U.S. District Court
Middle District of Florida
PLAINTIFFS EXHIBIT

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JEFFREY THELEN v. SOMATICS, LLC

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From: Conrad Swartz <cswartz@gmail.com>
Sent: Tuesday, December 12, 2006 4:34 PM

To: Holly Lisanby

**Subject:** book plan up to now

Attachments: ECTmonog.rtf

Hi, Holly

Attached is the up-to-date book plan. Please elucidate the last section on TMS, VNS, and DBS. Please comment on the rest as you like.

Best regards, Conrad

## **Book Proposal**

Electroconvulsive Therapy and Other Brain Field Therapies editors: Conrad M. Swartz, Ph.D., M.D., and Sarah H. Lisanby, M.D.

## Target audience:

This will be a comprehensive scholarly book. Other brain field therapies in the title refers to non-convulsive uses of electrical and magnetic fields, now specifically magnetic brain stimulation, vagal nerve electrical stimulation, and deep brain electrical stimulation. The term electroconvulsive therapy is used here nonspecifically, including other methods of convulsive therapy.

This book is primarily directed towards psychiatrists and psychiatric resident physicians in training. We expect it should be in the library of every medical school and every hospital that gives ECT treatment. Some sections of the book should be useful to other professionals and their trainees. Graduate students in clinical psychology should appreciate the entire sections on Sociological Perspectives, Scientific and Experimental Bases, and Non-convulsive Electrical and Magnetic Brain Stimulation and of the chapter on Patient Selection within the Manual section. Their school libraries should buy this book but we suppose that sales to individual nonphysician faculty and students will be rare. Anesthesiologists and nurse anesthetists involved with ECT should find the chapters on ECT Hospital Policy, ECT Anesthesia, and Concurrent Medical Illnesses useful, but this is only a small part of the book. We expect that most anesthesia doctors and nurses involved with ECT will feel that the medical journal articles in the anesthesiology literature suffice although these articles miss important basic concepts and facts; their departments might buy a few dozen books.

About 3500 psychiatrists in the USA are identified by the American Psychiatric Association as involved with ECT, either giving it themselves or sending their hospitalized patients for it. This apparently underestimates the number by about 100% because of the number of MDs known in some regions who should be on this list but are not. So we suppose the total USA psychiatrist audience for this book is 7000. In addition there are over 1000 new psychiatry residents each year, or over 5000 in 5 years. So we suppose the total US target audience is about 13,000. The total audience in Canada, Australia, and the U.K. should be similar.

#### Competing publications:

There are two books on ECT in English at this time. One is written entirely by Richard Abrams M.D. Dr. Abrams retired about 12 years ago but revised his book for publication in 1997 and 2002 anyway. The only clinical opinions in his book are his, and they are abundant. However, Dr. Abrams' last substantial clinical ECT seervice was about 30 years ago, so these clinical opinions are either dated or not based on clinical experience. The sections on literature review are reasonably complete, but they are often mixed with his clinical opinions. His book largely omits the "Administrative Perspectives" section below; we believe this is an important omission. His fourth edition (2002) has 250 pages plus references.

The other book is American Psychiatric Press' APA Task Force report (2001), "The Practice of Electroconvulsive Therapy. Recommendations for Treatment, Training, and Privileging. Second Edition." It has 243 large-print pages plus references. This book is psychiatrist-centered and apparently aims to make permissible as much as possible. This is what a Task Force should do. To illustrate the extremity this is taken, the book section section on patient selection figuratively throws up its hands about which patients with major depression should or should not receive ECT. It is a book of administrative policy that withholds basic judgments--including clinical advice about what works best. This book probably decreases litigation risks because virtually everything is permissible. Although this is nice for clinicians it provides virtually no guidance about how to practice.

So, both books are short on good-sense clinical judgment grounded on experience. For example, every ECT expert should be experienced in each of the four major modern ECT electrode placements--as they should be experienced with every antidepressant medication--but neither book says so. The APA Task Force Report mentions only two of these placements. Dr. Abrams gives substantial emphasis to two obscure placements that no one uses or recommends, left unilateral and bianterior. He describes

bianterior as if it were bifrontal but it is not. His extensive praise of left unilateral ECT is idiosyncratic and accounts for about 1% of his entire text. For both he centers the discussion on his own publications.

A third publication is a programmed text to teach ECT to residents, by Richard Weiner, M.D. and other faculty at Duke. It is basic and is not a substantial reference. Its market is psychiatry resident physicians, and this book aims to represent what they need to know about ECT to get through their residency. For many residents this is enough. For those whose future patients might receive ECT it is not enough.

# Specific plan of the book:

Each paragraph below represents a separate chapter. Each chapter will have a doctoral author (or several) who has published what the editors consider insightful work on that topic. All chapter authors are TBA except the few with a listed name.

### Sociological Perspectives

History (by Edward Shorter, Ph.D.) This will describe what the clinician psychiatrist needs to know about the history of ECT to practice psychiatry well. It will include how convulsive therapy and ECT began, how did ECT usage spread in the USA, and the historical landmarks in refining ECT such as introducing muscle relaxants, brief pulse stimuli, and physiological monitoring. It will also mention how ECT achieved credibility.

Biographical books and movies. Kitty Dukakis is the latest in a series of people whose ECT treatment is described in a biography or movie. Others include Norman Endler, Janet Frame, and David Helfgott.

Professional obstructions to ECT. There are large obstructions to ECT within the systems of healthcare in the USA. Many state government-run hospitals do not provide ECT in their hospital and maintain tight bottlenecks to sending their patients elsewhere for it. Several psychiatrists agitate against ECT, and each seems to have an interesting family, personal, or financial reason for doing so; these include E. Fuller Torrey, Peter Breggin, and Thomas Szasz. Perhaps the largest obstruction is ignorance or dismissal of the evidence about ECT usefulness. (perhaps William Reid, M.D.)



### Administrative Perspectives, consisting of

ECT Training and Qualifications. This describes the published expected qualifications for physicians who deliver the ECT procedure, along with reasonable changes if any and corresponding justifications.

ECT in Psychiatric Residency Training. This describes the published minimum requirements, along with reasonable changes if any and corresponding justifications.

ECT Hospital Policy and Quality Assurance. Every hospital that gives ECT must maintain a written policy approved by the service chiefs of psychiatry and anesthesiology. This chapter will describe what such a policy specifically looks like. Most hospitals that give ECT maintain one or more QA monitors about ECT. This chapter will describe examples of useful ECT QA monitors.

ECT Nursing Management and Physical Arrangement. There are several ways to arrange an ECT unit, both physically and with staff. This chapter describes them. To avoid re-inventing these plans or overlooking good possibilities every hospital that wants to open an ECT unit needs to learn about this.

ECT Forms for Physicians and Nurses. Modern ECT requires routine completion of a variety of forms that organize psychiatric, anesthesia, and recovery data. This chapter provides examples of forms for these purposes, and examples of data typically collected. Book owners should be permitted to photocopy or adapt these forms for their own clinical use. Ideally each book should have a serial number and this serial number should be placed on each form and on each form adapted from these.

Lawsuits related to ECT and Other Brain Field Therapies. Lawsuits involving ECT are rare. They mostly involve failure to diagnose a serious medical condition that is present. This chapter reviews the history of lawsuits related to ECT, magnetic brain stimulation, deep brain stimulation for psychiatric purposes, and vagal nerve stimulation.

ECT in the world with subchapters as listed below.

ECT Availability in the USA, including Geography, types of hospitals. ECT is widely available in most cities with medical schools, but rarely anywhere else. It is available in most federal hospitals (e.g., VA, military) but rarely in state hospitals.

ECT in Scandinavia. Perhaps because of the long winter night and perhaps because of excellent education, ECT has long been widely used in Scandinavia.

ECT in the U.K. ECT is matter-of-fact and widely available in the U.K., perhaps for the same geographical reasons as in Scandinavia. Recently the national health care system began obstructing ECT, using a report written by inexperienced nonpsychiatric authors from the National Center for Clinical Excellence (NICE). There are also some reports about how ECT in the U.K. is widely given by untrained psychiatric residents. This chapter will describe these concerns.

ECT in Canada, Australia, and New Zealand. These countries seem to have the high ECT usage rates of the U.K. but less adversariality.

ECT in Asia, including China, India, Pakistan, Indonesia, Japan, and South Korea. ECT is widely used in India, China, and Japan. Stigmatization is high in Japan but low in India.

ECT in Continental Western Europe. Although Italy is the birthplace of ECT it is virtually banned there now. Germany has long made ECT widely available but pretended not to because of stigmatization. Yet, in the Netherlands ECT is not stigmatizing.

ECT in Russia and Eastern Europe. Greece and Turkey widely use modern ECT. Russia resembles the USA in that ECT is easily available in some places but not in many others. Russian ECT doctors commonly believe that anesthesia blocks ECT effectiveness.

# Scientific and Experimental Bases

Electricity and the Neurophysiology of Electrical Seizure Induction (Swartz). This chapter reviews the physical characteristics of electricity that relate to ECT and how electricity induces seizure.

The Neurochemical Changes of Electrically Induced Seizures. Neurochemically a seizure consists of releases of a variety of neurotransmitters. This chapter will describe the changes that might be related to the clinical effects of ECT.

Brain Imaging of ECT Effects. PET scanning and functional MRI scanning illuminate the time course of oxygen usage and thereby brain activity. This chapter will describe the findings in patients who receive ECT.

Neuroendocrine and Cardiac Effects of ECT (Swartz). Seizure induces release of some but not all neurohormones, and elevation of heart rate and blood pressure for about as long as the seizure lasts. These can reflect the intensity and extent of the seizure and represent the therapeutic impact of the ECT treatment. This chapter will review this area.

Non-electrical Convulsive Therapies. Before ECT there were drug-induced seizure treatments, including insulin-induced hypoglycemia, camphor injection, pentylenetetrazol injection, and inhaled flurothyl. There have also been reports claiming beneficial effects from brief non-convulsive chemical treatments, such as by ketamine and isoflurane. This chapter will review these. The primary focus will be on lessons and implications from these for modern ECT, rather than the historical development, controversy, or demise of these other methods.