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ELECTROCONVULSIVE THERAPY: BABY BOOMERS MAY BE IN FOR THE SHOCK OF THEIR LIVES

Helia Garrido Hull*

“Well, what is the sense of ruining my head and erasing my memory, which is my capital, and putting me out of business? It was a brilliant cure but we lost the patient.”¹

I. INTRODUCTION

Following the death of her husband, the onset of age-related medical complications, and the stark realization that she was no longer self-sufficient, Mary slipped into a deep state of depression. She stopped eating and emotionally withdrew from her environment. Fearing that Mary posed a risk to herself, her daughter reluctantly committed Mary to a psychiatric facility for evaluation. Mary’s condition worsened as her mind failed to respond to the daily pharmacological cocktail administered to her.

After a brief consultation with her nurse practitioner, Mary agreed to sign a document authorizing the use of electroconvulsive therapy (ECT) to treat her depression. Sensing her fear of the treatment, the nurse gave Mary tranquilizers to help her fall asleep. The following morning, Mary awakes to find her bed in another room. Two staff members reach underneath Mary and lift her onto a padded bed. A nurse places an oxygen mask over Mary’s nose, and another

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¹ See Leonard Roy Frank, *Electroshock: Death, Brain Damage, Memory Loss, and Brainwashing*, 11 J. MIND & BEHAV. 489, 508 (1990) (citing statement made by Ernest Hemingway to an interviewer at the Mayo Clinic, where Hemingway received involuntary shock therapy and subsequently killed himself with a shotgun).

staff member places straps around her wrists and ties them tight to the sides of the bed. A few moments later, a nurse injects atropine into Mary's vein to prevent Mary from suffocating from the physiological insult her body is about to experience. A moment later, the nurse returns and begins applying electroconductive jelly to the top of Mary's head to protect her scalp from electrical burns that could result from the massive jolt of electricity racing through her head. The nurse places one electrode on Mary's right temporal lobe and then another on the top of Mary's head. Mary starts to fall asleep as the nurse administers barbiturates² intravenously. Once unconscious, Mary is injected with succinylcholine to temporarily paralyze her muscles and reduce the risk of physical injury that could result from the convulsions she is about to experience. Virtually paralyzed, Mary is given oxygen from a mask. A flexible piece of rubber is inserted into her mouth to prevent tooth fracture or jaw injury when her jaw muscles contract from the shock. With the push of a button, a pulse of electricity races through Mary's brain and induces a seizure. Her body convulses, her muscles contract, and her jaw clamps down, but Mary feels no pain because she is unconscious. In less than a minute, it is over.

Thirty minutes later, Mary awakens and feels disoriented. She complains of headaches and nausea. Her skin appears blue, and she feels her heartbeat race as she struggles to breathe. Her caregivers discount her concerns and tell her that she will feel better in the morning after some rest. The following morning, Mary appears engaged and shows signs of recovery from her depression. She complains, however, that she cannot remember anything that happened the day before. Again, she is informed that she has nothing to worry about and that her memory will return in a few days or weeks. Encouraged by what they view as progress, Mary's doctors encourage her to repeat the procedure eleven more times over the next four weeks. With each administration, Mary appears more focused. Ostensibly she is improving, but Mary senses something is wrong.

After completing a routine course of ECT treatment, Mary is visited by her daughter. Mary seems distant, almost disinterested in her daughter's presence. Her daughter hands her a picture of a young woman wrapped in the arms of a decorated veteran, but Mary stares blankly. She is handed a picture of two

² Barbiturates are a class of sedative-hypnotic agents derived from barbituric acid or thiobarbituric acid and commonly used as intravenous anesthetics or anticonvulsants. *See, e.g.*, Dorland's Medical Dictionary for Healthcare Consumers, http://www.mercksource.com/pp/us/cns/cns_hl_dorlands_split.jsp?pg=/ppdocs/us/common/dorlands/dorland/one/000011649.htm (last visited Feb. 5, 2009).

precocious teenagers marching for civil rights and suddenly recognizes herself but not the other girl. Her daughter then hands her a picture of a baby in a white baptism gown and asks if Mary remembers the ceremony. Mary stares at the image for several moments and realizes that she does not remember. A tear trickles down her cheek as she realizes that she no longer remembers precious moments that have defined her life.³

Mary's experience is not unlike that of many individuals who have survived ECT.⁴ Convinced by medical professionals that ECT is a safe and effective way to treat depression and other mental illnesses,⁵ each year thousands of individuals undergo treatment⁶ after signing consent forms that suggest they have been fully apprised of the risks and benefits of ECT.⁷ Like Mary, many individuals find out too late that the risks of ECT often outweigh its benefits.⁸ Sadly, for many, the damage caused by ECT is permanent.⁹

Depression in the elderly is an increasingly acute public health concern. More than 6.5 million Americans sixty-five years of age or older suffer from depression.¹⁰ The World Health Organization estimates that, at current rates, depression will be the second most common cause of disability worldwide by 2020.¹¹ Older individuals face dramatic life changes, such as the death of a spouse or loss of independence due to age-related medical complications, that

³ Although Mary is a fictitious person, many individuals who have been administered ECT have reported similar memory loss as a result of receiving ECT. See generally The Committee for Truth in Psychiatry, http://www.ect.org/ctip_about.shtml (last visited Jan. 13, 2009). This is a group of 500 survivors of ECT who have suffered memory loss as a result of treatment.

⁴ *Id.*

⁵ The APA Task Force on Electroconvulsive Therapy, *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging* app. B, <http://www.ect.org/resources/apatask.html> (last visited Jan. 13, 2009).

⁶ RICHARD ABRAMS, *ELECTROCONVULSIVE THERAPY* 9 (3d ed. 1997).

⁷ The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

⁸ The Committee for Truth in Psychiatry, *supra* note 3.

⁹ *Id.*

¹⁰ Nat'l Alliance of Mental Illness, *Depression in Older Persons: What is Depression?*, http://www.nami.org/Content/ContentGroups/Helpline1/Depression_In_Older_Persons.htm (last visited Jan. 13, 2009); see also Dennis S. Charney et al., *Depression and Bipolar Support Alliance Consensus Statement on the Unmet Needs in Diagnosis and Treatment of Mood Disorders in Late Life*, 60 ARCHIVES GEN. PSYCHIATRY 664, 664 (2003) (noting that depression in the elderly is a growing public health problem).

¹¹ Catherine M. Michaud et al., *Burden of Disease—Implications for Future Research*, 285 JAMA 535, 537–38 (2001).

may lead to depression.¹² Late-life depression contributes to personal suffering, distress, and impairments in physical, mental, and social functioning.¹³ Depression is also a leading cause of disability, mortality, and suicide in elderly adults.¹⁴ The incidence of depression in the elderly as a group is expected to increase substantially over the next decade as baby boomers settle into retirement.¹⁵ In 2011, the oldest of the 78.2 million baby boomers, the generation born between 1946 and 1964, will turn sixty-five years old.¹⁶

Despite its prevalence, depression in the elderly often goes undiagnosed and untreated.¹⁷ This is because detection is rendered difficult by the different clinical presentation of older adults.¹⁸ For example, both age-related and pathological cognitive decline impact the effective identification and assessment of mental illness in late life.¹⁹ Often the signs and symptoms of age-related afflictions mask evidence of major depression in the elderly.²⁰

Electroconvulsive therapy has a long, but not entirely honorable, history in the treatment of psychiatric conditions, including late-life depression in the elderly.²¹ As a group, the elderly have historically constituted a particularly high proportion of the patients who receive ECT.²² Although there is currently no federal reporting requirement for the administration of ECT, the most recent studies show that the use of ECT on elderly patients with mood disorders may

¹² U.S. Dep't of Health & Human Servs., *Mental Health: A Report of the Surgeon General, Depression in Older Adults*, <http://www.surgeongeneral.gov/library/mentalhealth/chapter5/sec3.html> (last visited Jan. 13, 2009).

¹³ *Id.*

¹⁴ John L. Beyer, *Managing Depression in Geriatric Populations*, 19 ANNALS CLINICAL PSYCHIATRY 221, 224-25 (2007).

¹⁵ Depression has been reported to be more common among the baby boomers than it is among those born before World War II. See Nat'l Alliance of Mental Illness, *supra* note 10.

¹⁶ U.S. Census Bureau, *Oldest Baby Boomers Turn 60!*, Jan. 3, 2006, http://www.census.gov/PressRelease/www/releases/archives/facts_for_features_special_editions/006105.html (last visited Jan. 13, 2009).

¹⁷ Charney et al., *supra* note 10, at 664-65.

¹⁸ U.S. Dep't of Health & Human Servs., *Mental Health: A Report of the Surgeon General, Overview of Mental Disorders in Older Adults*, <http://www.surgeongeneral.gov/library/mentalhealth/chapter5/sec2.html> (last visited Jan. 13, 2009).

¹⁹ *Id.*

²⁰ U.S. Dep't of Health & Human Servs., *supra* note 12.

²¹ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *THE PRACTICE OF ELECTROCONVULSIVE THERAPY: RECOMMENDATIONS FOR TREATMENT, TRAINING, AND PRIVILEGING* 42 (2d ed. 2001).

²² *Id.* (noting that the resurgence in ECT use in the United States between 1980 and 1986 was "fully attributable to its greater use in elderly patients").

be as high as five times that of younger patients with the same disorders.²³ Psychiatrists have identified age-related resistance to pharmacotherapy as the primary justification for the increased use of ECT in elderly patients.²⁴ However, despite forty-five years of use, the efficacy of ECT remains a subject of intense debate within the medical profession and among patients who have received ECT. Anecdotal evidence from patients and conflicting medical research regarding the risks and benefits of ECT raise new concerns regarding elderly patients' right to be fully informed of the true risks and benefits of undergoing ECT.

This Article examines the use of ECT on the elderly and concludes that most elderly patients who undergo the procedure are not fully informed of its consequences.

Section II provides a brief discussion of the development and utilization of ECT, with emphasis on its use on elderly patients. Section III discusses the scientific chasm that exists in the literature regarding the efficacy of ECT and also discusses the elevated risk elderly patients face when subjected to ECT. Section IV evaluates the requirement of informed consent and the problems inherent in the administration of ECT to the elderly.

Section V examines an American Psychiatric Association-approved informed consent form utilized by psychiatrists and provides commentary on the limitations of the forms for use with elderly patients. Section VI offers recommendations for change.

II. DEVELOPMENT AND USE OF ECT

A. *Background*

The use of electrical current as a therapy to treat illness dates back to 46 A.D., when Scribonius Largus described the healing powers of standing in water near a fish capable of producing an electric discharge.²⁵ As court physician to Emperor Claudius of Rome, Largus used an electric eel to treat the

²³ *Id.* (citing a 1986 study that found that 15.6% of patients with mood disorders received ECT if they were over sixty-five years of age, whereas the rate was 3.4% among younger patients with the same disorders).

²⁴ *Id.* at 43.

²⁵ History of ECT, *Early History*, <http://www.ect.org/resources/history/frank1.gif> (last visited Jan. 13, 2009).

emperor's headaches.²⁶ Throughout early history, electrical current was employed to cure mental illness believed to be caused by the devil.²⁷ Modern use of physiological shock to treat mental illness has its roots in a belief that such illness is caused by "pathological alterations of the brain, chemical or structural."²⁸ In 1932, Ladislaus von Meduna observed a marked increase in the growth of glial cells in the brains of epileptic patients compared to no growth in schizophrenic patients.²⁹ Meduna believed that a "biological antagonism" existed between epilepsy and schizophrenia, and he hypothesized that the chemical induction of grand mal seizures could cure schizophrenia.³⁰ In 1934, Meduna chemically induced a seizure in a schizophrenic patient who had been in a catatonic state for four years. The patient experienced an epileptic attack so severe that the sight of it nearly caused Meduna to faint.³¹ Meduna reported that after the patient underwent a short series of chemically induced seizures, the patient fully recovered from his psychosis.³² Meduna later repeated the process on twenty-six patients, only half of whom experienced a change in condition.³³ Despite his limited success, Meduna's therapeutic approach spread quickly throughout Europe.³⁴ Soon, however, it became clear that while chemically induced convulsions were useful for the treatment of schizophrenia, the practice was too dangerous and uncontrollable to be applied in all settings.³⁵

In the early 1930s, Italian neurologist Ugo Cerletti conducted groundbreaking research with animals on the "neuropathological consequences of repeated epilepsy attacks."³⁶ He "used a[n] electroshock apparatus to provoke repeatable, reliable epileptic fits in dogs and other animals."³⁷ After observing anesthetized pigs in a comatose state that were given electrical shocks before being butchered, Cerletti endeavored to develop electrical

²⁶ S. Brandon, *The History of Shock Treatment*, in *ELECTROCONVULSIVE THERAPY: AN APPRAISAL* 3-10 (Robert L. Palmer ed., 1981).

²⁷ History of ECT, *supra* note 25.

²⁸ Renato M.E. Sabbatini, *The History of Shock Therapy in Psychiatry*, http://www.cerebromente.org.br/n04/historia/shock_i.htm (last visited Jan. 13, 2009).

²⁹ ABRAMS, *supra* note 6, at 5.

³⁰ *Id.* at 4-5.

³¹ *Id.* at 5.

³² *Id.*

³³ *Id.*

³⁴ *Id.* at 6.

³⁵ *Id.*

³⁶ Sabbatini, *supra* note 28.

³⁷ *Id.*

stimulus parameters that could be used to induce therapeutic convulsions safely and effectively in humans.³⁸

In 1938, Cerletti and Italian psychiatrist Lucio Bini used ECT for the first time on a thirty-nine-year-old unidentified homeless man.³⁹ The first administration of electrical current failed to produce a convulsion.⁴⁰ A few days later, a second attempt was made to induce a convulsion in the patient. Against the man's protestation—"Not again, it's murderous"—Cerletti and Bini shocked the patient again with current sufficient to induce a convulsion.⁴¹ According to Cerletti, after awakening,

[t]he patient sat up of his own accord, looked about him calmly with a vague smile, as though asking what was expected of him. I asked him: "What has been happening to you?" He answered, with no more gibberish: "I don't know; perhaps I have been asleep."⁴²

Cerletti and Bini later reported that following a course of eleven ECT sessions, the patient experienced a full recovery.⁴³ Because ECT provoked retrograde amnesia, their patients suffered loss of all memory of the events immediately prior to the shock.⁴⁴ Therefore, their patients offered no negative feelings towards the therapy.⁴⁵ By demonstrating an ability to reliably and inexpensively induce what appeared to be therapeutic convulsions in humans, Cerletti and Bini ushered in a new era of psychiatric care.⁴⁶ Although initially introduced to treat schizophrenia, psychiatrists quickly expanded ECT's use in patients with mood disorders, including depression.⁴⁷ Despite its experimental nature and the absence of any studies regarding its efficacy, by 1940 ECT was quickly becoming the therapy of choice in hospitals and asylums throughout the world.⁴⁸

³⁸ ABRAMS, *supra* note 6, at 6.

³⁹ *Id.*

⁴⁰ *Id.* at 6-7.

⁴¹ *Id.* at 7.

⁴² *Id.*

⁴³ Sabbatini, *supra* note 28 (noting that other patients who experienced ten to twenty ECT sessions appeared to show similar improvement).

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ ABRAMS, *supra* note 6, at 7.

⁴⁷ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 8.

⁴⁸ Sabbatini, *supra* note 28.

ECT is the passage of electric current, usually from temple to temple, through the frontal lobes for the purpose of inducing “therapeutic” grand mal convulsions.⁴⁹ The procedure of ECT has changed since its introduction. Fractures, joint dislocations, respiratory problems, circulatory problems, and damage to skeletal muscles, tendons, and ligaments were common side effects from ECT before modifications.⁵⁰ Anesthetics, muscle relaxants, and oxygenation have been introduced to the procedure over time in an attempt to relax the body prior to electrical stimulation.⁵¹ Psychiatrists also experimented with electrode placement on the head in an effort to identify the optimal placement.⁵² Today, use of ECT without modification is rare in the developed world, but the practice is still used in developing nations because of its reduced cost.⁵³

The first administration of ECT in the United States occurred in 1940 at Columbus Hospital in New York City.⁵⁴ Throughout the 1940s and 1950s, ECT was most often administered to the severely disturbed patients residing in large mental institutions.⁵⁵ As a direct result of movements in the United States against institutionalized psychiatry in the 1960s and 1970s, however, the use of ECT declined.⁵⁶ Part of the resistance to ECT was predicated on the lack of evidence regarding its efficacy, and part was the result of institutional misuse of ECT as a means of controlling unruly patients.⁵⁷ The development of new psychopharmacologic medications in the mid-1970s also contributed to the decline in ECT use.⁵⁸ However, that decline ended in the 1980s, primarily as a result of ECT’s increased utilization in treating elderly patients with mental disorders.⁵⁹ Today, approximately 100,000 patients are treated with ECT in the

⁴⁹ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 150-53.

⁵⁰ Leonard Roy Frank, *The Electroshock Quotionary* 3-4 (2006), http://www.endofshock.com/102C_ECT.PDF.

⁵¹ *Id.*; see also Edward Shorter, *The History of ECT: Some Unsolved Mysteries*, PSYCHIATRIC TIMES, Feb. 1, 2004, at 95, available at <http://www.psychiatrictimes.com/display/article/10168/47006?pageNumber=3>.

⁵² Shorter, *supra* note 51.

⁵³ Frank, *supra* note 50, at 3.

⁵⁴ ABRAMS, *supra* note 6, at 8.

⁵⁵ Nat’l Inst. of Mental Health Consensus Conf., *Electroconvulsive Therapy*, 254 JAMA 2103, 2103 (1985).

⁵⁶ Sabbatini, *supra* note 28.

⁵⁷ Nat’l Inst. of Mental Health Consensus Conf., *supra* note 55.

⁵⁸ Sabbatini, *supra* note 28.

⁵⁹ ABRAMS, *supra* note 6, at 9; James W. Thompson et al., *Use of ECT in the United States in 1975, 1980, and 1986*, 151 AM. J. PSYCHIATRY 1657, 1659.

United States each year.⁶⁰ Because ECT is used in virtually every country of the world, it is estimated that between one and two million patients per year receive ECT.⁶¹ Strikingly, recipients continue to be primarily older white patients in private institutions.⁶²

B. Use of ECT in Elderly Populations

Although state and national agencies collect annual data on mental health, very little information is collected on the utilization of ECT. There is no federal reporting requirement for ECT, and only six states currently require some level of ECT reporting.⁶³ Most of those data, however, are unpublished. As a result, accurate statistics regarding the use of ECT in the United States are impossible to obtain, but data that are publicly available show that ECT remains a commonly prescribed treatment for the elderly.⁶⁴ In California, between 1989 and 1994 approximately half of all patients receiving ECT were sixty-five years of age or older.⁶⁵ A 1996 study from Vermont revealed that 58% of patients receiving ECT were at least sixty-five years of age, and 20% were at least eighty years of age.⁶⁶ A 2006 annual report of ECT administration in Texas revealed that 24% of patients receiving ECT were sixty-five years of age or older and that 5% were at least eighty years of age. Three patients were at least ninety years old.⁶⁷ Data from Canada also show that ECT is commonly administered to the elderly. In Ontario's provincial psychiatric hospitals, ECT

⁶⁰ ABRAMS, *supra* note 6, at 9.

⁶¹ *Id.*

⁶² Thompson et al., *supra* note 59; see also Worrawat Chanpattana, *A Questionnaire Survey of ECT Practice in Australia*, 23 J. ECT 89, 89 (2007) (noting that patients who received ECT in Australia were in an age group older than sixty-five years (38.4%), followed by forty-five to sixty-four years (28.3%), twenty-five to forty-four years (26.3%), eighteen to twenty-four years (6.9%), and less than eighteen years (0.2%)).

⁶³ Juli Lawrence, Paper Presented at 2001 Mental Health Statistics Conference: ECT Reporting—The Statistical Gap (July 24, 2006), available at <http://www.ect.org/paper-on-ect-statistics-at-mh-stats-conference>.

⁶⁴ Mark J. Rapoport et al., *Electroconvulsive Therapy in Older Adults: 13-Year Trends*, 51 CAN. J. PSYCHIATRY 616, 618 (2006).

⁶⁵ Cal. Dep't of Mental Health, <http://www.ect.org/resources/castats.html>.

⁶⁶ See Peter R. Breggin, *Electroshock: Scientific, Ethical, and Political Issues*, 11 INT'L J. RISK & SAFETY MED. 5, 6 (1998) (reporting on a personal communication from W. Sullivan, Executive Director of the Vermont Protection and Advocacy Agency in Montpelier, Vermont, with data from the Vermont Hospital discharge data set of 1996).

⁶⁷ See TEX. DEP'T HEALTH SERVS., QUALITY MANAGEMENT ELECTROCONVULSIVE TREATMENT REPORTS FY06 ECT DATA (2006), http://www.dshs.state.tx.us/mhquality/FY06/FY06_ECT-data.pdf.

use in patients sixty-five years of age or older grew from 33% in 1990-91, to 40% in 1993-94, to 44% in 1994-95.⁶⁸ The study revealed that in 1994-95, at least fourteen women eighty years of age or older were subjected to an average of eleven ECT treatments.⁶⁹

Older women are twice as likely as men to become seriously depressed.⁷⁰ Not surprisingly, in the United States and Canada, elderly women are more likely to receive ECT than any other group.⁷¹ In fact, today the model ECT patient is an elderly woman.⁷² Some suggest that this change in demographics is related to the availability of Medicare and to insurance companies' desire to provide cheap, fast treatment in lieu of costly, effective therapy.⁷³ Although there is little data to support the accusation, at least one study found that ECT use increased at the same time federal health benefits became available.⁷⁴ In Texas, one of the few states where ECT reporting is mandatory, one report revealed a 360% increase in the use of ECT between adults aged sixty-four and sixty-five.⁷⁵ In the United States, ECT treatment is typically administered during six to twelve sessions over a three-week period on an inpatient or outpatient basis at a cost that typically exceeds \$1000 per treatment.⁷⁶ The fact that physicians are reimbursed by Medicare for this treatment, coupled with the dramatic increase in ECT use in patients eligible to receive Medicare benefits, has led some to suggest that economics, rather than health care, is a primary driving force behind ECT use in the elderly.⁷⁷

⁶⁸ See Don Weitz, *Electroshocking Elderly People: Another Psychiatric Abuse*, 15 CHANGES: INT'L J. PSYCHOL. & PSYCHOTHERAPY (May 1997), available at <http://www.ect.org/resources/elderly.html>.

⁶⁹ *Id.*

⁷⁰ Nat'l Alliance of Mental Illness, *supra* note 10.

⁷¹ Breggin, *supra* note 66, at 24.

⁷² Loren R. Mosher & David Cohen, *The Ethics of Electroconvulsive Therapy (ECT)*, 5 VIRTUAL MENTOR (2003), available at <http://virtualmentor.ama-assn.org/2003/10/oped1-0310.html>.

⁷³ See Mental Health America, *Factsheet: Electroconvulsive Therapy (ECT)*, <http://www.nmha.org/go/information/get-info/treatment/electroconvulsive-therapy-ect>.

⁷⁴ John Breeding, *Electroshock*, 40 J. HUMANISTIC PSYCHOL. 65 (2000), available at <http://www.wildestcolts.com/mentalhealth/shock.html>.

⁷⁵ *Id.*

⁷⁶ Modern-Psychiatry.com, *Electro-Convulsive Treatment of Depression*, <http://www.modern-psychiatry.com/ect.htm> (last visited Feb. 5, 2009).

⁷⁷ Breeding, *supra* note 74; see also DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., MEDICARE REIMBURSEMENT FOR ELECTROCONVULSIVE THERAPY 2 (2001), <http://oig.hhs.gov/oei/reports/oei-12-01-00450.pdf> (noting that Medicare allowed charges for ECT in 1998, 1999, and 2000 at \$13.3 million, \$13.6 million, and \$13.6 million respectively).

III. EFFICACY OF ECT

A. *Theoretical Basis of ECT*

Shock therapy has been performed for decades, yet medical science has yet to adequately explain the basis for its claimed therapeutic effect. Some scientists believe that ECT works by changing the way brain receptors receive important mood-related chemicals.⁷⁸ Some believe that ECT-induced seizures teach the brain to resist seizure, which, in turn, stabilizes the individual's mood by limiting abnormally active brain circuits.⁷⁹ Other scientists believe that ECT-induced seizures cause part of the brain to release chemicals that cause changes throughout the body that regulate mood.⁸⁰ Scientists do agree that ECT acts by temporarily altering some of the complex electrochemical processes in the brain that contribute to mental illness.⁸¹ Opponents of ECT, however, believe that each shock causes physical damage to the brain, which manifests in memory loss and disorientation that falsely lead the individual to believe that the illness has been eliminated.⁸² Because studies suggest that only about half of all elderly patients who undergo pharmacological treatment for non-psychotic major depressive disorders respond to such treatment, psychiatrists have increasingly turned to ECT to treat the elderly.⁸³ Irrespective of how ECT impacts the individual, the disagreement regarding the efficacy of ECT creates cause for concern, particularly among elderly patients who may be more vulnerable to the side effects of the therapy.

B. *Scientific and Anecdotal Evidence: The Chasm Widens*

ECT has been said to produce an “electrically induced, close-head injury” in patients.⁸⁴ Because many elderly individuals have more fragile brains and already suffer from some level of memory loss, they are more vulnerable to the

⁷⁸ Dennis Cauchon, *How Shock Therapy Works*, USA TODAY, Dec. 6, 1995, available at <http://www.harborside.com/~equinox/ect4.htm> (last visited Jan. 13, 2009).

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ American Psychiatric Association, *Electroconvulsive Therapy (ECT)*, <http://www.ect.org/resources/apa.html> (last visited Jan. 13, 2009).

⁸² Cauchon, *supra* note 78.

⁸³ Henry C. Driscoll et al., *Getting Better, Getting Well: Understanding and Managing Partial and Non-Response to Pharmacological Treatment of Non-Psychotic Major Depression in Old Age*, 24 DRUGS & AGING 801, 802, 811 (2007).

⁸⁴ See generally APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 42–46.

negative impacts of ECT.⁸⁵ Despite this fact, the scientific community continues to minimize the special dangers elderly patients face.⁸⁶ According to the American Psychiatric Association (APA), there are no contraindications for ECT use in the elderly, and ECT may be used regardless of age.⁸⁷ In fact, the APA has taken the position that administering ECT to treat depression presents less medical risk than administering antidepressants in medically compromised elderly patients.⁸⁸ Scientific studies, however, call this view into question.

The cardiovascular system, the central nervous system, and the pulmonary systems have the greatest risk of injury from ECT.⁸⁹ Of these, the majority of medical complications and deaths associated with ECT are related to heart problems.⁹⁰ Studies demonstrate that individuals with "unstable cardiac disease" or "increased intracranial pressure may be at increased risk for complications" from ECT.⁹¹ This is because ECT-induced seizures cause a rapid rise in blood pressure at the same time the brain experiences a significant reduction in blood flow.⁹² A Mayo Clinic study of elderly patients over the age of eighty-five receiving ECT found that 79% of the patients suffered treatment complications, including a 32% incidence of confusion and delirium.⁹³ The study also found that 67% of the patients experienced transient high blood pressure, while 18% experienced serious heart arrhythmias during treatment.⁹⁴

Studies documenting brain damage in humans and animals subjected to ECT were well established immediately after the introduction of ECT, but those studies are largely ignored today based on a generally held belief that new ECT machines use lower current and are therefore safer than the original devices.⁹⁵

⁸⁵ Breggin, *supra* note 66, at 24.

⁸⁶ *Id.*

⁸⁷ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 42-43.

⁸⁸ *Id.* at 43.

⁸⁹ *Id.* at 27.

⁹⁰ *Id.* at 27.

⁹¹ Sarah H. Lisanby, *Electroconvulsive Therapy for Depression*, 357 NEW ENG. J. MED. 1939, 1941 (2007).

⁹² R. Rosenberg et al., *Effect of ECT on Cerebral Blood Flow in Melancholia Assessed with SPECT*, 4 CONVULSIVE THERAPY 62-73 (1988); Mark C. Webb et al., *Cardiovascular Response to Unilateral Electroconvulsive Therapy*, 28 BIOLOGICAL PSYCHIATRY: A JOURNAL OF PSYCHIATRIC RESEARCH 758, 758-59, 763 (1990).

⁹³ Tracey A. Tomac et al., *Safety and Efficacy of Electroconvulsive Therapy in Patients over Age 85*, 5 AM. J. GERIATRIC PSYCHIATRY 126, 127-28 (1997).

⁹⁴ *Id.* at 128.

⁹⁵ C. Edward Coffey, *Structural Brain Imaging and ECT*, in PROGRESS IN PSYCHIATRY: THE CLINICAL SCIENCE OF ELECTROCONVULSIVE THERAPY 73, 86 (C. Edward Coffey ed., 1993).

However, modern ECT devices may actually be more powerful than their predecessors. Through electrical compensation, the new devices have the capacity to emit far greater energy.⁹⁶ In fact, some reports suggest that today's ECT devices are over eight times more powerful than the original Cerletti-Bini device that is notorious for inducing permanent memory loss.⁹⁷ This increase in energy is required, in part, because the modifications used to protect patients from physical harm resulting from the procedure work to raise the patient's seizure threshold.⁹⁸ As a result, more electrical current is required to induce the convulsion.⁹⁹ Today, "suprathreshold amounts of electricity," approximately two and a half times greater than that required to induce the convulsion, "are commonly administered in the belief that they are more effective."¹⁰⁰ Remarkably, the Food and Drug Administration (FDA) disregarded the risk posed by the new devices, just as it disregarded the risk posed by the original devices.¹⁰¹ To date, the FDA has never required anyone to prove the safety of any ECT device.¹⁰²

Despite the scientific community's general disregard for the potential for harm posed by ECT, studies continue to emerge that challenge ECT's safety. Recent studies conflict as to ECT's ability to physically damage the human brain. For example, in one study, researchers examined the postmortem brain of a ninety-two-year-old woman who was subjected to ninety-one sessions of ECT over twenty-two years.¹⁰³ The researchers "found no pathological changes that could be attributed to ECT."¹⁰⁴ In another study, however, researchers found that 11% of elderly patients who were administered ECT to treat depression remained delirious between ECT sessions for no discernible medical

⁹⁶ Douglas G. Cameron, *ECT: Sham Statistics, the Myth of Convulsive Therapy, and the Case for Consumer Misinformation*, 15 J. MIND & BEHAV., 177, 191-93 (1994).

⁹⁷ *Id.* at 192.

⁹⁸ Breeding, *supra* note 74.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ See Neurological Devices: Proposed Rule to Reclassify the Electroconvulsive Device Intended for Use in Treating Severe Depression, 55 Fed. Reg. 36578 (proposed Sept. 5, 1990) (to be codified at 21 C.F.R. pt. 882) [hereinafter Proposed FDA Rule].

¹⁰² See Electroconvulsive Therapy Device, 21 C.F.R. § 882.5940 (2009) (classifying electroconvulsive therapy devices as Class III devices and noting that no effective date has been established of the requirement for premarket approval).

¹⁰³ Jason Scalia et al., *Neuropathologic Examination After 91 ECT Treatments in a 92-Year-Old Woman with Late-Onset Depression*, 23 J. ECT 96, 96 (2007).

¹⁰⁴ *Id.*

reason other than the ECT itself.¹⁰⁵ Of those patients, brain MRI scans revealed that 90% had lesions in the basal ganglia areas of the brain, and 90% also had moderate to severe white-matter lesions.¹⁰⁶ In another study, researchers concluded that ECT resulted in brain disease.¹⁰⁷

Of all the complications associated with ECT, the one that creates the greatest controversy is memory loss. The Committee for Truth in Psychiatry is a group of approximately 500 patients who claim to suffer from permanent memory loss as a direct result of ECT.¹⁰⁸ Their anecdotal evidence of harm has been largely ignored by the medical community. Yet, studies suggest that their concerns should not be so quickly disregarded.

Scientists frequently disregard concerns of memory loss following ECT treatment based on an assumption that such loss is temporary. This is because many studies have shown that shortly following the ECT treatment, most patients manifest deficits in retaining newly learned information (anterograde amnesia) and recalling events that occurred in the weeks or months preceding the ECT course (retrograde amnesia).¹⁰⁹ Some studies have suggested that anterograde amnesia typically resolves soon after ECT is completed.¹¹⁰ However, a study by California's Department of Mental Health revealed that more than 99% of patients who experienced an average of five to six ECT treatments complained of memory loss three months following treatment.¹¹¹ In another long-term study, researchers found that one half of the persons who had received bilateral ECT reported poor memory three years after the treatment.¹¹² Other studies have demonstrated that preexisting illness does not account for the memory loss. In one study, subjects who had previously received ECT had

¹⁰⁵ G.S. Figiel et al., *Brain MRI Findings in ECT-induced Delirium*, 2 J. NEUROPSYCHOLOGY & CLINICAL SCI. 53 (1990).

¹⁰⁶ *Id.*

¹⁰⁷ John Friedberg, *Shock Treatment, Brain Damage, and Memory Loss: A Neurological Perspective*, 134 AM. J. PSYCHIATRY 1010, 1010 (1977).

¹⁰⁸ See generally The Committee for Truth in Psychiatry, *supra* note 3.

¹⁰⁹ Harold A. Sackeim, *The Cognitive Effects of Electroconvulsive Therapy*, in COGNITIVE DISORDERS: PATHOPHYSIOLOGY & TREATMENT, 183, 216 (Leon J. Thal, Walter H. Moos & Elkan R. Gamzu eds., 1992).

¹¹⁰ Lisanby, *supra* note 91, at 1943.

¹¹¹ Susan Rogers, *Draft Surgeon General's Report Endorses ECT Despite Evidence of Its Dangers*, <http://www.ect.org/resources/surgeongeneralrebuttal.html> (last visited Jan. 14, 2009) (citing A. Lazarow, Chief, Office of Human Rights, Cal. Dep't of Mental Health (1996)).

¹¹² Larry R. Squire & Pamela C. Slater, *Electroconvulsive Therapy and Complaints of Memory Dysfunction: A Prospective Three-Year-Follow-up Study*, 142 BRIT. J. PSYCHIATRY 1, 7 (1983).

further impairment on a variety of learning and memory tests as compared to patients with no past ECT.¹¹³ The authors concluded that the degree of impairment could not be accounted for by illness at the time of assessment.¹¹⁴ Recently, Harold Sackeim, the most recognized proponent of ECT use, reversed positions and acknowledged for the first time that ECT routinely causes permanent memory loss and deficits in cognitive abilities.¹¹⁵ Sackeim's admission followed his study that provided the first evidence in a large, prospective sample that adverse cognitive effects can persist for an extended period following ECT.¹¹⁶ He noted that certain processes employed, including electrode placement, resulted in more severe and persistent deficits, and he acknowledged that there is little uniformity within the industry regarding electrode placement.¹¹⁷

Studies that have examined patients pre- and post-ECT also suggest that memory loss following ECT treatment is a significant problem. In one study, researchers asked ECT recipients personal, biographical questions before they underwent ECT and then repeated the same questions four weeks after the completion of treatment.¹¹⁸ The researchers found that in all cases, whether or not the recipients themselves recognized memory loss, they had forgotten much of their personal history.¹¹⁹ In a separate study, approximately 30% of the patients evaluated believed that their memory was permanently affected.¹²⁰ Later discussions with some of the patients led the scientists to reach the same conclusion regarding the permanent nature of ECT-induced memory loss.¹²¹ Other studies have supported this view.¹²² Interestingly, the primary reason that

¹¹³ Glenda MacQueen et al., *The Long-Term Impact of Treatment with Electroconvulsive Therapy on Discrete Memory Systems in Patients with Bipolar Disorder*, 32 J. PSYCHIATRY NEUROSCIENCE 241, 245-46 (2007).

¹¹⁴ *Id.* at 246.

¹¹⁵ Harold Sackeim et al., *The Cognitive Effects of Electroconvulsive Therapy in Community Settings*, 32 NEUROPSYCHOPHARMACOLOGY 244, 252 (2007).

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ Irving L. Janis, *Psychologic Effects of Electric Convulsive Treatments (I. Post Treatment Amnesias)*, 3 J. NERVOUS & MENTAL DISEASE, 359, 360-62 (1950).

¹¹⁹ *Id.* at 364.

¹²⁰ C.P.L. Freeman & R.E. Kendell, *ECT: I. Patients' Experiences and Attitudes*, 137 BRIT. J. PSYCHIATRY 8, 14 (1980).

¹²¹ Janis, *supra* note 118, at 381.

¹²² Squire et al., *supra* note 112, at 6-7.

many scientists continue to be unaware of the problems of ECT-induced memory loss is that they do not routinely test for such loss.¹²³

The risk of ECT-induced memory loss may be more likely in elderly individuals because preexisting cognitive impairment is predictive of amnesia after ECT, and amnesia is more likely in older adults.¹²⁴ For example, one study demonstrated that patients who manifested global cognitive impairment before treatment were more vulnerable to persistent retrograde amnesia for autobiographical information.¹²⁵ Another study revealed that advancing age was associated with greater cognitive deficits following ECT.¹²⁶

ECT use in the elderly is frequently justified by the higher incidence of suicide among the elderly and ECT's purported success in treating suicidal depression.¹²⁷ While the APA recommends ECT as an initial treatment for suicidal depression,¹²⁸ studies show that there is "no statistically significant difference between the number of suicide victims and controls receiving ECT."¹²⁹ However, studies differ regarding ECT's effect on suicidally inclined depressed patients.¹³⁰ For example, one study demonstrated that ECT was particularly useful and suggested that ECT use should be an early consideration for suicidal patients.¹³¹ Yet other studies suggest that ECT has no effect on suicidal depression. One study demonstrated that a lifelong history of ECT did not have an influence on mortality from suicide.¹³² A five-year study

¹²³ Peter Sterling, *Comments on Brain Damage and Memory Loss from Electroconvulsive Shock* 3 (2002), http://wellbeingfoundation.com/downloads/Sterling_on_ECT.pdf.

¹²⁴ Benoit H. Mulsant et al., *A Prospective Naturalistic Study of Electroconvulsive Therapy in Late-life Depression*, 4 J. GERIATRIC PSYCHIATRY & NEUROLOGY 3, 3 (1991).

¹²⁵ Christina Sobin et al., *Predictors of Retrograde Amnesia Following ECT*, 152 AM. J. PSYCHIATRY 995, 999 (1995).

¹²⁶ Sackeim et al., *supra* note 115, at 253.

¹²⁷ See generally The Merck Manual of Geriatrics § 4 *Psychiatric Disorders*, ch. 33 *Depression*, available at <http://www.merck.com/mkgr/mmg/sec4/ch33/ch33a.jsp>.

¹²⁸ Douglas Jacobs & Margaret Brewer, *APA Practice Guidelines: Provides Recommendations for Assessing and Treating Patients with Suicidal Behavior*, 34 PSYCHIATRIC ANNALS 379, 379 (2004), available at <http://www.stopasuicide.org/downloads/Sites/Docs/APASuicideGuidelinesReviewArticle.pdf>; Verinder Sharma, *Retrospective Controlled Study of Inpatient ECT: Does it Prevent Suicide?* 56 J. AFFECTIVE DISORDERS 183, 185 (1999).

¹²⁹ Sharma, *supra* note 128, at 185.

¹³⁰ Malini Patel et al., *Should Electroconvulsive Therapy Be an Early Consideration for Suicidal Patients?*, 22 J. ECT 113, 115 (2006); Verinder Sharma, *The Effect of Electroconvulsive Therapy on Suicide Risk in Patients with Mood Disorders*, 46 CAN. J. PSYCHIATRY 704, 704, 707 (2001).

¹³¹ Patel et al., *supra* note 130, at 115.

¹³² Donald W. Black et al., *Does Treatment Influence Mortality in Depressives?*

demonstrated that the suicide rate for depressed patients who received ECT was the same as for those who did not receive ECT.¹³³ The long-term follow-up of a study of 1076 depressed patients who were categorized according to whether they received ECT, high doses of antidepressant medications, low doses of antidepressant medications, or neither ECT nor medications, revealed that all groups had the same rate of suicide, indicating that the incidence of suicide was not affected by treatment.¹³⁴ Similar findings are documented in other studies.¹³⁵

Statements that ECT is beneficial to prevent death from suicide find little support in the medical literature. In fact, just the opposite may be true. In one study of 3288 patients who received treatment, ECT recipients were found to have an increased death rate from all causes.¹³⁶ In another study, the survival rate in sixty-five patients hospitalized and treated for depression was evaluated.¹³⁷ The authors found that the thirty-seven patients who received ECT had survival rates of 73% at one year, 54.1% at two years, and 51.4% at three years. In contrast, depressed patients who did not receive ECT had survival rates of 96.4%, 90.5%, and 75% at one, two, and three years respectively.¹³⁸

Courts have also recognized that ECT may negatively affect memory and cause injury. In *McNall v. Summers*,¹³⁹ the plaintiff underwent ECT to treat her depression and later complained of severe confusion and memory loss, but she continued to receive treatments based on the advice of her psychiatrist that the problem was temporary and that her memory would return.¹⁴⁰ When the plaintiff's memory did not improve, she was told that the problems were the result of her depression and that she would need a psychiatrist for the rest of her

A Follow-up of 1076 Patients with Major Affective Disorders, 1 ANNALS CLINICAL PSYCHIATRY 165, 165 (1989).

¹³³ Haroutun M. Babigian et al., *Epidemiologic Considerations in Electroconvulsive Therapy*, 41 ARCHIVES GEN. PSYCHIATRY 246, 247, 252 (1984).

¹³⁴ Black et al., *supra* note 132, at 165.

¹³⁵ Babigian et al., *supra* note 133, at 249-52; M.R. Eastwood et al., *Seasonal Patterns of Suicide, Depression and Electroconvulsive Therapy*, 129 BRIT. J. PSYCHIATRY 472, 474-75 (1976); Victor Milstien et al., *Does ECT Prevent Suicide?*, 2 CONVULSIVE THERAPY 3, 3 (1986).

¹³⁶ Babigian et al., *supra* note 133, at 249, 252.

¹³⁷ David Kroessler & Barry S. Fogel, *Electroconvulsive Therapy for Major Depression in the Oldest Old: Effects of Medical Comorbidity on Post-Treatment Survival*, 1 AM. J. GERIATRIC PSYCHIATRY 30, 33 (1993).

¹³⁸ *Id.* at 34.

¹³⁹ 30 Cal. Rptr. 2d 914 (1994).

¹⁴⁰ *Id.* at 915.

life.¹⁴¹ Tests showed that the plaintiff suffered a stroke as a result of the ECT and that her memory loss was related to that injury.¹⁴² Unfortunately, after finding that the plaintiff's "serious and continuous loss of memory [after undergoing electroconvulsive therapy] constitut[ed] injury," the court dismissed the medical malpractice suit against the psychiatrist because it was barred by the statute of limitations.¹⁴³

In *Shafran v. St. Vincent's Hospital & Medical Center*, the plaintiff's decedent sustained serious injuries and eventually died after receiving electroconvulsive therapy while in the defendants' care.¹⁴⁴ Shortly after the seizure was induced during ECT, the plaintiff's decedent lapsed into a coma for approximately ten days and sustained permanent injuries, including bilateral deafness, memory loss, and seizure disorder, all of which persisted until she died six years later.¹⁴⁵ The court found that the medical witnesses and ECT specialists should be allowed to testify.¹⁴⁶

In *Winger v. Franciscan Medical Center*, parents brought a wrongful death action against a hospital and psychiatrist after their son committed suicide while in the defendants' care for severe depression.¹⁴⁷ Upon admission, the patient underwent an "aggressive" treatment of ECT.¹⁴⁸ Following administration of ECT, the patient told nurses that his life was hopeless and that he felt "bad all the time."¹⁴⁹ He later committed suicide by hanging himself with his shoelaces from a showerhead in his bathroom.¹⁵⁰ The court found that issues of fact existed as to whether the patient's suicide was foreseeable and whether the defendants' conduct was reasonable under the circumstances, which precluded summary judgment.¹⁵¹

In *Powell v. Hawkins*, the plaintiff was burned when one of the electrodes attached to his head separated from the skin.¹⁵² In overturning a lower court's

¹⁴¹ *Id.*

¹⁴² *Id.* at 916.

¹⁴³ *Id.* at 919-20.

¹⁴⁴ 694 N.Y.S.2d 642, 643 (N.Y. App. Div. 1999).

¹⁴⁵ *Id.* at 555.

¹⁴⁶ *Id.* at 557.

¹⁴⁷ 701 N.E.2d 813, 814 (Ill. App. Ct. 1998).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.* at 820.

¹⁵² 885 N.E.2d 958, 959 (Ohio Ct. App. 2007).

grant of summary judgment in favor of the psychiatrist, the court opined that “[m]edical treatment should not involve setting a patient’s head on fire.”¹⁵³

Considerable uncertainty exists within the scientific community regarding how stimulus dose, seizure threshold, and seizure duration impact the efficacy and side effects of ECT. Despite repeated claims that ECT works, relapse rates after ECT remain high, often between 50 and 95%.¹⁵⁴ Studies repeatedly demonstrate that use of ECT in depressed or severely depressed patients shows an effectiveness lasting no more than four weeks.¹⁵⁵

Despite ECT’s continued use, substantial disagreement exists in the medical community as to when or whether ECT should be utilized. The chasm that currently exists among scientific studies and anecdotal evidence regarding the efficacy of ECT poses substantial questions regarding the validity of information provided to patients who consent to treatment. The disagreement has caused some to suggest that history will view ECT “promoters as kin to the promoters of the lobotomy.”¹⁵⁶

IV. INFORMED CONSENT

A. Background

Informed consent is a legal construct grounded in principles of individual autonomy and emanates from the fundamental concept that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”¹⁵⁷ Built upon the elements of information, decisional capacity, and voluntarism, the doctrine of informed consent recognizes that patients have a right to be fully informed of the alternatives to and risks of a proposed procedure prior to being subjected thereto.¹⁵⁸ The failure to obtain

¹⁵³ *Id.*

¹⁵⁴ Georgios Petrides, *Continuation ECT: Relapse Prevention in Affective Disorders*, 10 *CONVULSIVE THERAPY* 189, 189 (1994).

¹⁵⁵ Breggin, *supra* note 66, at 8.

¹⁵⁶ Peter Sterling, *ECT Damage Is Easy to Find if You Look for It*, 403 *NATURE* 242, 242 (2000).

¹⁵⁷ *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 92 (N.Y. 1914), *abrogated by* *Bing v. Thunig*, 143 N.E.2d (N.Y. 1957).

¹⁵⁸ *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972); *see also* *RESTATEMENT (FIRST) OF TORTS* § 49 (1934) (“To constitute a consent to an intended invasion of an interest of personality, there must be (a) an assent to the particular invasion suffered, (b) given (i) to the person invading the interest, (ii) by one who is capable of giving consent thereto and whose

such consent before acting may constitute a breach of duty and subject the medical provider to liability.¹⁵⁹ Valid informed consent also requires the absence of coercion and the presence of a competent patient.¹⁶⁰

For individuals living with mental illness, the doctrine of informed consent has particular significance. This is because for some elderly individuals, personal autonomy is compromised by the illness itself. Recent evidence suggests that treatment decisions made by individuals with mental illness often stem from the coercive effects of distorted perception and motivation incident to the illness rather than from the patient's own goals and values.¹⁶¹ Others simply fail to receive sufficient information from which to make a free, informed decision. The existing method of seeking patient consent to ECT is flawed because it fails to assess whether a patient truly understands the nature and risks of the treatment, fails to insure that the patient is competent to voluntarily consent to the treatment, and fails to assess whether the patient has the decisional capacity to agree to treatment. As a result, physicians continue to subject patients to ECT treatment without obtaining informed consent.

(1) Information

Due care demands that a physician place the interest of the patient first. This requires the physician to fully inform the patient of the medical condition, advise the patient of the need for or desirability of any alternative treatment promising greater benefit than the treatment being pursued, and warn the patient of any risks to his well-being that the contemplated therapy may involve.¹⁶² From the patient's perspective, informed consent can only be obtained when the patient has sufficient information from which he or she can make a knowing and intelligent decision regarding the procedure. This requires full knowledge of all alternative procedures available, the inherent risks of undergoing the procedure, and the risks of not having the procedure performed.¹⁶³

The typical patient, however, has little or no medical training and is unfamiliar with the complex medical vernacular. As a result, he or she is

assent has neither been procured by such duress as makes it inoperative as a consent nor given under a mistake as to the validity of an asserted legal authority.").

¹⁵⁹ *Canterbury*, 464 F.2d at 782-83.

¹⁶⁰ See RESTATEMENT (FIRST) OF TORTS, *supra* note 158.

¹⁶¹ See Marsha Garrison, *The Empire of Illness: Competence and Coercion in Health-Care Decision Making*, 49 WM. & MARY L. REV. 781, 806-35 (2007).

¹⁶² See, e.g., *Wall v. Brim*, 138 F.2d 478, 481 (5th Cir. 1943).

¹⁶³ *Dunham v. Wright*, 423 F.2d 940, 943-44 (3d Cir. 1970).

forced to rely on the physician's disclosures for guidance in making an informed choice. In most jurisdictions, courts hold that a physician discharges the duty of disclosure by making reasonable efforts to convey sufficient information needed by the patient, even if the patient does not actually understand the information conveyed.¹⁶⁴ The extent of the disclosure, however, changes based on the patient's jurisdiction. In some jurisdictions, a valid consent requires only that a physician inform a patient of the general terms of treatment, without disclosing the risks of such treatment.¹⁶⁵ In other jurisdictions, physicians are only required to inform patients of "significant perils" involved in the procedure.¹⁶⁶ In all jurisdictions, however, the extent of the disclosure is limited by the physician's assessment of the negative psychological effect the disclosure may have on the patient.¹⁶⁷ Thus, the depth of information that must be provided to meet the requirement of informed consent is based on the physician's perception of what the patient needs to know to make an informed choice. This runs counter to principles of autonomy and usurps the patient's right to make a free and informed choice regarding therapy.

Ethically, a physician may never fail to disclose or minimize the known dangers of a procedure in order to induce a patient's consent.¹⁶⁸ When the medical community cannot agree on the nature of the risk posed by the procedure, the sufficiency of the information conveyed to patients regarding the risks of ECT must be challenged and should not serve as a basis to establish patient consent. With regard to ECT treatment, the APA simply requires "the provision of at least a minimum measure of information" to support a finding of informed consent.¹⁶⁹ According to the APA, informed consent forms used in hospitals and psychiatric facilities provide sufficient patient information to allow psychiatrists to obtain informed consent through patient signatures.¹⁷⁰

¹⁶⁴ *Canterbury*, 464 F.2d at 780; *Miriam Mascheck, Inc. v. Mausner*, 264 So. 2d 859, 861 (Fla. Dist. Ct. App. 1972).

¹⁶⁵ *Sikorski v. Bell*, 307 S.E.2d 701, 703 (Ga. Ct. App. 1983).

¹⁶⁶ *Craig v. Borcicky*, 557 So. 2d 1253, 1258 (Ala. 1990).

¹⁶⁷ *Natanson v. Kline*, 350 P.2d 1093, 1104 (Kan. 1960) (noting that the disclosure of every possible contingency, no matter how remote, may increase the "risks by reason of the physiological results of the apprehension itself").

¹⁶⁸ *Id.*

¹⁶⁹ The APA Task Force on Electroconvulsive Therapy, *supra* note 5.

¹⁷⁰ *Id.*

However, evidence suggests that the content of those forms is often inadequate and that the practice of obtaining consent is fraught with problems.¹⁷¹

In *Akkerman v. Santa Barbara Cottage Hospital*, the plaintiffs sued their doctor and the hospital after the husband suffered impaired cognitive functioning following the administration of ECT.¹⁷² The plaintiffs alleged that they were given “out-dated and incomplete” patient consent forms which failed to advise them that ECT treatments may cause “irreversible, permanent memory loss.”¹⁷³ At trial, the testimony demonstrated that the form used by the doctor was not the one approved by the state for use in ECT.¹⁷⁴ The doctor acknowledged that he had used the form for nine years to perform “over one hundred” state-required pre-ECT informed consent reviews.¹⁷⁵ He also admitted that he repeatedly signed the forms even though he was not board certified and therefore not an eligible psychiatrist under California law, and he noted that the hospital was aware that he lacked the qualifications.¹⁷⁶ The jury found that the doctor was “negligent in obtaining the informed consent of [the plaintiff, and that the hospital] was negligent in performing the informed consent review.”¹⁷⁷

The medical community has recognized the need to fully inform patients but acknowledges the practical difficulties associated with obtaining true informed consent. In one study, the author acknowledged the requirement of obtaining informed consent to proceed with treatment but noted that “[t]his process takes time . . . and for the busy health-care provider there is often the temptation to hand the patient a consent form to sign.”¹⁷⁸ These problems raise questions about the sufficiency of the documents being utilized and the manner in which patient signatures are obtained. Perhaps more troublesome, however, is the effect prior treatment for mental illness has on a patient’s ability to consent to future treatment.

¹⁷¹ See The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

¹⁷² 2d Civ. No. B181579, slip op. at *1 (Cal. App. 2 Dist. Oct. 19, 2006).

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ Peter B. Terry, *Informed Consent in Clinical Medicine*, 131 CHEST 563, 563 (2007).

(2) Decisional Capacity

Implicit in the concept of personal autonomy are requirements of capacity. To the extent that a mental illness impairs an individual's capacity to exercise autonomy, the illness restricts the person's ability to participate competently in treatment decisions.

The ability of the patient to understand the medical information conveyed and his or her ability to act reasonably on that information may be impaired by the illness itself. A growing body of scientific literature suggests that the physiological progression of mental illness alters treatment preferences.¹⁷⁹ For example, studies have shown a strong correlation between a patient's major depression and his or her desire for death.¹⁸⁰ In one study, 58.8% of those suffering from major depression expressed a desire to die.¹⁸¹ Similarly, other studies have found that major depression has a statistically significant relationship with the patient's desire for "hastened death."¹⁸²

ECT is commonly administered to elderly individuals suffering from major depression. Most of these individuals have already undergone unsuccessful treatment with psychotropic drugs at the time they are asked to provide informed consent to ECT.¹⁸³ This treatment practice raises important questions regarding the individual's decisional capacity at the time consent is requested. Psychotropic drugs are chemical substances specifically designed to act upon the central nervous system to alter brain function.¹⁸⁴ The substances, which include antidepressants, alter the brain's neurochemistry to cause temporary changes in perception, mood, consciousness, and behavior.¹⁸⁵ Psychiatrists often administer the substances on a trial-and-error basis because there is no way to know how a patient will respond to a particular treatment.

¹⁷⁹ See generally Garrison, *supra* note 161.

¹⁸⁰ Harvey M. Chochinov et al., *Desire for Death in the Terminally Ill*, 152 AM. J. PSYCHIATRY 1185, 1187-88 (1995); K. Mystakidou et al., *Depression, Hopelessness, and Sleep in Cancer Patients' Desire for Death*, 37 INT'L J. PSYCHIATRY MED. 201, 201 (2007); see also William Breitbart et al., *Depression, Hopelessness, and Desire for Hastened Death in Terminally Ill Patients with Cancer*, 284 JAMA 2907, 2910 (2000) (reporting that terminally ill cancer patients with symptoms of major depression were four times more likely than patients without such symptoms to demonstrate "a high desire for hastened death").

¹⁸¹ Chochinov et al., *supra* note 180, at 1187-88.

¹⁸² Mystakidou et al., *supra* note 180, at 201.

¹⁸³ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 7.

¹⁸⁴ See generally Science Daily Science Reference, *Psychoactive Drug*, http://www.sciencedaily.com/articles/p/psychoactive_drug.htm (last visited Jan. 27, 2009).

¹⁸⁵ See generally *id.*

The effects of psychotropic drugs on the mental processes of elderly patients, some of whom already suffer from age-related deterioration of cognition, suggest that the decisional capacity of elderly patients who undergo ECT may be severely restricted. Because studies show that depression alters treatment decisions, and treatment for depression requires powerful psychotropic drugs, it is logical to assume that an elderly depressed patient undergoing treatment is unable to make a genuine, autonomous decision to submit to ECT. More likely, manifestations of depression act as a coercive influence that interferes with the patient's capacity to freely elect to undergo ECT, and with each subsequent administration of ECT, the patient's capacity likely decreases.¹⁸⁶

(3) *Voluntariness*

In a clinical setting, a person who has capacity to make a decision regarding therapy must also voluntarily agree to participate in the therapy.¹⁸⁷ The individual may not be coerced to participate or be promised benefits unlikely to result from the therapy.¹⁸⁸ The decision must be an independent choice based on the complete disclosure of all pertinent information.¹⁸⁹ Many factors can interfere with an individual's ability to voluntarily agree to undergo a certain procedure. Family members or friends may exert powerful influence over the decision by espousing their views on what is best for the patient.¹⁹⁰ Physicians may exert undue influence by suggesting a preference for one treatment option over another, without providing full disclosure regarding the risks and benefits of each choice.¹⁹¹ In some cases, this can result in the manipulation of how pertinent information regarding a procedure is presented in an effort to persuade the patient to elect one option over another. Indeed, some psychiatrists openly acknowledge that they often "feel required to restrict freedom and use coercion in the provision of care."¹⁹² For some elderly patients already suffering from age-related cognitive impairments, the risk of intentional or unintentional coercion resulting from the incomplete or inaccurate delivery of information may be much higher.

¹⁸⁶ The APA Task Force on Electroconvulsive Therapy, *supra* note 5.

¹⁸⁷ *Id.* ("Informed consent is defined as voluntary.").

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² Axel Liégeois & M. Eneman, *Ethics of Deliberation, Consent and Coercion in Psychiatry*, 34 J. MED. ETHICS 73, 73 (2008).

Another problem with the issue of voluntariness is the complete disregard for competence when a patient agrees to a recommended treatment. When a patient consents to a recommended treatment, the law assumes that the choice is informed and made freely. The patient's acquiescence is seen as a sign of his or her understanding of the need for beneficial treatment, and the law recognizes the patient's right to make that decision. This approach disregards the possibility that the patient may actually be incompetent to make a decision, because in the view of the medical profession, the patient made the correct choice. In many instances, the decision may be made involuntarily as a result of external coercive factors.

In those instances when a patient withholds consent to a particular procedure, the legal system takes a protective stance. Operating under its *parens patriae* power, the State may challenge the individual's competency in court.¹⁹³ If adjudicated incompetent by a court of law, the patient may lose all control over medical decision making to the patient's caregivers or a third party. The prospect of losing all rights as a result of a declaration of incompetence serves as a powerful deterrent to resistance and creates an impediment to a patient's ability to make a free, informed, and voluntary decision to submit to a medical procedure.¹⁹⁴ The ability to exert such a coercive effect on a patient's voluntarism is sufficient reason to invalidate any consent obtained.¹⁹⁵

B. The Reasonable Patient Standard

Before administering diagnostic or treatment procedures, physicians have an obligation to obtain the informed consent of their patients.¹⁹⁶ In the absence of an emergency, written informed consent generally must be obtained from psychiatric patients.¹⁹⁷ The failure to obtain consent may subject the physician to liability for battery.¹⁹⁸ To recover for an injury resulting from the negligent nondisclosure of information, the patient has the burden of demonstrating that a

¹⁹³ See generally *In re C.E.*, 641 N.E.2d 345, 359 (Ill. 1994) (discussing the state's *parens patriae* interest in furthering the treatment of mentally ill persons and the liberty interests implicated where treatment is involuntarily administered).

¹⁹⁴ The APA Task Force on Electroconvulsive Therapy, *supra* note 5 ("Threats of involuntary hospitalization . . . represent a clear violation of the informed consent process.").

¹⁹⁵ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 97-98.

¹⁹⁶ *Barcai v. Betwee*, 50 P.3d 946, 959 (Haw. 2002).

¹⁹⁷ *Id.* at 959.

¹⁹⁸ *Riedisser v. Nelson*, 534 P.2d 1052, 1054 (Ariz. 1975).

reasonable person in the patient's position, knowing of the risk, would have withheld consent to the treatment.¹⁹⁹

This "reasonable patient" standard of informed consent recognized by courts is problematic when applied to patients undergoing ECT.²⁰⁰ By definition, a "reasonable" patient is one capable of exercising "the degree of attention, knowledge, intelligence, and judgment that society requires of its members for the protection of their own and of others' interests."²⁰¹ Most patients are administered ECT only after prolonged, but unsuccessful, treatment, with psychotropic drugs.²⁰² If, as courts have recognized, psychotropic drugs "assist the patient in organizing his or her thought processes and regaining a rational state of mind," then most patients who provide written consent to ECT are not functioning as reasonable patients.²⁰³ That is, as a result of their failure to respond to the psychotropic drugs prescribed, they are incapable of acting with the degree of attention, knowledge, intelligence, and judgment necessary to protect their own self-interests. Under these circumstances, it is impossible for a court to objectively evaluate how a reasonable person might act in the patient's position. Given the complexities of mental illness and the myriad of ways it manifests in different people, identifying a single objective definition of reasonableness is impossible. It is logical to conclude, however, that a reasonable patient would expect to be informed of those risks whose likelihood of occurring is at least subject to fair debate. The APA-approved informed consent form for ECT fails to provide this information,²⁰⁴ and therefore signed consent forms should not operate as proof that the patient was adequately informed.

C. Gaps in Existing Informed Consent Forms

The APA recommends that "[i]nformational material provided as part of the consent process should be sufficient in scope and depth to allow a

¹⁹⁹ *Riedisser*, 534 P.2d at 1055; *Foster v. Traul*, 175 P.3d 186, 192 (Idaho 2007); *Tompkins v. Bryan*, 975 So. 2d 723, 725 (La. Ct. App. 2008); *Canesi v. Wilson*, 730 A.2d 805, 812 (N.J. 1999).

²⁰⁰ See *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972) (first identifying the standard of disclosure as that which a "reasonable patient" would require to make an informed decision).

²⁰¹ See BLACK'S LAW DICTIONARY 1294 (8th ed. 2004) (defining the "reasonable person"). The standard that applies to persons should also apply to patients.

²⁰² APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 7.

²⁰³ *People v. Stokes*, 776 N.E.2d 657, 660 (Ill. App. Ct. 2002).

²⁰⁴ The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

reasonable person to understand and evaluate the risks and benefits of ECT compared with treatment alternatives.²⁰⁵ The APA suggests that sufficient information is conveyed through the dissemination of literature, audio visual aids, and communication with physicians.²⁰⁶ No study has directly evaluated the accuracy of this proposition in the United States, but several international studies suggest that a large percentage of ECT patients do not believe they received sufficient information to provide informed consent. In a recent study from England, for example, researchers found that one third of all patients who received ECT did not feel they had freely consented to ECT even when they had signed a consent form.²⁰⁷ The authors concluded that “[n]either current nor proposed safeguards for patients are sufficient to ensure informed consent with respect to ECT.”²⁰⁸ In another study from England carried out to assess the knowledge of ECT among mental health staff in a general hospital setting, only 36% of those staff members who directly provide information to patients and caregivers had sufficient knowledge of the laws regarding informed consent and ECT.²⁰⁹ Because information regarding ECT is disseminated to patients in the United States in much the same way that it is in England, it is likely that similar problems exist in this country.

Opponents of ECT argue that “true informed consent is almost never obtained” because no rational person would sign a truthful ECT consent form.²¹⁰ Although the major information gaps will be discussed with regard to the APA-approved informed consent form, it is important to note that some states have developed modified variations of the APA form that contain similar

²⁰⁵ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 100.

²⁰⁶ *Id.*

²⁰⁷ Diana S. Rose et al., *Information, Consent and Perceived Coercion: Patients' Perspectives on Electroconvulsive Therapy*, 186 *BRIT. J. PSYCHIATRY* 54, 54 (2005); see also Mehreen Arshad et al., *Awareness and Perceptions of Electroconvulsive Therapy Among Psychiatric Patients: A Cross-Sectional Survey from Teaching Hospitals in Karachi, Pakistan*, 7 *BMC PSYCHIATRY* 27, 27 (2007) (identifying “a serious lack of dissemination of information regarding ECT by the psychiatrists and the mental health care providers” and suggesting that it may be due to “a lack of concern about the mentally ill patients”); Anto P. Rajkumar et al., *Perspectives of Patients and Relatives About Electroconvulsive Therapy: A Qualitative Study from Vellore, India*, 22 *J. ECT* 253, 253 (2006) (finding that more than half of the ECT recipients were not aware of the details of ECT even at the end of the course of therapy).

²⁰⁸ Rose et al., *supra* note 207, at 54.

²⁰⁹ Renu Culas et al., *Knowledge of ECT Among Staff of a Mental Health Service*, 19 *J. ECT* 245, 245 (2003).

²¹⁰ Mosher et al., *supra* note 72.

omissions.²¹¹ Key areas of the APA form that impact an individual's ability to provide true informed consent are discussed below.

(1) *Explanation of Risks and Benefits*

The APA informed consent form contains a statement that the "risks and benefits [of ECT] have been fully described" to the patient.²¹² The statement provides no guidance on what information is actually conveyed. According to one health care insurer, "[p]atients and relatives are prepared for ECT by being shown video tapes that explain both the procedure and the risks involved. The physician then answers any questions these individuals may have, and the patient is asked to sign an 'Informed Consent Form.'"²¹³ A review of the so-called "educational videos," however, shows that they fail to objectively state the scientific evidence currently available regarding ECT.²¹⁴ In one such video, two elderly individuals who did not suffer complications associated with ECT are interviewed.²¹⁵ After numerous laudatory remarks regarding how ECT positively changed their lives, one individual is observed during his preparation for ECT administration.²¹⁶ Interestingly, the video shows the patient filling out the ECT informed consent form while in the waiting area, outside the presence of his doctor.²¹⁷ More interesting, perhaps, is what the video fails to show. Despite showing the patient lying on a gurney and being injected with anesthetics, the video does not show the application of the electrical charge or the patient's response thereto.²¹⁸ The video then provides graphics that tell the

²¹¹ See, e.g., Health and Human Services Agency, State of California Electroconvulsive Treatment (ECT), Informed Consent Form MH300 (11/90), <http://www.dmh.ca.gov/News/Publications/Forms/docs/MH300.pdf>; Department of Health, State of Vermont Informed Consent Package for Electroconvulsive Therapy (ECT), <http://www.timesargus.com/assets/pdf/BT345781212.PDF>.

²¹² The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

²¹³ Donald G. Barstow, *Electroconvulsive Therapy*, GALE ENCYCLOPEDIA OF MED. (Dec. 2002), available at <http://medical-dictionary.thefreedictionary.com/Electroconvulsive+Therapy>.

²¹⁴ See, e.g., Emory Healthcare, *Educational Video on Electroconvulsive Therapy (ECT)*, available at http://www.emoryhealthcare.org/departments/fuqua/patient_info/Electroconvulsive_Th.html; see also Dennis Cauchon, *Memory Loss Prompts Woman to Stop Treatment*, USA TODAY, Dec. 6, 1995 (noting that an ECT patient educational video, sold by ECT machine manufacturer MECTA Corp., did "not mention death rates or the views of critics who believe that shock causes brain damage").

²¹⁵ Emory Healthcare, *supra* note 214.

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ *Id.*

viewer that memory problems “Will Resolve After ECT Treatment” and that ECT “Produces No Permanent Memory Loss.”²¹⁹ In commentary, the viewer is repeatedly informed that ECT has an “eighty percent response rate” and that of all the people who have undergone ECT, “eighty percent would do it again.”²²⁰

The video does not mention death rates, misrepresents competing evidence regarding ECT success rates, affirmatively misstates evidence regarding long-term and permanent memory loss, offers patient satisfaction rates based on pure speculation, and omits any suggestion that there are competing viewpoints within the medical profession regarding the efficacy of ECT.²²¹ These educational videos demonstrate that putative ECT patients are not getting the whole story prior to signing the consent form. In view of the blatant misrepresentations and bias exhibited in these videos and evidence that patients sign the informed consent form outside the presence of their physicians, the signed forms should not be viewed as proof that the patient consented to the procedure.

(2) *Experimental Nature of Device*

Despite having been administered to millions of people worldwide since its inception, ECT has never been subject to wide-scale randomized control trials that are common for other routinely prescribed procedures.²²² The few, small randomized control trials that have been conducted have failed to conclusively demonstrate ECT’s effectiveness and have presented more questions than answers.²²³ Further, as a result of intense lobbying by the APA, the safety of ECT machines currently in use has never been tested.²²⁴ While certain members of the medical community continue to argue that the new ECT devices are much safer than earlier versions that caused horrific injuries to patients, evidence suggests that the new devices are actually much more

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.*

²²² Bob Johnson, *An Informed Consent Form for Electroconvulsive Therapy (ECT)*, Draft 1, Dec. 6, 2003, <http://www.psychrights.org/Research/Digest/InformedConsent/DrJohnsonECTInformedConsent.pdf>.

²²³ See generally Breggin, *supra* note 66, 8-9 (stating that randomized control trials are recognized as the best evidence that a procedure works).

²²⁴ See Letter from Max Fink to FDA (Oct. 26, 1990), available at <http://www.ect.org/max-fink-letter-to-fda/>.

powerful and capable of generating larger electrical charges for longer durations.²²⁵

ECT devices currently in use are recognized by the FDA as Class III devices.²²⁶ This is the highest risk class of medical devices, and includes those devices that present a potential unreasonable risk of illness or injury.²²⁷ Class III devices are those for which insufficient information exists to assure patient safety.²²⁸ Despite requests from the APA to reclassify the device to Class II and thereby obtain recognition that the ECT device was safe, the FDA refused to do so.²²⁹ Instead, the FDA decided that ECT devices would remain Class III devices until the effective date of a performance standard which assured the safety and effectiveness of the device.²³⁰ That day has never arrived, and patients should be informed of this fact.²³¹

(3) ECT Procedure

The APA informed consent form indicates that bilateral or unilateral ECT may be administered to the patient.²³² In bilateral ECT, electrodes are placed on both sides of the head and the electrical current is passed across the entire brain.²³³ In unilateral ECT, both electrodes are placed on one side of the head and electrical current is passed across one side.²³⁴ Both procedures produce a seizure.²³⁵ Bilateral ECT is more widely used because it works more quickly and effectively, but right-side unilateral ECT has fewer side effects and results in less memory loss.²³⁶ Although the choice of whether to undergo bilateral or unilateral ECT should rest with the patient, the APA form provides the physician with the choice regarding which procedure to use. The form simply states that the patient will receive one form or the other, and the patient is

²²⁵ See, e.g., Cameron, *supra* note 96.

²²⁶ 21 C.F.R. § 860.3 (2009).

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ See Proposed FDA Rule, *supra* note 101.

²³⁰ *Id.*

²³¹ See 21 C.F.R. § 882.5940 (2009) (classifying electroconvulsive therapy devices as Class III devices and noting that “[n]o effective date has been established of the requirement for premarket approval”).

²³² The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

²³³ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 154.

²³⁴ *Id.*

²³⁵ *Id.* at 153.

²³⁶ *Id.* at 150.

unconscious when the procedure is performed.²³⁷ Given a choice, the patient would likely elect the procedure that had the smaller chance of causing memory impairment or other side effects. In view of the disagreement within the medical field regarding the harm ECT causes, it seems possible that some physicians simply discount the possibility of harm and proceed according to their own views. This is troubling in view of the recent calls within the medical community to discontinue the use of bilateral ECT due to its propensity to cause broader and more severe short-term cognitive effects than right unilateral ECT.²³⁸

(4) *Acute and Maintenance Phase Administration of ECT*

The APA informed consent form indicates that a typical course of ECT requires four to twenty treatments, with some patients needing fewer and some needing more treatments.²³⁹ The form notes that to prevent the return of symptoms, the patient will need additional treatment with medication, psychotherapy, and/or ECT.²⁴⁰ The form does not explain the likelihood of relapse or how many courses of treatment may be needed to eliminate the illness. Studies show that ECT has a clinical effectiveness that lasts no more than four weeks in a severely depressed patient.²⁴¹ Moreover, without active treatment, virtually all remitted patients relapse within six months of stopping ECT.²⁴² As a result, at least one patient has received more than a hundred ECT treatments.²⁴³ Given the conflicting evidence regarding whether a course of ECT causes some form of damage to the brain, patients will likely be concerned with the cumulative effect of multiple treatments. The form in use fails to adequately notify patients of the extent to which they will likely be required to undergo subsequent courses of ECT during a maintenance phase.²⁴⁴ This leaves patients with no way of assessing how much electrical insult their brains will experience. Patients should be presented with accurate information

²³⁷ The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

²³⁸ Sackeim et al., *supra* note 115, at 252.

²³⁹ The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

²⁴⁰ *Id.*

²⁴¹ Breggin, *supra* note 66, at 8.

²⁴² Harold Sackeim et al., *Continuation Pharmacotherapy in the Prevention of Relapse Following Electroconvulsive Therapy: A Randomized Controlled Trial*, 285 JAMA 1299, 1311 (2001).

²⁴³ Pamela Fayerman, 130 *Shock Treatments: 'They Hurt, I Don't Want It,' Public Trustee's Office Investigates Riverview Case*, VANCOUVER SUN, Apr. 17, 2002, available at <http://www.ect.org/news/130shocks.html>.

²⁴⁴ The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

regarding the actual effect each administration of ECT is likely to have on their illness.

(5) *The Nature of the Seizure*

The APA form indicates that the electrical current produces a seizure in the brain, that the patient will be provided oxygen to breathe, and that the patient's heart, blood pressure, and brain waves will be monitored.²⁴⁵ In reality, the seizure causes massive physiological disturbances in the brain, some of which are permanent. Research has demonstrated that during an ECT-induced seizure, blood pressure increases to the point where the blood-brain barrier is compromised.²⁴⁶ These events may result in hemorrhage, edema, and possibly toxic effects to the brain from exposure to chemicals in the blood from which the brain is normally protected.²⁴⁷ This causes irreversible death of neurons in the brain and could result in the spread of disease.²⁴⁸ Further, EEG studies demonstrate that seizure activity alters brain physiology from normal to abnormal and that the effects may be permanent.²⁴⁹ Perhaps more troubling is that the seizure threshold rises with increasing age, making effective seizures difficult to induce in the elderly.²⁵⁰ In fact, the APA has acknowledged that some elderly patients may have seizure thresholds that exceed the maximum output of ECT devices currently in use.²⁵¹ Thus, for some elderly patients the electrical insult to the brain during ECT is much greater than expected.

The APA informed consent form fails to inform the patient of these physiological disturbances and therefore eliminates any possibility for the patient to evaluate these factors when deciding whether to consent to treatment. Moreover, the form improperly minimizes the known risks of the procedure.

²⁴⁵ *Id.*

²⁴⁶ Peter Sterling, Testimony Prepared for the Standing Committee on Mental Health of the Assembly of the State of New York, *Brain Damage and Memory Loss from ECT* (Oct. 5, 1978), available at <http://www.ect.org/brain-damage-and-memory-loss-from-ect/>.

²⁴⁷ *Id.*

²⁴⁸ *Id.*; see also Linda M. Dallasta et al., *Blood-Brain Barrier Tight Junction Disruption in Human Immunodeficiency Virus-1 Encephalitis*, 155 AM. J. PATHOLOGY 1915 (1999) (finding that disruption of the blood-brain barrier serves as the main route of HIV-1-infected monocyte entry into the central nervous system).

²⁴⁹ Sterling, *supra* note 246.

²⁵⁰ APA COMMITTEE ON ELECTROCONVULSIVE THERAPY, *supra* note 21, at 44-45.

²⁵¹ *Id.* at 45.

(6) Patients at Greater Risk of Harm

The APA informed consent form fails to distinguish risks in certain populations of individuals. The omissions are curious in light of the APA's most recent report on ECT that devotes an entire chapter to the special risks associated with ECT use in certain populations.²⁵² According to the APA, "coexisting medical illnesses and their treatments may have an impact on both the likelihood of response and the risks of ECT."²⁵³ For example, individuals with certain cardiovascular conditions and uncontrolled hypertension are believed to be at increased risk if given ECT.²⁵⁴ Patients with diabetes and joint or bone disease also require special consideration.²⁵⁵ These problems are particularly acute in elderly populations.²⁵⁶ Of the individuals over sixty-five years of age who were alive in the United States between 2004 and 2006, approximately 31.7% suffered from heart disease, 11.7% had experienced a heart attack, 9.4% had experienced a stroke, 50.3 % suffered from joint disease (arthritis), and 17.4% suffered from diabetes.²⁵⁷ Despite the APA's own acknowledgment of ECT-related complications associated with these conditions, its consent form fails to address the issue of ECT use in special populations.

(7) Memory Loss

The APA form notes that memory loss is a "common side effect of ECT" and that patients may be left with "some permanent gaps in memory."²⁵⁸ The form defines memory loss as the inability to remember "past events" and "new information" and suggests that memory improves as time from treatment increases.²⁵⁹ This simplistic statement is inadequate to fully apprise an individual of the true memory-loss risks associated with ECT. The amount of memory lost to ECT-induced amnesia cannot be predicted, and in some cases it

²⁵² *Id.* at 31.

²⁵³ *Id.*

²⁵⁴ *Id.* at 35-36.

²⁵⁵ *Id.* at 37; *see also* The APA Task Force on Electroconvulsive Therapy, *supra* note 5.

²⁵⁶ CDC, Health Data Interactive, *Chronic Conditions Ages 18+; U.S. 1998-2006, Years 2004-2006*, <http://205.207.175.93/HDI/TableViewer/tableView.aspx?ReportId=101> (last visited Feb. 5, 2009).

²⁵⁷ *Id.*

²⁵⁸ The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

²⁵⁹ *Id.*

may have devastating permanent impacts.²⁶⁰ Studies demonstrate that ECT-induced memory loss is not limited to information about discrete events or facts that are easily regained, but encompasses all thoughts, feelings, personal interactions and relationships, learning, and skills associated with the erased time that may never be recaptured.²⁶¹ For some elderly individuals, signs of cognitive decline can lead to even greater depression and feelings of hopelessness.²⁶² Patients should be made aware of the real risks of memory loss and educated about how such loss may impact different aspects of their lives.

(8) *Efficacy*

The APA form does not provide information on the effectiveness of ECT and simply notes that the patient may recover completely, partially, or not at all.²⁶³ Within the medical community, opinions regarding ECT range from those who consider it a completely safe and effective treatment to those who believe ECT is ineffective and likely causes brain damage. Yet, patients are only provided with the former view. To ensure that they have the capacity to provide informed consent, patients must be provided with objective commentary covering both sides of the debate.

V. RECOMMENDATIONS

A. *Amend Informed Consent Form*

A prerequisite to obtaining true informed consent is the objective dissemination of accurate information. Informed consent forms provided to patients must contain authentic information regarding the risks and benefits of ECT. The forms should include objective commentary on the experimental nature of the procedure, the regulatory status of the device used in the procedure, and an explanation of the nature and duration of electrical insult the patient's brain will endure with each treatment. Such discussion should acknowledge the conflicting views within the medical community regarding the risk of suffering permanent brain damage following ECT. The form must

²⁶⁰ Harold Robertson & Robin Pryor, *Memory and Cognitive Effects of ECT: Informing and Assessing Patients*, 12 ADVANCES IN PSYCHIATRIC TREATMENT 228, 234 (2006).

²⁶¹ *Id.*

²⁶² See generally David J. Vinkers et al., *Temporal Relation Between Depression and Cognitive Impairment in Old Age: Prospective Population Based Study*, 329 BMJ 881 (2004), available at <http://www.bmj.com/cgi/content/abridged/329/7471/881>.

²⁶³ The APA Task Force on Electroconvulsive Therapy, *supra* note 5, app. B.

provide objective commentary regarding the chasm that currently exists within the scientific literature regarding the overall efficacy of ECT, the impact electric shock is believed to have on cognition, and an accurate recitation of patient relapse rates following ECT. The form should objectively detail how drugs administered during treatment impact the patient's body and provide information relevant to populations of patients at special risk. Because ECT is often administered to treat suicidally depressed patients, to be effective the form must provide objective commentary on the efficacy of ECT in the prevention of suicide. Most importantly, the form should provide objective commentary regarding memory loss. Such discussion must faithfully follow the scientific literature and acknowledge the true nature and extent of memory loss. Additional pertinent information should be added to the form as it becomes available and accepted within the medical community. These changes will allow physicians to more realistically fulfill their legal obligation to obtain informed consent prior to administering ECT.

B. Establish a National Reporting System for ECT

Despite more than six decades of controversy surrounding the use of ECT, the practice has largely been ignored by state and federal agencies. While all states regulate ECT administration to some degree,²⁶⁴ only six states currently require health care facilities to keep records or provide reports on ECT's use and outcomes.²⁶⁵ Despite the reemergence of ECT, there is no mechanism in place to determine the number of patients receiving ECT or to assess patient outcomes. Moreover, there is no mechanism to assess how patients respond to the different forms of ECT that may be administered. These problems are contributing factors to the chasm that currently exists within the medical community regarding ECT. A national reporting system will address these problems and create a national databank that scientists, policy makers, and the general public may mine for information relevant to their needs.

Under the proposed national reporting system, all medical facilities and health care providers that administer ECT would be required to make quarterly reports to an identified agency within the United States Department of Health and Human Services.

²⁶⁴ William J. Winslade et al., *Medical, Judicial, and Statutory Regulation of ECT in the United States*, 141 AM. J. PSYCHIATRY 1349, 1349 (1984).

²⁶⁵ Lawrence, *supra* note 63 (noting that Massachusetts, Illinois, Vermont, Colorado, California, and Texas require some form of reporting related to ECT administration).

The information reported should, at a minimum, include the diagnosis for which ECT was administered; the type of machine utilized; the type, duration, and strength of the electrical stimulation utilized; a list of the medications administered; the name, age, and gender of the patient; the number of treatments given; the source of the treatment payment; an evaluation of comorbidity and risks associated therewith; and a detailed account of any complications or adverse effects that the patient experienced.

Requiring all facilities and physicians to collect and report information on ECT administration will serve several important goals. First, to collect and report such data facilities and physicians will necessarily have to increase oversight of the administration of ECT to ensure accurate reporting. Indirectly, this will result in patients receiving better overall care. Second, requiring such reporting will allow for the creation of a national database containing information of value to researchers, policy makers, and the general public. Informational gaps within the scientific literature created the current debate among health care providers. By creating a national database of information, physicians can evaluate the results of ECT more thoroughly and make more informed, patient-specific decisions concerning the value of ECT. Third, requiring facilities and physicians to file quarterly reports will likely result in the formation of more appropriate standards and rules for ECT administration and lead to greater accountability within the medical community.

The regulation of electroconvulsive therapy is accepted as a legitimate exercise of a state's inherent police power because each state has an interest in seeing that such procedures are performed under circumstances ensuring maximum safety for the patient. However, the current system does not go far enough to ensure patient safety and protect patient autonomy. This is because no uniform system is in place for state health officials to effectively evaluate the risks and benefits of ECT administration. The establishment of a national reporting system will address this problem.

C. Fund National Studies on ECT

The debate regarding ECT's therapeutic value is based largely on the absence of empirical evidence obtained from the study of large homogenous populations. To ensure that patients are adequately apprised of the risks and benefits of ECT, further research is warranted. Studies should focus on observed differences in pre- and post-ECT memory in large populations, and within smaller subpopulations that may be at special risk. Because more than 72 million baby boomers are heading toward retirement and depression is prevalent among the elderly, ECT will likely play a very important role in

psychiatric care. Thus, studies examining the efficacy of ECT are both necessary and timely.

VI. CONCLUSION

ECT remains one of the most controversial treatments administered to psychiatric patients. Despite offering ECT for more than sixty years, the medical community has failed to reach a consensus regarding ECT's therapeutic value, its optimal method of administration, or its potential to cause serious and permanent harm to patients. In view of these disagreements and the fact that patients who receive ECT are often in extremely vulnerable states of mind, ECT should be banned until further research justifies its continuation. Because an outright ban is unlikely for a practice that many psychiatrists use as a treatment of last resort, greater care must be taken to ensure that health care professionals obtain true informed consent before administering ECT. Obtaining true informed consent is not possible without immediate change, however, because health care professionals continue to marginalize or deny conflicting evidence of ECT's harmful effects. This approach results in the continued dissemination of inaccurate or incomplete information, making it impossible for a patient to truly understand the nature of the procedure or comprehend its real risks and potential benefits. The best way to address this problem is to revise existing ECT informed consent forms to include objective commentary regarding the nature, inherent risks, and potential benefits of ECT that faithfully follows the existing scientific data. To ensure that updated, accurate information is available for dissemination, a mandatory national reporting system should be established to collect critical data on ECT use in all states. As a check on the accuracy of the data reported, large-scale randomized control trials designed to test the efficacy of ECT should be conducted. By making the appropriate changes and engaging in further research, health care providers can satisfy their mandate to obtain true informed consent from patients. In view of ECT's widespread use among the elderly and the imminent retirement of millions of baby boomers, immediate change is warranted.