Governor Tim Walz
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April 5, 2021

Dear Governor Walz,

Happy Spring! Though spring is in the air, I wish I wrote you under better circumstances.

I'm a certified rehabilitation counselor and former professor of clinical psychiatric rehabilitation at San Diego State University. For the past eleven years, I've researched electroconvulsive therapy and its long-term consequences in an effort to better create rehabilitation interventions for Electroconvulsive Therapy (ECT) recipients.

Recently I learned about Charles Helmer's court mandated shock therapy. He is a young man living with autism whose behavior deteriorated after toxic mold exposure. Though the hospital feels Mr. Helmer is living with schizophrenia, they mention nothing of his primary diagnosis, Autism, in court proceedings. This is particularly unusual because historically people with autism have difficulties with sound and light sensitivity—two things which will become worse with ECT's repetitive mild intracranial traumatic brain injury.

As a rehabilitation professional, it concerns me that Mr. Helmer's primary diagnosis and recent toxic mold exposure are not being considered by the court. Any mandated treatment should not worsen a primary diagnosis. I'm also concerned whether the court will mandate comprehensive assessment of ECT's "serious adverse effects" and comprehensive lifetime rehabilitation interventions as indicated—especially if they worsen his primary diagnosis of autism. These comprehensive brain injury assessment and rehabilitation intervention services should be in place and paid for by the state since Mr. Helmer was mandated to receive shock by the state—against his and his mother's consent. They should not be stuck with the lifelong financial burden of brain injury rehabilitation intervention.

I make this inquiry about long-term follow up because the FDA required device manufacturers to warn "long-term safety and effectiveness of ECT treatment has not been demonstrated, long-term follow-up may be needed."[1] Since Mr. Helmer received ECT as mandated by the state of Minnesota, the financial burden of long-term follow-up is the state's responsibility.

In recent years, ground-breaking data from manufacturers, researchers and neuropathologists explain why ECT's immediate and long-term effects warrant mandated long-term follow-up and intervention. For example:

October 2018

Riera vs Somatics, LLC (maker of the Thymatron ECT medical device) case settled confidentially after court deposition revealed that in the company's 35 years of operation it no policy to routinely investigate or follow-up on severe adverse event reports filed with the FDA.[2] Within days of settling, Somatics published a "regulatory update" for their Thymatron user manual citing the American Psychiatric Association as recognizing seven independent risks associated with "permanent brain damage and permanent memory loss."[3]

- Bilateral electrode placement
- Sine wave stimulation
- High electrical dosage relative to seizure threshold
- Closely spaced treatments
- Larger numbers of treatments
- Concomitant psychotropic medications
- High dosage of barbiturate anesthetic agents

As you can see, during the course of treatment, patients can be exposed to more than one risk at the same time. Some patients are exposed to all seven risks as treatment proceeds.

Question for state consideration:

1. What measures does the state have in place to assess for and reduce the risk of "permanent brain damage and permanent memory loss" in court mandated ECT recipients?
2. In the event of injury, what rehabilitative measures are presently in place to ameliorate life-long consequences of court mandated treatment?

December 2018

The FDA acknowledged having never received animal and human safety testing for ECT using modern clinical parameters to establish universal dosing limits.[4] These limits are required to reduce likelihood that ECT recipients will experience permanent brain damage and permanent memory loss.

Question for state consideration:

3. What will be done to ensure hospitals providing ECT—especially state mandated ECT—are using administration technique and electrical dosing parameters which reduce the likelihood of "permanent brain damage and permanent memory loss"?
4. How will the state verify such measures are in place?
5. Who is responsible for routinely auditing the regulatory process ensuring patient safety of state mandated ECT recipients?

August 2019

Dr. Bennet Omalu, internationally recognized neuropathologist spoke about ECT during a traumatic brain injury advisory board meeting at the California Department of Rehabilitation. (He's the forensic neuropathologist who first published autopsy findings of NFL players living with Chronic Traumatic Encephalopathy—a newly recognized neurodegenerative disorder). Minutes of that meeting state:

> Dr. Bennett Omalu confirmed repetitive head trauma causing functional injuries are not readily seen on standard scans. (including mechanisms of trauma that are sports

> related, domestic violence, shaken baby syndrome, electrical exposure, repeated toxic exposure, anoxia (oxygen deprived) etc.). Dr. Omalu also confirmed that neuropathology of electrical injury as well as the neuropathology of people with a history of **electroconvulsive therapy is well recognized as causing extensive functional changes to brain activity and should be considered in the context of both electrical injury and repetitive electrical trauma to the head** because natural laws governing electricity aren't changed based on the intent of medical administration. [5]

In light of Dr. Omalu's advice that ECT recipients be considered through the lens of electrical injury, "delayed electrical injury" is a reality which causes a host of severe effects (including motor neuron diseases); symptom onset ranges from 2.5-10+ years after high field electrical exposure.[6–13]

Question for state consideration:

6. What measures are currently in place to ensure court mandated ECT recipients receive treatment interventions and comprehensive support from medical providers trained in repetitive mild traumatic brain injury?
7. What measures are currently in place to ensure court mandated ECT recipients receive treatment interventions and comprehensive support necessary from medical providers trained in pulsed, high fields of electricity?

That same year, the peer-reviewed medical journal, *Anesthesiology* reported extracting data from the full-text of 82 studies involving 106,569 ECT patients and 786,995 ECT treatments. "The most commonly reported major adverse cardiac events were acute heart failure, arrhythmia, and acute pulmonary edema." Their study summary states "**Major adverse cardiac events and death after ECT** … **occur in about one in 50 patients and after about one in 200 – 500 ECT treatments.**"[14]

Question for state consideration:

8. In the event a court mandated ECT recipient develops acute heart failure, arrhythmia, or acute pulmonary edema, will the state ensure appropriate medical intervention?
9. In the event of a court mandated ECT recipient's death, what measures are in place to reduce the likelihood of that reoccurring?
10. How will the state compensate a family for losing an irreplaceable family member?

Also in 2019, Somatics, LLC published a revealing user manual update reiterating FDA warnings "The long-term safety and effectiveness of ECT treatment has not been demonstrated, and long-term follow-up may be needed." It is safe to assume that every person receiving court mandated ECT should be assessed for and provided long-term follow-up for the following serious adverse effects:

- Cardiac complications (i.e., heart attack),
- Stroke
- Cognition and memory impairment
- brain injury
- dental/oral trauma;
- general motor dysfunction;
- fractures, contusions, injury from falls, dental
- postictal delirium

- neurological symptoms movement disorders, developing a seizure disorder
- non-convulsive status epilepticus;
- pulmonary complications (i.e., aspiration/inhalation of foreign material, pneumonia, hypoxia, respiratory obstruction such as laryngospasm, pulmonary embolism, prolonged apnea);
- visual disturbance
- auditory complications; onset/exacerbation of psychiatric symptoms;
- suicide; homicidality; substance abuse;
- coma;
- device malfunction (creating potential risks such as excessive dose administration),
- death.

Additionally, extensive research discusses how pulsed high electric fields cause a permanent dysregulation of electrolytes which pass through voltage-gated ion channels. [15–27] Channelopathies are associated with neuromuscular disorders (some of which are progressive), cardiac abnormalities, migraines, seizures, exercise intolerance and other severe conditions.[25,27–34]

Question for state consideration

11. Is the state willing to track and routinely assess court mandated ECT recipients for developing symptoms of "delayed electrical injury" even if it means tracking people for decades?
12. How will the state ensure mandated ECT recipients receive comprehensive rehabilitation interventions appropriate to potential treatment consequences listed above?
13. How will the state compensate the recipient for loss of quality of life and increased morbidity following a court mandated ECT treatment in the event court mandated ECT causes electrolyte dysregulation (acquired channelopathies) or motor neuron disease from lengthy repeated exposure to pulsed, high electric fields?

2020

Two studies conducted by the US Veteran's Administration examined rates of suicide among all veterans receiving mental health services through the VA over a nine-year period. They discovered people receiving ECT were **16 times more likely to attempt suicide and 1.3x more likely to die by suicide** within a year of receiving treatment compared to veterans receiving mental health treatment without ECT.[35] They also discovered that **in the two years following ECT, people are 5.7x more likely to die by suicide**.[36] This is consistent with suicide rates for people with repeated head injuries. They concluded that **"receiving ECT represents a substantial marker for high suicide risk"**[35] **Suicide rates after ECT are higher than suicide rates in concussed individuals who are 3-4 times more likely to suicide.**[37] **Perhaps that's because ECT is a series of closely spaces repetitive intracranial traumatic brain injuries. Historically we know "each additional concussion [is] associated with a further increase in suicide risk."**[37]

Question for state consideration:

14. What suicide interventions are presently in place to protect court mandated ECT recipients from attempting and/or completing suicide?
15. In the event of suicide, how will the state compensate the family of a court mandated ECT recipient for having mandated a treatment which elevates suicide risk?

2020

Associate Director of Harvard placebo studies co-authored a meta-analysis of all available ECT randomized control placebo trials with a well-published international ECT researcher and colleague. Using Cochrane's systematic review of placebo studies and criterion specific to ECT administration, they concluded:

> The quality of most [Placebo vs–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 children and 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.** [38]

Question for state consideration:

16. Why is the state willing to mandate someone receive ECT which a medical trial expert determined its risks outweigh the benefits?

March 2021

The State of Minnesota has no routine auditing measures in place to ensure FDA's patient safety guidelines are actively followed. There is no state regulatory body auditing ECT use. This month, researchers in the United Kingdom audited the rates of ECT use across the UK based on population. They discovered some ECT providers gave ECT 47x more frequently than other ECT providers. This population-based discrepancy indicates doctors can successfully treat severe mental illness without ECT. It also indicates "the probability of getting ECT seems to be a postcode lottery based on the personal opinions of one or two local psychiatrists. Regional variation is found within other countries and also between countries."[39–41] The study also discovered deficits in routinely providing recommended assessments and an increasing use of unquantified subjective, assessments.

Questions for state consideration:

17. What measures are presently in place to routinely assess for all severe adverse effects recognized by a device manufacturer?
18. What policies must be created to prioritize and enforce the safe administration of ECT for court mandated recipients?
19. What policies must be created to ensure those injured by state mandated ECT receive comprehensive rehabilitation and support for the duration of their life after treatment?

Mandating ECT requires careful consideration of state responsibilities regarding FDA's recommended long-term follow-up. In light of growing knowledge regarding the nature of repetitive intracranial traumatic brain injury, mandating ECT in its present, unstandardized, limitless form is dangerous to the

recipient. Providing a medical treatment which ethically requires life-long care and management of potential electrical injury and repetitive brain injury symptoms is expensive. Treatment results can cause a tremendous, life-long taxpayer burden.

Though my questions and concerns may sound theoretical, I became interested in researching appropriate rehabilitation interventions for ECT recipients because I am one. Initially I experienced 36 years of dense amnesia which erased my personal autobiographical experience including my college education. The State of California's Department of Rehabilitation paid for my re-education after ECT. After obtaining my degree, and getting hired as a professor and research assistant, I began experiencing symptoms of delayed electrical injury. Today, eleven years after ECT, I live with a growing number of serious adverse effects listed in the device manual. I also live with progressive neuromuscular problems which baffles medical providers untrained in electrical injury. Only a handful of doctors understand electrical injury nationwide. Currently, I use a power wheelchair when leaving my home and a speech generating device. Life after ECT is rough. Aging is not a graceful process. I am only 45.

I live with a preventable brain injury. Most medical providers are ill equipped to treat it. Until now, repetitive electrical injuries were considered rare. ECT has yet to be formally considered in that context, but the Brain Injury Association of America (BIA) recognizes "shock" as a form or acquired Brain Injury. In the United Kingdom, Headway Foundation (their equivalent of BIA

I interact regularly with several hundred ECT recipients in online forums who seek medical providers willing to examine their injuries as Dr. Omalu recommends. ECT recipients in their 30's and 40's are being diagnosed with early-onset dementia.

Like others with repetitive brain injury, no two people have the exact same symptom manifestations, but patterns among ECT recipients are emerging which must be addressed.

Minnesota does not have a good reputation for investigating the consequences of ECT use. Last February (before COVID), a medical examiner unfamiliar with ECT's pathology concluded a young person had "sudden cardiac death in Schizophrenia," designating it a natural cause. That person died within 24 hours of receiving ECT. His independent living facility did not check on him when he fell asleep (as directed) after treatment. One staffer went their entire shift on the day of the person's death without checking on the person. Documentation for safety checks were not filled out.

I feel the death may have been prevented. Here's why:

Perhaps facility staff did not understand ECT produces a seizure so violent it silences brain activity for up to several minutes. Brain activity resumes as coma waves, from which the person awakes.[42] After starting ECT and before this person died, newspaper reports parents were unaware their child developed a seizure disorder after starting treatment. There are no regulations in place to monitor for and report known serious adverse effects. ECT providers are not mandated to inquire whether anything has changed since the previous treatment, consequently pursing treatment as frequently as three times a week—the equivalent of sending a recently concussed NFL player back onto the field without proper evaluation. The FDA has no safety protocols in place to immediately suspend treatment in the event a ECT recipient developing severe adverse effects.

Making matters even worse, The Minnesota Department of Health's Office of the Inspector General reported that "During the course of the investigation, we determined that … violations occurred...

However, 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."[43]

Question for state consideration:

20. What state policies will prevent future violations resulting in an ECT recipient's death?

Conclusion

Governor Walz, I appreciate in advance your consideration of grave concerns regarding mandated ECT treatment. In 2008, a report from the United Nations entitled "Torture and other cruel, inhuman or degrading treatment or punishment" stated "it is of vital importance that ECT be administered only with the free and informed consent of the person concerned, including based on information on the secondary effects and related risks such as heart complications, confusion, loss of memory and even death."[44]

It is evident Charles Helmer does not consent to ECT. Now you understand why. He has the capacity to raise his valid concerns about risk benefit ratio with others. His insight into potential problems caused by ECT motivated him to seek outside support from a network of individuals familiar with ECT's immediate and long-term consequences. Each subsequent court mandated treatment he is at greater risk of suicide and future neurodegenerative diseases.[45]

Each person receiving Electroconvulsive therapy—especially those receiving court-mandated ECT—must weigh long-term consequences of treatment with 4-8 day symptom reprieve typical in those who do not respond to medication.[46] Long-term risks (and cost of care) outweigh short-term benefits.

I respectfully request the state carefully consider my 20 questions when evaluating risk benefit ratio associated with court mandated ECT and its impact on life after ECT. Information presented in this letter is intended to augment your understanding of Mr. Helmer's treatment concerns.

Please take action to prioritize patient safety by implementing policy which reflects emerging data on a medical treatment with no acknowledged safety testing or dosing protocols on record with the FDA.

Respectfully,

Sarah Price Hancock, MS, CRC

Author of the patient safety petition to "Standardize, Regulate & Audit Shock Treatments (Electroconvulsive therapy or ECT)" (nearly 12,500 signatures and counting)

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