repetitive mild traumatic brain injuries (mTBI) and traumatic brain injuries shines a new light on ECT's imminent threat to life or physical safety of recipients. "The process always damages the brain, resulting each time in a temporary coma and often a flatlining of the brain waves, which is a sign of impending brain death. After one, two or three ECTs, the trauma causes typical symptoms of severe head trauma or injury including headache, nausea, memory loss, disorientation, confusion, impaired judgment, loss of personality, and emotional instability. These harmful effects worsen and some become permanent as routine treatment progresses."[66] "Early detection and management of brain injuries … are of utmost importance in preventing chronic neurological and psychiatric decline."[67]
- ECT's "Therapeutic effect" is caused by a temporary Postictal Suppression or "electrical silence," the absence of brain activity. (a sign of severe damage and impending brain death) by forcing 2.5-6 times the body's seizure threshold worth of electricity through the brain. Electrical silence is documented to last up to more than six minutes in some patients given ECT at levels above the threshold. When/if spontaneously resolved, brain activity slowly resumes in bursts of sporadic coma (delta) waves until "silence" is completely replace with delta waves and the patient awakes from coma activity. [1,2,68–73]
- 55% of ECT recipients self-reported negative effects on memory. Tests which accurately capture the extent and type of memory loss and cognitive deficits reported by patients, are not routinely used in every ECT patient, though FDA guidelines recommend it. Consequently ECT patients are rarely, referred for timely, comprehensive brain injury assessment or rehabilitation.

- The more ECT Treatments a patient has, the greater the likelihood they will suffer seizure, respiratory distress, syncope, paralysis, dizziness, Loss of consciousness and/or death with the introduction of lidocaine during subsequent, unrelated medical and dental procedures. [28,74]

Manufacturer & APA recognized risks of "Permanent Memory Loss and Permanent Brain Damage"

Brain damage is defined by the American Heritage Medical Dictionary as "the physically subtle, but functionally serious, injury … [including] repeated multiple small hemorrhages sustained in boxing. Brain damage often affects the areas of higher function in a patchy way with loss of certain functions and retention of others. ... A proportion of brain-damaged people end up in a state of almost complete loss of the higher mental functions (amentia).[75] The American Psychiatric Association [and ECT device manufacturer recognizes [seven] treatment parameters are each independently associated with more intense cognitive side effects … [including] permanent memory loss or permanent brain damage."[2,3] (Patients can potentially be subjected to more than one risk at a time with each treatment.)

How many people receive ECT yearly?

In 2004, Dr. Harold Sackeim, America's leading researcher on ECT use in clinical settings, testified in court deposition that an estimated two million people receive ECT yearly worldwide.[76] American ECT use has never been routinely audited nationwide to confirm how many Americans receive ECT, how many treatments each patient receives, how closely spaces treatments are, and what form of ECT they receive .[77] Yet modern media routinely quotes an arbitrary 1970's statistic that estimated 100,000 Americans receive ECT yearly without recent audits to confirm that estimate.

Since the 2018 reclassification of ECT as a Class II device for treatment resistant depression and catatonia in children (13+ years old) and adults, the 2020 Substance Abuse and Mental Health Services Administration's National Directory of Mental Health Treatment Facilities shows a 34% increase in the number of facilities providing ECT across the nation when compared to the 2018 directory.[78,79]

ECT and Death

Deaths of ECT patients are rarely acknowledged publicly, investigated, or properly addressed to ensure future patient safety.

For example, on 21 February 2020, an outpatient ECT recipient and resident of *Stepping Stones for Living* "received electroconvulsive therapy from a specialized clinic and was told to expect to be groggy and sleepy. Upon returning to [*Stepping Stones for Living*], the person went to bed and never left it, and was declared dead almost 24 hours later.[80] Autopsy report given to newspaper reporter by family, stated medical examiner, Dr. A. Quinn Strobl, determined "Sudden Cardiac Death in Schizophrenia" as cause of death (Slater, B. personal communication, June 17, 2020). Though patient safety violations are now acknowledged by investigation, "due to the unprecedented public health challenges during Minnesota's peacetime state of emergency due to the COVID-19 pandemic, a correction order will not be issued." [81]

Aging after ECT

In addition to those who have and will die in all cause mortality from ECT this year, we know that Animal and Human ECT Neuropathology studies and studies specific to high-field strength electrical contact with human cells document the following evidence for brain, nerve and muscular damage in animals and

humans which increases morbidity. Consider quality of life while aging with the following microstructural damages caused by ECT:

- "increased gliosis; diffuse degeneration; petechial hemorrhages in the brain stem with fat embolism; and more commonly edema and subarachnoid hemorrhage"[8]
- An "edematous brain" with neuronal damage and increased lipofuscin pigmentation.[8]
- neurovascular insults [6,7]
- Astrocytosis[7,12]
- petechial and capillary hemorrhages[1,2,6–8,10,11]
- Frontal Lobe atrophy[82]
- Severe and irreversible injury to the nervous system[14]
- Astrocytosis and its resulting effects on the Blood-Brain Barrier (BBB) integrity and motor neuron function subsequent neurodegeneration.[33,83]
- Permanent changes in how the body regulates electrolytes (Acquired channelopathies).[24–32]
- Long-term sequelae of low-voltage electrical injury[38–40,51,56]
- Permanent EEG abnormalities after ECT[73,82]
- Changes in Evoked Potential testing[17,46]
- Doctor acknowledged and Patient reported movement disorders and sleep disorders after ECT. [9,84,85]
- Repeated ECT causes hyper immune reactivity [15]
- ECT can potentially permanently change brain metabolism [14,16]
- Non-dominant Unilateral ECT uses "six times the seizure threshold to achieve therapeutic effect means confining most damage to the nonverbal side of the brain, usually the right hemisphere. This exploits the well-known neurological phenomenon of anosognosia, or denial, that is associated with right-hemisphere lesions." Patients cannot recognize something is wrong, nor can they express it. [1,13]

How much electricity do they use compared to what makes the body seizure?

ECT providers tell the public that just enough electricity is used to cause a seizure, but not going over the significantly over an individual's seizure threshold will not create a "therapeutic response." The APA and device manufacturers recognize "High electrical dosage relative to seizure threshold" as one of the seven independent risks associated with "permanent memory loss and Permanent brain damage."[3,86] But MECTA instruction manual states "when an ultra-brief stimulus is used, the traditional bilateral (bifrontotemporal) placement has reduced efficacy even when dosage is set at 2.5 times the initial seizure threshold. At a traditional pulse width of 1.0 ms or more, right unilateral ECT has been shown to match the efficacy of bilateral ECT, when dosage is 6.0 times the initial threshold."[1] Uncrupulous doctors do not adjust for electrical output based on electrode placement, nor are they mandated to do so.

Taking Medications while having ECT

Another independent risk of permanent brain damage and permanent memory loss recognized by the APA and ECT device manufacturers is "Concomitant psychotropic medications." This is because Electrical fields "enhanc[e] drug delivery across multiple biological barriers."[87] Which means taking medication while undergoing ECT amplifies medications' effect. During ECT, not only does a patient have anesthesia, muscle relaxants and possibly caffeine in their system per modern clinical parameters, most treatment

resistant patients take multiple classes of medications during the course of ECT. At this time, there are no standards of care or PDP to safely taper patients off psychiatric medications prior to having ECT in an effort to reduce recognized risks of permanent brain damage and permanent memory loss.

Unstandardized Medical Devices

Psychiatric facilities give patients ECT using a variety of ECT machines with varying electrical outputs. Not only does the output differ by manufacturer, it also differs vastly by country in which its sold. This renders doctors unable to apply the research conducted on one machine in one country, to the same manufacturer's device sold in another country, nor can they apply outcomes to different ECT devices. None of the devices ever underwent the rigorous scrutiny of a premarket approval application (PMA) for safety testing. They were grandfathered into FDA approval. In addition to a lack of PMA, there are no universally recognized Product Development Protocols (PDP)to establish the limits of safe use in medical devices for people of varying ages or diagnoses. According to personal communication with Dr. Kenneth Castleman, retired NASA biomedical engineer and forensic expert, "On the Thymatron, the pulse width, pulse frequency, and output power can all be set independently … Doctors set the pulse width, pulse frequency, and output power (0 - 100%), and the device figures out the duration of the treatment.

> The current is always 0.9 amp, and the voltage goes up to whatever is required to force 0.9 amp through the patient's head. Some combinations of low frequency and narrow width can't produce 100% output in 8 seconds and it will tell you to increase one or the other."

Imagine having high-field strength electricity flowing through your head for up to eight seconds, repeatedly.

Consequences of using anecdotal, unreplicable results instead of Evidence-Based Medicine

Without safe administration PDP universally built into the standard of care for Electroconvulsive Therapy, every positive and negative research finding and patient experience is mere anecdotal evidence. More than seven independent administration variables make it impossible to replicate outcomes universally in community settings. Sackeim et al inadvertently demonstrated how a lack of strictly regulated PDP impacted 347 patients living with depression who received ECT at seven facilities in the New York City metropolitan area. They concluded:

> adverse cognitive effects were detected 6 months following the acute treatment course. Cognitive outcomes varied across treatment facilities and differences in ECT technique largely accounted for these differences. Sine wave stimulation and Bilateral electrode placement resulted in more severe and persistent deficits.[88]

The public believes that because Electroconvulsive therapy's FDA approved, it met rigorous safety testing to establish safety limits using modern clinical parameters. It didn't. They believe all ECT is created equal and that everyone who has it can reliably expect the "same safe and effective" results. They can't. There is no specific guidance product protocols for the devices' special controls (technical parameters, waveform, output mode, pulse duration, frequency, train delivery, maximum charge and energy, and the type of impedance monitoring. Consequently, there is a vast outcome dichotomy ranging from symptom improvement to death with the majority of ECT recipients landing on a bell curve somewhere in between. Problem is, without routine assessment for every single recipient and tracking

of neurological symptoms after treatment, there is an absence of evidence but “absence of evidence is not evidence of absence.”

Is memory loss the only side effect of ECT?

While 29-55% of ECT recipients believe they have long-lasting or permanent memory problems, as you can see, memory loss is but one aspect of negative outcomes associated with ECT. According to Somatics’ User manual for Thrymatron System IV, other lasting severe effects include:

> cardiac complications, brain injury, stroke, deficits in cognition and executive functioning, dental/oral trauma, general motor dysfunction, physical trauma (including fractures, contusions, injury from falls, dental or oral injury), treatment emergent mania and postictal delirium, neurological symptoms (e.g., paresthesia, dyskinesias), tardive seizures; prolonged seizures; non-convulsive status epilepticus; pulmonary complications (e.g., aspiration/inhalation of foreign material, pneumonia, hypoxia, respiratory obstruction (laryngospasm, pulmonary embolism, prolonged apnea); visual disturbance; auditory complications; onset/exacerbation of psychiatric symptoms; completed suicide; homicidality; substance abuse; coma; and death.[2]

Given the lengthy detailed severe effects outlined in the Thymatron User Manual, it appears they acknowledge their device is "an imminent threat to the life or physical safety of an individual."

Pay attention to both the good and the bad ECT stories

While we acknowledge patients and doctors reporting mood improvement after ECT, we must also acknowledge “the lack of reports of movement disorders and dementia …. latrogenic diseases generally go underreported.”[9] For that reason, every patient experience, positive and negative must be taken into consideration when weighing eminent threat to life or physical safety.

Medical Device’s Mechanism of Action

Contrary to CFR Section 882.5940 (E), medical device manufacturers must legally provide “Information on how the device operates and the typical course of treatment,” ECT device manufacturers have never provided “a description of the principle of operation or mechanism of action for achieving the intended effect” as directed by the 510(k) checklist (non-binding) stipulations for medical device information.

Patients receiving ECT and doctors providing it do not know the devices’ mechanism of action works. Consequently, in when severe adverse events occur, doctors are unprepared to provide routinely comprehensive neuropsychiatric, cardiopulmonary, optical and auditory assessments to every patient receiving ECT. They have never studied the neuropathology of repetitive high field strength electricity to the brain with a focal point on the brainstem (in the case of bilateral treatment) and are simply at a loss as to how to provide follow-up care for the duration of a patient’s life after ECT.

We’re requesting expedited release of ECT’s PMA and PDP in an effort to disseminate this information with urgency to inform the public” so that the public can understand how FDA approved ECT for human use is being conducted to reduce the life-altering risks of permanent brain damage and permanent memory loss. The public deserves to understand which safety testing has been conducted and what protocols are in place to ensure safety. The public also need to know what is being done to routinely assess for each of the severe effects outlined in user manuals and how patients will be cared for as they age after ECT’s repetitive brain injury.

If at this time, you do not feel we have provided sufficient information to adequately demonstrate "imminent threat to the life or physical safety" or the need to provide information to the public, please consider this FOI request in light of the devices having been grandfathered into use without PMA or PDP and the reclassification as a Class II devices for use on children 13 and older. This request is but an echo of your own office's request in their final ruling of 1979. In which case, the request was first processed nearly 41 years ago.

Protecting children, adults and elderly adults protected as a marginalized demographic by the Americans with Disabilities Act should be a priority for the FDA. The continued use of unstandardized medical devices used in delivering ECT without product development protocols causes imminent danger to uncalculated number of American and international ECT patients whose countries rely on FDA data to develop safety standards.

In conclusion, let me just quote from the recent publication peer-reviewed article entitled "Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses"

> "The quality of most SECT–ECT studies is so poor that the meta-analyses were wrong to conclude anything about efficacy, either during or beyond the treatment period. There is no evidence that ECT is effective for its target demographic—older women, or its target diagnostic group—severely depressed people, or for suicidal people, people who have unsuccessfully tried other treatments first, involuntary patients, or adolescents. *Given the high risk of permanent memory loss and the small mortality risk, this longstanding failure to determine whether or not ECT works means that its use should be immediately suspended until a series of well designed, randomized, placebo-controlled studies have investigated whether there really are any significant benefits against which the proven significant risks can be weighed*"(italics added for emphasis).[89]

Given the significant risks outlined above, we look forward to receiving an expedited response to Request number: 2020-7319.

Respectfully,

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Certified Rehabilitation Counselor, Patient Safety Advocate, ECT Survivor (116 treatments)

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