Future Role of ECT-
The FDA Hearing Story

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Nyköping, Sweden

May 25, 2016

Something is Rotten in the State of ~~Denmark~~ USA

- Trump
- Scientology
- FDA

FDA Classification of Medical Devices

- The FDA categorizes medical devices into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.
- Class I – lowest risk
- Class II – intermediate risk
- Class III – high risk

History of FDA Classification of ECT Devices

- 1976, FDA “grandfathers” ECT devices as class III
- 1978, FDA recommends placing ECT devices in Class II.
- 1979, after public hearing, FDA reverses itself, changes ECT devices to Class III.
- 1982, APA submits reclassification petition.
- 1982, after another public hearing, FDA publishes notice of intent to reclassify ECT devices to Class II (never finalized).

History of FDA Classification of ECT Devices

- 2009, Government Accountability Office recommends FDA require all grandfathered Class III devices (including ECT devices) to either submit PMA or be reclassified into Class I or II.
- September 2009, FDA opened docket for public comment on how devices should be classified. A number of entries opposing ECT and antagonistic to psychiatry posted.
- January 2011, FDA holds public hearing of FDA Neurological Devices Review Panel.

2011 FDA Public Hearing

- FDA presentation about regulatory background, clinical and regulatory history
- Testimony from ISEN, APA and APNA
- Personal experiences about life-saving aspects of ECT- Amy Lutz spoke of son Jonah's therapeutic treatment, Kitty Dukakis and Julie Hersh- "I would not be alive today without ECT"
- Anti-ECT testimony from Citizen's Commission of Human Rights (Scientology founded organization)

2011 FDA Public Hearing

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- Amy Lutz spoke of son Jonah's therapeutic treatment (Jonah's story)

2011 FDA Neurological Devices Review Panel

- All panel members “Temporary Non Voting”
- Chair of panel a neurologist
- Members included psychiatrists, neurologists psychologists, biostatisticians, an anesthesiologist
- Vote was supposed to be “unofficial,” “advisory”

2011 FDA Neurological Devices Review Panel

- By slim majority, voted to keep ECT devices in Class III for all indications, except catatonia (Class II)
- Vote was along discipline lines: psychiatrists/ anesthesiologist voted for Class II, psychologists, neurologists, biostatisticians for Class III
- Psychiatric Times: “more heat than light.”

Kellner CH, The FDA Advisory Panel on the Reclassification of ECT Devices. Psychiatric Times, 2011.

History of FDA Classification of ECT Devices

- December 2015, FDA proposes new rules for classification of ECT devices in the USA.
- December 2015 – March 2016, period of public comment on FDA website dockets.
- Effective mobilization of ISEN Executive Committee outreach to members, PAC to patients and families, blogs and social media to provide public comment

FEDERAL REGISTER
The Daily Journal of the United States Government

Proposed Rule

Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses


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Neurological Devices; Reclassification of Electroconvulsive Therapy (ECT) Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for ECT for Certain Specified Intended Uses
Docket Folder Summary
View all documents and comments in this Docket
Docket ID: FDA-2014-N-1210 Agency: Food and Drug Administration (FDA)
Parent Agency: Department of Health and Human Services (HHS)
RIN: Not Assigned
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3,434
Comments Received *
Primary Documents
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Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses

Draft Guidance for Industry, Clinicians and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: December 29, 2015

This guidance was updated on January 19, 2016 to correct an incorrect regulation citation.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Peter G. Como, Ph.D., at 301-796-6919 or peter.como@fda.hhs.gov

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Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Neurological and Physical Medicine Devices
Physical Medicine and Neurotherapeutic Devices Branch


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Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians and FDA Staff; Availability
Docket Folder Summary
View all documents and comments in this Docket
Docket ID: FDA-2014-D-1318
Agency: Food and Drug Administration (FDA)
Parent Agency: Department of Health and Human Services (HHS)
RIN: Not Assigned
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FDA Proposed Rule Problems

- Limitation on indications
- Limitation on patient populations
- Disparagement of maintenance ECT
- Onerous/incorrect/ridiculous “special controls”

FDA "Cleared Indications for Use" ECT Devices

1. Depression (unipolar and bipolar)
2. Schizophrenia
3. Bipolar manic (and mixed) states
4. Schizoaffective disorder
5. Schizophreniform disorder
6. Catatonia

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FDA Draft Guidance

427 *4.9.1.5 Precautions*

428 The following precautions should be provided.

429 • **Lack of Evidence for Efficacy or Safety in Specific Patient Populations.** Labeling
430 should include Precautions for the use of ECT devices in the treatment of patients
431 with psychiatric conditions where safety and efficacy has not been established. This
432 may include patients with:

433 - age less than 18

434 - schizophrenia

435 - schizophreniform disorder

436 - schizoaffective disorder

437 - biopolar mania or mixed states

FDA Draft Guidance

4.9.1.2 Intended Use

The labeling should include an intended use statement with specific indications of the intended patient population meeting DSM-V[2] criteria for MDE associated with MDD or BPD. In addition, the indications for use should specify that the device is indicated for severe MDE in treatment-resistant patients. The indications for use should specify the conditions of use and the patient population. For example, ECT devices are intended only for use in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. In addition, you should specify whether the device is intended to be used as sole therapy or as an adjunct to other therapies, including medications in the specified population. The labeling should also contain a description of the clinical trial population that identifies the population studied according to treatment severity and resistance.

FDA Draft Guidance

368 *4.9.1.3 Contraindications*

369 Each contraindication in the labeling should describe the consequences of contraindicated
370 use. Contraindications should include:

371 • Severe and unstable cardiovascular conditions (e.g. recent myocardial infarction,
372 unstable angina, congestive heart failure, critical aortic stenosis, uncontrolled
373 hypertension/hypotension)

374 • Cerebrovascular conditions (e.g. aneurysm, arteriovenous malformation)

375 • Increased intracranial pressure

376 • Space-occupying cerebral lesions (e.g. tumors)

377 • Recent stroke (hemorrhagic or ischemic)

378 • Severe and unstable pulmonary conditions (e.g. chronic obstructive pulmonary
379 disease, asthma, pneumonia)[3]

APA 2001 refers to these as “medical conditions associated with substantial risk.”

FDA Draft Guidance

4.9.1.4 Warnings

FDA is proposing a special control that would require labeling for ECT devices to include a prominently placed warning:

Warning: ECT device use may be associated with: disorientation, confusion, and memory problems.

FDA is also proposing a special control that would require labeling for ECT devices to include the following warning, prominently placed, unless performance data demonstrating a beneficial effect of longer term use, generally considered treatment in excess of three months, is provided:

Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.

Longer term use is generally considered treatment in excess of three months.

FDA Draft Guidance

- **Psychiatric.** FDA recommends including a warning that ECT device use may be associated with:

  - Risk of Ineffective Therapy: The labeling should include appropriate warnings for use in patient populations where efficacy has not been established and where treatment may represent a risk to the patient. ECT device use may be associated with ineffective treatment of your primary psychiatric condition, or may lead to worsening of psychiatric symptomatology.

  - Treatment-emergent mania: The labeling should include appropriate warnings regarding the occurrence of manic symptoms (including euphoria and/or irritability, impulsivity, racing thoughts, distractibility, grandiosity, increased activity, talkativeness, and decreased need for sleep) following treatment.

  - Risk of Relapse: The labeling should include appropriate warnings for use that effectiveness greater than one month after treatment completion has not been established.

Example of Docket Comment

Comment from Lisa de Haas

This is a Comment on the **Food and Drug Administration** (FDA) Proposed Rule: **Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses**

For related information, **Open Docket Folder**

Comment

I strongly oppose to the use of ECT in any case. It is a barbaric torture that has absolutely no use in modern day life. It has never proven to be beneficial to anyone, but just fries a brain so that the person is no longer aware of the fact that they have a problem - the problem is still there! Anyone who says otherwise, let them undergo ECT and see what they say!
Please do not reclassify, but ban this practice all together. If you have any hesitancy, try ECT yourself and decide then.

Example of Docket Comment

Comment from Anne Wendland

This is a Comment on the **Food and Drug Administration** (FDA) Proposed Rule: **Neurological Devices; Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses**

For related information, **Open Docket Folder**

Comment

I support the reclassification of ECT devices to Class II for depression, as well as for the other indications for which it has been shown to be safe and effective, including schizophrenia, schizoaffective disorder, mania, and catatonia. Furthermore, maintenance ECT and ECT for appropriately selected patients under 18 should remain widely available.

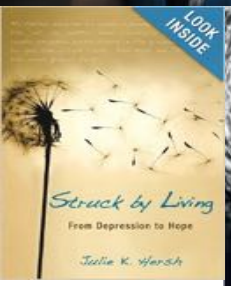
Creation of ISEN Patient Advisory Committee

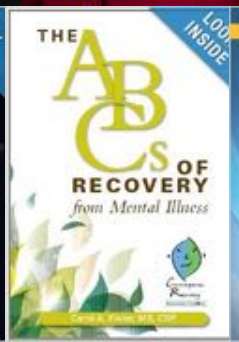
Courageous Recovery Wellness Model - Treatment for Depression

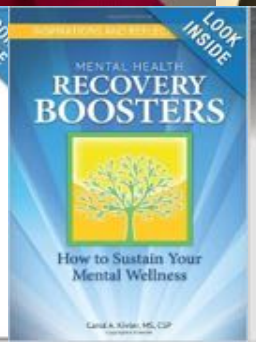
"Shocking the Shrink: A Psychiatrist Undergoes ECT"

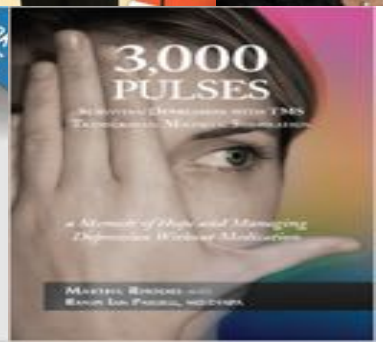
EASI FOUNDATION
Ending Aggression and Self-Injury in the Developmentally Disabled









The FDA and ECT

William M. McDonald, MD, Richard D. Weiner, MD, PhD,† Laura J. Fochtmann, MD, MBI,‡§‖ and W. Vaughn McCall, MD, MS¶*

The practice of electroconvulsive therapy (ECT) in the United States has come to a very important juncture, and we believe this is a critical period that will have a long-term impact on ECT practice in the United States and potentially in other countries. On December 29, 2015, the Food and Drug Administration (FDA) Office of Device Management proposed new rules for the reclassification of ECT devices in the United States. The proposal includes limitations on the indications for use of ECT devices and warnings that will need to be given to patients and their families who are considering ECT (the full texts of the proposed rule [https://www.gpo.gov/fdsys/pkg/FR-2015-12-29/pdf/2015-32592.pdf] and guidance document [http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM478942.pdf] are available for review).

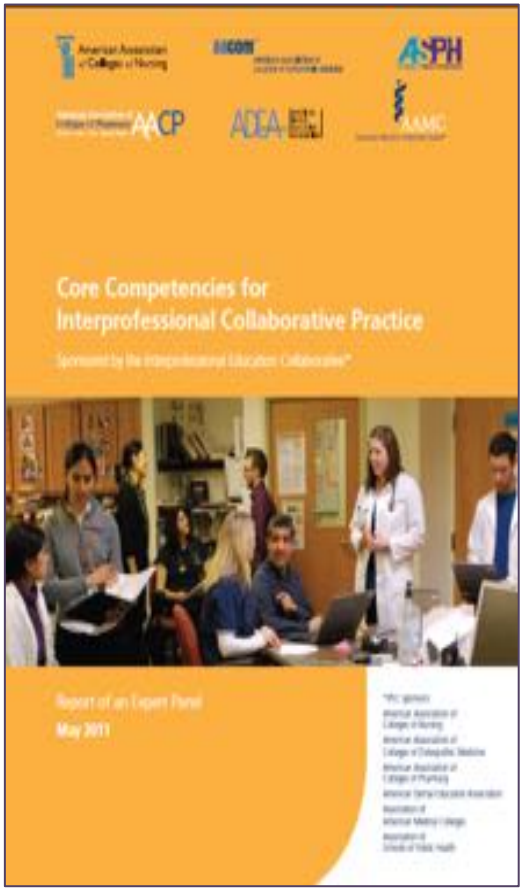
Some key features of the proposed device labeling requirements include reclassifying the use of the devices into the less restrictive category II for the treatment of "severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients 18 years of age or older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition" (albeit with warnings or "special controls"). While this is a positive step forward, the FDA labeling proposes that ECT devices remain in a more restrictive category (i.e., class III) for patients who are diagnosed with catatonia, schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar mania, or mixed states and for patients who are younger than 18 years. Electroconvulsive therapy device labeling would also be required to have special controls that include "a precaution that describes the limitations of available information on the safety and effectiveness of long-term treatment with the ECT device, also known as maintenance ECT."

Even if the proposed FDA device classification and labeling is finalized, a physician could presumably use the device "off-label" to treat other disorders such as schizophrenia and catatonia or to administer maintenance ECT. However, we are concerned that the labeling as written may have an adverse effect on the availability of ECT. Insurance companies may well deny coverage for treatments that

McDonald WM et al., The FDA and ECT. J ECT, 2016.

Preserving Access to ECT: An “All Hands on Deck” Approach


Community and Population Oriented
Interprofessional Teamwork and Team-based Practice
Interprofessional Communication Practices
Values/Ethics for Interprofessional Practice
Roles and Responsibilities for Collaborative Practice
Patient and Family Centered
The Learning Continuum pre-licensure through practice trajectory


AACP
ADEA
AAMC
Core Competencies for Interprofessional Collaborative Practice
Report of an Expert Panel
May 2011

ICCAS - Interprofessional Collaborative Competencies Attainment **PRE**-Survey #_____

Please answer the following questions by filling in the circle that most accurately reflects your opinion about the following interprofessional collaboration statements: 1 = strongly disagree; 2 = moderately disagree; 3 = slightly disagree; 4 = slightly agree; 5 = moderately agree; 6 = strongly agree; na = not applicable

Please rate your ability for each of the following statements:

Before participating in the learning activities I was able to:

	1	2	3	4	5	6	na
Communication							
1. Promote effective communication among members of an interprofessional (IP) team*	○	○	○	○	○	○	○
2. Actively listen to IP team members' ideas and concerns	○	○	○	○	○	○	○
3. Express my ideas and concerns without being judgmental	○	○	○	○	○	○	○
4. Provide constructive feedback to IP team members	○	○	○	○	○	○	○
5. Express my ideas and concerns in a clear, concise manner	○	○	○	○	○	○	○
Collaboration							
6. Seek out IP team members to address issues	○	○	○	○	○	○	○
7. Work effectively with IP team members to enhance care	○	○	○	○	○	○	○
8. Learn with, from and about IP team members to enhance care	○	○	○	○	○	○	○
Roles and Responsibilities							
9. Identify and describe my abilities and contributions to the IP team	○	○	○	○	○	○	○
10. Be accountable for my contributions to the IP team	○	○	○	○	○	○	○
11. Understand the abilities and contributions of IP team members	○	○	○	○	○	○	○
12. Recognize how others' skills and knowledge complement and overlap with my own	○	○	○	○	○	○	○
Collaborative Patient/Family-Centered Approach							
13. Use an IP team approach with the patient** to assess the health situation	○	○	○	○	○	○	○
14. Use an IP team approach with the patient to provide whole person care	○	○	○	○	○	○	○
15. Include the patient/family in decision-making	○	○	○	○	○	○	○
Conflict Management/Resolution							
16. Actively listen to the perspectives of IP team members	○	○	○	○	○	○	○
17. Take into account the ideas of IP team members	○	○	○	○	○	○	○
18. Address team conflict in a respectful manner	○	○	○	○	○	○	○
Team Functioning							
19. Develop an effective care*** plan with IP team members	○	○	○	○	○	○	○
20. Negotiate responsibilities within overlapping scopes of practice	○	○	○	○	○	○	○

*The patient's family or significant other, when appropriate, are part of the IP team.

**The word "patient" has been employed to represent client, resident, and service users.

***The term "care" includes intervention, treatment, therapy, evaluation, etc.

Adapted from MacDonald, Archibald, Trumpower, Jelley, Cragg, Casimiro, & Johnstone, 2009.

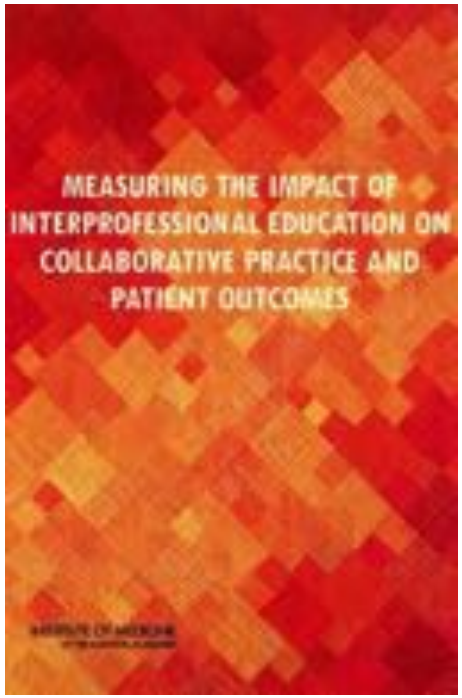
Evaluating IPE

Surveys

- Attitudes
- Behavior
- Knowledge, Skills, Ability
- Organizational Practice
- Patient Satisfaction
- Provider Satisfaction
- Faculty Satisfaction

- ECT Utilization
- Graduate Follow-Up

National Center for Interprofessional Practice and Education



Future role of ECT-the FDA hearing story

Protecting ECT will Require Science: Clinical Science and Team Science and International Partners

- The Interprofessional Collaborative Competencies Attainment Survey (ICCAS) will evaluate competencies across six topic areas:
- Communication
- Collaboration
- Roles and responsibilities
- Collaborative patient/family-centered approach
- Conflict management/resolution
- Team functioning

There is no Crystal Ball but Story has not Yet Been Fully Told