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Supreme Court of California
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No. S273887

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

MICHELLE HIMES
Plaintiff-Appellant
v.

SOMATICS, LLC
Defendant-Respondent

On Request from the U.S. Court of Appeals for the Ninth Circuit
for Answer to Certified Questions of California Law

APPLICATION FOR PERMISSION TO FILE *AMICUS CURIAE* BRIEF IN SUPPORT OF NEITHER PARTY; *AMICUS CURIAE* BRIEF OF AMERICAN PSYCHIATRIC ASSOCIATION

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November 18, 2022

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APPLICATION FOR PERMISSION TO FILE BRIEF *AMICUS CURIAE*

Pursuant to Rule 8.520(f) of the Rules of Court, the American Psychiatric Association ("APA") respectfully requests permission to file the attached *amicus curiae* brief, in support of neither party, to provide pertinent information to the Court and to correct misstatements of the Plaintiff-Appellant regarding electroconvulsive therapy. APA is a national medical specialty society representing more than 37,000 psychiatric physicians and their patients.

APA seeks permission to file the accompanying brief in support of its goal to promote safe and effective treatment for all those affected by mental health disorders.

More broadly, no party, counsel for a party, or judicial member drafted this brief or participated in the decision to file this brief. Other than APA and its members, no person or entity, including any party or party's counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

Dated: November 18, 2022 Respectfully submitted,

/s/ Reid M. Figel

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AMICUS CURIAE BRIEF

INTRODUCTION AND STATEMENT OF INTEREST

Amicus American Psychiatric Association ("APA"), with more than 37,000 members, is the nation's leading organization of physicians who specialize in psychiatry. Its member physicians work to ensure high-quality care and effective treatment for all persons with mental health disorders. Association members engage in psychiatric treatment, education, research, and forensic activities, and many of them regularly treat patients with serious mental illness.

APA has participated as *amicus* in many cases involving mental health issues. APA and many of its members have substantial knowledge and experience relevant to electroconvulsive therapy ("ECT"), its clinical uses, the potential risks and side effects associated with ECT, and the manner in which physicians obtain informed consent from patients for its use.

A large body of scientific evidence demonstrates that ECT is a safe and effective treatment for certain serious mental illnesses. Indeed, ECT can be lifesaving: in some cases, it is both more effective and faster acting than other treatment options.

Plaintiff's briefing provides an inaccurate and unscientific description of ECT and its potential risks and benefits, while also distorting the role of treating physicians in obtaining the informed consent of patients to the administration of ECT. Because accurate information about these issues may importantly inform this Court's resolution of the question referred by the Court of Appeals, APA files this brief to provide the latest scientific and medical consensus on these issues.

ARGUMENT

I. ECT is an Important and Effective Treatment for Several Severe Mental Health Conditions

A. Scientific Evidence Demonstrates that ECT Can Be an Effective Treatment, Particularly When Other Treatments Fail

Extensive scientific evidence shows that ECT is an effective treatment for major depression and catatonia.[1] *See* Richard D. Weiner,

[1] *See* Julian Mutz et al., *Comparative Efficacy and Acceptability of Non-Surgical Brain Stimulation for The Acute Treatment of Major Depressive Episodes In Adults: Systematic Review and Network Meta-Analysis*, BMJ, Mar. 2019, https://bit.ly/3X5YUVd; Peter Giacobbe et al., *Improvements in Health-Related Quality of Life With Electroconvulsive Therapy: A Meta-analysis*, 34 J. ECT 87-94 (June 2018); Federica Luchini et al., *Electroconvulsive Therapy in Catatonic Patients: Efficacy and Predictors of Relapse*, 5 World J. Psychiatry 182-192 (2015), https://bit.ly/3UWiWj0. Catatonia is a psychomotor

The Practice of Electroconvulsive Therapy 327 (2001). The efficacy of ECT has been documented in a substantial body of research going back to the 1940s. *See* Charles H. Kellner, *Handbook of ECT: A Guide to Electroconvulsive Therapy for Practitioners*, at ix (2019) ("ECT has a remarkable track record of safety and efficacy, and a large scientific evidence base to support it."). Notably, the U.S. Food and Drug Administration ("FDA") has determined that there is sufficient evidence for the safety and effectiveness of ECT for treatment of major depressive episodes and catatonia for individuals age thirteen and older. 83 Fed. Reg. 66,103 (2018).

Meta-analysis of the efficacy of ECT in treatment of severe depression in patients who have not responded to medications shows "significant superiority of ECT" in comparison with trials of antidepressant drugs. Kellner, *supra*, at 13. This benefit of ECT is significant, both because the failure to respond to medications is common and because the burden of untreated depression is substantial

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syndrome that occurs in patients with acute psychiatric illnesses and is most commonly characterized by immobility and mutism. *See* Sean A. Rasmussen et al., *Catatonia: Our Current Understanding of its Diagnosis, Treatment and Pathophysiology*, 6 World J. Psychiatry 391-98 (2016), https://bit.ly/3gfUn1N.

– including risk of death (mainly due to cardiovascular events and suicide).[2] The data thus "suggest that ECT is a valid therapeutic tool in the armamentarium for depression, including severe and resistant forms." *Id.* at 20. ECT also shows particular efficacy in individuals with severe depression that is accompanied by psychosis.[3] Additionally, ECT can be fast acting as compared to treatment with medication; it is common for symptoms of major depression to improve significantly after only a few ECT treatments.[4] ECT has also been successfully used to treat other conditions, such as primary psychotic disorders (*e.g.*, schizophrenia) and episodes of mania in bipolar disorder.[5]

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[2] *See* Charles Welch et al., *Electroconvulsive Therapy*, *in Massachusetts General Hospital Comprehensive Clinical Psychiatry* 433-40 (6th ed. 2010).

[3] *See* Linda van Diermen et al., *Prediction of Electroconvulsive Therapy Response and Remission in Major Depression: Meta-Analysis*, 212 British J. Psychiatry 71-80 (Feb. 2018), https://bit.ly/3US0t7k; Linda van Diermen et al., *Erratum*, 212 British J. Psychiatry 322 (May 2018), https://pubmed.ncbi.nlm.nih.gov/29436330/.

[4] Mustafa M. Husain et al., *Speed of Response and Remission in Major Depressive Disorder With Acute Electroconvulsive Therapy (ECT): A Consortium for Research In ECT (CORE) Report*, 65 J. Clin. Psychiatry 485-91 (May 2004), https://bit.ly/3EeS4E6.

[5] *See*, *e.g.*, Sani A. Ali et al., *Electroconvulsive Therapy and Schizophrenia: A Systematic Review*, 5 Molecular Neuropsychiatry 75-83 (Apr. 2019), https://bit.ly/3EaP2kh; Alby Elias et al.,

Because of its swiftness and efficacy, ECT can be lifesaving in serious cases (*e.g.*, those involving acute suicide risks). *See* Weiner, *supra*, at 327 ("When patients have life-threatening psychiatric problems, such as suicidal tendencies, ECT is . . . often recommended because it usually provides faster relief than medications."); 83 Fed. Reg. at 66,106 (noting ECT's benefits "for patients who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition"). Most studies show suicidal ideas or behaviors decrease with ECT treatment.[6]

B. Patients and Physicians Must Weigh Potential Side Effects of ECT – Including Cognitive Side Effects – Against Treatment Benefits

As with any medical treatment, ECT carries a risk of side effects. Accordingly, a clinician's decision to recommend ECT is always based on a risk/benefit analysis. As part of that calculus, the risks of ECT treatment are weighed against the benefits of ECT treatment not only relative to non-treatment but also relative to other available

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Electroconvulsive Therapy in Mania: A Review of 80 Years of Clinical Experience, 178 Am. J. Psychiatry 229-39 (Mar. 2021).

[6] *See* Mehmet Utku Kucuker et al., *A Systematic Review of Neuromodulation Treatment Effects on Suicidality*, Front Human Neuroscience, June 2021, https://bit.ly/3tB3Qny.

treatments, including medications. In this regard, when ECT is prescribed, it is generally when a rapid response is needed due to severe symptoms or when other treatment options have failed (often repeatedly).

Serious adverse events – including severe cardiovascular and pulmonary complications or death – are rare.[7] *See* Weiner, *supra*, at 59 ("The rate of mortality attributed to ECT is estimated to be approximately the same as that associated with minor surgery or . . . childbirth."). Longitudinal studies have shown that mortality rates following hospitalization are lower among depressed patients treated with ECT than among patients who received other treatments, or who received no treatment at all. *Id.*

Demonstrable cognitive side effects may occur with ECT treatment and are variable in seriousness, ranging from mild to severe.[8] Most patients will have a brief period of confusion and disorientation

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[7] *See* N. Torring et al., *The Mortality Rate of Electroconvulsive Therapy: A Systematic Review and Pooled Analysis*, 135 Acta Psychiatrica Scandinavica 388 (2017) (finding an ECT-related mortality rate of 2.1 deaths per 100,000 treatments).

[8] ECT can also commonly cause physical side effects such as headaches, nausea, and muscle soreness.

while awakening from the procedure. Loss of memories of events or conversations that occur around the time of treatment is also common, but generally does not last for more than a few weeks after treatment. *See id.* at 329. Gaps in memories from weeks or months before the treatment can also occur. *Id.* This type of memory loss typically diminishes as the time since ECT increases, but in some cases the memory loss can be persistent or permanent. *Id.* at 71-72. However, ECT does not appear to result in lasting impairment of other cognitive functions. *Id.* at 70.

C. Ethical and Legal Standards Require Obtaining Patients' Informed Consent Before Administering ECT

Clinicians are trained to respect patient autonomy and the principle of informed consent. As with any medical procedure (especially one that includes general anesthesia), informed consent is required before ECT is administered. *See* John L. Beyer & Mehul V. Mankad, *Patient Referral and Evaluation*, *in Clinical Manual of Electroconvulsive Therapy* 38 (2010). If a patient lacks capacity to consent to treatment, informed consent can only be obtained as specified via applicable law. *Id.* at 41. While specific regulations

concerning the informed consent process vary from state to state, it includes providing information about: (1) the benefits of treatment (including potential duration of effect); (2) the risks of treatment; and (3) alternatives to ECT. *Id.* at 39.

Clinicians make a recommendation for ECT based on an overall assessment of risks and benefits, informed by education, training, and clinical expertise. Ultimately, however, the judgment about whether to undergo ECT is made by the patient or the patient's authorized legal representative.

D. Portrayal of ECT As Cruel or Inhumane Is Inconsistent with Modern ECT Practice

Early, now-outdated ECT techniques and practices, along with media portrayals, contribute to a stigma around ECT despite modern advances in its application. Prior to the emergence of ECT in the 1930s, psychiatric patients had few effective treatment options. Psychotherapy was the main treatment for outpatients, but "little more than custodial care or prevention of harm could be done for the most severe cases, which required inpatient management." John L. Beyer, *History of Electroconvulsive Therapy*, *in Clinical Manual of Electroconvulsive Therapy* 3 (2010). There were attempts to identify

somatic therapies, but most were ineffective (*e.g.*, hydrotherapy with cold packs, insulin comas, and prolonged sleep therapy). *Id.* With the development of ECT in the late 1930s, there was suddenly an effective, reliable treatment for serious psychiatric illnesses. *Id.* at 5. Despite its side effects, ECT quickly became the dominant somatic treatment for schizophrenia and other major mood disorders. *Id.*

In the mid-1950s, with the increasing availability of antidepressant and antipsychotic medications, the use of ECT began to decline and continued to decline for many years.[9] *Id.* Another likely contributing factor for the continuing decline in the use of ECT was a number of highly negative media portrayals, including the film *One Flew Over the Cuckoo's Nest*.[10]

ECT treatments from that early era bear little resemblance to modern practice. For example, while ECT was frequently administered

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[9] *See also* Haroutun M. Babigian et al., *Epidemiologic Considerations in Electroconvulsive Therapy*, 41 Arch Gen Psychiatry 246-53 (Mar. 1984); Edward Shorter & David Healy, *Shock Therapy: A History of Electroconvulsive Treatment in Mental Illness* (2007).

[10] *See* Steven M. Jenkusky, *Public Perceptions of Electroconvulsive Therapy: A Historical Review*, 10 Jefferson J. Psychiatry 2-11 (June 1992), https://bit.ly/3TBEQqM; Andrew McDonald & Gary Walter, *The Portrayal of ECT in American Movies*, 17 J. ECT 264-74 (2001).

without anesthesia when it was first introduced, the use of anesthesia has now been common for decades. *Id*. at 6. Today, ECT is administered using general anesthesia, precisely controlled electrical stimulation, and physiological monitoring (*e.g*., seizure monitoring, blood pressure monitoring, electrocardiograms, and oxygenation monitoring) to achieve the greatest benefits with the least possible risk. *Id.*

Major technical advances have also occurred in instrumentation, with the present generation of ECT devices incorporating decades of research and refinements. ECT devices marketed in the United States in recent decades are largely standardized; they have had similar technical parameters, including constant current output, impedance monitoring, and maximum charge settings, and they are designed to only deliver brief or ultrabrief pulse stimuli (not sine wave stimuli). *See* Richard D. Weiner, *Basics*, *in Clinical Manual of Electroconvulsive Therapy* 54-55 (2010).

The FDA recently undertook a careful examination of regulations applicable to ECT devices. In particular, the FDA reclassified ECT devices for use in treating catatonia or major depressive episodes

associated with major depressive disorder and bipolar disorder from Class III devices – which are higher risk and require pre-market approval ("PMA") – to Class II devices – which are moderate risk and do not.[11] The FDA determined that reclassification was justified because Class II controls (like labeling) could provide reasonable assurance of ECT's safety and effectiveness for patients age thirteen years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. 83 Fed. Reg. at 66,103. In doing so, the FDA observed that the "majority of [published] studies reported the safe use of ECT with minimal and reversible adverse events," *id.* at 66,107, and that "ECT in the indicated populations provides a treatment option for serious diseases where other treatments are less or minimally effective." *Id.* at 66,108.

Overall, improvements and innovations in ECT techniques have contributed to a growing acceptance of ECT by both practitioners and

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[11] *See* U.S. Food & Drug Admin., *FDA In Brief: FDA Takes Action to Ensure Regulation of Electroconvulsive Therapy Devices Better Protects Patients, Reflects Current Understanding of Safety and Effectiveness* (Dec. 21, 2018), https://bit.ly/3UPfsPW. Because ECT devices were in commercial distribution before 1976, they were automatically classified as Class III devices, but were not required to submit PMA applications. *Id.*

patients.[12] Epidemiological evidence of favorable patient outcomes supports the use of ECT, with informed consent, in the treatment of serious psychiatric disorders.

CONCLUSION

The Court should answer the referred question in a manner that avoids jeopardizing patient access to ECT where medically indicated.

[12] *See* Kitty Dukakis & Larry Tye, *Shock: The Healing Power of Electroconvulsive Therapy* (2006); Trine Munk-Olsen et al., *Electroconvulsive Therapy: Predictors and Trends in Utilization from 1976 to 2000*, 22 J. ECT 127-32 (June 2006).

Dated: November 18, 2022 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE PURSUANT TO CALIFORNIA RULES OF COURT 8.204 AND 8.520

Pursuant to California Rules of Court 8.204 and 8.520(b) and (c), and in reliance upon the word count feature of the software used to prepare this document, I certify that the foregoing Amicus Brief of the American Psychiatric Association contains 2,209 words, exclusive of those materials not required to be counted under Rule 8.520(c)(3).

Dated: November 18, 2022

/s/ *Reid M. Figel*
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DECLARATION OF ELECTRONIC SERVICE

On November 18,2022, I served the foregoing document described as **APPLICATION FOR PERMISSION TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF NEITHER PARTY; AMICUS CURIAE BRIEF OF AMERICAN PSYCHIATRIC ASSOCIATION** on the interested parties in this action by sending a true and correct copy addressed to each through TrueFiling, the electronic filing portal of the California Supreme Court, pursuant to Local Rules, which will send notification of such filing to the email address denoted on the case's Electronic Service List.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed at Washington, D.C. on November 18, 2022.

/s/ Reid M. Figel
Reid M. Figel, *counsel of record*

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STATE OF CALIFORNIA
Supreme Court of California

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

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