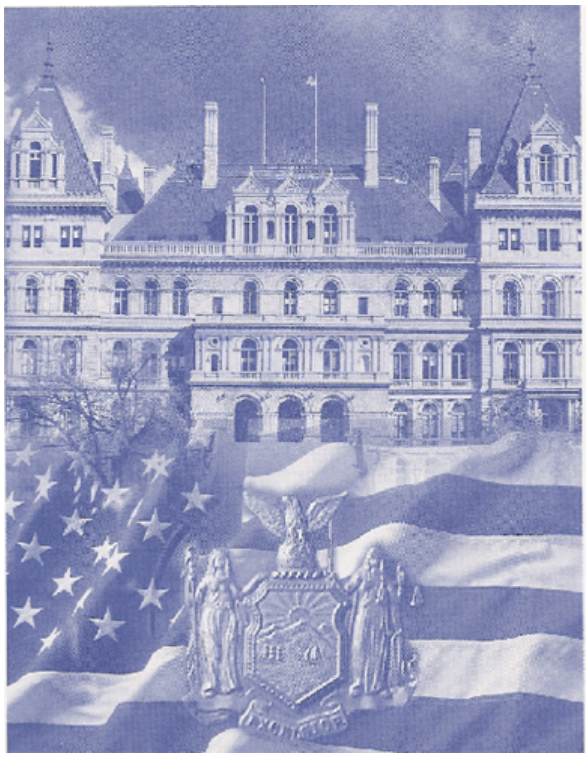
New York State Assembly

Report on Electroconvulsive Therapy (ECT)



Committee on Mental Health
(March 2002)

Martin A. Luster, CHAIR

NEW YORK STATE ASSEMBLY
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Table of Contents

EXECUTIVE SUMMARY

Electroconvulsive Therapy (ECT) is a procedure that continues to be the subject of serious controversy and disagreement, even within the psychiatric profession. ECT entails sending an electrical current into the brain of a patient to produce a grand mal epileptic seizure. It has been used for many years to treat certain types of mental illnesses, primarily as a last resort when all other treatment modalities failed. More recently, the New York State Office of Mental Health has encouraged the use of ECT as an initial or mid-level treatment option.

The New York State Assembly's most recent examination of the issue of ECT began in February, 2001. On February 14, 2001 at a public hearing in Syracuse, New York regarding the proposed closing of the Hutchings Psychiatric Center , a presenter discussed the case of Paul Henri Thomas, then a patient at Pilgrim Psychiatric Center who had been receiving ECT against his will. The Assembly subsequently became aware of the case of Adam S., another patient at Pilgrim P.C. who was a recipient of ECT therapy against his wishes and those of his family.

Since the State Legislature had not conducted a formal review of ECT use in New York State since the mid-1970s, the Assembly scheduled hearings in New York City on May 18, 2001 and in Albany on July 18, 2001. The purpose of the first hearing was to determine the incidence of ECT use in the State, its efficacy, benefits and risks, and to examine issues related to informed consent and involuntary court ordered ECT. The second hearing was held to obtain feedback on the initial series of proposed legislation addressing ECT introduced by the Assembly.

It was clear from testimony received that there was a wide variation of opinion related to the use of ECT. Proponents claimed that ECT is a safe, effective procedure with no permanent adverse side effects and cited a figure of 1 in 10,000 deaths related to ECT to document its safety. In contrast, opponents maintained that ECT causes brain damage, can result in permanent memory loss and, in some cases death, and asserted that the death rate related to ECT was closer to 1 in 200. Opponents expressed additional concerns about the utilization of

ECT on children, the elderly, other vulnerable populations and possible use as a behavior modifying, non-therapeutic intervention for mentally retarded individuals.

Currently, there is no regulation of ECT protocols by the State or federal governments. However, the federal Food and Drug Administration (FDA), which has regulatory authority over ECT devices, considers ECT machinery to be experimental, Class III devices. Such a classification is used for pre-market approval for medical devices that show an unreasonable risk of illness or injury. Although the FDA has never completed testing of ECT devices to determine its safety, ECT has been in use since the 1930's.

In addition to the public hearings, New York State Assembly Mental Health Committee Chairman, Martin A. Luster, and Committee staff met with proponents and opponents of ECT, as well as representatives from the State Office of Mental Health (OMH), Office of Mental Retardation and Developmental Disabilities (OMRDD), Commission on Quality of Care for the Mentally Disabled (CQC), and the Mental Hygiene Legal Service (MHLS). Committee staff also reviewed extensive literature regarding ECT.

The Committee sought information regarding the prevalence of ECT use within the State and found there were no available statistics. The Committee requested the CQC complete a survey of ECT use in State operated psychiatric centers. The CQC found that protocols varied at the five State-operated psychiatric centers that perform ECT. CQC recommended that OMH establish a Blue Ribbon Task Force to develop procedures for consistent application throughout State facilities administering ECT use, while simultaneously promoting the application of best practices and strict adherence to statutory and regulatory standards for safeguarding patient rights. The Committee has requested the CQC complete another survey of ECT use in non-state operated facilities. The results of this survey are not yet complete.

Moreover, the Committee requested the MHLS provide statewide statistics on applications for court orders authorizing ECT. In April 2001, the MHLS reported a 73% increase in such applications between 1999 and 2000. On May 17, 2001, in a written response to the Committee's initial public hearing notice, the MHLS identified concerns with respect to the current practices for obtaining consent for ECT.

The Committee also reviewed the American Psychiatric Association's (APA) 2001 Task Force report, **The Practice of Electroconvulsive Therapy, Recommendations for Treatment, Training, and Privileging, Second Edition**, which delineated issues related to the education and training of ECT practitioners, procedures for obtaining informed consent, standards for ECT administration and safety of ECT equipment. The Task Force report further identified certain equipment that should no longer be used to provide ECT and expressed concern that ECT facilities be properly equipped and staffed with personnel to manage potential clinical emergencies. During its review, the Committee uncovered instances where ECT had been administered with equipment that the APA stated should no longer be used and on an outpatient basis in physician offices where emergency equipment and staff were unavailable.

Article VII of the New York State Constitution states that the aid, care and support of the needy are public concerns (Section One), that the protection and promotion of the health of the State's inhabitants are also matters of public concern (Section Three) and that the care and treatment of persons suffering from a mental disorder or defect, as well as the protection of the mental health of inhabitants may be provided by State and local authorities in such manner as the Legislature may from time to time determine (Section Four).

In an effort to mitigate identifiable areas of concern, the Assembly has introduced five legislative proposals to ensure proper use and administration of ECT:

- Resolution 2097 - Resolution calling upon the United States Congress to require the FDA to determine safety of ECT equipment and to pass legislation establishing proper protocols and administration of use.

- A.9081 - Defines capacity as well as procedures for assessing a patient's mental capacity in supplying consent for ECT treatment. Requires written disclosure of benefits, risk and alternatives as a component of authorized (i.e. signed) informed consent.

- A. 9082 - Creates a temporary advisory council on ECT to address associated issues, including but not limited to education and training of ECT practitioners on standards for administration and equipment safety.

- A. 9083 - Requires mandatory reporting of information regarding ECT use to enable the OMH Commissioner to better regulate its application and help ensure that the Legislature effectively exercise its constitutional oversight function.

- A. 9084 - Mandates all facilities practicing ECT to provide accessible emergency treatment.

INTRODUCTION

In order to better understand the issues related to the efficacy and use of Electroconvulsive Therapy (ECT), Committee staff conducted extensive research. Individuals with a working knowledge of ECT were interviewed, including ECT recipients, proponents, opponents, researchers, medical and mental health professionals and human rights advocates. Staff reviewed numerous documents to gain insight regarding ECT's historical basis, its efficacy related to certain mental health diagnoses, evolution of equipment and protocols, and potential risks and benefits. Public hearings were held in New York City on May 18, 2001 and in Albany on July 18, 2001 to receive input regarding the efficacy of ECT, to identify possible legislative actions, and to receive feedback on proposed legislation. This report is intended to summarize the Committee's findings and provide a basis for legislative action regarding ECT.

This report is organized in the following manner to assist the reader in understanding the issues, controversies and recommended legislative actions: Introduction, Background, Incidence of Use, Safety, Protocols, Special Populations, Informed Consent, Cases of ECT and Conclusion.

The Committee selected eight documents for inclusion in this report, as well as testimony from its public hearings on ECT and excerpts of communications received or distributed. The documents referred to throughout the report include, but are not limited to the following:

- "Electroconvulsive Therapy. National Institutes of Health, Consensus Development Conference Statement," June 1985.
- New York State Protection and Advocacy for Individuals with Mental Illness Advisory Council (PAIMI), Resolution, March 15, 1996.
- "ECT Practices in the Community, an unpublished report," J. Prudic, M. Olfson, and H.A. Sackeim.
- **The Practice of Electroconvulsive Therapy, Recommendations for Treatment, Training, and Privileging**, Second Edition, Task Force Report of the American Psychiatric Association, 2001.
- Written Comments to the Committee regarding ECT by the Mental Hygiene Legal Services (MHLS), May 17, 2001.
- "Information about ECT," Office of Mental Health, July 2001.
- "Survey of the Provision of Electro-Convulsive Therapy (ECT) at New York State Psychiatric Centers," Commission on Quality of Care for the Mentally Disabled, August 7, 2001.
- "ECT: Sham Statistics, the Myth of Convulsive Therapy, and the Case for Consumer Misinformation," Douglas Cameron, **The Journal of Mind and Behavior**, Winter and Spring 1994, Volume 15, Numbers 1 and 2.

BACKGROUND

The use of Electroconvulsive Therapy (ECT) has been a subject of controversy since it was first introduced in 1938. The process of sending an electrical shock into a person's brain in order to produce an epileptic grand mal seizure does not appear as a safe process to many people, including health care professionals and mental health experts. Further, the fact that mental health experts do not fully understand how ECT works, coupled with its indiscriminate use to treat a variety of mental illnesses following the first few decades of its introduction, have contributed to the ongoing controversy. The lack of federal testing of ECT devices, as well as an absence of federal or state regulation of ECT protocols and demographic and statistical data related to ECT use, have also contributed to the longstanding controversy surrounding its safety and efficacy.

The following reflects opinions from well known established organizations addressing mental health concerns in New York State and nationwide:

NATIONAL INSTITUTES OF HEALTH CONSENSUS STATEMENT, JUNE, 1985

In June 1985, the National Institutes of Health (NIH) published a Consensus Statement regarding ECT. NIH Consensus Statements are prepared by a non-advocate, non-federal panel of experts and reflect the panel's assessment of medical knowledge available at the time the statement was written. Following are excerpts from the NIH statement.

> Electroconvulsive therapy is the most controversial treatment in psychiatry. The nature of the treatment itself, its history of abuse, unfavorable media presentations, compelling testimony of former patients, special attention by the legal system, uneven distribution of ECT use among practitioners and facilities, and uneven access by patients all contribute to the controversial context in which the consensus panel has approached its task...To prevent misapplication and abuse, it is essential that appropriate mechanisms be established to ensure proper standards and monitoring of ECT (NIH, pgs. 11-12).
>
> Electroconvulsive Therapy (ECT) is a treatment for severe mental illness in which a brief application of electrical stimulus is used to produce a generalized seizure. In the United States in the 1940s and 1950s, the treatment was often administered to the most severely disturbed patients residing in large mental institutions. As often occurs with new therapies, ECT was used for a variety of disorders, frequently in high doses and for long periods. Many of these efforts proved ineffective and some even harmful. Moreover, its use as a means of managing unruly patients, for whom other treatments were not then available, contributed to the perception of ECT as an abusive instrument of behavioral control for patients in mental institutions for the chronically mentally ill, (NIH, p. 2).
>
> Although ECT has been in use for more than 45 years, there is continuing controversy concerning the mental disorders for which ECT is indicated, its efficacy in their treatment, the optimal methods of administration, possible complications, and the extent of its usage in various settings. These issues have contributed to concerns about the potential for misuse and abuse of ECT and the desire to ensure the protection of patient's rights. At the same time, there is concern that the curtailment of ECT use in response to public opinion and regulation may deprive certain patients of a potentially effective treatment (NIH, p. 2). To maximize the benefits of ECT and minimize the risks, it is essential that the patient's illness be correctly diagnosed, that ECT be administered only for appropriate indications, and that the risks and adverse effects be weighed against the risks of alternative treatments (NIH, p.5).

NEW YORK STATE PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS ADVISORY COUNCIL (PAIMI), MARCH 15, 1996 RESOLUTION

The Protection and Advocacy for Individuals with Mental Illness Amendments Act of 1991 (Public Law 100-509) provides legal advocacy supports for individuals who have been diagnosed as mentally ill and who reside in any residential facility which provides care and treatment, or who are in the process of being admitted or recently discharged from such facility. The PAIMI system investigates complaints about abuse, neglect and violation of rights, and provides both legal and non-legal advocacy on behalf of individuals. On March 15, 1996, PAIMI, a federally funded arm of the New York State Commission on Quality of Care for the Mentally Disabled, issued a resolution requesting that New York State consider development of legislation that would provide for monitoring of the provisions of ECT, as well as for informed consent of ECT recipients. According to PAIMI:

- Electroconvulsive therapy (ECT) is a procedure that continues to be the subject of serious controversy and disagreement, even within the psychiatric profession.
- There is a growing body of evidence that there is substantial potential for irreversible brain damage and permanent memory loss.
- No standards exist which pertain to the mechanical safety of equipment used to administer ECT or to the certification of the operators of such equipment.
- No State regulation or policy exists which governs the manner in which ECT is administered.
- No safeguard exists which assures truly informed consent.

When contacted by Committee staff prior to the first public hearing on ECT, PAIMI reaffirmed its support of its 1996resolution.

ECT PRACTICES IN THE COMMUNITY (an unpublished report)

In a 1997 study, funded in part by the National Institute of Mental Health, the New York State Psychiatric Institute and Columbia University conducted a survey of 86 facilities in the greater New York Metropolitan area that used ECT. Responses were received from nearly 70% (59) of these facilities.

The survey revealed that facilities varied considerably in many aspects of ECT practice, including frequent departures from field standards. It further found that the more intensive the form of ECT used at the facilities, the less likely cognitive status was assessed following

the course of treatment. The survey concluded that, "the marked departures from the field standards of care and the wide variability in how ECT is conducted, undoubtedly raise public health concerns." (Prudic, Olfson and Sackeim, p. 8)

TASK FORCE REPORT OF THE AMERICAN PSYCHIATRIC ASSOCIATION, 2001

The Practice of Electroconvulsive Therapy, Recommendations for Treatment, Training, and Privileging, Second Edition is a Task Force report of the American Psychiatric Association. Following are some key excerpts:

- The decision to recommend the use of ECT derives from a risk/benefit analysis for the specific patient.
- ECT should not be reserved for use only as a last resort.
- The likely speed and efficacy of ECT are factors that influence its use as a primary intervention. Additional considerations for the first line use of ECT relate to the patient's medical status, treatment history and treatment preference.
- ECT is most often used in patients who have not responded to other treatments.
- There are no diagnoses that should automatically lead to treatment with ECT.
- To some extent, medical adverse events can be anticipated.
- Continuation therapy has become the rule in contemporary practice…the risk of relapse after ECT is very high, particularly during the first few months…the need for aggressive continuation therapy…is compelling and should be instituted as soon as possible.
- After ECT, concern over recurrence of illness is so great…that maintenance therapy should be initiated for virtually all patients receiving continuation therapy. At present, no applicable data indicate how long maintenance therapy should be sustained after ECT.

INCIDENCE OF USE

Information regarding the incidence of ECT use in New York State is currently not required by the State. Information regarding equipment type, a provider registry (by classification), protocols utilized, consent procedures and demographic statistics need to be collected and reported in order to ensure that patient rights, safety protective measures and efficacy are comprehensively examined on an ongoing basis with regard to the administration, use, oversight and outcomes of ECT treatment in New York State.

When the issue of ECT was brought to the Committee's attention, efforts were made by Committee staff to ascertain the prevalence of ECT use in New York State. It soon became apparent that such information was not available. The Committee requested the Office of Mental Health, Commission on Quality of Care for the Mentally Disabled and Mental Hygiene Legal Services, collect specified information. The Committee also reviewed an unpublished joint report by the New York State Psychiatric Institute and Columbia University, which summarized the results of a 1997 survey of ECT use in the greater New York Metropolitan area. In lieu of comprehensive statewide information regarding ECT, the Committee has compiled anecdotal information that provides a snapshot of ECT use in the State.

NIH CONSENSUS STATEMENT, JUNE, 1985

> The panel is concerned that there are only limited data on the manner and extent of ECT administration in the United States and on the training of personnel involved in it. A national survey should be undertaken to assemble basic facts about the status of ECT treatment (NIH, p. 10).

ECT PRACTICES IN THE COMMUNITY (an unpublished report)

The 1997 study, completed by the Departments of Biological Psychiatry and Clinical and Genetic Epidemiology at the NYS Psychiatric Institute and Departments of Psychiatry and Radiology, College of Physicians and Surgeons, Columbia University, stated that ECT is utilized in the U.S. far more in private and academic medical facilities than in public sector hospitals. The report elaborates that "Age, income and race are powerful predictors of ECT utilization in the U.S., which is higher among older, more affluent, and white patients…The greater utilization in older patients has been attributed to the high presentation in this group

of medical intolerance…The greater use of ECT in non-minority populations and those of higher income is unexplained" (p. 3). In addition, the report found that:

- Nine of the 59 reporting facilities treated 58% of the patients receiving ECT in the Greater Metropolitan New York City area.
- The majority of patients were greater than 60 years of age.
- No facility reported treating children under age 13 and ECT use among adolescents from ages 13-18 years was extremely rare.
- The great bulk of ECT was performed exclusively on an inpatient basis.
- The high volume ECT facilities were more likely to utilize outpatient ECT.
- On average, 46.2% of patients had cognitive impairment following ECT.
- Recent literature suggests that relapse rates in the year following ECT may be 60% and higher. The facilities estimated that the relapse rate is only 20.2%, a striking contrast.

Dr. Harold Sackeim, Chief of Biological Psychiatry at the New York State Psychiatric Institute, member of the APA's Task Force Committee on Electroconvulsive Therapy, and co-author of the Task Force report and more than 200 other publications relating to ECT, testified at the May 2001 public hearing. Dr. Sackeim stated there are no known statistics on the use of ECT in NYS. However, based upon the 1997 survey, he surmised that the 59 respondent facilities average 51 patients annually for ECT treatment (which totals 3,009 individuals). Dr. Sackeim advised, given his best estimate, that approximately 100,000 patients receive ECT per year in the U.S., and proportionately nearly 7,000 NYS residents receive such treatment annually. Dr. Sackeim cautioned that his figures are likely to be conservative given higher rates associated with ECT use concentrated in metropolitan areas.

On April 12, 2001, the MHLS, at the request of the Committee, reported on the collection of statewide statistics on applications for court orders authorizing ECT. While stating there may be a few cases not captured due to minor variations at the field staff level in the coding of treatment proceedings, the MHLS noted a 73% increase in applications in 1999 to 2000, from 59 to 97. Since 1997, applications for court orders authorizing ECT increased by 125% (43 to 97). The MHLS stated that more often than not, ECT is administered without court involvement. Additionally, MHLS advised it is not routinely notified when a patient does not object or when the ECT is performed per the patient's consent or in instances when someone other than the patient grants consent on their behalf without judicial intervention.

On June 1, 2001, OMH provided the Committee with limited demographic information regarding ECT use. The Committee requested additional information, which was received in June 2001 and summarized below:

- Five of OMH's 27 facilities currently provide ECT on site and 12 facilities used offsite providers in calendar year 2000.
- The five OMH operated facilities, which provide ECT on site, are in compliance with APA guidelines.
- A total of 134 inpatients received ECT during calendar year 2000 (CY2000).
- Of the 134 individuals in OMH facilities receiving ECT in CY2000, 26% were court ordered. Since 1998, the number of court ordered ECT procedures increased by 52%.
- During (1998-2000), the distribution by gender was 45% male and 55% female.
- By age, the distribution was 33% for persons 18-44 years; 43% for ages 45-64 and 24% for recipients 65 and older.
- In CY2000 there was one patient, age 17 years and 8 months, in a children's facility who received ECT.
- According to SPARCS data from the New York State Department of Health, the rate of ECT was 1.8% (1,822 individuals) of the total number of persons served in non-OMH facilities in CY2000.

SURVEY OF THE PROVISION OF ELECTRO-CONVULSIVE THERAPY AT NEW YORK STATE PSYCHIATRIC CENTERS, COMMISSION ON QUALITY OF CARE, AUGUST 7, 2001

On October 2, 2001, the CQC forwarded the Committee its report, "Survey of the Provision of Electro-Convulsive Therapy at New York State Psychiatric Centers." dated August 7,

2001, which reflected its findings from the most recent survey conducted on the provision of ECT at New York psychiatric centers. Following are report excerpts:

> The purpose of this survey was to obtain information about the frequency of administration of this treatment; facilities' management of such, and the patients who undergo this treatment, but not to evaluate its efficacy. As a result, the Commission obtained information about facility-specific procedures governing the use of ECT; protocols for privileging physicians to administer the procedure; and demographic information regarding age, gender, diagnosis and capacity to consent for those persons receiving ECT in state psychiatric centers between June 1, 1999 and May 31, 2001...ECT is currently administered in Manhattan Psychiatric Center, Creedmoor Psychiatric Center, Pilgrim Psychiatric Center, the Psychiatric Institute (PI), and Rockland Psychiatric Center (p. 1).

The Commission identified 164 patients that had received ECT during the timeline within 1999-2001 as outlined above. Excluding PI, where all ECT patients are voluntary participants in a research protocol, approximately 40% are receiving ECT pursuant to court orders. The CQC found that ECT was not administered to children at state psychiatric centers and was given to women (62%) more often than men (38%).

HILLSIDE HOSPITAL

On June 26, 2001, the Committee requested OMH conduct a formal investigation of the use of ECT at Hillside Hospital in Queens. This request followed articles appearing in the **New York Post** alleging that patients at Hillside Hospital were being given ECT as a behavioral modification mechanism and that patients had been coerced to agree to ECT.

On February 8, 2002, OMH staff verbally reported the findings of this investigation to Committee staff. During the period of January 1999 through July 2001, a total of 360 inpatients received ECT, of which one person was retarded, another autistic and one other diagnosed with delirium. Moreover, 10 of the 360 inpatients were adolescent recipients of ECT between the ages of 14 -17. While OMH did not find evidence to support the allegations reported in the **New York Post**, it is continuing its review of ECT practices at Hillside in response to questions raised by Committee staff at the February 8, 2002 briefing.

SAFETY

There is a great deal of controversy regarding the safety of ECT equipment, its use, and its long-term impacts, including permanent memory loss and death. The safety of ECT devices will remain a contentious issue until appropriate testing of all types of ECT devices is completed. The Committee received testimony and reviewed written materials regarding the efficacy of ECT and its safety.

ECT PROPONENTS AND OPPONENTS

Proponents assert that ECT is a relatively safe procedure with minimal long-term cognitive effects on memory and further cite a death rate of 1 in 10,000 to document safety.

Dr. Richard Weiner, Professor of the Department of Psychiatry at Duke University Medical Center, Chairperson of the APA's Task Force Committee on Electroconvulsive Therapy, and co-author of the Task Force report, appeared before the Committee at its May 18, 2001 public hearing on behalf of the APA. Dr. Weiner outlined that ECT is a highly effective and rapid treatment for individuals with certain defined severe mental illnesses.

At the same hearing, Dr. Sackeim, another APA representative and colleague on the Task Force, stated in his written testimony:

> The efficacy of ECT in specific psychiatric conditions is amongst the most well established of any treatment in all of medicine…The beneficial effects of ECT are not expected to last unless other biological treatments are used as maintenance treatments…The medical morbidity and mortality rates with ECT are low. Despite some media statements to the contrary, a fair estimate is that death associated with ECT occurs in approximately 1 in 10,000 patients, approximately the same as receiving general anesthesia alone. This is particularly noteworthy since ECT is often used in patients with serious medical complications….A limiting factor in the use of ECT is its cognitive effects…the negative effects of ECT on cognition involve two types of deficits. During and following ECT, patients will show rapid forgetting of newly learned information. This is termed anterograde amnesia…All available information, from scores of studies, indicates that this deficit disappears within days to a few weeks following the end of ECT. ECT also results in a loss of memory for events that occurred prior to the receipt of the treatment. This type of memory loss is termed retrograde amnesia…All recent published surveys of patients who have received ECT have shown that the vast majority report that this form of memory loss is a small price to pay for the therapeutic effects of the treatment. As with all medical treatments, there are individual differences, and some very rare patients may manifest more extensive memory loss....There is no firm estimate on this incidence…but my estimate would be on the order of 1 in 500 patients. Careful scientific

> study has shown that ECT does not cause brain damage (cellular death)…To the contrary, all antidepressant treatments promote the development of new neurons (brain cells), a recently discovered fact. ECT is the most effective in this regard.

The Committee also received testimony and letters from recipients of ECT. One representative letter stated, "I suffer from chronic depressive disorder recurrent and received ECT two years ago… ECT has allowed me to function again. I will be eternally grateful that ECT was available to me and hope that it will continue to be available in the future" (undated letter received June 2001).

Opponents, on the other hand, paint a very different picture. Dr. Peter Sterling, a neuroscientist at the University of Pennsylvania testified on July 18, 2001 regarding the effects of ECT on the brain. He stated:

> ECT unquestionably damages the brain, and there are a variety of mechanisms that lead to this damage. In the first place, the electroshock delivered to the skull is basically similar to what you would get out of an electrical wall outlet, except that there is a transformer in the ECT machine that steps up the voltage…when this is done two or three times a week for weeks, it's just completely obvious that this is going to eventually cause some kind of brain damage…Now the second point, source of brain damage for ECT is that it causes…grand mal epileptic seizures…and this causes an acute rise in blood pressure, well into the hypertensive range…And it frequently causes small… hemorrhages in the brain. And wherever a hemorrhage occurs in the brain, nerve cells die, and they are not replaced. And so one can accumulate these hemorrhages over a period of treatments leading to brain damage. A third thing that ECT does is to rupture the blood brain barrier. This barrier normally protects the brain from potentially damaging substances in the blood….breaching this barrier exposes nerve cells in the brain to chemical insults that can kill them…also leads…to swelling of the brain…swelling leads to local arrest of blood supply, to loss of oxygen…and to death of neurons. The fourth thing…is that ECT…causes neurons to release large quantities of … glutamate. Glutamate excites further neuronal activity…and this becomes a vicious cycle… Neurons literally…kill themselves from over activity….the key manifestation of this brain damage is retrograde memory loss….the tide seems to have turned. And one of the most important proponents of ECT, Dr. Harold Sackeim now acknowledges that memory and cognitive losses are real…excerpt from Dr. Sackeim's recent editorial in the *Journal of ECT*…Virtually all patients experience some degree of persistent and, likely, permanent retrograde amnesia. A series of recent studies demonstrates that the retrograde amnesia is persistent, and that this long-term memory loss is substantially greater with bilateral than right unilateral ECT.

ECT adversaries also state that the death rate is much higher than 1 in 10,000 and more likely is 1 in 200 for elderly persons undergoing ECT. Opponents cite data collected in Texas, the only state presently requiring reporting of the incidence of ECT. Mr. William Sullivan, Executive Director of the Mental Health Association of Essex County, testified that deaths do occur from the procedure, whether from the insult to the brain, a result of anesthesia, or muscle relaxants used. Mr. Sullivan called for objective research to determine the risks.

Again, the Committee received information and testimony from ECT recipients, as well as from family members regarding the adverse and/or permanent effects of ECT use on loved ones. The testimony of Linda Andre, Director of the Committee for Truth in Psychiatry, at the May 18th hearing, supplied the Committee with insight from a "survivor's" perspective:

> I am a survivor of ECT. I had involuntary ECT, though not court-ordered ECT, and I had a fairly typical experience with it. By that I refer to the fact that I lost five years of my life, which were erased as if they had never happened…I have documented brain damage, including 38 points off my IQ, and I live with daily memory disability and cognitive disability that made it impossible for me to return to my career.

EQUIPMENT

The safety of the devices used to administer ECT has been an issue of longstanding contention among professionals and advocacy bodies. In 1976, Congress enacted legislation granting the federal Food and Drug Administration (FDA) authority to regulate certain medical devices, including machines used to administer ECT. However, the FDA was given only limited jurisdiction regarding ECT equipment due to a grandfather clause that allowed continued use absent FDA testing. Subsequently, in 1979, the FDA designated and classified ECT devices as Class III medical devices. A Class III designation is used for pre-market approval for devices that show an unreasonable risk of illness or injury. Yet, no formal tests were conducted by the FDA to determine the safety of such devices.

The APA, in its 2001 ECT Task Force report, identified certain devices that should no longer be used, including sine wave, constant voltage and constant energy devices, due to their negative impacts on post ECT cognitive functioning of patients. The APA recommended the use of brief pulse devices that would be safer. However, the extent to which older ECT devices, no longer justified according to the APA, continue to be used is unknown. Though difficult to track, given existing oversight mechanisms, it appears likely that such devices will remain in the marketplace to some degree throughout the country and within New York State.

As an addendum to Ms. Andre's testimony was an article, "ECT: Sham Statistics, the Myth of Convulsive Therapy, and the Case for Misinformation," by Douglas Cameron, of the World Association of Electroshock Survivors:

> It has now become fashionable to declare brain damage from ECT a thing of the past because of "new refinements" in the procedure and in the machines…The implication that the sine wave device of old has been replaced by the brief pulse device of present lurks behind much of the continued use of ECT….Modern day BP devices are not "lower current" machines, as most proponents claim. Through electrical compensation, they equal SW devices in every respect, and emit far greater energy….Most experts agree that current, not convulsion…is responsible for long term memory loss and severe cognitive dysfunction….Manufacturers may have parted from the convulsion theory exemplified by just above seizure threshold devices of the past, to what might be just above damage threshold devices of the present, and if not forced to stop and prove the safety of their devices (allowing for even more powerful machines), might be embarking upon just above agnosognosic threshold appliances of the future.
>
> In summary, modern electric shock machine companies are attempting to redefine safety from the original convulsion concept of "just above seizure threshold" to "safer wave form." The Food and Drug Administration must rescrutinize today's SW and BP devices, withdrawing their "grandfathered in" status under compulsive therapy devices. Because they utilize an entirely different principle,…all modern EST device manufacturers must be required to prove machine safety to the Food and Drug Administration, prior to further utilization of new machines.

PROTOCOLS

There are no minimal, federally approved standards governing the education, training and privileging of medical practitioners of ECT. Further, there are no federally approved standards for required protocols to ensure the safety and efficacy of ECT. In effect, this has resulted in the implementation of a patchwork of protocols across the nation. The efficacy of ECT and the impacts on patient safety can be significant if certain equipment, protocols and procedures are used. Yet, the 1985 NIH Consensus Statement regarding ECT did not include specific recommendations for ECT protocols, nor does the APA's 2001 Task Force report outline or advocate for mandatory safeguard requirements. On the contrary, the APA's report, identifies suggested protocols for voluntary implementation, which does not provide the assurance necessary to protect the health and safety of ECT patients.

NIH CONSENSUS STATEMENT, JUNE, 1985

> An area location should be designated for the treatment of ECT and for supervised medical recovery from the treatment. This area should have appropriate health care professionals available and include equipment and other medications that could be used in the event of cardiopulmonary or other complications resulting from the procedure (NIH, p. 9).

2001 APA TASK FORCE REPORT

- ECT is a complex procedure that requires a well-trained, competent staff of professionals if it is to be administered in a safe and effective fashion.
- ECT training in residency programs in the United States ranges from excellent to totally absent. In many cases, training is no more than minimal.
- No national accrediting body presently provides assurance of competence in ECT. Accordingly, clinical competency of practitioners is presently ensured through local privileging.
- Each member of the ETC team should be clinically privileged to practice his or her respective ECT duties or be otherwise authorized by law to do so.
- It is clear that general privileging in psychiatry will not suffice and that specific clinical privileges to administer ECT should be required.
- It is incumbent on facilities using ECT to implement and monitor compliance with reasonable and appropriate policies and procedures.
- ECT facilities should be appropriately equipped and staffed with personnel to manage potential clinical emergencies.
- A variety of devices to administer ECT are in use.
- There is evidence that disruption of the EEG is more profound with sine wave stimulation. Consequently, the continued use of sine wave stimulation in ECT is not justified.

- ECT devices also differ in whether they operate on principles of constant current, constant voltage or constant energy.
- No conceptual justification exists for the use of a constant voltage device in ECT.
- There is no conceptual justification for the use of a constant energy device in ECT.
- Device manufacturers should provide detailed descriptions of testing procedures and preventative maintenance instructions.
- As with other medical devices, a regular schedule of retesting or recalibration by biomedical engineers or other qualified professionals should be implemented.
- Electrode placement affects the breadth, severity and duration of cognitive side effects. Bilateral ECT produces more short and long term adverse cognitive effects than right unilateral ECT.
- The extent to which practitioners use unilateral or bilateral ECT varies considerably.
- The choice of stimulus dosing strategy should consider that initial seizure threshold may vary widely among patients and generally increases over the treatment course.
- The choice of stimulus dosing strategy should also consider that therapeutic and adverse effects might vary depending upon the extent to which the stimulus intensity exceeds the seizure threshold.
- Before the muscle relaxant is administered, a blood pressure cuff should be inflated. Use of the cuff procedure allows for timing of unmodified convulsive movements without risk to the patient.
- At a minimum, one channel of EEG activity should be monitored with a paper record or auditory output.

INFORMATION ABOUT ECT, OFFICE OF MENTAL HEALTH, 2001

In July 2001, OMH submitted written information to the Committee regarding ECT. This OMH document states:

> In order to maximize effectiveness and minimize side-effects, OMH is committed to ensuring that practitioners administering ECT in New York State follow the latest (second edition, 2001) guidelines published by the American Psychiatric Association (APA) Task Force on ECT. OMH psychiatric centers which provide ECT adhere to the APA's Guidelines regarding its administration.

Two of the guidelines cited in this document were:

- Procedures for obtaining written consent for the administration of ECT for patients who possess the capacity to consent
- Staff requirements, including medical disciplines, privileging, training and specific treatment responsibilities

While OMH acknowledges that APA suggested guidelines are worthy of adherence and assert they are being abided by OMH psychiatric centers, unless OMH establishes stringent mandates requiring such conformity, providers of ECT treatment will not consistently apply the use of these parameters statewide. Again, the APA's guidelines are recommendations, not required mandates.

ECT PRACTICES IN THE COMMUNITY (an unpublished report)

> The 59 facilities surveyed varied considerably in many aspects of ECT practice: stimulus waveform, electrode placement, stimulus dosing, primary anesthetic agent, physiological monitoring, frequency of cognitive assessment, and so on….In a number of instances, the practices reported by the facilities clearly departed from the 'standards' in the field….Finally, this study did not audit actual practices, but relied on the report of the Directors of ECT Services. Concerned about the correspondence between the reports and actual patterns of practice, we also reviewed the medical charts …When discrepancies were found between the survey results and the review of the medical records, they were consistently in the direction of… the reports by the ECT service directors being more in line with guideline recommendations than actual practices of the facilities (pgs. 8-9).

The report found:

- The forms of ECT administered varied widely.
- EEG monitoring was not used in 14% of the facilities.

- Monitoring of the motor seizure with the cuff technique was not conducted in 53% of the facilities.
- Approximately 11% of patients received sine wave stimulation.
- Approximately 75% of patients were treated with bilateral ECT.
- The primary strategy was fixed dosages at 11 facilities.
- Nine facilities reported some use of multiple-monitored ECT, in which more than one seizure is evoked in a session.

SURVEY OF THE PROVISION OF ELECTRO-CONVULSIVE THERAPY (ECT) AT NEW YORK STATE PSYCHIATRIC CENTERS BY THE COMMISSION ON QUALITY OF CARE, AUGUST 7, 2001

The CQC survey determined that protocols varied in detail regarding the procedure itself, as well as in issues such as physician privileging and determining capacity to consent. The CQC report stated, "While all facilities have policies and procedures in place governing the use of ECT, policies regarding the credentialing of physicians and addressing informed consent varied widely" (pg. 5).

The CQC recommended that OMH establish a Blue Ribbon Task Force charged with the responsibility of developing ECT protocols that can be consistently applied in state facilities administering ECT and which promote the application of best practices while ensuring strict adherence to statutory and regulatory standards for safeguarding patient rights. In response, OMH stated that, in January 2001, the Office began reviewing an ECT checklist that had been used by State psychiatric centers administering ECT for the prior two-year period. OMH also stated it had drafted guidelines for consistent ECT administration and was planning to submit these guidelines to the APA and HANYS (Health Association of NYS) for review.

On October 11, 2001 Assembly Mental Health Committee Chair, Martin Luster, wrote to OMH Commissioner Stone. Chairman Luster's correspondence requested specifics including the following:

> In chairing two public hearings on ECT, I have come to recognize the wide range of opinions regarding the efficacy and best practices relative to the administration of ECT. I am interested to know what measures you have taken to ensure OMH's in-house review will address the broad scope of issues that exist and include the varying opinions that a blue ribbon task force would be charged with addressing. Could you please provide me with an update on your progress with regard to OMH's in-house review of ECT policies and a copy of OMH's draft guidelines for state facilities administering ECT, with a list of individuals consulted in the drafting of these guidelines? A complete understanding of your goals, how you intend to achieve these goals, and your progress in this task will be helpful to me in determining whether an independent task force, such as suggested by the CQC, remains necessary.

On November 6, 2001, OMH Commissioner James Stone responded. He stated:

> OMH's review found that equipment and administration of ECT in our state-operated hospitals complies fully with these APA guidelines. One area where further refinement was recommended concerned informed consent and procedures….Concerning ECT administration on the community side, my staff…have developed draft guidelines…The most representative means of reviewing these guidelines will be to submit them to the Mental Health Services Council for review and comment…Once the Council has had the chance to review these draft guidelines, I will be happy to share them with you, along with a list of the committee members who developed this document.

While the Committee recognizes that OMH is conducting an in-house review of applicable guidelines, it is apparent based upon the Commissioner's response that such review will not include all of the issues identified by the Committee. Furthermore, though OMH's planned process will help foster and facilitate a timely discussion and review of protocols by a knowledgeable advisory body, it appears it will be depending largely upon input from an organization lacking the requisite expertise regarding issues relating to ECT. More specifically, the Committee acknowledges the Mental Health Services Council's contributions to the field as an organization representing a diversified mental health constituency. However, MHSC is not a professionally based entity comprised of persons with specific expertise on medical consent and/or in the establishment of medical related guidelines. Therefore, it is recommended that OMH expand its review process to ensure it comprehensively examines the issues and concerns raised by the Committee, and solicits feedback from varying constituencies with expertise in the areas under consideration.

SPECIAL POPULATIONS

The use of ECT on special populations needs careful review. In the case of human research, the federal government recognizes that particular populations need extra protections. These populations include children, pregnant women and the mentally disabled. It is the Committee's opinion that these same populations should be entitled to extra protections with issues involving ECT. The Committee further asserts that such safeguards should apply to older persons who often fall under the designation of "specialized populations" and require much needed protections.

In the case of children, ECT can adversely impact brain development. Similarly, protection of the fetus needs to be a top priority when pregnant women are recommended for ECT. Additionally, there needs to be a mechanism for ensuring that mentally retarded and developmentally disabled individuals truly understand the need for ECT and the associated benefits and risks, prior to furnishing informed consent. Currently, the integrity of the consent protocol is questionable given the mental capacity of some disabled individuals. Moreover, the possible use of ECT, not as a therapeutic intervention, but to control behavior among this population can also not be discounted. Particular care and special protections need to be secured to assure that the rights of the mentally retarded and developmentally disabled are not violated.

Use of ECT on the elderly is also in need of thorough examination. Currently, older adults number almost 35 million or about 12.7% of the population within the United States. Considering that by the year 2030, the "baby-boom" generation will be fully retired, it is estimated that persons over 65 will represent about 20% of the U.S. population. (U.S. Census Bureau, 2000 Census Estimates and Hobbs, FB & Damon, BL (1996) **65+ in the United States**, U.S. Census Bureau, Economics and Statistics Administration Publication #P23-190.) Given that older persons are more apt to receive ECT than any other age group, are more resistant to medications and, in many cases, need higher electrical stimulation to produce the required seizure, there is increasing concern when contemplating the potential impact of such use on a significant percentage of the nation's population. In many cases, due to the temporary benefits of ECT, continued ECT treatments are often necessary over extended periods of time. This may increase the risks of permanent cognitive deficits, which can often serve to exacerbate some memory loss or other retention related issues that can begin to present in persons entering the latter stages of life. Finally, there is concern among ECT opponents that this therapeutic option can impact on the physical and emotional health of the elderly and lead to premature death.

Following are some excerpts from the 2001 APA Task Force Report regarding the elderly, pregnant women, and children/adolescents.

APA TASK FORCE: ELDERLY

- ECT has a special role in the treatment of late-life depression and other psychiatric conditions in the elderly, who as a group constitute a particularly high proportion of the patients who receive ECT.
- It is suspected, but not well documented, that resistance to the therapeutic effects of antidepressant medication is age related, with depression in late life more likely to be medication resistant.
- Administration of ECT in the elderly presents certain age-related issues. Seizure threshold may rise with increasing age, and effective seizures may be difficult to induce.
- Especially when treated with bilateral ECT, some elderly patients may have seizure thresholds that exceed the maximum output of current-generation ECT devices in the United States.
- Elderly patients may be at greater risk for more persistent confusion and greater memory deficits during and after ECT treatment.

APA TASK FORCE: PREGNANCY

- Recent case material supports the use of ECT as a treatment with low risk and high efficacy in the management of specific disorders in all three trimesters of pregnancy.
- The risks of ECT anesthetic agents to the fetus are likely to be less than the risks of alternative pharmacologic treatments for psychiatric disorders and also less than the risks of untreated mental illness.
- When gestational age is more than 14-16 weeks, non-invasive monitoring of fetal heart rate should be done before and after each ECT treatment.
- If pregnancy is high risk or close to term, additional monitoring may be indicated at the time of ECT administration.

- At facilities administering ECT to pregnant women, resources for managing obstetric and neonatal emergencies should be readily accessible.

APA TASK FORCE: CHILDREN AND ADOLESCENTS

- Few studies address the use of ECT among children and adolescents.
- First-line use of ECT in children and adolescents is particularly rare.
- ECT treatment should be provided with the concurrence of two consultants experienced in treating psychiatric disorders of children.
- The consent process, including discussion of the risks and benefits of ECT should involve the parents or guardians of the child.
- Stimulus dosing must take into account that seizure thresholds in children and adolescents are likely to be considerably lower than those in adults.
- Because of the possibility for increased likelihood of prolonged seizures in children and adolescents, the treatment team ought to be prepared to intervene with appropriate medication to terminate the seizure.
- Comprehensive guidelines for the use of ECT in adolescents are presently under development by the American Academy of Child and Adolescent Psychiatry. (NOTE: When contacted on March 13, 2002, the Academy advised Committee staff that the draft guidelines were still being reviewed.)

DEVELOPMENTALLY DISABLED

The Committee found little material relating to the use of ECT on mentally retarded individuals. Committee staff contacted the New York State Office of Mental Retardation and Developmental Disabilities (OMRDD) regarding this matter. Subsequently, on June 25, 2001, the **New York Post** ran an article describing how ECT was administered to a mentally retarded woman at Hillsdale Hospital in Queens. The Committee requested the CQC to look into this matter. While the CQC found the process followed by the facility to be appropriate, the facility discontinued ECT.

In January 2002, Committee staff visited the Institute for Basic Research, an OMRDD facility, and learned of at least two other mentally retarded individuals that had or were currently receiving ECT. The Committee requested information from OMRDD on the incidence of ECT use on this population. In a letter dated January 15, 2002, OMRDD Commissioner Tom Maul responded.

> ECT is a &aquot;professional medical treatment" under 14 NYCRR 633.11. As such, informed consent is required by OMRDD regulation…If the person lacks capacity to give informed consent…. then informed consent is obtained from a qualified surrogate or court order.… OMRDD does not require that consumers who access professional medical treatment such as ECT report these instances. Rather, it is expected that our 633 regulation governing informed consent is strictly adhered to, and that good clinical practice is followed in diligently pursuing appropriate medical treatments, and second opinions where warranted. Therefore, I cannot give an absolute number of persons with mental retardation and developmental disabilities who have received ECT to address symptoms of mental illness.

At a meeting with Chairman Luster on March 4, 2002, the CQC indicated it had identified at least 24 mentally retarded individuals that had received ECT in 2000.

INFORMED CONSENT

The issue of informed consent is critical in enabling a patient to make a decision regarding the use of any medical intervention. The courts in New York State have consistently recognized and upheld the right of every individual to make his or her own treatment decisions. It is a firmly established principle of the common law of New York that every individual "of adult years and sound mind has a right to determine what shall be done with his body" and control the course of his or her medical treatment. (*Schloendorff v. New York Hospital*, 211 NY 129 (1905)). Pursuant to *Rivers v. Katz*, 67 N.Y. 2d 485 (1986) the patient's right to self-determination is deemed paramount to a physician's obligation to provide medical treatment, as is a competent patient's right of refusal for treatment.

There is a significant degree of variability among facilities regarding information provided during the informed consent process, including risks/benefits, the type of ECT device to be

used, number and specific placement of electrodes and the need for continuation and maintenance of ECT for extended periods. The ability of a patient to obtain appropriate information regarding ECT and the timeframe in which s/he must evaluate the efficacy of the information, as it relates to the patient, is crucial for the patient to make a reasoned and informed decision

Steven Brock, a lawyer who once managed the Mental Health Law Project for Nassau/Suffolk Law Services, under a grant funded by the Office of Mental Health, and founder of the Mental Disability Law Clinic at Touro Law School in New York, in written testimony stated:

> A commission should be established to manage independent investigation of ECT risks and benefits and improve the current, drastically inadequate procedures for informed consent….Given the uncertainty as to the safety of ECT, consent procedures should immediately be enhanced. A commission could be charged with developing appropriately conservative requirements for disclosure of the risks of ECT to insure that a reasonable range of information on risks is provided to persons asked to consent to the procedure.
>
> In order to make consent to treatment a real process, it must be made independent of the treating psychiatrists. The current reality is that persons who consent are deemed competent and persons who decline to follow a psychiatrist's recommendation are at severe risk of forced treatment. An independent decision maker, not the treating psychiatrist, should decide competency to consent to ECT in the first instance. And a decision on competency should be made before consent is requested. Those found competent will decide for themselves whether to consent to ECT. Those found not competent will require court approval for ECT whether or not they consent.
>
> Ultimately, the determination of a person's competency to consent to treatment is a legal question quite different from the technical medical and scientific matters in which psychiatrists are trained. Psychologists, on the other hand, receive training that makes them well suited to address both the legal and medical issues involved in determinations of competency. The current system grants the treating physicians extreme power to determine the course of treatment of persons in psychiatric institutions and override their objections to treatment. And in those instances when there is disagreement, the legal process casts the psychiatrist as the adversary of the person he or she is treating, which can profoundly and adversely affect the therapeutic relationship.

Dr. Laura Fochtmann, a psychiatrist and Director of the Electroconvulsive Therapy Service at the State University at Stony Brook, member of the APA's Task Force and co-author of the APA's report and numerous other articles appearing on the neurobiology of ECT, appeared before the Committee on May 18, 2001 to testify on behalf of the state and national American Psychiatric Association. In relation to informed consent, Dr. Fochtmann stated in her written testimony:

> In choosing any medical intervention for a given individual, the potential benefits of treatment must always be weighed against the potential for adverse effects….Discussing alternative therapeutic options, with their corresponding risks and benefits, is but one aspect of the informed consent process with ECT. In fact, the APA ECT practice recommendations on informed consent are extraordinarily comprehensive and detailed…modeled after those used at the New York State Psychiatric Institute, include a description of the standard ECT procedure as well as statements that there is no guarantee of the efficacy of ECT…and that consent is voluntary and can be withdrawn at any time….The informed consent process does not end with the initiation of the ECT course. Rather, consent is an ongoing process in which the patient receives ongoing feedback on clinical progress and on side effects and has continued opportunities to have questions or concerns addressed.
>
> Also crucial to the informed consent process is the assessment of capacity to provide consent. Individuals with mental illness are considered to have the capacity to consent to ECT unless the evidence to the contrary is compelling….Under such circumstances, the patient's underlying psychiatric disorder may alter their decision-making capacity, impairing their ability to consent to ECT or other treatments.
>
> In these cases, ECT is sometimes the treatment of choice for individuals who lack capacity to give a fully informed consent…. Nonetheless, a complex balance must be achieved between the rights of an individual to autonomous self-determination and the moral and legal obligations of facilities to provide needed treatment if individuals are dangerous to themselves and others….Under the ruling in **Rivers v. Katz**…the New York Court of Appeals delineated a two step process in order to provide psychiatric treatment for a non-consenting incapable patient. First, the proponent of the treatment must establish by clear and convincing evidence that the patient lacks capacity to make treatment decisions…the court must then determine that clear and convincing evidence establishes that "the proposed treatment is narrowly tailored to give substantial effect to the patient's liberty interests, taking into consideration all relevant circumstances, including the patient's best interests, the benefits to be gained from the treatment, the adverse side effects associated with the treatment and any less intrusive alternative treatment."
>
> We believe that the strict requirements for judicial approval for court ordered treatment strikes a proper balance between protection of individual autonomy and dignity and the right of all persons to receive appropriate medical care and be free from unnecessary pain and suffering…With regard to ECT…, relatively few requests are made for court ordered treatment relative to the total number of patients receiving ECT….APA and NYSPA strongly believe that the APA recommended

informed consent process and materials insure the provision of informed consent and that additional regulatory efforts in this area are unnecessary.

NIH CONSENSUS STATEMENT, JUNE, 1985

> When a physician has determined that clinical indications justify the administration of ECT, the law requires and medical ethics demand, that the patient's freedom to accept or refuse treatment be fully honored. An ongoing consultative process should take place…they should discuss the character of the procedure, its possible risks and benefits (including full acknowledgment of post treatment confusion, memory dysfunction, and other attendant uncertainties), and the alternative treatment options (including the option of no treatment at all).
>
> It is not easy to achieve this ideal of "informed consent" in any aspect of medical practice and there are special difficulties that arise regarding the administration of ECT. In particular, the patients for whom this procedure is medically appropriate may be suffering from a severe psychiatric illness that, although not impairing their legal competency to consent, may nonetheless cloud judgment in fully weighing all of the available options. Such judgmental distortion does not justify disregarding the patient's choices; rather, it makes it all the more important that the physician strive to identify and clarify the options that the patient alone is entitled to exercise.
>
> The consent given by the patient at the outset of treatment should not be the final exchange on this issue but should be reexamined with the patient repeatedly throughout the course of treatment. These periodic reviews should be initiated by the physician and not depend on patient initiative to "rescind" consent.
>
> There are several reasons for this repeated consenting procedure: because of the rapid therapeutic effect of the procedure itself, the patient, after initial treatments is likely to have enhanced judgmental capacities; the risks of adverse effects increase with repeated treatments, so that the question of continued treatment presents a possibly changed risk/benefit assessment for the patient; and because the short term memory deficits that accompany each administration of ECT, the patient's recollection of the prior consenting transaction might itself be impaired, so that repeated consultations reiterating that patient's treatment options are important to protect the patient's sense of autonomy throughout the treatment process. Moreover, if the patient agrees, the family should be involved in each step of this consultative process (NIH p. 8).

2001 APA TASK FORCE REPORT

- The patient should provide informed consent unless s/he lacks capacity or as otherwise specified by law.
- There is no clear consensus about what constitutes the capacity to consent.
- Capacity to consent should be assumed to be present unless compelling evidence exists to the contrary. The occurrence of psychotic ideation, irrational thought processes or involuntary hospitalization does not, by themselves, constitute such evidence.
- There may be concern that the attending physician is biased toward finding that capacity to consent exists when the patient's decision agrees with his or her own.
- Informed consent is defined as voluntary when the consenter's ability to reach a decision is free from coercion or duress. In practice, the line between "advocacy" and "coercion" may be difficult to establish

MENTAL HYGIENE LEGAL SERVICES (MHLS)

On May 17, 2001, MHLS provided written comments to the Committee regarding ECT. The MHLS represents patients on facility applications to the courts for orders authorizing the administration of ECT. Under current laws and regulation, the MHLS is not ordinarily notified of cases in which consent for the procedure is obtained from the patient or a surrogate, without court involvement. The MHLS identified a number of concerns with respect to the current practices for obtaining consent for ECT, including:

- **OMH regulations do not contain adequate safeguards for ensuring that the patient has been fully informed of the risks and benefits of the procedure and is capable of giving informed consent.**

  In addition to calling for a written consent document that becomes part of the patient record, including a written disclosure of the risks and benefits, the MHLS maintained that OMH should establish a protocol for assessing a person's capacity to give or withhold informed consent to ECT. The MHLS stated that, "It has been our experience, in both ECT and other treatment cases, that all too often the determination of capacity turns on whether or not the patient agrees with the Doctor."

- **In the case of non-objecting, incapacitated patients, we question whether OMH has the power to vest relatives with the authority to give surrogate consent to ECT. We also question whether the OMH regulations on surrogate consent for ECT comport with the current statutory framework.**

The MHLS stated, "The question of who may give informed consent on behalf of an incapacitated patient is a legislative judgment…the Legislature has promulgated a statutory mechanism for securing consent from the courts for ECT on behalf of incapacitated persons…The Court may…authorize or deny a course of treatment directly, without the appointment of a guardian. The Legislature has authorized non-judicial surrogate consent for other forms of treatment in very limited circumstances, but **has not** empowered others to give surrogate consent for ECT for incapacitated persons…In *T.D. v. OMH* , 228 AD 2nd 95, the Appellate Division "specifically reject[ed]" OMH's assertion that MHL Section 33.03 empowers OMH to promulgate surrogate consent procedures."

- **OMH regulations are inadequate with respect to the procedure to be followed when surrogate consent for ECT is sought and refused.**

  According to the MHLS, "Even if OMH has the authority to empower third persons to give surrogate consent for ECT, Part 27 of the OMH regulations violates due process principles, as it fails to require notice to the patient that he or she is believed to be incapacitated and that surrogate consent for ECT will be sought…In addition, we are aware of cases where consent for ECT has been refused by a surrogate and the facility has ignored the surrogate's refusal of consent and shopped the OMH surrogate list for someone else who would agree. This approach is not permissible under OMRDD regulations, which establish a hierarchy of surrogates and require a court application where the first available surrogate objects."

- **The Legislature should consider amending Section 35 of the Judiciary Law to make it clear that independent psychiatrists and psychologists may be appointed by the courts in ECT and other cases in which judicial authorization is sought for treatment.**
  According to MHLS, currently Section 35 of the Judiciary Law expressly provides for the appointment of an independent psychiatrist or psychologist to assist the courts only in commitment and habeas corpus proceedings arising out of State operated facilities.

INFORMATION ABOUT ECT, OFFICE OF MENTAL HEALTH

In regard to OMH's proposed consent procedure, the July, 2001 OMH document states:

> In New York State, persons treated by ECT must be given an explanation of the proposed procedure and course of treatment, including a discussion of the expected benefits, reasonable foreseeable risks, and any reasonable alternative to the proposed treatment. New York's law and regulations state that no patient may be treated with ECT over his or her objection as long as s/he retains the capacity to make a reasoned decision concerning treatment.

SURVEY OF THE PROVISION OF ELECTRO-CONVULSIVE THERAPY (ECT) AT NEW YORK STATE PSYCHIATRIC CENTERS BY THE COMMISSION ON QUALITY OF CARE, AUGUST 7, 2001

At the request of Mental Health Committee Chairperson Luster, the CQC agreed to conduct a survey of the provision of ECT at state psychiatric centers. ECT is currently administered in Manhattan Psychiatric Center, Creedmoor Psychiatric Center, Pilgrim Psychiatric Center, the Psychiatric Institute (PI) and Rockland Psychiatric Center. The results of this survey, received by the Committee on October, 2, 2001 found that "protocols varied in detail regarding the procedure itself, as well as in issues such as physician privileging and determining capacity to consent." (October 2, 2001 letter.)

Regarding informed consent, the CQC report states:

> Obtaining a patient's informed consent for ECT… is the subject matter of 14 NYCRR Section 27.9. Section 27.9 …has been superceded, though only in part. Section 27.9…provides that if the patient does not have the requisite capacity to consent to ECT treatment but does object, the objection may be overridden administratively by the hospital. However, this provision of Section 27.9 has been superceded as a result of the Court of Appeals' 1986 decision in **Rivers v. Katz**. OMH promulgated Section 527.8 to supercede this provision in order to clarify that an incapacitated patient may be treated over objection only by a court order.
>
> Only Pilgrim's operational policy defines capacity to consent….For a patient who has sufficient mental capacity to give informed consent to ECT, according to policy at PI, Pilgrim and Creedmoor, only the patient can give consent, and if the patient refuses to consent, ECT will not be administered and the hospital will not go to court. If ECT treatment is deemed necessary for a competent patient who refuses ECT, Rockland and Manhattan policy allows them to go to court to obtain an order for treatment over objection.
>
> Policies generally define the length of time a consent is valid. At PI, the informed consent is good for up to 25 treatments of a single course of ECT…At Pilgrim, consent is good for 25 treatments or three months, whichever comes first…Creedmoor requires new consent every three months. Rockland requires that consent be updated every six months. Manhattan has no written requirement for renewing informed consent, but does require that MHLS be notified before anyone, consenting

> or not, receives ECT. Policies at PI, Pilgrim, Creedmoor indicate that legally designated surrogates or a court of competent jurisdiction can give consent to ECT if the patient lacks capacity…but does not object. Creedmoor mandates that two psychiatrists, neither associated with the ECT unit, must certify that a patient lacks capacity…and they must further certify that the patient does not object. At Manhattan and Rockland, court orders are required before ECT can be given to anyone who is determined to lack capacity to give consent (pgs.6-7).

The impact of bias on the determination of capacity to consent necessitates extensive review as part of the informed consent process. While the APA Task Force Report identified the possibility of bias by the attending physician regarding capacity when the patient agrees with the attending physician's decision, it did not comment on the possibility of bias when the patient does not agree with the attending physician's decision to use ECT. Another instance of possible bias may occur when the patient does not have capacity and does not object to ECT. Great care needs to be taken to ensure that the patient's diagnosis is the correct one. ECT has been shown to be effective with certain diagnoses and not with others. Misdiagnosis, either as the result of bias or human error, can lead to faulty judgments regarding capacity to consent and validity of information provided during the informed consent process. The involvement of mental health professionals, such as clinical psychologists, who have no involvement in ECT, will help to ensure that patients are diagnosed correctly and that bias in capacity determinations is minimized.

CASES OF ECT

Listed below is a synopsis of cases submitted to the Committee regarding recipients of ECT therapy. Such cases help to illustrate the issues related to determination of capacity, informed consent, possible bias and implementation of protocols at state psychiatric centers.

PAUL HENRI THOMAS

The Committee first became aware of the issue of ECT at a public hearing held by the Committee in Syracuse on February 14, 2001 regarding the proposed closure of Hutchings Psychiatric Center by the Governor. One of the individuals testifying that day brought up the case of Paul Henri Thomas, then a patient at Pilgrim Psychiatric Center who had been receiving ECT against his will. Subsequently, members of both Houses of the Legislature were inundated with e-mails regarding this matter. Mr. Thomas had apparently received over 60 ECT treatments over his objection since 1999.

Shortly after the Syracuse hearing, the Committee requested the CQC look into the use of such therapies as ECT, patients' rights in such matters, and any specifics the CQC might be able to share regarding Mr. Thomas. On April 6, 2001, the CQC reported back to the Committee stating its review found documentary evidence and expert medical opinion that the treatment provided was an effective modality for Mr. Thomas and that the facility was in substantial compliance with applicable regulations of OMH regarding treatment over objection. Only minor issues relative to documentation of Pilgrim P.C.'s adherence to procedural requirements were identified.

In the interim, on March 3, 2001, **Newsday** reported that OMH officials had made activists feel unwelcome at a judicial hearing regarding Mr. Thomas held on facility grounds.

On March 12, 2001 **Newsday** reported on a judicial proceeding regarding Mr. Thomas, whereby he had originally been diagnosed with a schizophrenic affective disorder. However, more recently, he had been diagnosed with bipolar mania with psychotic features. (Note: The National Institute of Health's 1985 Consensus Statement indicated that the proper diagnosis was essential in determining the efficacy of ECT on a particular patient.)

On March 16, 2001, **Newsday** reported that in June 1999, Mr. Thomas had agreed to undergo ECT. At that time he was deemed competent to provide his consent. After the third ECT treatment, Mr. Thomas refused to undergo further ECT treatments. At that time, his doctors determined that Mr. Thomas no longer had the capacity to make this decision. According to **Newsday**, "The revelation of a kind of Catch-22 --the strange circumstance that Thomas was fine when he consented to the procedure but mentally incompetent when he refused it -- took center stage at a hearing yesterday to determine whether doctors may again shock Thomas against his will." **Newsday** also reported that on February 1, 2001, Pilgrim P.C.'s Associate Medical Director and Director of ECT had signed a form authorizing a court order for additional ECT treatments without first examining Mr. Thomas in violation of State regulations.

On March 28, 2001, **Newsday** also reported that Pilgrim P.C. had issued a written order that all papers signed by Paul Henri Thomas must be intercepted and inspected and that he was

not allowed unrestricted visitors unless they were family members or attorneys. There was to be one to one supervision for non-family visitors.

In April 2001, the Committee learned of an allegation that an OMH employee had been forced to resign because of advocacy on behalf of Mr. Thomas. On May 1, 2001, the former employee, Anne Krauss, e-mailed the Committee stating:

> I am extremely concerned about possible violations in regulation and procedure which I fear have occurred in relationship to Mr. Thomas, and which may quite possibly occur in relationship to other people in situations similar to his….Mr. Thomas' case sheds light on serious erosion of the system of checks and balances which should put limitations on the power of the treating psychiatrist in ordering major medical procedures and treatment….As I stated in my letter of resignation…I was especially troubled by my agency's apparent failure to observe some of its own regulations and procedures…Specifically, it appears that 14 NYCRR 527.8 (c) (4) (ii) was violated:
>
> - The treating physician failed to conduct a comprehensive review of capacity.
> - A second physician did not personally examine Mr. Thomas before signing the application.

On May 23, 2001, the Committee requested CQC revisit the case of Paul Henri Thomas enumerating a number of issues of concern. On October 1, 2001 the CQC responded.

ISSUE: Visiting Restrictions

MHLS brought action that was subsequently settled. "It is our understanding that supervision protocols put into place since the settlement have not met with any allegations that claim infringement of Mr. Thomas' rights."

ISSUE: Physician Actions

"The physician appointed to conduct the second review and examination, completed and signed the application to the court for authorization for administration of ECT over objection prior to his personal examination of Mr. Thomas…he did fail to follow established and required procedure…we are confident that such a procedural error is not likely to occur in the future."

ISSUE: Former OMH Staff Person, Anne Krauss

Regarding Anne Krauss, "your questions pertain to personnel issues within the internal control of the administration of OMH, so this matter is outside the purview of the Commission."

ISSUE: Bilateral vs. Unilateral ECT

Regarding bilateral vs. unilateral ECT, Pilgrim policy clearly favors the use of bifrontal bilateral electrode placement. According to Pilgrim's Policy Manual, "Unless compelling considerations favor unilateral ECT, bilateral ECT will be the recommended initial treatment." Pilgrim's Director of ECT told ECT investigators that much more stimulus was needed to obtain the same effect with unilateral ECT.

In the interim, **Newsday** reported the following on September 21, 2001 that Paul Henri Thomas had been released after his condition improved without the shocks.

> Thomas got a court order in March (2001) barring doctors from administering the procedure, which can cause disorientation and memory loss, and which he described as a form of "torture"….The state had been appealing the judge's ruling barring shock treatments on Thomas, but both sides said the appeal is now moot and will be dropped…a spokesman of the state Office of Mental Health…said…"Any discharge is based on clinical considerations."…The state Attorney General's office, which represented Pilgrim in court, said… "That avenue (shock treatments) had been blocked by the court and, obviously, they had to go to Plan B, which was come up with a different approach in terms of medication…And they happened to put together an approach that Mr. Thomas responded to very positively." Anne Krauss, a friend of Thomas, was ecstatic over his release. "It shows they could recognize he had recovered and that recovery took place without the electroshock that they previously felt was necessary…And in that way it's excellent.

ADAM S.

On May 24, 2001, the Committee requested the CQC look into the case of Adam S., a patient at Pilgrim P.C. Anna Szyszko, sister of Adam S., appeared before the Committee at its May 18, 2001 public hearing in New York City. She stated that Adam suffers from schizophrenia. The facility obtained a court order authorizing ECT in 2000. Adam had been determined to lack the capacity to make an informed decision regarding ECT use. The family objected and wanted alternative treatments. On July 18, 2001, the Szyszko family appeared before the Committee at its second public hearing in Albany again calling for alternative treatments for Adam. The family alleged that Adam was being abused and wanted him transferred to another facility. On September 13, 2001 the CQC submitted its report to the Committee. The

CQC overall finding was that the recommendation that Adam S. receive ECT was appropriate. However, the CQC found several problems with his care unrelated to the administration of ECT, as well as documentation problems. The report, dated July 31, 2001, stated:

- On August 7, 2000 an adverse event occurred involving a physician…the physician exhibited very poor judgment and did not appreciate the seriousness of her actions. The physician resigned the next morning and it is our understanding that Pilgrim reported her to the national physician data base.
- The second area of concern pertained to the failure of nursing staff to adequately monitor Mr. Szyszko…The physician orders that specified every fifteen minute vital signs…were not carried out, nor was it documented that nursing had notified the physician of the inability to carry out the order.
- A number of documentation errors were identified.

On August 27, 2001 the Supreme Court of the State of New York, Appellate Division: Second Judicial Department vacated the stay of administration of ECT. However, to date, Pilgrim P.C. has not proceeded with ECT on Adam S.

PAM S.

On May 24, 2001, the Committee requested the CQC review the case of Pam S., a patient at Mid-Hudson P.C., who was appealing a decision to give her ECT over her objections. The Committee received the CQC report, dated July 3, 2001 on August 1, 2001. The report stated:

> The facility petitioned the court for ECT over objection…Two psychiatrists determined that (Pam S.) did not have the capacity to consent to ECT. Although the court ordered the treatment(s)…staff had difficulty arranging for the provision of ECT treatments…In the interim, MHLS obtained a restraining order (April, 2001). MHFPC requested to have the order lifted, but was unsuccessful (May, 2001). The case is currently on appeal…In summary, we determined that MHFPC is providing appropriate treatment…in accordance with applicable regulations and policies. Further, the plan to provide…ECT appears to be a reasonable clinical treatment approach, considering the seriousness and intractability of her illness.

On August 27, 2001, the Supreme Court of the State of New York: Second Judicial Department denied the petition to proceed with ECT. "…the petitioner failed to prove by clear and convincing evidence that the patient lacked the capacity to make a reasoned decision regarding her treatment, which was the sole basis argued for the relief sought *(see,Rivers v. Katz, supra)*…In light of this conclusion, we need not determine whether the petitioner established by clear and convincing evidence that the proposed treatment was narrowly tailored to preserve the patient's liberty interest *(see Rivers v. Katz, supra, at 497-498)*.

The Committee was concerned that the CQC found ECT appropriate in all three cases, even though two of the cases were dismissed because of the patient's recovery without ECT and because of the court's finding that the patient had the capacity to refuse consent to ECT. The CQC indicated that it does not evaluate the efficacy of the patients' diagnoses. The CQC assumes the diagnoses to be correct. The CQC ascertained the viability of ECT as an accepted treatment modality based on the diagnoses recorded in the patients' records.

CONCLUSION

This report is the culmination of a one-year review of the practice of ECT in the State of New York. Proponents and opponents of ECT passionately debate and defend their perspectives. Literature can be found supporting the contentions of both sides of this debate. The Committee received testimony and written communications from individuals who had benefited from ECT and from individuals who had suffered permanent damage.

Based on its review, the Committee is not prepared to call for a ban on ECT use in the State. However, the Committee identified several issues of concern and has proposed legislation to address these concerns. Much of the argument that swirls around ECT relates to its safety. The federal Food and Drug Administration (FDA), considers ECT devices to be experimental, Class III medical devices. Such a classification is used for pre-market approval for devices that show an unreasonable risk of illness or injury. The FDA has never tested ECT devices to ensure their safety. The American Psychiatric Association (APA) has identified certain devices that should no longer be used for ECT, yet it is apparent that these devices continue to be used. In order to render the safety argument moot, the federal government needs to test all ECT devices for safety and to promulgate protocols that will maximize the benefits and minimize associated risks. Accordingly, the Committee calls upon

the Legislature to pass a resolution urging the U.S. Congress to require the FDA to test ECT equipment for safety

The lack of minimum federally approved standards and protocols have exacerbated the problem. The American Psychiatric Association (APA) has recognized and promulgated standards and protocols in 1990 and again in 2001. However, these are voluntary standards and are not being implemented in all facilities that provide ECT. The Committee's review found several instances in both state operated and private sector facilities where protocols recommended by the APA were not being followed. For this reason, the Committee also calls on the Legislature to pass a resolution urging the U.S. Congress to enact legislation establishing proper protocols for the administration of ECT.

The Committee recognizes that the federal government may take some time to act. In the interim, there are steps the Legislature can take now to improve the safety of ECT use in the State.

Currently, there is no effective reporting mechanism regarding ECT use in the State. The Committee finds there is little information regarding how ECT is practiced in the State. Based upon existing information, there is considerable variation in the nature of ECT practices. Moreover, patients are being treated in a fashion that markedly departs from professional standards of practice recommended by the APA. Assembly bill A. 9083 requires mandatory reporting of information regarding ECT to enable the OMH Commissioner to better regulate the use of ECT and help ensure that the Legislature can effectively exercise its constitutional function. The report will include:

- The number of patients who receive ECT, both inpatient and outpatient.
- The number of patients for whom a court order was sought, including the results of such action.
- The age, sex, race and diagnosis of patients who receive ECT.
- Injuries reported and autopsy findings if the patient died within fourteen days of the administration of ECT.

Assembly bill A. 9082 establishes a temporary advisory council to address issues related to ECT, including but not limited to:

- Education and training of ECT practitioners and standards for ECT administration
- Safety of equipment
- An analysis of the efficacy of ECT on special populations
- Resources to be given to patients to help them learn more about ECT

Assembly bill A. 9084 requires all facilities practicing ECT be accessible to emergency treatment. As the NIH and the APA have pointed out, ECT can have serious adverse physical consequences. It is prudent to require such access in order to avoid life-threatening situations that may be associated with the use of ECT.

Protecting the mental health of the people of the state by providing appropriate care and treatment to persons afflicted with mental illness and ensuring that such persons are treated with dignity and respect are matters of public concern. Protecting the rights of patients and ensuring the appropriateness of medical interventions are based on proper diagnoses and are therefore also matters of public concern.

The Committee identified weaknesses regarding the determination of the capacity of a patient to make an informed decision regarding the use of ECT. The Committee also identified weaknesses in the informed consent process. Assembly bill A. 9081 requires:

- In addition to the treating physician, a licensed psychologist who is not an employee of the facility will provide a written opinion regarding the patient's capacity to consent to ECT.
- If a patient is determined to possess capacity to consent, the patient will be:
    - Given written disclosure of the benefits and risks, and any less intrusive alternative treatments.
    - Provided with a list of resources to learn more about ECT.
    - Given a minimum of five business days to decide whether to consent.

    - Asked to sign a consent to treatment form which, with the written disclosure will be included in the patient's clinical record.

    - Informed, in writing, that the patient may withdraw consent to the treatment at any time.
- If the patient is determined to lack capacity and that ECT is appropriate, the clinical director may apply for court authorization

- The determination of incapacity and the determination that the proposed treatment is in the best interests of the patient will be based on clear and convincing evidence. The burden of proof will rest with the clinical director of the facility.

The Legislature has a constitutional obligation to protect and promote the health including, specifically, the mental health of the residents of the State. The federal government also has an obligation to protect and promote the health and well being of its residents.

The Committee has identified areas of concern and proposed the aforementioned legislative initiatives to address issues in need of attention. The Committee recognizes that these legislative initiatives will satisfy neither proponents nor opponents of ECT. Proponents will argue that the legislation goes too far in regulating the use of ECT and that voluntary compliance with standards and protocols developed by the American Psychiatric Association are sufficient. Opponents will argue the legislation does not go far enough and have called for, at the very least, a ban on involuntary, court ordered ECT. Simply, adversaries would prefer a total ban on the use of ECT.

The Committee finds that the proposed legislative initiatives are prudent, given the present state of information regarding the safety of ECT equipment, protocols, capacity and informed consent determination procedures, and risks/benefits associated with ECT, based on diagnoses, age and other factors.

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Back