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THE PUBLIC'S ROLE IN THE EVALUATION OF HEALTH CARE TECHNOLOGY

The Conflict Over ECT

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Abstract

The use of electroconvulsive therapy (ECT), controversial since its inception, offers an instructive case study on the challenge of addressing patients' perspectives in the evaluation of health care technology. Despite widespread professional acceptance of ECT, groups of former psychiatric patients have worked through the U.S. legal system to restrict and even ban ECT in the treatment of mental illness. This unusual lay participation in the regulation of health care illustrates how differing conceptions of evidence can affect the evaluation of technology. ECT provides a powerful example of the value of a more complex definition of the significant outcomes of treatment and the growing practice of outcomes assessment, especially as such research is used to shape health policy.

Disagreement between health care providers and their patients about the definition of appropriate treatment can have serious consequences for the successful application of medical technology. Where this conflict is not resolved, the health of individuals and society, and the public image of the health professions, may suffer. Nonetheless, the public's perception of health care technology has typically had a limited impact on formal technology assessment or resulting policy.

In the United States, members of the lay public have increasingly resorted to the legal system to make their voices heard in the regulation of medical practice. Nowhere has this phenomenon been more evident than with respect to the use of electroconvulsive therapy (ECT). For almost three decades, lay patients' rights and "anti-psychiatry" organizations have engaged psychiatrists in a series of regulatory battles over the use of ECT. As part of their efforts, these lay groups have challenged psychiatrists' commitment both to their patients' welfare and the scientific evaluation of psychiatric interventions.

Much of the controversy rests on the claim of former psychiatric patients that ECT offers no medical benefit and does great physical, psychological, and emotional harm. Since the early 1970s, various groups of anti-ECT activists have sought to

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outlaw the procedure, insisting that ECT is a technological form of "psychiatric assault." Psychiatrists and medical organizations nationwide have mounted a vigorous defense, pointing to years of research on the safety and effectiveness of ECT. These professionals question the lay person's ability to assess medical technology and argue that the role of patients in regulating ECT should be minimal.

ECT is an almost 60-year-old treatment that poses a special set of questions for technology assessment. This essay traces the philosophical, scientific, and regulatory conflict over ECT in the United States since the 1970s and lay efforts to have ECT outlawed in the individual states. The arguments of professional groups and lay activists highlight the tensions inherent in public involvement in medical technology assessment and illustrate some of the difficulties of participatory democracy in health policy.

THE HISTORY OF ECT

ECT was developed during the late 1930s by Ugo Cerletti, an Italian neurologist who conducted animal research into epilepsy in the 1920s and 1930s. The theory of ECT was based on the work of Ladislas Meduna, a Hungarian psychiatrist whose research on drug-induced grand mal seizures in the 1920s and 1930s suggested that induced seizures could be therapeutic for schizophrenia (53;54). Cerletti and his colleague Lucio Bini were studying the anatomical changes associated with epilepsy using electrically induced seizures in animals, when they learned of Meduna's findings. Cerletti was hesitant to induce seizures in humans electrically because of the high mortality rate in his animal studies, until he observed butchers at a slaughterhouse applying electrified tongs to animals' heads (53;54). Rather than killing the pigs, the shock from the tongs induced an epileptic coma that kept them from struggling against the butcher's knife. Cerletti was impressed with the immediate convulsion that the electric shock produced, compared with the unpredictable reaction that camphor and metrazole caused in human subjects (11;25).

Cerletti experimented with the procedure using dogs. His first human subject was a disoriented 39-year-old man, thought to be schizophrenic, who had been found by police wandering in a railroad station. Following the shock-induced seizure and postictal stupor, Cerletti reported that the subject regained his orientation and ability to think clearly (25). In subsequent work with human subjects, electrically induced convulsions surpassed the expectations of early researchers in the speed, efficiency, and reproducibility of their results (1).

The first use of ECT was also the beginning of controversy over the technology. On the 25th anniversary of ECT's development, Cerletti reminisced that the patient's reaction to the shock made him look forward to a time when another treatment would replace it (11). But while Cerletti found the act of applying electrical current to the human brain to be distressing, he valued the procedure's results. Other psychiatrists working with chemical convulsants were soon similarly convinced that the ends achieved by ECT far outweighed the distasteful aspects of the procedure. Over the next few years the use of ECT spread rapidly throughout Europe and North America, and the use of chemical convulsants almost disappeared (1).

ECT found wide acceptance in the United States in the 1940s, particularly in psychiatric institutions. ECT seemed to offer, for the first time in history, the promise of a successful form of physical intervention in psychiatry. Although little was known about the means by which induced convulsions affected mental illness, ECT was

administered to patients diagnosed with a wide range of psychiatric disorders (1;240, 6,57;53;54;86).

ECT diffused into practice on an entirely empirical basis (30). Over the next 30 years, psychiatric researchers explored the optimum number of treatments, the necessary level and duration of the current, the best electrode placements, and the conditions most responsive to ECT (1;2;30;86). As with early research into other new technologies (62), much of this work was optimistic about ECT's benefits and focused on questions of technique as much as on its mechanisms of action or absolute outcome. By the 1970s, the therapeutic efficacy of ECT was so widely accepted in practice that blinded, randomized controlled trials were thought to be unnecessary and perhaps even unethical (35;44).

There is still no accepted theory on ECT's mechanism of antidepressant action; which has been referred to by researchers and practitioners as a "mystery" (28;36; 55;59). More recent evaluations of ECT have criticized the overall quality of research on ECT (6;74;77;85;86). In 1987 the professional literature on ECT was described by one reviewer as "rife with contradictory findings" (77). The U.S. Food and Drug Administration's 1990 reclassification of ECT devices found that much of the scientific literature on ECT's effectiveness was "seriously deficient in one or more aspects" (85, 36582). A 1985 consensus statement from the National Institutes of Health (NIH) (86) and a 1990 task force report from the American Psychiatric Association (APA) (6), in particular, called for more comprehensive investigation into ECT's mechanisms and long-term effects and the identification of specific groups that have been particularly helped or harmed by the treatment.

These panels and other contemporary psychiatrists working with ECT have noted that, in the past, particularly in psychiatric hospitals, ECT was often used indiscriminately and that its use with some patients may have been abusive (1;6;7;63;86). However, proponents are quick to point out that the indications for ECT have been narrowed considerably in the past decade. Today psychiatrists typically limit their use of ECT to the treatment of severe delusional depressions, acute mania, some forms of acute schizophrenia, and catatonia, as outlined in the APA recommendations on the practice (6;7;72;86). In these contexts, practitioners may consider ECT to be preferable to drug therapy because of the need for a quick response or the difficulty of administering adequate levels of medication.

Supporters also note that, although earlier methods of administering ECT sometimes resulted in physical harm to patients, standard practice—what was originally called "modified ECT"—now includes a number of important safety measures (36). In particular, general anesthesia provides hypnosis and muscle relaxation to prevent the muscle and bone injury once caused by the physical convulsion, and the administration of oxygen prevents brain damage from apnea caused by the seizure (66;514-16;77). Some of ECT's most enthusiastic practitioners suggest that, based on the demonstrated safety and efficacy of the procedure in reducing the duration of illness and suffering, ECT should be the treatment of choice, the "first" treatment for established indications, rather than a last resort (36).

THE LAY CRITICS' VIEW OF ECT

As ECT came to prominence in the late 1960s and early 1970s, the rise of consumerism in the United States provided a stimulus for an unprecedented public examination of medicine, including psychiatry. Simultaneously, widespread political concern for civil rights led to substantial criticism of mental institutions and psychiatry's role in

the oppression of mental patients (1,248;16;39). As a part of this criticism, there was a crescendo of organized protest against ECT, which portrayed the intervention as a form of torture and social control rather than as a treatment (16,198–215;37; 38;65).

Negative public opinion was inflamed by descriptions of ECT in popular literature and film. George Orwell's *1984* (68), Sylvia Plath's *The Bell Jar* (71), and Ken Kesey's *One Flew Over the Cuckoo's Nest* (57) portrayed ECT as both painful and terrifying. The critically acclaimed film version of Kesey's novel, which was seen by a wide lay audience, showed ECT being used as punishment for uncooperative patients. Lesser known works that describe the experience of ECT, both fictional and biographical, have had wide circulation among psychiatry's critics. Together with occasional stories about the abuse of patients in psychiatric hospitals, accounts of the misuse of ECT have continued to appear in popular magazines and newspapers. One vivid example was a two-day, front-page series published by the national newspaper *USA Today,* which detailed the recent death of a patient following ECT and reported financial conflicts of interest among ECT's most published researchers and strongest advocates (20;21;22;23;24).

From the outset, opponents of ECT typically based their efforts on the work of psychiatrists who questioned the treatment of patients in institutions and who criticized ECT for its role in the social and behavioral control of the mentally ill. In the 1960s and 1970s, Thomas Szasz, Ronald Liefer, and R. D. Laing argued against treatment modalities like ECT because they questioned the presupposition that mental illness can be contained in medical models (14;50). Members of the "anti-psychiatry movement" argued that modern psychiatry provides society with a set of classifications for labeling and controlling moral behavior, and under the shield of self-regulation prevents others' research and alternative treatments that would challenge these classifications (14;37;50;65).

Many of the most vocal critics of ECT have been former psychiatric patients who had themselves undergone the procedure (16,214–15). Since the 1970s, former patients across the United States have formed organizations that combined psychosocial support with political advocacy. For the past two decades, these organizations, and other groups concerned with patients' rights issues, have collected patients' accounts of their experiences with ECT. Their primary goal has been to contest psychiatrists' claims about the safety and efficacy of the treatment with conflicting data documenting ECT's short- and long-term outcomes (16). While concerned with the broader question of patients' rights, they have specifically condemned ECT as causing pain, memory loss, and brain damage.

CONFLICTING REPORTS OF SIDE EFFECTS AND OUTCOMES

Patients' experience of pain during ECT has been a major point of contention between psychiatrists and former patients. Patients who received ECT without anesthesia in the 1960s and 1970s have been widely cited by ECT's contemporary opponents. They use vivid images to describe the electric shock: "a jolting pain . . . like an electric crowbar"; "a flash of lightning"; "a firecracker, pain and lights, burning, screaming" (38). However, few of the descriptions of pain used by critics of ECT refer specifically to the modified procedure.

With the use of short-term general anesthesia for ECT, practitioners now describe the procedure as "painless" (51). More typically, ECT is likened to a trip to the dentist, a comparison made by patients responding to post-ECT surveys in the 1970s

(40;41;49;52). Some psychiatrists have acknowledged that some patients may be aware of the shock, since the level of anesthesia obtained may vary in clinical practice (43). Others have suggested that persons who receive ECT do not really experience pain, but rather that "it is possible that in reconstructing what may have happened to them, some patients may *think* that they actually felt pain" (51). As with the documentation of pain generally (60), pain with ECT remains a difficult phenomenon to quantify and assess; moreover, postanesthetic and/or postictal amnesia may affect patients' reports of any sensation immediately before or during the procedure.

Long-term loss of memory and confusion after ECT are also effects under debate (45). Psychiatrists once believed that memory loss was an important part of ECT's therapeutic effect and postconvulsive hypoxia was not corrected in order to maximize memory loss (34). In the last 20 years, however, research has shown that memory impairment is not therapeutic, and modifications in ECT technique were intended to decrease the severity and duration of memory loss. In particular, the effects of unilateral (modified) versus bilateral electrode positioning on memory have been the subject of multiple studies (2;17;36;76;78), with unilateral ECT reported to be as efficacious and less debilitating.

For a time, proponents of modified ECT contended that no memory loss occurred as a result of the modified procedure (1,245;35). Today, however, practitioners distinguish between memory functioning—the ability to learn and retain new information, the permanent amnesia surrounding events during the course of treatment, and the experience of impaired memory that cannot be measured objectively (1,192;86). Even among ECT's advocates, however, there remain conflicting accounts of whether and how much either bilateral or modified ECT affects these three aspects of memory. The NIH Consensus Panel concluded that "deficits in memory function, which have been demonstrated objectively and repeatedly, persist after a normal course of ECT," and that the severity, not the effect of memory deficit itself, is related to the placement of electrodes, number of treatments, and type of electric stimulus (86,2105). The APA and some individual ECT researchers, however, maintain that neither form of ECT affects memory function, and that amnesia surrounding the time of treatment results only from bilateral ECT (1;6).

Based on the results of standardized pre- and posttreatment tests of memory, proponents of ECT report that patients' memory abilities typically return to baseline performance within weeks (1;6,109;36). Proponents also cite a number of studies that demonstrate no persistent impairment after 6 months (1;36). However, long-term studies of memory after ECT, like long-term studies of medical intervention generally, have been relatively rare (79;86). A 3-year follow-up study in 1988 found no objective signs of memory impairment among a group that had received ECT for depression, but noted that a large number of individuals reported subjective difficulty with both memory functioning and amnesia, and that many of them experienced frustration and despair over persistent memory loss (79).

Anti-ECT activists want psychiatrists to take these complaints more seriously (16;38;43;44). Some psychiatric interpretation of these subjective reports suggests that such patients' experience and subsequent anger is the result of underlying depression (5,136;31;80;86) and even subclinical dementia (5,136), which might be resolved through effective treatment. Others suspect that the patients who complain about ECT are those who have been committed to psychiatric facilities against their will and the few whom the treatment has not helped (1,241–42;5,136;42). However, ECT's critics are angered by the contention that what they consider a side effect is instead a sign that additional treatment is warranted.

ECT's critics attribute memory loss to brain damage. The scientific standard for evidence of brain injury is a crucial point of contention between lay and professional evaluations of ECT. Lay opponents particularly cite the work of neurologist and anti-ECT activist John Friedberg (16;38). His 1976 report of patients who had received ECT 10 to 15 years earlier found "dramatic deficits" and concluded that the data "suggest ECT causes irreversible brain damage" (44). They also point to early research and commentaries by some practitioners, including some contemporary advocates, that ECT can be compared with head trauma and that ECT-related brain damage is essential to its therapeutic effect (16,198-99).

Friedberg and others have argued that despite modern efforts to make ECT safe, the neurophysiologic studies from the 1940s and 1950s that consistently show "severe brain damage" after ECT are still quite valid because neither the voltage needed to induce convulsions nor the nature of the human brain has changed since they were done (16;43). They further argue that unilateral placement of electrodes still causes brain damage, but that the damage is simply not as apparent because the right side of the brain is primarily involved with more subtle dimensions of personality and behavior. Moreover, these critics contend, modified, dose-response ECT is even more likely to be damaging because it requires additional electricity to compensate for the antiseizure effects of anesthetic agents (16). More recent work advocating high-dose right unilateral ECT (76) would raise similar criticism.

Proponents insist that while the universal assumption that ECT causes brain damage is hard to combat, current research on brain injury and persistent memory deficit fails to support patients' subjective complaints (1,69-76;34). Contemporary prospective imaging studies with computed tomography (CT) and magnetic resonance imaging (MRI) have found no evidence that ECT produces physical damage (28). Autopsy studies on persons who have undergone ECT, which opponents seek as confirmation of a link between subjective complaints of memory impairment and brain damage, are typically disregarded by ECT researchers as subject to too many confounding variables to be meaningful (1,72;35).

INFORMED CONSENT AND LEGISLATIVE JURISDICTION OVER ECT

Although patients typically have little formal role in judging the overall risk, benefits, and value of interventions, individually they are routinely expected to assess therapies proposed specifically for them through the process of informed consent. Explicit in the concept of informed consent is the patient's legal and ethical right to refuse treatment that he or she finds inappropriate in any way. Informed consent for ECT has been complicated, however, by two factors: the special status of the brain and the traditional denial of informed consent to those psychiatric patients who are judged to be incapable of making decisions concerning their own welfare (5,141-42).

Patients with conditions traditionally considered treatable with ECT who refuse the intervention have been of special concern for informed consent. In cases where the patient suffers from severe depression and there is a risk of suicide or self-harm, the common view among psychiatrists is that the patient who cannot decide individually in a rational manner stands to gain more than he or she will lose from forced treatment (63). Nonvoluntary intervention is based on the physician's ethical commitment to relieve suffering and to prevent self-inflicted harm (63).

Critics of the nonvoluntary use of ECT have contended that such intervention contains a circular argument: If the patient disagrees with the psychiatrist's recommendation of ECT, the patient's judgment, and even capacity to consent, may be

questioned by the psychiatrist (46). ECT's opponents have argued that professional ethical standards alone do not provide enough control over the nonvoluntary application of ECT, despite guidelines on the surrogate consent of family members.

In the late 1960s and early 1970s, litigation and legislative activity across the country began to establish formal legal standards for informed consent both for medical treatment generally and, more specifically, for psychiatric treatment (33). In a landmark series of cases, litigation over the involuntary use of ECT led a federal court in Alabama to establish, among other requirements, a basic right to informed consent for ECT (13;61;89). In 1974 the APA appointed a task force to establish guidelines on ECT, with special attention to informed consent.

That same year, activists in California began an unprecedented lay campaign for legislative controls on ECT (1;16;75). The San Francisco-based Network Against Psychiatric Assault (NAPA), composed of former psychiatric patients and their supporters, and the Citizens Commission on Human Rights, an international anti-psychiatry group established by the Church of Scientology, presented their views on ECT to California Assemblyman John Vesconcellos (D-San Jose). That June, Vesconcellos introduced Assembly Bill (AB) 4481, drafted in part by NAPA members, to the California legislature (75).

AB 4481 amended portions of California's Welfare and Institutions Code outlining the legal rights of psychiatric patients. The final draft of the bill provided a detailed right to informed consent for ECT and psychosurgery to all persons admitted as voluntary patients to private psychiatric hospitals or state and county mental institutions, mentally retarded persons committed to state hospitals, and persons involuntarily detained for observation, evaluation, or treatment in any hospital. The bill specifically defined informed consent to include the right to refuse ECT and psychosurgery at any time.

Under AB 4481, the physician recommending ECT was required to document in the patient's chart that ECT was medically necessary, the reasons for the treatment, the fact that the treatment was critically needed, and that all other appropriate forms of treatment had been tried unsuccessfully. This record then was to be reviewed by a standing committee of three physicians, who were required to agree unanimously with the treating physician's report and assessment of the patient's ability to give informed consent.

ECT could be given then only after the patient had signed a written consent form stating that the treating physician had explained orally to him or her and a responsible relative, guardian, or conservator the following information: the nature of the patient's condition and its seriousness; the procedures to be carried out; the benefits to the patient to be gained by the procedure; all of the possible risks and side effects; the degree of uncertainty of the benefits and the risks; possible alternative therapies; the right to refuse treatment at any time; and the possible conditions under which treatment could be given without consent.

No patient was to be given ECT if he or she was judged to be capable of giving consent and refused to do so. In the event that the patient was judged to be incapable of giving informed consent, ECT could not be administered until the review committee agreed unanimously to the treating physician's findings, and a responsible relative, guardian, or conservator gave consent and confirmed that he or she had been given the necessary oral statement by the physician. Physicians in violation of this law were subject to a civil penalty of revocation of license, a fine of up to $10,000, or both. In addition, patients whose rights were violated could bring civil suit against the physician for damages, judgment, reasonable attorney's fees, and court costs.

Assembly Bill 4481 was passed by both houses of the California legislature with only one dissenting vote. On September 27, 1974, then-Governor Ronald Reagan signed the bill into law (18). Despite this apparent legislative agreement, there was considerable opposition from the medical community. The bill was challenged by the Association of California Branches of the American Psychiatric Association, the California Medical Association, the California Hospital Association, and the California Conference of Local Mental Health Directors (75).

The bill's opponents cited several areas in which it raised questions for actual clinical practice. Major concerns included the breach of medical confidentiality and patients' privacy through the availability of clinical records, vague definitions of terms, which would invite suit and professional conflict, and increased length of hospital stays and costs due to delayed treatment. But these organizations found even more disturbing the fact that the legislature had mandated activities that had been under the direct jurisdiction of the medical and psychiatric profession itself. The definition of information to be given to the patient and his or her relative allowed no exercise of clinical judgment, contrary to previous court decisions on informed consent for other branches of medicine. The bill also required consultation among psychiatrists, overriding medicine's own peer review system.

Most importantly, these groups argued that "a legislature's proscribing and prescribing clinical procedures, without specifying and negotiating its concerns with the profession involved, was a dangerous precedent, inviting further arbitrary, ill-considered, poorly informed, unilateral decisions affecting the quality of human life and patient care" (75). They denied the legislature's right to regulate clinical treatment, but contested the new law's constitutionality based on its purported violation of patients' right to privacy.

In December 1974 a superior court issued a temporary restraining order against the implementation of AB 4481, pending a decision by the Fourth District Court of Appeals of the state of California. In April 1976, the Court of Appeals found certain provisions of AB 4481 to be unconstitutional but in May stated that it could not separate the unconstitutional from the constitutional (3). On the issue of informed consent, the court declared that special requirements for informed consent by psychiatric patients were appropriate because of such persons' questionable ability to consent to treatment. The court let stand the requirement that patients be given an explanation of all of the possible risks and side effects of ECT, as well as the degree of certainty of those risks and benefits. It further held that for "intrusive and hazardous" procedures such as ECT, the legislature may impose stricter requirements for informed consent than are generally required.

The court's decision on AB 4481 was particularly significant because it established the general right of the legislature to regulate medical treatments that it considered to be intrusive or hazardous. Overriding the medical profession's objections, the court ruled that the regulation of public health and safety is under the purview of the legislature and that reasonable classification of forms of treatment can be established when doing so is substantially related to a true legislative purpose.

In 1976 the California legislature enacted Assembly Bill 1032 to address the court's criticism of AB 4481; it was signed into law by then-Governor Jerry Brown that same year (75). Although the court had supported the requirement of a detailed explanation of ECT as part of the informed consent process, AB 1032 redefined the procedure for consent. The new law required that instead of all possible risks and side effects, ECT patients were to be told the nature, degree, duration, and probability of side effects and significant risks commonly known to the medical profession.

Because the court had found AB 4481 unconstitutional in its failure to provide for competency hearings for patients who refused ECT, AB 1032 established regulations governing such review. AB 1032 also added to the restrictions placed on ECT by AB 4481 with respect to minors. It completely prohibited the application of ECT for anyone under the age of 12. While 16- and 17-year-old patients were declared to have the rights of adults with respect to ECT, 12- to 16-year-olds were permitted to receive ECT only if all other provisions of the law were met and the treatment was deemed necessary and lifesaving in an emergency situation.

NAPA and other anti-ECT groups saw the court ruling as a substantial victory but considered it to be only the first step in a series of efforts to have ECT abolished nationally. Encouraged by the court's pronouncement on the legislature's jurisdiction over medical treatment, they hoped to campaign for more restrictive legislation across the country. The APA (5) soon responded with an extensive report on the theory and practice of ECT, which was sharply critical of the view of the informed consent process expressed in AB 1032. The report included a discussion of the theory of informed consent in psychiatry and included recommendations for presenting the risks and benefits of ECT to patients and their relatives as part of the consent process. Despite the significant drop in the use of ECT after passage of the restrictive legislation (58), ECT's opponents were soon disappointed to find that many patients still consented to ECT. They felt that instead of providing psychiatric patients with the opportunity to refuse ECT, the legislation had made psychiatrists more coercive and paternalistic (26).

BANNING ECT AND COMMUNITY CONSENT

In early 1982 NAPA and a group of organizations known collectively as the Coalition to Stop Electroshock sought to enact a complete ban against ECT as a form of community-informed consent. In April, they sponsored a voter initiative petition[1] in the city of Berkeley calling for such a ban. Fourteen hundred signatures were needed to place the issue on the November ballot; by the end of July the drive had gathered over 2,500 signatures (47). In the first week of August, the initiative was placed on the ballot as Proposition T, which declared in part that Berkeley residents "have a fundamental right against interference with their thought processes and states of mind through the use of electric shock treatment" (47). Proposition T made the administration of ECT a misdemeanor punishable by a fine of up to $500 or up to 6 months in jail.

The referendum received a great deal of national attention. It also received considerable criticism from the medical and psychiatric communities, worried that "a ban would be an intrusion on the rights of citizens as well as the rights of professionals to exercise good medical judgment" (47). Legal critics also insisted that the measure conflicted with already existing state laws that regulated the practice of ECT, and as such, was likely to be struck down by the courts immediately if it did pass.

After a heated campaign, Proposition T passed by a vote of 25,380 to 15,765 (61.8% to 38.2%) (56). Backers of the measure were elated and promised to help ECT's opponents elsewhere pass similar laws in a nationwide effort to eliminate the practice of ECT. Berkeley's ban on ECT went into effect on December 3, 1982 (48). Less than 2 weeks after the ban became law, a group of professional psychiatric organizations filed suit in Alameda County Superior Court, seeking to invalidate the ordinance. The organizations claimed that medical practice was not a "municipal affair" and that the ban directly conflicted with a state law that recognized the right

of individual patients to consent to ECT and that regulated its use (48). They also stated that the ban violated patients' constitutional right to privacy as provided for under state and federal law. On January 18, 1983, presiding Judge Donald F. McCullum issued an injunction restraining the city from enforcing its ban pending the outcome of a trial on the issues involved (12).

On September 15, 1983, Alameda County Superior Court Judge Winston McKibben placed a permanent injunction on the ban, declaring it unconstitutional because it was preempted by a broader state law regulating ECT (67). In the ruling he concluded that the state law must take precedence over more restrictive local ordinances. Although he issued no official statement, McKibben commented to the Associated Press that "you can't have each local community governing situations differently" (10), and added that state-imposed safeguards were an adequate form of control. A representative of the professional organizations that had brought suit stated that the groups were quite pleased with the injunction and claimed that the court had affirmed that "the ultimate right is the citizen's right to have his healer unobstructed" (10).

Acting on a vote of the Berkeley City Council, in December 1983 attorneys for the city of Berkeley appealed the dismissal of the ban to the 1st District Court of Appeals (64). The appeal sought to overturn the Superior Court's ruling on the grounds that ECT is not a valid form of therapy, but rather "one of several unproven treatments that have been in vogue at various times in the psychiatric profession" (9). On February 28, 1986, Presiding Judge Clinton White and a panel of the appeals court denied the appeal, granting summary judgment to the psychiatric organizations that had contested the ban in an unequivocal affirmation of the original ruling (67). Three months later, the California Supreme Court refused to hear Berkeley's further appeal of the case.

Although there have been no further legislative efforts toward limiting ECT in California, opponents have attempted to curtail the use of ECT by limiting or eliminating governmental and insurance payments to hospitals and psychiatrists for ECT, and by lobbying for stricter regulation of ECT through the U.S. Food and Drug Administration's (FDA) medical device act (1,243-44;16,215).[2] Now two decades old, the state's laws remain some of the most restrictive in the country and continue to serve as the benchmark for patients' rights groups that seek to regulate ECT.

LEGISLATIVE EFFORTS OUTSIDE OF CALIFORNIA

Motivated by the success of efforts in California, anti-ECT activists elsewhere pursued similar legislative initiatives to restrict its use. By 1983 over 30 states had either statutes or other regulations limiting the practice of ECT (89). In 1979 Colorado passed legislation (29) that paralleled California's law on consent. Texas passed similar legislation in 1993 (83). Both Colorado and Texas law prohibit the use of ECT for minors aged 16 and under and restrict its use with involuntarily committed patients; both states also require specific elements of informed consent and extensive reporting on the administration of ECT. Texas further mandates the registration of ECT equipment. A bill modeled after Texas law is pending in the West Virginia Senate Committee on Health and Human Resources (88) as of this writing.

Legislation promoted by anti-ECT activists has also been introduced in both Vermont and Texas to ban ECT. The first of these bills was introduced in the Vermont legislature in 1985 and was defeated in committee. The same provisions have been unsuccessfully introduced in virtually identical bills in each of the subsequent biennial

sessions; most recently, House Bill H313 died after legislative hearings in April 1986 (87). The bill's supporters are considering reintroduction of the provisions in the coming session, as well as separate legislation that would restrict the use of ECT with minors and require specific consent procedures. The second was introduced in the Texas House in 1995. House Bill 2452 (84) sought to make any administration of ECT punishable by a fine of up to $10,000, six months in jail, or both. This bill, too, died in committee on its first appearance, but its authors vow to reintroduce it in the next session. In both states, the bills and the anti-ECT groups that support them have received significant media attention and have provoked considerable public discussion of the controversial aspects of ECT and its history.

A ROLE FOR LAY PERSPECTIVES IN TECHNOLOGY ASSESSMENT AND HEALTH POLICY

Society has traditionally exempted medical practice from the public regulation typical of other activities, in recognition of the health professions' proclaimed commitment to the values and norms of scientific excellence and compassionate care (82,97). Organized psychiatry has repeatedly sought to claim this exemption, arguing that defining treatment and appraising its adequacy are matters for medical determination (4;70), and that legislators, judges, and other lay bodies are not qualified to judge clinical issues and complex medical questions (39;56). This view is expressed most fully in the declaration of one ECT advocate that "scientific integrity and commitment to the care of the individual patients are better regulators of clinical practice than legal decree or public involvement in clinical decision-making" (15,9).

Public trust is essential for public endorsement of the right to self-regulation. ECT's critics have been able to influence a significant amount of restrictive legislation by challenging both the scientific validity of psychiatric research and the ethics of using a procedure that some patients deplore. In short, they have challenged the professional trustworthiness of psychiatry. Their impassioned portrait of former ECT patients as victims betrayed by psychiatrists is compelling to many lawmakers and the public at large, who may already harbor apprehensions about psychiatry in general (16). The negative image of psychiatry that activists hold up to the public is only intensified by the persistent contradictions and unanswered questions in the professional literature on ECT. As the courts and legislatures have found the science behind ECT lacking, they have been more willing to limit psychiatry's right to control its use than they might have been otherwise (39,255;89).

What is unfortunate about much of the conflict over ECT is that many on both sides assume that scientific evidence and patients' experiences are incommensurate and that there is a fundamental dichotomy between "objective research" and "subjective reports." Many researchers acknowledge that criticism from ECT's opponents over the past decade has prompted important new research into the technology (27; 53;69). Still, not much headway has been made in the formal evaluation of patients' experiences and views of the contemporary practice of ECT, despite the formal call for such work from the NIH and FDA (85;86). Because the "anecdotal" evidence of patients' accounts cannot be linked to documented, much less controlled, episodes of ECT, it is dismissed by researchers; and because researchers' formal statistical data bear little resemblance to their personal stories, patients and patient advocacy groups reject the professional literature as irrelevant. Neither ECT's advocates nor its opponents appear interested in the systematic appraisal of patient experience as part of an integrated evaluation of the technology's effects.

Such narrow definitions of meaningful information ultimately hinder the stated objectives of both groups: to help people with mental illness and to understand and improve the range of useful interventions. Because these narrow models of effect discourage multidisciplinary interpretation, they confine their proponents' interactions to the political sphere, where many other interests may prevail over the good of the mentally ill. Political power rather than a desire for consensus thus shapes which view is accepted in policy making, and all sides typically feel disadvantaged by others' "unwarranted" influence.

Integrating patients' perceptions and experiences of treatment into the interpretation of clinical data is an essential element of efforts to restrict the influence of political interests in health care in the 1990s. Outcomes research, one of the decade's most heralded approaches to technology assessment for health policy, demands that the evaluation of an intervention include not only what difference it makes with respect to patient outcomes but whether decisions about treatment alternatives reflect patients' values (73). Many types of health services researchers and agencies, not just physicians and medical professional groups, are capable of conducting outcomes research using clinical data; increasing numbers of lay analysts and policy makers have undertaken outcomes research in response to concerns about the economic efficiency of health care. Although most of these efforts have been in other "priority" areas of medicine (73), outcomes research on ECT is likely as federal agencies and managed care organizations consider the cost-benefit of mental health services generally.

Both the proponents and critics of ECT have much to gain from taking part in such integrated research. Professional and lay groups truly committed to the practice of good mental health care will have an opportunity to prove the strength of their own positions in an arena where each may challenge the accuracy and completeness of others' work and address others' biases and conflicts of interest. Patients and their advocates will gain both procedural and substantive authority in their interactions with health professionals, and their more open relationship will be less adversarial and more satisfying for both parties (32).

There is also much to lose from ignoring such research. Early proponents of outcomes assessment have argued that the real threat that faces clinicians is not the loss of control that comes from regulation, but rather the loss of control over the science of medicine that occurs when someone else knows more about the effect of doctors' work than they do (32). While the APA has maintained that "there is no division of *informed* opinion" about ECT (5,145), ECT's practitioners could lose their authority if others' detailed outcomes research informs policy makers differently about ECT's broader, long-term consequences. Similarly, anti-ECT activists could lose their public support if comprehensive documentation of contemporary patients' experience with ECT does not confirm earlier patients' complaints.

Careful quality-of-life studies and research into the long-term daily consequences of medical intervention hold the promise of including patient's perspectives in evaluation in ways never considered in the past era of clinical research. Increasingly, public opinion and community standards will be important in the definition of the common interest in health care and the day-to-day regulation of its practice. Both critics and advocates of ECT would do well to demand that policy makers accept only state-of-the-art techniques in evaluating the "mystery" of ECT and put an end to the controversy of the past two generations.

NOTES

[1] The voter initiative petition is a means available in some U.S. states by which citizens can create new law by local, countywide, or statewide referendum. This right is used actively by citizens groups in California.

[2] While a full consideration of FDA regulation of ECT equipment is beyond the scope of this paper, public commentary has had a significant effect there as well. In 1976, when it first received authority to regulate medical devices, the FDA assigned ECT machines to class III – devices that have not been proven safe and effective. This classification was, in part, the result of extensive testimony from former patients who claimed injury as a result of ECT. When the APA petitioned FDA for reclassification in 1982, negative commentary from former patients to the agency was again tremendous. In September 1990 the FDA did reclassify into class II ECT devices intended to be used solely for the treatment of severe depression, effective upon the establishment of performance standards for their safe and effective use. As the process of establishing performance standards is expected to take many years, their use remains effectively regulated under the standards for class III devices (85).

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