

FDA: No down-classification of shock machines (ECT) without a full safety investigation.



OVERVIEW

INTRODUCTION::

We write in response to Docket # FDA-2009-N-0392 and oppose the down classification of shock machines. Many of us want to see them entirely banned.

FDA, do you know this procedure is routinely court-ordered, coerced, and performed without full informed consent - even on children and senior citizens?

DEEP CONCERNS:::

How can the FDA not require PreMarket Approval Applications for ECT devices?

EXCERPTS FROM:::

- People who had ECT or have been suggested to have ECT;
- People who identify themselves as family members or witnesses of people who had ECT; and
- People who identify themselves as psychologists or medical doctors.

THEMES:::

Torture; Dangerous & Dangers; Brains, Brain Damage, & Memory Loss; Psychiatric, Pharmaceutical, & Manufacturing Industries; Not Unlike, Like, & Akin To.

CONCLUDING THOUGHTS

- Ban the use of all shock devices on minors.
- Ban the use of shock devices for all forced, coerced, and uninformed shock procedures.
- Institute a moratorium on ALL use of shock devices until proven safe.

HERE ARE SOME COMMENTS, FDA, LOUD AND CLEAR:::

CALL IT SAFE?! ARE YOU KIDDING?! PEOPLE WANT TO SEE ECT - ESPECIALLY FORCED ECT - BANNED.

The Opal Project opposes the reclassification of the ECT device to Class II by the FDA in the absence of adequate scientific evidence of its safety, and requests the agency call for PreMarket Approval Applications for the device.

Electroshock (electroconvulsive treatment, ECT) is a controversial procedure which causes brain damage including memory loss, damage to the body, and destruction of life. The United Nations Special Rapporteur on Torture (2008) has put forth that electroshock without anesthesia, or without free and informed consent even if anesthesia is given, may constitute torture or ill-treatment.

The Opal Project appreciates that there is a public comment period and actively engaged in an outreach campaign to get the word out to people about it. www.TheOpalProject.org acted as a repository for comments. As a result, eighty (80) petitions were mailed to the FDA which stated, "The undersigned opposes the reclassification of the ECT device to Class II by the FDA in the absence of adequate scientific evidence of its safety, and asks the agency to call for PreMarket Approval Applications for the device." Seventy-four (74) of these mailed petitions to the FDA included personal comments from individual senders, which are represented in this letter.

Many of the people who are currently being shocked may have no idea there is an opportunity to comment on the potential declassification of the shock machine without a safety investigation. Many of these people - including children and senior citizens - may be involuntarily committed, barred access to the outside world, and the Internet, leaving their opinions

discounted. Various reasons such as poverty, illiteracy, fear of retaliation, lack of access to the Internet, fear of 'coming out', and saddest, for those whose death's are a result of ECT, which in itself is a crime against humanity, will prevent some people's voices from being heard.

So while in numbers we may not be able to rise against the strength of the industries that will undoubtedly prosper from a down-classification of the shock machine, please bear in mind what it means for someone to speak up and voice their opinion and share their personal experience. For these reasons, in this letter we write for those who have made their voices known and, for those who are currently locked up, dead, or for some other reason silenced.

To fully appreciate the gravity of this issue, people's personal stories must be heard.

Herein, we offer a qualitative reflection of the comments we received. It is imperative that this information be made public because the rest of the world often makes decisions based on American standards. Indeed, we received comments from people sharing their personal negative experiences with the shock device from all over the world, including Canada, the United Kingdom, Denmark, and of course, America. Due to the fact that personal letters and individuals' names are being withheld from publication to protect private medical information we have created this compilation removing all identifying information.

The FDA's ruling on the shock machines must meet the highest, most stringent, and rigorous standards there can be to protect people from the undo harm shock is known to cause.

***Excerpts From People Who Had ECT or,
Were advised to pursue ECT as a “treatment option”.***

“I received ECT in 1972 & continue to experience cognitive impairment, in my opinion. I was gratified to see that Dr. Harold Sackeim, the federal governments' chief researcher on ECT, has corroborated the fact that ECT routinely causes long term cognitive impairment in his landmark 2006 study, "The Cognitive Effects of Electroconvulsive Therapy in Community Settings”.”

“As a result of ECT's, some of the permanent problems I live with include memory (both long and short term), finding words to say, and knowing what an object is but not knowing what it is called. I never received any significant help from ECT's. I was left with "less" instead of "more". ECT's left me completely devastated by its effects.”

“I have had 40 ECT's in the last 11 years and have had suffered brain damage as a result. First, the 4 years studying at Macmaster University has been erased from my memory. Second, the past 10 years of my life I have retained only small segments of time that I am able to recall...The combinations of brain damage that I suffered makes it impossible to be employed and will need to be dependent on ODSP for the rest of my life. ECT's need to be banned. I was never informed about the long lasting damage of ECT's. Please stop them now.”

“I experienced 18 shock treatments during the 90's and have never recovered the memories of the time period. I have lost that time. Two people I knew died during that time. I actually went to the funeral for one of them. Later, when I "found out", I grieved all over again, having no memory of the deaths.”

“I have undergone ECT myself. There is nothing about the whole procedure that is not extremely serious and scary. It induces a seizure, which causes memory loss and brain damage. It's also a complex procedure which involves general anesthesia. When I woke up after an ECT treatment I was always very disoriented and scared. ECT is a drastic measure which any good doctor is extremely hesitant to use. I can't say for sure one way or the other if it helped or hurt me, but I can say the FDA has no business downgrading ECT machines to Class II. How can you even consider something which induces a seizure to be less than extremely high risk?”

“I had ECT for 8 years and it destroyed my childhood and young adult memories. My clear memories only begin about 3 years ago, and I feel as if my whole life is lost. ECT is dangerous and it did not benefit me one bit.”

“My doctor suggested this for me, stating that anti depressants don't seem to be working. I had to step up working on my recovery more and not settle for this option, I simply said NO way. I talked to many people and am kicking myself for almost Considering ECT, but when you feel so depressed you feel willing to try whatever it takes and I feel as though they had me right where they wanted me. This simply is not an option and it scared me so much that they offered it, I couldn't really believe it, that this was happening”

Excerpts From People Who Identified Themselves as Family Members and Witnesses:

“ECT broke a couple of vertebrae in my dad's back and he was never the same after that. He was broken... 90 years old and broken... he died shortly thereafter.”

“I am a clinical therapist holding a Masters degree in social work. My journey into this field began as a way of healing the wounds as a daughter of a mother that was admitted to a psychiatric ward because of a debilitating episode of grief after loosing a loved one. She returned to me a dissociated child as a result of MULTIPLE rounds of electro shock therapy, that would continue for ten years. It was told to me that this device would only provide short term benefits, of even that she wasn't afforded.”

“My mother was administered this treatment 17 times, as a result of these treatments she lost her short term memory and experienced many other side effects. It is barbaric to even consider ECT's as a potential treatment....”

“I have lived with depression most of my life and would rather live with it than to have ECT! I have seen patients who have had ECT and I definitely do not want to be one of them! They cannot remember where they work. They can't even remember the way to their own homes! I had a good friend, who is now late, who was forced to have these treatments. Much of his former life was forgotten by him. My cousin had ECT and the same thing happened to her. The doctors will flat out tell you they do not know how ECT works, yet they are so entirely willing to use it! I'm starting to think our government doesn't really care about the lives of people who have a mental illness. Just shock us and make us forget our memories!”

“I was in a Psychiatric Hospital & they were giving ECT to some Patients. I saw what I call a nightmare. One (1) Girl was fine before going in & then when she came out she did not even know her own name Forget anything else, she could barely walk, talk or stand & looked a wreck, her hair was all messed up her eyes were bloodshot & she did not look the person I was talking to before she went in. I think that ECT should be Abolished & Never Return, just like Lobotomies.”

“My reservations are based on both the evidence base, and personal experiences with loved ones and acquaintances...If the FDA wants to approve ECT, it should look much farther down the road than months, and recognize that that damage that ECT can do can last a lifetime, and change so much for the worse, without altering anything in one's life.I exhort the FDA to perform a long-term follow-up of ECT recipients, and see whether this is truly a safe and effective treatment -- interview a substantial, random sample of individuals who have received ECT more than two years after the treatment was administered. And publish the data. That is the only way we will know if what we are doing is right.”

Excerpts From People Who Identified Themselves as Psychologists Or Medical Doctors

“It would be a disservice to the American public to reclassify the ECT device to Class II. . .The fact that the APA would lobby for its reclassification and oppose an investigation is in itself evidence that the APA has a conflict of interest that has led it to compromise its own ethical standards.”

“If every person who votes for this would subject themselves to the treatment, they too would agree that this is torture and abuse of human potential.”

“The safety of ECT devices need to be investigated using all known rigorous methods, including clinical trials.”

Themes

Excerpts From The Comments:::

Torture

- ▶ *“If every person who votes for this would subject themselves to the treatment, they too would agree that this is torture and abuse of human potential.”*
- ▶ *“Shock treatment is torture for many people; many have had horrible results.”*
- ▶ *“As a society we are obligated to keep people safe from torture and medical experimentation, with the understanding that any of us could become the victim of unscrupulous unsubstantiated psychiatric practices, under different circumstances.”*
- ▶ *“Stop sending electricity thru peoples brains it is barbaric and torture.”*

Dangerous and Dangers

- ▶ *“ECT has been shown to be extremely dangerous. . .”*
 - ▶ *“A current of electricity through a person's brain is a serious event and a dangerous procedure.”*
 - ▶ *“It is crucial that such a potentially dangerous piece of equipment receive considerably more scrutiny.”*
 - ▶ *“With all the evidence surfacing about the ineffectiveness and horrendous dangers of the current psychiatric medications, that a treatment such as ECT could be cleared without a serious investigation is ludicrous.”*
 - ▶ *“It is inherently a very dangerous procedure and needs to be closely regulated.”*
 - ▶ *“These are dangerous machines and if the manufacturers can not afford to test them, then they should not be allowed to market them.”*
 - ▶ *“To shock a living human being is extremely dangerous. . .”*
 - ▶ *“ECT is dangerous and it did not benefit me one bit.”*
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Brains, Brain Damage, and Memory Loss

- ▶ *“Isn't a person's brain too important for us to just ASSUME ECT is safe enough?”*
- ▶ *“ECT has been shown to be extremely dangerous, leading to brain damage and cognitive deficits.”*
- ▶ *“Shouldn't we have proof that there is some efficacy to utilizing a device that causes brain damage and memory loss?”*
- ▶ *“I know that many people who have elected to undergo ECT have been completely unaware of the risks and typical damages to the brain caused by the procedure, and indirectly by the ECT device.”*
- ▶ *“There is extensive literature showing memory loss and other indications of brain damage after shock.”*
- ▶ *“ECT treatment causes some memory loss and disorientation in all consumers because it works as a closed head injury to the brain.”*
- ▶ *“As a person in recovery from serious mental illness, I know that there are other avenues for treatment that cause less brain injury.”*
- ▶ *“This will one day be seen as brain dis-abling and barbaric as lobotomy.”*
- ▶ *“As mental illness knows no socio-economic boundaries, you let this machine continue to do its damage and you too might be subject to its ravages.”*
- ▶ *“This can make them worse and/or permanently damage them.”*
- ▶ *“It should be a simple matter to compare before-and-after CT scans of ECT recipients, which I think would answer the question scientifically as to whether ECT machines cause brain injury.”*
- ▶ *“I have had 40 ECT's in the last 11 years and have had suffered brain damage as a result.”*
- ▶ *“...the combinations of brain damage that I suffered makes it impossible to be employed and will need to be dependent on ODSF for the rest of my life....I was never informed about the long lasting damage of ECT's..”*
- ▶ *“...can cause extremely severe brain damage.”*
- ▶ *“To shock a living human being is extremely dangerous and there has been countless cases of memory loss, trauma, damages and more deficit than gain at the cost of using these devices.”*
- ▶ *“It induces a seizure, which causes memory loss and brain damage.”*
- ▶ *“Scientific evidence suggests that ECT can cause brain damage and memory loss...”*
- ▶ *“...recognize that that damage that ECT can do can last a lifetime...”*

Psychiatric, Pharmaceutical, and Manufacturing Industries

- ▶ *“Please do not cave into industry on this issue!”*
- ▶ *“Do not succumb to pressure from treating physicians, who seek indemnity from liability from using these machines.”*
- ▶ *“Stop being the pawn of the Pharmaceutical Companies and start actually protecting those in need of GOOD and EFFECTIVE care.”*
- ▶ *“Do not allow these companies to get away with this, please!”*
- ▶ *“Of course, the APA has opposed scientific research on this question. But I believe the FDA will have the courage to buck the APA and “do the right thing”.”*
- ▶ *“A scientific evaluation is called for, rather than research conducted by the same people who have written about the positive effects of ECT over the years and who may have financial conflicts of interest.”*
- ▶ *“You are supposed to be protecting the public, but your rubber stamping on this issue seems to be rather protecting the Psychiatry Industry.”*
- ▶ *“It is extremely unethical to simply cite the exclusive opinions of those advocating the use of such machines in medicine (not at all objective).”*

Not Unlike, Like, and Akin To

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- ▶ *“Prisoners facing elecricition are not unlike a patient who has EST.”*
 - ▶ *“These are no benign times for trust and respect among strangers but PLEASE don't destroy any more brilliant minds like this.”*
 - ▶ *“They'll push it like they pushed Zyperexa and all other new meds.”*
 - ▶ *“I do not see why the FDA cant do something so simple like test the device they plan to use or are using on people.”*
 - ▶ *“And stop treating us like cattle.”*
 - ▶ *“It is bad enough that when a person with a mental illness asks for help that he or she gets locked up and treated like a criminal.”*
 - ▶ *“I think that ECT should be Abolished & Never Return, just like Lobotomies.”*
 - ▶ *“To use a shock machine for mental illnesses is like using a fire hose to water your window plants!!”*
 - ▶ *“They were like shells of themselves following treatment, she has told me.”*
 - ▶ *“EST is akin to “frying” the brain, and or having lighting hit the brain.”*
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Themes Emerged From the Comments with Deep Concerns of the Down-Classification of Shock Devices Without A Safety Investigation:::

General comments have been grouped below by employing common recurring words/phrases or "themes" found therein.

- ▶ Real ethical problems the United States of America's Food and Drug Administration has for even considering down-classifying an already grandfathered-in, experimental device to a class which is thought to be safe. People want to know, "How can we trust anything said to be safe by the FDA if the FDA would do this with one of the most controversial devices on the market?"
- ▶ The FDA should not be relying on information that comes from people who ultimately profit from the use of this controversial, experimental device which has never been tested.
- ▶ Attempts and hopes to counteract the well-oiled machine of the American Psychiatric Association and other facets of the industry, including the makers of the shock machines.
- ▶ If shock devices are down-classified, human rights violations including abuse and torture will become more routine inside of mental health systems as there will be even less hesitation to use them.
- ▶ If shock devices are down-classified, forced, court-ordered treatment over objection, and coercion will be more routine, as the machine would be considered "safe".
- ▶ Down-classification of shock devices will make informed consent about ECT even more impossible to truly protect (and promote), as even now, people are not given full information about its many risks.
- ▶ If shock devices are down-classified, shock will be easier to force, court order, use over objection, and then clearly without informed consent.
- ▶ If shock devices are down-classified, how will we go about protecting and promoting human rights of people in this society, including enforcing patients rights.
- ▶ The focus of the FDA is still not on putting out a statement for alternatives, respect, honesty, and humanity within psychiatric systems based on free and full informed choice and informed consent.
- ▶ Children are going to be adversely affected by a down-classification and make the struggle to protect them from its use on them more difficult.
- ▶ Clearly, the language people use to describe shock repeatedly includes descriptive terms such as **"barbaric"**, **"inhumane"**, **"abusive"**, **"torture"**, **"harm"**, **"dangerous"**. **"horrible"**, and **"unethical"** throughout the comments.

FOOD AND DRUG ADMINISTRATION, PLEASE:::

"Please stop the use of ECT."

"Please do not cave into industry on this issue!"

"Please do not reclassify--unless you undertake investigation."

"PLEASE don't destroy any more brilliant minds like this."

"Please consider carefully the approval process and reclassification of ECT."

"Please do NOT reclassify the ECT device to Class II without first requiring PreMarket Approval Applications!"

"Please stop this process until you have had ample time to hear from those who know first-hand the effects of ECT."

"Do not allow these companies to get away with this, please!"

"Please be sure to do safety exploration and testing before moving forward."

"Please stop them now."

"Please do not allow ECT machines to be used as safe without proper investigation."

"Seems to me if even one was destroyed, that is one too many, please stop this treatment."



CONCLUDING THOUGHTS

The time is ripe for change.

The door has been opened on a very important conversation that has silently brewed amongst people who are survivors of shock treatment and their allies for decades with little effect. Our battle is now, as it has always been, will the people who have the power to end psychiatric abuse and torture and require full informed consent based on actual safety investigations, do so?

Hundreds of attempts of thousands of people over the decades have left many of us unhopeful that the FDA will adequately regulate this aspect of the psychiatric industry.

Shock Is A Social Justice Issue.

We are writing to make sure the FDA understands that in many states, like New York State, shock treatment is routinely performed on people - including children - over their objection and without their informed consent. People are routinely brought to court and are treated as if they were criminal for refusing the procedure at which point it is court-ordered.

If the FDA declares shock machines "safe" with no safety testing it will not matter to a Judge that there was no actual safety test. It will be used as leverage by the psychiatric industry to push this controversial procedure on people - people who most likely will be in great psychic pain, and often desperate for a solution that will make them feel better or used on people who are thought in need of social control.

Feel-better solutions cannot often be found in a drug - or electricity coursed through the brain, particularly when they are rooted in economics and real-life situations. Solutions can, however, be found in alternatives such as mutual assistance, self-help, and advocacy which need to be better promoted by the FDA.

COMMENTS WERE VOLUNTARILY SUBMITTED VIA THE INTERNET AND MAILED TO THE FDA ON JANUARY 4 & 5, 2010. THIS IS A COMPILATION OF THE 74 INDIVIDUAL WRITTEN COMMENTS OF 80 PETITIONS MAILED.

Our challenge to the FDA:::

Instead of calling the shock device safe without a safety investigation, why not put a moratorium on at least the use of forced, court-ordered, coerced, and uninformed shock until a rigorous evaluation of its risks and benefits can be made. But do not stop there - as one commenter said - "publish the results"!

FDA, we want to see you mandate that all States make public their data about the use of shock machines, in terms of use, expenditure, and demographics and ban the use of forced coerced, and uninformed use of the device.

Until we can be sure that shock is not being used on children, seniors, and everyone in between, we will not rest. If a PreMarket Application Approval is not required for this most controversial device under your watch, how will *you* rest?

FDA, we want you to:

- ▶ **Ban the use of all shock devices on minors.**
- ▶ **Ban the use of shock devices for all forced, coerced, and uninformed shock procedures.**
- ▶ **Institute a moratorium on ALL use of shock devices until proven safe.**

All of the comments discussed here have been mailed but are also available to the FDA in a PDF at your request.

This open letter will be made available to all major and minor media outlets and published on our websites.



The Opal Project
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