FDA

MAUDE Adverse Event Report: ECT

ECT

Back to Search Results

Event Date 07/01/2004
Event Type Injury
Event Description

In 2004, i was given ect. At no time was i ever informed of the possibly i could sustain permanent cognitive disabilities from this procedure. The treatments were given 3 days a week to start. When i stopped the treatment in late 2005, i was receiving treatments every other week. When i refused to have any more treatments, the dr threatened to place me in a long residential treatment facility. In late 2006, i had neuropsychological testing which showed, i had lost 22 points on my iq. I have problems with processing new info, attention problems, short term memory problems, i have no recall of any events in my life. I am easily distracted, forgotten my family members and friends, my education is completely erased. I am having to relearn everything i once knew including cooking and grocery shopping, i am constantly getting lost when i go someplace. I have lived in the same house for over 10 yrs and have forgotten my neighbors. I can no longer work and on permanent disability due to my cognitive problems. Dates of use: 2004 - 2005. Diagnosis or reason for use: severe depression. Event abated after use stopped or dose reduced? no.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Type of Device ECT
MDR Report Key 897552
Report Number MW5003411
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 08/10/2007
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 08/10/2007
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Is The Reporter A Health Professional? No
Is this a Reprocessed and Reused Single-Use Device? No

Deposition Exh. # 2
Case# 2:17-cv-06686-RGK
Date: 9-2-18
Abrams

Patient TREATMENT DATA
Date Received: 08/10/2007 Patient Sequence Number: 1

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#2-1

FDA

MAUDE Adverse Event Report: DON'T KNOW ECT

DON'T KNOW ECT

Back to Search Results

Lot Number N/Q
Event Date 09/01/2011
Event Type Injury
Event Description

I admit that ect seems to be the only cure for my depression (with antidepressants as well). It does however come at a price. The memory problems are downplayed. You hear things like - you could have some short term memory loss, but it's just temporary. I have had a total of 75 treatments over the course of 4 years. My short term memory loss is severe. Example: i wanted to open a bank account for my new grandson, but i was told by my daughter i had already done so. And, sure enough after looking for the paperwork i had in fact opened an account without remembering it even to this day. I have to write down everything because it simply disappears from my mind after a week or sometimes less. I have forgotten people, places, things i collect, clothing i own, everything; i grocery shop with my head down; i am so afraid of seeing someone i have been introduced to but don't remember. (b)(6) at the school where my husband teaches are filled with anxiety because people know me but i have no memory of them. I am too ashamed to tell them why i don't remember them so i just pretend i know them. I would say i forget app 80% of things. My long term memory is no also affected too, and is getting worse and worse. If i remember anything about my children's lives i write it in a journal because i don't want to forget them. And something i was never warned about. I have to look up simple words because i can't remember how to spell them, i never had a problem with spelling before. I have access to nearby magnetic therapy which has no memory issues, and my psychologists recommends it. My insurance however will not cover it even though it would be much cheaper for them.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name DON'T KNOW
Type of Device ECT
MDR Report Key 2392815
Report Number MW5023600
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 12/26/2011
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 12/26/2011
Is This An Adverse Event Report? No
Is This A Product Problem Report? No
Device Operator Service Personnel
Device LOT Number N/Q
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? No

Patient TREATMENT DATA
Date Received: 12/26/2011 Patient Sequence Number: 1

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FDA

MAUDE Adverse Event Report: ECT DEVICE

ECT DEVICE

Back to Search Results

Event Date 09/22/2009
Event Type Injury
Event Description

I had electroconvulsive therapy seven times and have had permanent problems. I have a very bad memory; long-term and short-term. I went from being an honor student to having a learning disability. I have problems understanding things now. School has become extremely difficult. I am very limited now on what i can do and comprehend. I am only (b)(6) and it destroyed my life! i have trouble at work as well. I went into the hospital for depression and walked out with much more damage. Other people i talked to in the hospital had bad experiences as well. The hospital was one of the best in the country too. I feel sorry for people that consider this treatment. If anything, there needs to be a limit on age, no one under 30 should do this. By going through with the procedure its really a gamble on whether or not you will become mentally disabled. Also, the doctors should not be allowed to ask people that are at their lowest point if they want the treatment. I was not in the mental shape to make such a decision. A depressed person will do anything to be happy when they are desperate.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Type of Device ECT DEVICE
MDR Report Key 2050302
Report Number MW5020200
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 04/06/2011
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 04/06/2011
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Service Personnel
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? No

Patient TREATMENT DATA
Date Received: 04/06/2011 Patient Sequence Number: 1

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FDA

MAUDE Adverse Event Report: ECT DEVICE NONE

ECT DEVICE NONE

Back to Search Results

Event Date 09/30/1987
Event Type Injury
Event Description

I was forced to have ect. I was traumatized by the callousness of staff and the disregard for my wishes. I do not know how much i have been harmed, but i think it has had a disabling impact on my life. In coinjection with the ect, i entered a coma and nearly died. I also was force drugged and had seizures as a result. The harmful effects included worsening of my short term memory. Having poor short term memory has resulted in disabilities related to work performance and ability to remember instructions and names. I do not believe i was mentally ill at the time the alleged treatments occurred. It was coercion and malpractice.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ECT DEVICE
Type of Device NONE
MDR Report Key 1505390
Report Number MW5012988
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 10/09/2009
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 10/09/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Service Personnel
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? No

Patient TREATMENT DATA
Date Received: 10/09/2009 Patient Sequence Number: 1

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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm

2-4

FDA

MAUDE Adverse Event Report: ECT DEVICE

ECT DEVICE

Back to Search Results

Event Date 07/30/2012
Event Type Injury
Event Description

Due to a severe and treatment-resistant bipolar depression that lasted for years, both before and after my treatment, my psychiatrist recommended as a last resort electro-conclusive therapy. My very competent husband (who still cares deeply for me and who used his broad network and excellent research skills) chose the absolutely higher rated electroconvulsive therapy hospital-based practice in (b)(6) and surrounding areas. I underwent as many as 200 or even more treatments (3 times a week for over a year, then tapering to 2x a week for a few months, then weekly for a few months, then every other week and so on.) not usually (and i had been warned), i have only 2, perhaps 3 snapshot sort of memories of the entire period of the nearly two years of my life lost to ect. I fully credit ect saving my life. My complaint, following, although dramatic, severe, and destructive to everything i enjoyed, learned and accomplished prior to ect is nevertheless a heavy price to pay. More important to me, and i have confirmed this through discussions with my husband who does have an above-average memory of that time, and through review of what disclose paperwork each of us recall, as well as through non-profit community lecture series by institutions claiming expertise in the diagnostic and treatment of bipolar disorder all pointed in the same direction: any memory loss beyond the period of ect administration is extremely rare. This "info" is also found all over the web's "official" medical advisory services for consumers. My own experience of ect's "extremely rare" side effect, and, to lesser or even greater functional impairments, that of nearly every other comrade i have come across who also chose ect therapy when nothing else worked, is of my memories of my absolutely entire life of 40 years totally gone. I remembered my husband who drove me to ect every morning around 6am, and i remembered my primary ect doctor, and i recognized the depression scales i had to fill out every morning. The only other things i felt confident about were: i was heart-broken over not having custody of my two children who, despite visits during the course of my ect, i could only picture as 5-10 years younger than their actual age, i could recognize our home in (b)(6), but could not tell you a single thing about any other home i had ever lived in other than my deduction from the likelihood that, at the ages of 9-13 (i still don't remember how only they were without doing the math) probably had separate rooms, so it must have had three bedrooms, i had to either move to (b)(6) for 24/7 supervision by my long-distance husband or face institutionalization in my home town. Everything else had to be either coaxed out of my memory gradually through pictures and stories (even my mother's childhood abuse of me), or had to be nearly retaught from the ground up. Tha's a lot of info for a summa cum laude in classics, and a stanford law school graduate with over 10 years in estate planning, trust and probate law (i even proved my experience and took a mini-bar like exam on only topics related to my filed in order to be approved by the state bar of california's board of legal specialization as a "certified specialist in estate planning, trust & probate law. " i am attempting but only slowly and painstakingly recovering a small portion of the knowledge that got me invited to speak/teach before live national audiences as recently as a year before my ect. I am still nationally known as one of, perhaps two or three, experts in the nation on snts because the reputation i stopped developing over 5 years ago was strong enough that my name is still associated with excellence and deep knowledge in that area, thought it no longer deserves to be. I don't want to ban life-saving ect, but to require honest disclosure of the actual likelihood of broad and severe memory loss. And cognitive impairments that aren't going away. Rx meds: none at the time treatment, or for several months after treatment. Now, a constantly changing array of medications because a given configuration loses effectiveness, or side effects at the effective dose are intolerable.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand NameECT DEVICE
Type of DeviceECT DEVICE
MDR Report Key5815123

25

FDA

MAUDE Adverse Event Report: ECT ELECTROCONVULSIVE THERAPY

ECT ELECTROCONVULSIVE THERAPY

Back to Search Results

Event Type Injury

Event Description

This is now my third attempt to write this because i keep deleting the form. I suffer from bipolar depression and was desperate to find something that would work so i could go back to work. None of the medication worked so i did 12 bilateral ect treatments back in 2008 or 2009. They were not successful. I was told that i would have memory problems for up to six months and then things would go back to normal. It's now 6 or 7 years and i have some long term memory problems but i mainly suffer from short term memory problems. I can't tell you how frustrating this is for me. I can't find simple words and try to describe it so someone can tell me what i'm looking for. I can watch a tv show or movie and not remember it. I watch it again like it's the first time. Sometimes i notice the tv show when i'm watching the following week and i don't remember how something happens or when. I've watched but forgotten the previous weeks show so i have to go back and watch the previous weeks show to catch up. Thank goodness for my (b)(6). I am very lucky to have such a patient husband because i am always asking things more than once or twice, searching for words and watching things over again. I used to be able to do complex math problems in my head and now i struggle to enter then into a calculator. My husband said i could do them in my head faster than he could input them into a calculator. That ability is gone. I have difficulty writing things that make sense and find spelling errors. I read it several times and still miss things. I tried to use the dictation feature on my phone but it still didn't all make sense. The most disturbing thing that happened the other day was i looked at my shoe and couldn't think how to tie it. It didn't take long to remember and do it but it has really bothered me. I sometimes joke that my phone is my brain but it really is. I have everything on a calendar with at least 2 reminders. I have alarms and alerts for everything so i don't forget something. I have all contacts listed, including home. I also input address into my map in case i do not know or forget how to get somewhere. I have an app on my phone for my grocery list. I input items on the list and my husband can add or delete items from his phone or computer. It has a box to check it off as you get it and when i think i'm finished, i click the trash can. If everything is gone then i got everything otherwise it shows me what i missed. I still suffer from severe depression with the occasional mania so nothing has worked. I know ect is a very effective treatment for many but it has been a nightmare for me. I ask that you continue to keep this high risk and do further investigations into the possible side effects. I wish i had known this was a possibility because i wouldn't have done it. I have also been checked for a stroke and my husband said he would have considered alzheimer's if it didn't begin with the treatments.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ECT
Type of Device ELECTROCONVULSIVE THERAPY
MDR Report Key 4652099
Report Number MW5041771
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 03/29/2015
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 03/29/2015
Is This An Adverse Event Report? No
Is This A Product Problem Report? No

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FDA

MAUDE Adverse Event Report: ECT MACHINE

ECT MACHINE

Back to Search Results

Event Type No Answer Provided

Event Description

Ect's caused perm. Seizures, bi frontal brain atrophy. Shrinking of grey and white matter in brain, perm. Cognitive physical behavioral issues. Was (b)(6) and now can't remember how to spell. The doctors kept telling my parents my memory and seizures and talk incomplete sentences would all be fine a few months after we stopped ects, but they kept doing them even after i have positive signs of brain damage shown in two eeg's and frontal atrophy in frontal lobes. The doctors kept saying i was fine and went on with treatment for two more years. I have been to 3-4 neurologist and had test with a physiologist at (b)(6). I live in (b)(6), but none of my doctors involved with ruining my life and ability to learn, will say anything about it. Just that it's too bad and they can't explain it. Even though we have an explanation. I also am (b)(6) now and still have to live with my parents. I finally now. After fighting and fighting with my doctors that there was something really wrong and finally going myself to (b)(6) to get a second opinion. They are sending me to traumatic brain injury rehabilitation. Still. Either of the doctors won't say it's from, ect. I have migraines everyday. I can't remember things. I can't control my anger and have lost my fiancee because of it. I was nothing like the person i now am, ect, ect, ect, ect. Ects should be illegal. Ect machines from 2007-2010. (b)(6), where i received treatment, got a different machine in 2009, i think the year was.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Type of Device ECT MACHINE
MDR Report Key 2888779
Report Number MW5028345
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 12/20/2012
2 DeviceS WERE Involved in the Event: 1 2
***1* Patient Was Involved in the Event**
Date FDA Received 12/20/2012
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? No

Patient TREATMENT DATA
Date Received: 12/20/2012 Patient Sequence Number: 1

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FDA

MAUDE Adverse Event Report: ECT ELECTROCONVULSIVE THERAPY

ECT ELECTROCONVULSIVE THERAPY Back to Search Results

Event Type Injury

Event Description

I received ect-electroshock therapy to treat depression in 2010 and 2013 from the (b)(6) hosp while a patient at (b)(6) hosp. The first course of 9, i don't remember anything after the second treatment and seemed to recover from it and not sure if it helped or not, but the second course i received of 19 plus was one of the worst experiences of my life and regret doing any ect at all and feel it should be banned. Yes in the short term, it does seem to help depression, but it never lasted more than a couple of weeks and suffered many disorientation, lost touch with reality, complete lack of control over my body at times and unable to eat, drink , dress, communicate. Bad headaches, nausea, brain zap, uncontrollable shaking, waking up in the night with ect nightmares and feelings of being fallen/swallowed up by darkness and black holes with zapping dying feelings is the best of how i can describe it and still every once in a while have having those nightmares. And i feel i suffered permanent brain damage. Before ect, i never had any problems with reading and comprehending and now i do. It has gotten better as time goes on, but it's been 2 years now and still have a hard time reading, doing puzzles etc, and feels just like when i had an ect treatment. Words get jumbled up in my head and my perception around me is different and is hard to explain, but again just feels like when i had an ect treatment but not as severe. Also my long term memory is fine, but my short term memory seems worse off. I try to just keep working through it, in hopes my brain might return back to normal, but i am scared it never will. I am feeling more stable and recovered with my mental illnesses, have been discharges, getting back into life, and want to go back to school so so badly to do something meaningful and helpful, and get off welfare, but i'm scared my brain won't be up to par like it used to be and won't be able to succeed. And i am angry with the doctors and staff who all pressured me and said things like i would never get better or be able to leave the state hosp if i did not do ect and angry with my parents who also really pressured me and everyone telling me it is safe. Luckily, i was transferred to a different unit, the 3rd one, with a better doctor and was able to find a med to help and was discharged and doing much much better, but still feel i suffer from the damaging effects of ect. I'm not sure reporting this is of any help, but i just strongly wish that ect would be banned so one else is traumatized and damaged by ect. I know several other people who have also done ect and all say similar things and how awful it was for them and never really helped. May be for some, they do help, but i've never met anyone, and i'm angry i trusted doctors to let them literally fry my brain and had to go through the awfulness of it. It causes harm, and lasting harm for some and thus should not be used as a form of treatment for depression. Its barbaric and cruel and inhumane even if they are using anesthesia, muscle paralyzers, and drugs. Really, putting innocent people into seizures is ok and making them suffer while going through it. Well for me, it is not ok and i hope ect will no longer be an option. Mental illness is a serious and sad disease with so many suffering, and it just makes me so sad in how people with mental illness can be treated in such cruel ways. Please don't allow ect to be used anymore.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ECT
Type of Device ELECTROCONVULSIVE THERAPY
MDR Report Key 4815071
Report Number MW5042926
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Other
Type of Report Initial
Report Date 05/23/2015

***1* Device Was Involved in the Event**

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FDA

MAUDE Adverse Event Report: ECT MACHINE ECT MACHINE

ECT MACHINE ECT MACHINE

Back to Search Results

Event Date 05/01/2007
Event Type Injury
Event Description

In 2006-2007 i had electroconvulsive therapy (ect). I cant remember most of my life before 2007. I not only have long term memory loss, but i have cognitive impairments and brain damage. I have the symptoms of a person with a traumatic brain injury. Ect ruined my life. Before ect i was working after ect, i was on disability. Not only do i still have treatment resistant depression, but now i have anxiety and the psychological trauma of being an ect survivor with brain damage and memory loss. I tried getting off disability an going back to school and work, but i can't function the way i did before ect and it's frustrating.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ECT MACHINE
Type of Device ECT MACHINE
MDR Report Key 5409638
Report Number MW5059997
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 01/31/2016
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 01/31/2016
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator NO INFORMATION
Was Device Available For Evaluation? No Answer Provided
Is The Reporter A Health Professional? No Answer Provided
Was the Report Sent to FDA?
Event Location No Information
Was Device Evaluated By Manufacturer? No Answer Provided
Is The Device Single Use? No Answer Provided
Is this a Reprocessed and Reused Single-Use Device?
Type of Device Usage

Patient TREATMENT DATA
Date Received: 01/31/2016 Patient Sequence Number: 1

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FDA

MAUDE Adverse Event Report: ECT MACHINE ELECTROCONVULSIVE THERAPY

ECT MACHINE ELECTROCONVULSIVE THERAPY Back to Search Results

Event Type Injury

Event Description

Extreme loss of memory, cognitive function, emotions and personality change began after 1st ect treatment in (b)(6) 2015. By 3rd or 4th treatment, doctor walks in operating room as i am being hooked up and anesthesia being started, and gleefully says well, (b)(6) so how do you think you're doing? much better!! i hesitated, said no, not really. Not yet (trying to be "complaint" as per my personality), i told him, but mentioned i'd seen while (b)(6) on my phone there were 2 different kinds of ect, with oral possibly working better. "bilateral?" i asked doctor said "oh, yes, well ok, yeah! we can try that", ok, so all i did was mention a term, for his explanation/clarification and any advise he had rather whether it may work better on my type depression. At no point before, or during the procedure was the true effectiveness stated to me, which is approx 52% for my mental illness-diagnosed with clinical depression over 25 yrs ago after meningitis with approx 20 yrs of medication resistance, including his monthly or b-monthly pt of over 5 yrs straight. He had tried me on over 10 different combinations of and depression and psychotic meds, all of little to no help or worse. Suicidal state for yrs and he had been strongly suggesting the ect for months with only glowing remarks about it's highly effective treatment of major depression stating (during a visit/consult with my mom, dad, rn sister and other sister, who is married to an internist pyd) a cure rate of over 80%. I vaguely remember he may have mentioned some confusion and loss of memory i may experience the day of treatment. Had been admitted to inpatient hospital psyche ward previous day to 1st ect treatment. I was awoke after 10:30 pm that night after nurse giving me my nightly meds including sleeping pill) when he stepped in my dark room, woke me up and asked could i come with him. We needed to go over stuff (i'm assuming that was my signing of the consent in order to begin treatment the next am. All i remember is sitting across from my dr at a small round table while he flipped through a huge binder taking while all i could do was repeat over and over in my head "why am i in here? wasn't i just asleep? try to ack like you're listening. " so i was working hard to pretending to listen while he had to know i was out of my mind. Found a job (b)(6) 2016 which lasted 2 wks. Recd (b)(6) scholarship in (b)(6) and passed medical billing and conding fast track at local community college (b)(6) 2016 with an "a" avg, then failed (36%) (b)(6) cert test (b)(6) 2016. Working with long time friend who hired me pt (b)(6) 2016 after a week she kept saying "(b)(6), i told you, whatever it was" so i finally had to tell her i'd had ect and lost memory and ability to comprehend/remember things. She had not seen me in 10 yrs and the look in her eyes told me everything i proceeded to write down my schedule wrong several times and had to be called in. It's retail, and i have to ask customer's name to write on their dressing room door and half the time after standing by closed door a bit, finally have to embarrassingly ask "ma'am, what did you say your name was?" ect has devastated me. As if suicide and depression that never lifted in yrs, now i can't do the one thing i've excelled in since i could write. I'm constantly misspelling words or locking up spelling if i'm able and transposing numbers and even my own name! you can't imaging the feeling if i notice my signing stuff at work or a card or something, and misspelled my own name. Ect disclosures do not back up specific evidence and research is mostly irrelevant since i find out regs being used over 20-30 yrs outdated and bad to no clinical f/u, after 6 months from my findings. And ect still being used by a "temporary" fda approval? surely this is incorrect.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ECT MACHINE
Type of Device ELECTROCONVULSIVE THERAPY
MDR Report Key 6215334
Report Number MW5066992
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient

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FDA

MAUDE Adverse Event Report: ECT MACHINE NONE

ECT MACHINE NONE

Back to Search Results

Event Date 02/01/2007
Event Type Injury
Event Description

I underwent outpatient ect at the hospital. I was told prior to treatment that ect carried a risk of some memory loss, but that this was minor and usually was recovered within 3 months of treatment. Infact, i lost many memories of the entire year before treatment, as well as for many months afterwards. Today, nearly 3 years later, i am still discovering memory deficits. I know that depression itself can cause memory problems, but these memory lapses are clustered in time around my ect. I believe the memory impairments of ect are grossly understated and that this risk is especially high for people who need a high degree of mental functioning in their careers. (i am a writer).

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ECT MACHINE
Type of Device NONE
MDR Report Key 1545751
Report Number MW5013673
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 11/17/2009
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 11/17/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Is The Reporter A Health Professional? No

Patient TREATMENT DATA
Date Received: 11/17/2009 Patient Sequence Number: 1

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6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm

2-11

FDA

MAUDE Adverse Event Report: ELECTRO SHOCK

ELECTRO SHOCK

Back to Search Results

Event Date 08/19/2013
Event Type No Answer Provided
Event Description

After an (my) attempted suicide i was hospitalised in the local psychiatric ward of my local hospital. I was recommended/ referred and transported to a (b)(6) hospital that offered a larger psychiatric mood disorder behavior unit and surgical floor. I spent a week at my local hospital until a bed and placement was open for me at this (b)(6) clinic (b)(6). I was sent there for prescribed treatment plan was estimated to start with a minimal 6 treatments and target end goal of 12 ect treatments. I was given "generic", short, brief warnings about possible side affects and extremely vague pamphlets and quick overview with the treating surgeon and nurse explaining the process, and again benefits (which was given in elaborate detail) and possible side affects and very brief, vague hastily told about the "very rare" side affects. Once the etc treatments began, the entire surgical procedures were as if a "fast food drive through process. Monitoring of my physical, neurological, and emotional health was lax to non existent. After my third treatment i knew i had to get out of there. Long term, not just the "short term" memory was fragmented and/or gone completely. I had to be told i even had an ex husband. I didn't know why i was there. Every time i was wheeled down to surgery i thought and verbally said "oh wow, this is real, i thought it was all a dream". I affected my ability to write and read. Took over a month to get back to "normal" with that. At treatment 7 (my last one, i couldn't handle anymore) is when i went into a documented psychosis that took about 10 days to come out of. I thought and fully believed that my attempted suicide actually was a success and that i was in hell, limbo, purgatory. I was under the care of my mother who took me to nonstop doctor appointments where i pleaded for them to let me stop the treatments. That this world was not real. They were not real. My children were not my children, (i believed i was in a parallel universe) and the only way to get out of the parallel universe and limbo was to kill myself again so i could wake up back in the real one. (this one). It has been 5 months since my last ect. I am still having daily memory loss and fragmentation. Still have permanent memory loss surrounding the time period of ect to several years ago. My depression has been made worse because ect was toted as a cure with just headaches and some temporary amnesia surrounding the day before and day of a treatment. I now have also post traumatic stress disorder and debilitating headaches that come from no where. During a conversation i will be talking about something and stop mid sentence, completely having forgotten what i was going to say and said.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ELECTRO SHOCK
Type of Device ELECTRO SHOCK
MDR Report Key 3672457
Report Number MW5034856
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 03/02/2014
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 03/06/2014
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? Yes
Device Operator Health Professional

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FDA

MAUDE Adverse Event Report: ELECTROCONVULSIVE SHOCK THERAPY

ELECTROCONVULSIVE SHOCK THERAPY Back to Search Results

Event Date 04/30/1997
Event Type Injury
Event Description
I was catatonic, did not respond to medications. The doctors gave me too many treatments of ect and i now have permanent memory loss, very poor math skills and learning disabilities. I also have very poor recall. I was told i may have short term memory loss, but that was far from the truth. Dates of use: 1997. Diagnosis or reason for use: severe depressive episode, electroshock therapy. Event abated after use stopped or dose reduced?: yes.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ELECTROCONVULSIVE SHOCK THERAPY
Type of Device NA
MDR Report Key 1564749
Report Number MW5014057
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 12/19/2009
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 12/19/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? Yes

Patient TREATMENT DATA
Date Received: 12/19/2009 Patient Sequence Number: 1
Treatment
ELECTROCONVULSIVE SHOCK THERAPY

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3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm

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FDA

MAUDE Adverse Event Report: ELECTROCONVULSIVE THERAPY

ELECTROCONVULSIVE THERAPY

Back to Search Results

Event Date 01/01/2002
Event Type Injury
Event Description

I had over 100 ect's from 2002-2005 due to severe and treatment resistant depression. I and my husband were informed that i could experience some temporary short term memory loss. We were never informed that the memory loss could be permanent or that it could affect my long term memory. The ect's were given with our consent, but was certainly not "informed" consent. Ect treatments did keep me alive, and were effective for a few days to a couple of weeks. By 2005, memory problems were causing me to forget names of friends we had had for over 30 years. I got lost driving to familiar places, had trouble unloading the dishwasher - where do the dishes, etc. , and basically couldn't function. The memory deficits were now significantly contributing to the depression as well. I couldn't even work as a consultant in the field i had worked in for 25 years. I worked with special education students in my career and in talking with teachers i worked with, they reminded me that students who experienced seizures were treated aggressively by doctors to try to stop them. The reason? those who couldn't get their seizures under control experienced continued brain damage or at least measurable decrease of functioning. A medical letter sent out from the hosp had an article re: ect and never even mentioned the possibility of permanent or long term memory loss. Almost 4 years since my last ect, i have significant long term memory loss going back at least 30 years. Once a strength, i have a lot of difficulty with organization skills and get side tracked more easily.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Type of Device ELECTROCONVULSIVE THERAPY
MDR Report Key 1501185
Report Number MW5012924
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 10/01/2009
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 10/01/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Is The Reporter A Health Professional? No

Patient TREATMENT DATA
Date Received: 10/01/2009 Patient Sequence Number: 1

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2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm

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FDA

MAUDE Adverse Event Report: ELECTROCONVULSIVE THERAPY

ELECTROCONVULSIVE THERAPY

Back to Search Results

Lot Number 2009-N-0392
Event Date 09/23/2007
Event Type Injury
Event Description

I am not actually sure when the starting date of my second round of ect started. I have no paperwork, no consent form, my family didn't know how the procedures were affecting me, and my doctor was extremely reluctant to give me any info about the procedures afterward. I had asked to make another appointment with him about a year after the procedures were over. He refused. I found out about a year ago that i had a previous session of ect in 2006, which was cut short, due to the fact that my insurance company changed after 6 sessions. I have no idea who my caretaker was during that period. It is the ect that was started in 2007, that concerns me. My doctor did not inform anyone of the possibility of the severity of the memory loss or the loss of cognitive ability i could have. I ended up not remembering almost nothing of the last half of 2007. One thing that stuck, though, was that my doctor asked me for consent to add additional ect procedures while i was being treated. When i started treatment, a friend of mine, took me to appointments. After she took me home, apparently i was driving. My headlights and tail lights had been broken out. When i started getting my memory back, my family is unsure of how to deal with me. I dont' know how to deal with myself. My personality has totally changed. I cannot stop talking. I used to be extremely quiet and shy. My emotional reactions are very different. I am studying books in order to fit in with society. I still have memory loss; i carry a notebook around with me wherever i go to record appointments. I don't remember people's names that i have known for months. I don't know how to deal with this new me. I have alienated my family. I have no friends. None of my doctors will address this subject. None of them knew me prior to the ect. I used to be very intelligent. My college entrance exams would have allowed me to go to any college i wanted. I was in the 99th percentile. Now i cannot remember words. I write in gibberish. I have to wait until the next day, and rewrite letters. I don't even know what i was trying to say. I can only park my car to the left. My spatial recognition works only partially. This procedure needs to be researched before its use is continued, and some very specific guidelines need to be in place if its use is to be continued. Dates of use: 2006 - 2007. Diagnosis or reason for use: depression, depression/suicidal. Event abated after use stopped: no.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name ELECTROCONVULSIVE THERAPY
Type of Device ELECTROCONVULSIVE THERAPY
MDR Report Key 1577536
Report Number MW5014282
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 01/07/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 01/07/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device LOT Number 2009-N-0392

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MAUDE Adverse Event Report: ELECTROSHOCK - ELECTROCONVULSIVE - ECT

ELECTROSHOCK - ELECTROCONVULSIVE - ECT Back to Search Results

Event Date 08/26/2006
Event Type Injury
Event Description

I received electroconvulsive shock treatments -approx 48 bilateral in a period of about 1 year - 2006/2007. My diagnosis was clinical chronic depression recurrent -2001-2009. I refused ect treatments when offered. While on a 72-hr involuntary hold, i was coerced to accept ect. Two psychiatrists attested to having reviewed my medical files and rendered the professional opinion that ect was the least invasive form of treatment for a drug-resistant depression such as mine, for i had been prescribed all available medications to no avail. I was assured an 85% chance of recovery. I was informed that lapses in memory were experienced by some, and informed this was only temporary. All of this was untrue. When my psychiatrist retired, i was assigned to a younger psychiatrist. He had read my file. He proposed meds i had never been given before - turns out there is a lot of them. I thanked him for caring and trying despite my being "drug-resistant. " one week later, my depression started to lift. That was 19 months ago and i remain "depression-free. " sadly, the ect treatments injured my brain. Memory loss turned out to be permanent. Memory function - cognitive abilities - motor skills - speech - gravely impaired. My law degree and undergraduate records say summa cum laude, highest departmental honors, dean's lis, woman of the year. That is not me anymore. I once taught law students. My writings were published. I was a speaker at conferences. I translated books for a major publishing company. I handled a caseload of 300 files. And i volunteered. I had my own radio show. Clinically depressed and under the influence of psych meds, my mind remained intact. Brilliant. Outstanding. Privileged. Today, i don't recognize 85% of the entries in my phone book. Former students call seeking advice or recommendations, and i don't know them. The materials i taught - the books i wrote - i'm unable to understand their content. Worst yet, i can't re-learn them. And i wrote them and taught them to law students three years ago. (b)(6). I don't work anymore. Dose or amount: bilateral; approx 48 treatments. Frequency: 2-3 x's/wk - tapers. Route: intracerebral. Dates of use: varied, (b)(6)2006-(b)(6)2007. Diagnosis or reason for use: chronic clinical depression; drug-resistent. Event reappeared after reintroduction: yes.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name Unknown Brand Name
Type of Device ELECTROSHOCK - ELECTROCONVULSIVE - ECT
MDR Report Key 1828510
Report Number MW5017306
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 09/01/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 09/01/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? Yes
Device Operator Health Professional
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? No
Is this a Reprocessed and Reused Single-Use Device? Yes

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FDA

MAUDE Adverse Event Report: ELECTRO-SHOCK MACHINE

ELECTRO-SHOCK MACHINE Back to Search Results

Event Date 04/23/1972
Event Type Injury
Event Description
I was administered 45 electro-shock treatments at a private psychiatric hospital. These "treatments" have caused permanent memory difficulties and a lowering of 60 points on the wexler iq test. It has been a struggle to keep up with the demands of life. Diagnosis or reason for use: depression.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Type of Device ELECTRO-SHOCK MACHINE
MDR Report Key 1513522
Report Number MW5013084
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 10/18/2009
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 10/18/2009
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Service Personnel
Is The Reporter A Health Professional? No

Patient TREATMENT DATA
Date Received: 10/18/2009 Patient Sequence Number: 1

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4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm

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FDA

MAUDE Adverse Event Report: UNKNOWN UNSURE ECT MACHINE

UNKNOWN UNSURE ECT MACHINE

Back to Search Results

Event Date 05/11/2007
Event Type Injury
Event Description

This is to report an adverse effect from what i consider to be one of the most dangerous medical devices still allowed, under class 3 status, ect, electroconvulsive therapy. For me i have permanent brain damage, and permanent disability that is clearly attributed to my 9 treatments. My memory is now amnesic, which is a common side effect from electroshock. I also go into states of delirium, forget names, but i have read many studies, and talked to many other "survivors" of electroshock who tell an eerily similar, sometimes exactly the same story. I had my treatment at (b)(6) hospital, but i was not told of the possibility for permanent, even deteriorating memory loss, that i believe with the right help of experts in the field of psychiatry, and neurology i could prove. The problem is so many of us who have had electroshock, are ignored, or even told the memory, even personality loss, including for many permanent seizure disorder, chronic insomnia, list goes on, is not due to what the industry considers still "a safe and effective treatment. " my long term memory, basically is shot. I can only explain it in light of many others who have had this treatment, who have decades, even whole lifetimes of memory gone, or very faded, due to the uniquely brain damaging affects of high voltage electric current, that induces seizures in this device.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name UNSURE
Type of Device ECT MACHINE
Manufacturer *(Section D)* UNKNOWN
MDR Report Key 2237964
Report Number MW5022093
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 09/01/2011
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 09/01/2011
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? Yes
Device Operator Health Professional
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? No
Was the Report Sent to FDA? No
Is this a Reprocessed and Reused Single-Use Device? No

Patient TREATMENT DATA
Date Received: 09/01/2011 Patient Sequence Number: 1

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MAUDE Adverse Event Report: UNKNOWN UNKNOWN ELECTROCONVULSIVE THERAPY

UNKNOWN UNKNOWN ELECTROCONVULSIVE THERAPY

Back to Search Results

Lot Number UNKNOWN
Event Date 01/01/2007
Event Type Injury
Event Description

I had 20 something ect treatments in 2007. I don't remember the exact number. I was told memory loss would be minimal. I still don't remember most of my life. I have had to start writing everything down and i have to follow written directions for things i have done hundreds of times. Please make doctors be more honest about the lasting effects of ect. Dates of use: (b)(6) 2007. Diagnosis or reason for use: bipolar depression.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name UNKNOWN
Type of Device ELECTROCONVULSIVE THERAPY
Manufacturer *(Section D)* UNKNOWN
Unk
MDR Report Key 2006289
Report Number MW5019605
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 02/26/2011
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 02/26/2011
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device LOT Number UNKNOWN
Was Device Available For Evaluation? No
Is The Reporter A Health Professional? No
Is this a Reprocessed and Reused Single-Use Device? No

Patient TREATMENT DATA
Date Received: 02/26/2011 Patient Sequence Number: 1

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FDA

MAUDE Adverse Event Report: UNKNOWN UNKNOWN ECT

UNKNOWN UNKNOWN ECT

Back to Search Results

Event Date 09/01/2008
Event Type Injury
Event Description

After receiving ect treatment, pt immediately exhibited severe cognitive impairment, difficulty speaking, difficulty walking, can no longer read, concentrate and can no longer work. These changes seem to happen overnight. Pt was an educated intelligent, coordinated, fully functional member of the community. Pt received a total of 3 treatments before treatment was halted due to changes. Treatment dates (b) (6) - (b) (6). Medical community is in denial that this treatment has caused these changes.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name UNKNOWN
Type of Device ECT
Manufacturer *(Section D)* UNKNOWN
MDR Report Key 1583160
Report Number MW5014391
Device Sequence Number 1
Product Code GXC[24]
Report Source Voluntary
Reporter Occupation Patient
Type of Report Initial
Report Date 01/21/2010
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 01/21/2010
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Service Personnel
Is The Reporter A Health Professional? No

Patient TREATMENT DATA
Date Received: 01/21/2010 Patient Sequence Number: 1

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