FDA COMPLICITY ALLOWS MANUFACTURERS OF ELECTROSHOCK THERAPY DEVICE *NOT* TO CONDUCT CLINICAL TRIALS PROVING SAFETY—PUTTING 100,000 AMERICANS EACH YEAR AT RISK

EXECUTIVE SUMMARY

PREAMBLE: The FDA continues a 35-year practice of non-compliance regarding requiring Electroconvulsive Therapy (ECT) device manufacturers to submit a pre-marketing application (PMA) to prove the device is safe and effective and does not cause *brain damage* and *severe memory loss*. Psychiatrists still do not know how ECT works.

100,000 Americans every year are subjected to a device that emits up to 360 volts of electricity through the brain and puts them at risk of irreparable damage. The use of ECT is an estimated $1.2 billion a year industry (including costs of hospitalization).

The FDA is considering **a)** maintaining the ECT device in a Class III category (high risk) without requiring clinical trials to prove safety, thereby relying upon selective and, arguably, biased published studies—a "Paper PMA" or **b)** down-classifying the ECT device to Class II (lower risk and, therefore, able to be more widely used—including to children.) Thousands of consumers have objected to this.

For three decades, MECTA and SOMATICS INC, the two U.S. manufacturers of the ECT devices, have non-complied with FDA requests for a PMA and FDA has allowed this. They now claim clinical trials would be "too expensive."

- **1976**

  ECT devices were "grandfathered" into Class III (highest risk).

- **1979**

  The FDA formally classified the ECT device as Class III, demonstrating "an unreasonable risk of illness or injury." The manufacturer was required to provide a PMA by April 1982. THEY FAILED to do this.[1]

- **1982**

  Instead, on August 10, 1982, the American Psychiatric Association (APA) filed a petition to have the device classified as Class II based on their selective review of literature. NIMH supported the petition. Psychiatrist MAX FINK, who narrates ECT videos for SOMATICS from which he receives royalties, wrote the APA's first ECT Task Force report in 1978 upon which the APA petition was largely based.

- **1990**

  The Safe Medical Devices Act of 1990 required that the FDA either reclassify pre-1976 class III as Class I or Class II (lower risk) devices or mandate the manufacturers to produce a PMA. FDA failed to comply.

- **1995**
  The FDA gave the ECT device manufacturers two years to submit all safety and effectiveness information by August 14, 1997. The manufacturers did not comply. The FDA did not enforce it.

- **2009**
  The Government Accountability Office recommended the FDA expeditiously regulate these Class III devices.

- **2011**
  The FDA prepared an Executive Summary on the ECT device for its Neurological Devices Panel meeting in January 2011 and made this public for submissions.

  Seventy-nine percent (79%) of respondents expressed an opinion against reclassification and seeking to have the FDA ensure the public's protection and by maintaining the device as Class III. There were 92 group submissions, representing a total of 6,462 individuals, against reclassification.

  There were only 462 (7.1%) individuals in favor of downgrading to Class II. [FDA ECT Executive Summary, p. 14]

- **2011 (Neurological Devices Panel Meeting in January)**

  Panel chairman, neurologist Dr. Thomas Brott commented that *none* of the biological markers psychiatrists cited as evidence that ECT *does not* cause brain damage have "been shown to be reliable." He questioned why MRIs and EEGs had not been done to determine brain structural change. [Pages 221-22 Neurological Devices Panel hearing]

  The majority of panel members supported keeping the ECT device as Class III, except for catatonia, for which some recommended Class II—thereby suggesting a "split" classification, regardless of how dangerous the device may be.

- Malvina Eydelman, director of the FDA division covering neurological devices, said the agency would not necessarily require new trials *if existing evidence was strong enough to prove safety and effectiveness*—which, in more than 30 years, has never been scientifically substantiated and is still more procrastination. [Page 432 of Neurological Devices Panel transcript, Jan 28, 2011].

- **2011 (July)**
  The Institute of Medicine's (IOM) report regarding the FDA's 510(K) process—a premarketing submission when a PMA is not required (for Class II, for example)—said the process is "flawed." IOM stated: "The 510(k) process lacks the legal basis to be a reliable pre-market screen of the safety and effectiveness of moderate-risk Class II devices and cannot be transformed into one." [Page 2, IOM report, "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years."]

- The FDA should be questioned about whether it has colluded with the American Psychiatric Association not to mandate a PMA and clinical trials to prove device safety to protect consumers against *brain damage*. Numerous members of the four APA ECT Task Forces (1978, 1990, 2001, 2010) have had conflicts of interests with ECT device companies and have received NIMH grants to research ECT. [See attachment]

- FDA, NIMH, and APA have not insisted on clinical safety trials and now claim they are too expensive. Between 1999 and 2009, NIMH provided more than $23.7 million of taxpayer money for grants for ECT research, including to those sitting on the APA ECT Task Forces.[2]

- MECTA's principals admitted that they ignore all complaints made to their company which are derogatory because they *"feel"* the practice is safe and effective. They considered allegations of *brain damage* a "minority view" and that memory loss, while a complication, is "therapeutic." In deposition, the President of Mecta said the company "does not do research."[3] The dishonesty of manufacturers has aided to keep the field in darkness.

IN SUMMARY: Former patients have reported devastating, permanent amnesia and cognitive impairment from ECT. **In 2005, a jury in Columbia, SC, awarded an ECT patient $635,177 in compensation finding that her loss of 30 years of memory and cognitivie impairment was due to ECT. In 2000, Peggy S. Salters, 60, received an intensive course of ECT and lost all memories of the past, including memories of her husband of three decades and the births of her three children. Ms. Salters held a Masters of Science in nursing and had a long career as a psychiatric nurse, but lost her knowledge of nursing skills and was unable to return to work after ECT.** [4]

Safeguarding Children: Should the ECT device be made Class II, it could easily be used "off label," and children could be put at greater risk of being administered ECT. U.S. psychiatrists continue to conduct research using electroshock on adolescents, even though the **World Health Organization** has said, "**There are no indications for the use of ECT on minors, and hence this should be prohibited through legislation."**[5]

To protect the health and welfare of American citizens:

a) The ECT device should remain as Class III for all indications
b) FDA must demand that rigorous, ethically justifiable clinical trials be conducted to evaluate the safety of ECT devices
c) Additional studies the FDA relies upon must be by researchers free of conflicts of interest with the device manufacturers.
d) FDA officials involved in the ECT review and NIMH officers overseeing grants for the study of ECT, need to disclose any relationship—past or present—with psychiatrists/researchers with financial/consulting ties to ECT device manufacturers.
e) The FDA make public all correspondence between Mecta and Somatics since 1982 regarding the production of clinical trials and evidence, including

explanations regarding why the ECT device manufacturers did not comply with requirements to provide evidence and clinical trials in 1982 and 1997.

REFERENCES:

[1] Am J. Psychiatry 138:4, April 1981, p. 572
[2] NIMH Grant database
[3] Deposition from civil case Atze Akkerman vs Mecta, taken by Kendrick Moxon, attorney, cited in his submission to the FDA, 6 Jan. 2010.
[4] http://endofshock.com/litigation.htm
[5] Benedetto Saraceno, MD, "WHO RESOURCE BOOK ON MENTAL HEALTH, HUMAN RIGHTS AND LEGISLATION WHO 2005," p. 64.