

POTENTIAL CONFLICTS OF INTEREST BETWEEN ECT RESEARCHERS, ECT DEVICE MANUFACTURERS, FDA/NIMH

In 1985, NIMH used federal funds to pay for a “Consensus Conference on ECT”—organized by the American Psychiatric Association (APA), with the planning committee consisting of psychiatrists with long-standing financial relationships to the Electroconvulsive Therapy (ECT) device manufacturers. The two U.S. ECT device manufacturers are MECTA and Somatics, Inc.

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.¹

The FDA has relied, in part, upon APA ECT Task Force reports, which since 1978 have been prepared by committees whose members include psychiatrists with conflicts of interest with ECT device manufacturers.

- ❑ **In 2010, DR. LAWRENCE PARK, FDA medical officer, co-wrote the FDA’s Executive Summary on ECT.** He is a psychiatrist who has co-authored numerous studies on ECT.² Before he joined the FDA, he served as the Director of Research and Attending Psychiatrist for the Somatic Therapies Unit at Massachusetts General Hospital, where ECT is administered.³ **Its website states ECT does not cause brain damage and is a safe and relatively comfortable experience—contrary to thousands of ECT “consumers” who presented comments to the FDA stating the opposite.**⁴

MECTA’s submission to the FDA in 2010 cited 18 studies by **Harold Sackeim, Ph.D.**, 13 by **Dr. Richard Weiner** and 8 by **Dr. Andrew Krystal**—all of whom have conflicts of interest with MECTA and/or Somatics, Inc.⁵ Each has been a member of an APA ECT Task Force, with Dr. Weiner chairing the 1987-1990 Task Force.

- ❑ **DR. MATTHEW V. RUDORFER**, a psychiatrist who administers and oversees grant money for NIMH and is associate director for treatment research, told *The New York Times* in January 2011 that new clinical trials “might be too expensive” as the manufacturers “tend to be mom-and-pop operations.” Dr. Rudorfer is co-author of a 2003 ECT report with Harold Sackeim Ph.D., a consultant for MECTA and Somatics, Inc. (the two ECT device manufacturers) and member of the 1987-1990 APA ECT Task Force—while getting millions of NIMH grant dollars.⁶ Dr. Rudorfer is on the Editorial Board of the *Journal of ECT* (founding editor is Dr. Max Fink, consultant for ECT device manufacturers).⁷
- ❑ **DR. HAROLD SACKEIM, PH.D.**, Professor of Clinical Psychology in Psychiatry and Radiology, College of Physicians and Surgeons of Columbia University. Member of the APA ECT Task Force 2001. He is a consultant to and has received funding from Somatics, Inc. and MECTA.⁸ MECTA has also funded his ECT studies.⁹ In 1981, NIMH began giving Dr. Sackeim grants to study the “affective and cognitive

consequences of ECT.” Twenty years and \$8 million later, Sackeim was still to answer the questions posed in the first grant abstract.¹⁰ In testimony given to the New York State Assembly investigating ECT on May 18, 2001, it was stated: “Because Sackeim had a lock on this [NIMH] money for 20 years, because his money is renewed automatically for as long as he wants it without his proposals having to compete with other grants, and because he sits on the panel which decides who gets funded, other researchers aren’t able to get grants to do research in this area. Dr. Sackeim is on the American Psychiatric Association’s Task Force on ECT, and he’s the spokesman for industry... While he’s been getting millions of NIMH dollars, he’s also been a consultant for, and received grant money from the companies that make most of the shock machines in America... .”¹¹ Sackeim co-authored a 2003 ECT textbook with Dr. Matthew Rudorfer, a NIMH employee who oversees NIMH grants.¹² Dr. Sackeim was one of the committee members for the 1985 NIMH “Consensus Conference on ECT” along with Richard Weiner.¹³ He is on the Editorial Board of the *Journal of ECT*.¹⁴

- **DR. RICHARD WEINER**, Professor of Psychiatry at the Duke University School of Medicine.¹⁵ Weiner was Chairman of the APA ECT Task Force 1990. He was part of the 1985 NIMH “**Consensus Conference on ECT**” and in charge of the APA’s lobbying campaign at the FDA, while he had a long-standing relationship with MECTA and consulted for Somatics, Inc. No one at the conference or in the media was told that all had financial conflicts.¹⁶ He has appeared as an expert in the MECTA videos about ECT.¹⁷ In 2005, he was on the Speaker’s Bureau of MECTA.¹⁸ He is a co-inventor on a Duke University-patent licensed to MECTA but says he receives no royalties for the patent.¹⁹ Has received grants from NIMH to study ECT since 1978.²⁰ In the 1978 APA ECT Task Force Report, it acknowledges Weiner for his research, while not disclosing that as an engineer he had developed ECT machines for MECTA, wrote their instruction manuals and did a video for them.²¹ In 1995, he filed a patent for an “electroconvulsive therapy method using EEG data as an indicator of ECT seizure adequacy.”²² The report admitted the “published literature” on ECT “still provides only a limited number of well-controlled studies.”²³ Weiner testified before the FDA Neurological Devices Panel in January 2011 in favor of the ECT device being made Class II.
- **DR. CONRAD MELTON SWARTZ**, who co-founded Somatics, Inc. in 1983, told the FDA in 2011 that his company could not afford an in-depth safety study.²⁴ Yet, between Somatics, Inc. and MECTA, the companies earned an estimated \$24 million from sales of the ECT devices and the companies each have annual revenue exceeding \$1 million.²⁵ He is on the Editorial Board of the *Journal of ECT*.²⁶ He told *USA Today* in 1995 that his profits from Somatics, Inc. were equivalent to an additional psychiatry practice (valued at \$131,300 in 1993) but he asserted that his financial conflict was a “non-issue.”²⁷
- **RICHARD ABRAMS**, a professor of psychiatry at the Chicago Medical School who in 1983 started his own electroshock device company, Somatics, Inc., with Dr. Conrad

Swartz. Somatics, Inc. makes the Thymatron ECT device—from which Abrams derived 50% of his income. He was listed among those individuals who “provided comment on the draft of the ECT Task Force Report” for the APA in 1990. Nine of his publications were cited in the report’s bibliography, making him by far the most heavily represented author. The report does not mention any link between the Thymatron and Abrams.²⁸ He writes that ECT is safe, even in children and the elderly. He also told *USA Today* in 1995 that ECT should be considered as the *first line* treatment given, not as the last resort.²⁹ This is the potential risk if the device is made Class II.

- **SARAH H. LISANBY, M.D.**, Chair of the 2010 APA ECT Task Force, who also sat on the FDA’s Neurological Devices Panel, had at least four of her ECT studies cited in MECTA’s submission to the FDA. She said it is unlikely ECT manufacturers could “*finance the studies required to get it approved...*”³⁰ Dr. Lisanby is on the Editorial Board of the *Journal of ECT*, along with Harold Sackeim and Max Fink (consultants to the device makers) and Dr. Richard Abrams, co-owner of Somatics, Inc.³¹ Fink, who receives royalties from ECT videos made by the manufacturers, wrote the first APA ECT Task Force Report and has been a member of a subsequent APA Task Force—reports the FDA considers.³²
- **DR. CHARLES H. KELLNER**, the Director of the ECT service at the Mount Sinai Hospital in New York City³³ and was a member of the APA ECT Task Force in 2001 and 2010. He is a consultant for MECTA and Somatics, Inc. and wants the ECT device down classified.³⁴ From 1994 to 2004, he was the Editor-in-Chief of the *Journal of ECT*. From 1993 to 1998, he organized an annual 2-day training course on ECT for practitioners that was sponsored in part by educational grants from Somatics, Inc. and MECTA.³⁵ He has led the collaborative ECT research group CORE (Consortium for Research in ECT) for the past decade, which operates programs in five hospitals across the country supported by NIMH.³⁶ Despite the World Health Organization recommending a ban of ECT on children and adolescence and some U.S. states banning its use on minors, in 2010, a Kellner study on ECT urged, “removal of impediments to ECT access in this population.”³⁷
- **ANDREW KRYSTAL, MD**, Professor in the Department of Psychiatry and Behavioral Sciences at Duke University Medical Center is a member of the APA’s 2010 ECT Task Force under the chair of Dr. Sarah Lisanby.³⁸ He and psychiatrist Richard Weiner are the inventors listed on a U.S. patent that Duke University has licensed to MECTA Corporation.³⁹ He has received NIMH funding to study improving ECT's effectiveness.⁴⁰
- **WILLIAM McDONALD**, Professor of Psychiatry at Emory University, Georgia.⁴¹ He is Chair of the American Psychiatric Association (APA) Committee on Electroconvulsive Therapy and Other Electromagnetic Therapies and a member of the APA Council on Research.⁴² Member of the APA ECT Task Force in 2010. He sat on the FDA Neurological Devices Panel meeting in January 2011 supporting a

downgrade to Class II for ECT for all indications (depression, bipolar, schizophrenia/affective, and catatonia) except for schizophreniform. He has also received NIMH funding.⁴³

- **DR. HUSAIN MUSTAFA**, Professor of psychiatry at the University of Texas Southwestern Medical Center in Dallas and head of its ECT services.⁴⁴ Member of the APA ECT Task Force 2010. He is on the Editorial Board for the *Journal of ECT*.⁴⁵ Mustafa has received NIMH grant funding.⁴⁶ On July 23, 2008, the Department of Health and Human Services wrote Mustafa saying that the FDA had conducted an inspection at his clinical site to ensure that data and information contained in requests for Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k) were “scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.” The inspection “revealed serious violations of Title 21, Code of Federal Regulations (21 CFR) Part 812 --Investigational Device Exemptions, and Section 520(g) (21 U.S.C. 3 60j(g)) of the Act.⁴⁷ On February 4, 2011, the Medical Board and Dr. Hussain entered into an Agreed Order requiring Dr. Hussain to complete within one year five hours of CME in medical record-keeping. The basis for action was Dr. Hussain’s failure to maintain adequate medical records respecting his clinical trials and failure to obtain appropriate informed consents.⁴⁸
- **DR. MAX FINK**, Professor Emeritus of Psychiatry and Neurology and considered the “grandfather of ECT.” He was part of the first APA ECT Task Force in 1978 and was responsible for writing its report. He served on the APA’s 1990 ECT task force, which drafted guidelines for the treatment. He has made several videos about ECT, which sell for about \$350 and are used by hospitals that administer ECT. Fink said that Somatics, Inc. paid him \$18,000 for the rights to the videotapes; he said he receives 8 percent of the royalties. He has declined to disclose how much money he has earned from the videos.⁴⁹ In a 1978 article Fink wrote for the official journal of the Psychopathological Association, he wrote: “The principle complications of EST [ECT] are death, brain damage, memory impairment, and spontaneous seizures. These complications are similar to head trauma to which EST has been compared.”⁵⁰ Dr. Fink also promotes the use of ECT for children.⁵¹ In 1997, he was a principal investigator in a multicenter collaborative study group known as CORE (Consortium for Research in ECT) under grants from NIMH (along with Charles Kellner).⁵²

REFERENCES

- ¹ NIMH Grant database.
- ² “Lawrence T. Park, MD,” Advisory Board, Mass. General Hospital, <http://www2.massgeneral.org/allpsych/ced2/clinicians/park.html>.
- ³ “Lawrence Park, MD, Find a Doctor Page, Georgetown University Hospital, http://www.georgetownpsychiatry.org/body_dept_fw.cfm?id=556736&action=detail&ref=3584&dept=556736; “Somatotherapies Unit (ECT),” Mass. General Hospital, <http://www2.massgeneral.org/allpsych/PsychNeuro/ect.asp>.
- ⁴ “Somatotherapies Unit (ECT),” Mass. General Hospital, <http://www2.massgeneral.org/allpsych/PsychNeuro/ect.asp>.
- ⁵ <http://ajp.psychiatryonline.org/cgi/content/full/158/6/974>.
- ⁶ “Testimony of the Director of Committee for Truth in Psychiatry,” New York State Assembly, May 18, 2001, <http://www.ect.org/news/newyork/andretest.html>.
- ⁷ <http://journals.lww.com/ectjournal/pages/editorialboard.aspx>.
- ⁸ Chris Dubey, “A summary of references against electroshock treatment,” *Examiner*, Nov 21, 2012, <http://www.examiner.com/article/a-summary-of-references-against-electroshock-treatment>.
- ⁹ Comprehensive CV of Sackeim, as published by *Clinical Neuropsychiatry Journal of Treatment Evaluation*, www.clinicalneuropsychiatry.org/biografie/sackeim.php.
- ¹⁰ Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 195-198.
- ¹¹ Testimony of the Director of Committee for Truth in Psychiatry, New York State Assembly, May 18, 2001, <http://www.ect.org/news/newyork/andretest.html>.
- ¹² Gardiner Harris, “F.D.A. Panel Urges Stronger Warning on Antidepressants,” *The New York Times*, 15 Sept. 2004, <http://www.antidepressantsfacts.com/2004-09-15-NYTimes-SSRI-black-box2.htm>.
- ¹³ Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 161-162.
- ¹⁴ <http://journals.lww.com/ectjournal/pages/editorialboard.aspx>.
- ¹⁵ ECT hearings from the FDA Medical Devices Advisory Committee transcript, January 27-28, 2011.
- ¹⁶ Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 161-162.
- ¹⁷ Douglas G. Cameron, “ECT: Sham Statistics, the Myth of Convulsive Therapy, and the Case for Consumer Misinformation,” *The Journal of Mind and Behavior*; Winter and Spring 1994, Vol. 15, Nos. 1 and 2; Pages 177-198, http://www.stopshrinks.org/reading_room/ecb/docs/sham.htm.
- ¹⁸ American Psychiatric Association, *The Practice of Electroconvulsive Therapy Recommendations for Treatment, Training, and Privileging (A Task Force Report of the American Psychiatric Association)*, Second Ed (Washington, D.C.: American Psychiatric Association, 2001).
- ¹⁹ Mehul Mankad, MD, et al., “Clinical Manual of Electroconvulsive Therapy,” American Psychiatric Publishing, Inc., 2010.
- ²⁰ Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) pp. 196-198.
- ²¹ *Electroconvulsive Therapy*, ECT Task Force report, (APA) Sept. 1978, pp. iii.
- ²² Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 198-199.
- ²³ *Electroconvulsive Therapy*, ECT Task Force report, (APA) Sept. 1978, pp. vii-ix.
- ²⁴ Duff Wilson, “F.D.A. Is Studying the Risk of Electroshock Devices,” *The New York Times*, 23 Jan. 2011, <http://www.nytimes.com/2011/01/24/business/24shock.html?pagewanted=all>.
- ²⁵ Duff Wilson, “F.D.A. Is Studying the Risk of Electroshock Devices,” *The New York Times*, 23 Jan. 2011, <http://www.nytimes.com/2011/01/24/business/24shock.html?pagewanted=all>.
- ²⁶ <http://journals.lww.com/ectjournal/pages/editorialboard.aspx>.
- ²⁷ Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) pp. 208-209.

- ²⁸ Peter Breggin MD, “Electroshock: Scientific, Ethical, and Political Issues,” *International Journal of Risk & Safety in Medicine* 11 (1998) 5-40, IOS Press, <http://www.sntp.net/ect/breggin1.htm>.
- ²⁹ Dennis Cauchon, “Doctor’s Financial Stake in shock therapy,” *USA Today*, 6 Dec. 1995, <http://usatoday30.usatoday.com/life/health/lhs194.htm>.
- ³⁰ Jim Amos, “Future of ECT as Life-Saving Treatment at Risk?” *The Practical Psychosomaticist*, March 10, 2011, <http://jajsamos.wordpress.com/2011/03/10/future-of-ect-as-life-saving-treatment-at-risk/>; “Study: Electromagnets Can Relieve Depression,” CBS News, 5 May, 2010, http://www.cbsnews.com/2100-500368_162-6462525.html.
- ³¹ *Journal of ECT* Editorial Board, <http://journals.lww.com/ectjournal/pages/editorialboard.aspx>.
- ³² “ECT Experts’ Ties to Shock Machine Industry,” <http://www.ect.org/news/posta.html>.
- ³³ “ECT in the 21st Century: Challenges and Opportunities,” Duke University Events Calendar, <http://calendar.duke.edu/events/show?fq=id%3ACAL-8a087089-36828808-0137-145456cc-0000073ddemobedework%40mysite.edu>.
- ³⁴ Linda Andre, *Doctors of Deception: What They Don’t Want You to Know about Shock Treatment*, (Rutgers University Press, 2009) p. 101.
- ³⁵ American Psychiatric Association, *The Practice of Electroconvulsive Therapy Recommendations for Treatment, Training, and Privileging (A Task Force Report of the American Psychiatric Association)*, Second Ed (Washington, D.C.: American Psychiatric Association, 2001).
- ³⁶ “Research Findings” University of Medicine & Dentistry of New Jersey, <http://www.theuniversityhospital.com/ect/findings.htm>.
- ³⁷ Lee E. Wachtel, Dirk M. Dhossche, and Charles H. Kellner, “When is electroconvulsive therapy appropriate for children and adolescents?,” *Medical Hypotheses*, Volume 76, Issue 3, Mar. 2011, Pages 395–399, <http://www.sciencedirect.com/science/article/pii/S0306987710004640>.
- ³⁸ Andrew D. Krystal, Richard D. Weiner, “Letter to the Editor,” *Am J Psychiatry*, 2001;158:974-974, <http://ajp.psychiatryonline.org/cgi/content/full/158/6/974>.
- ³⁹ Andrew D. Krystal, Richard D. Weiner, “Letter to the Editor,” *Am J Psychiatry*, 2001;158:974-974, <http://ajp.psychiatryonline.org/cgi/content/full/158/6/974>.
- ⁴⁰ Leye Jeannette Chranowski, “My Turn: ECT Editorial Casts Shadow on Author and JAMA’s Credibility – ECT,” Healthy Place, <http://www.healthyplace.com/depression/articles/my-turn-ect-editorial-casts-shadow-on-author-and-jamas-credibility/ect/>.
- ⁴¹ ECT hearings from the FDA Medical Devices Advisory Committee transcript, January 27-28, 2011.
- ⁴² Mustafa A. Muftic, *et al*, “Bupropion Decreases Resting Motor Threshold: A Case Report,” *Brain Stimul.* 2010 July ; 3(3): 177–180.
- ⁴³ American Psychiatric Association, 158th Annual Meeting Program Guide 2005.
- ⁴⁴ Aaron Levin, “Consent Process Said Crucial at Each ECT-Treatment Step,” *Psychiatric News*, July 16, 2010, Vol. 45, No. 14, Page 6.
- ⁴⁵ Mustafa Husain, M.D. Faculty Page, Southwestern Medical Center, <http://www.utsouthwestern.edu/fis/faculty/13437/mustafa-husain.html>.
- ⁴⁶ American Psychiatric Association, 155th Annual Meeting Program Guide 2002.
- ⁴⁷ Department of Health and Human Services, Warning Letter to Mustafa M. Husain, M.D., July 23, 2008, http://www.circare.org/fdawls3/husain_20080723.pdf.
- ⁴⁸ Hussain, Mustafa, M.D., Lic. No. J1695, Amarillo, <http://www.tmb.state.tx.us/news/press/2011/021611.php>
- ⁴⁹ “ECT Experts’ Ties to Shock Machine Industry,” <http://www.ect.org/news/posta.html>.
- ⁵⁰ Alliance For Human Research Protection, “Latest Electroshock Propaganda--It’s the ‘Penicillin of Psychiatry’” January 30, 2008, <http://endofshock.com/Sharav%20on%20electroshock.pdf>.
- ⁵¹ Alliance For Human Research Protection, “Latest Electroshock Propaganda--It’s the ‘Penicillin of Psychiatry’” January 30, 2008, <http://endofshock.com/Sharav%20on%20electroshock.pdf>.
- ⁵² Arline Kaplan, “Through the Times With Max Fink, M.D.,” *Psychiatric Times*, September 1, 2005, <http://www.psychiatristimes.com/depression/content/article/10168/52281?pageNumber=5>.