

Excerpts from Docket # 82P-0316

Dear Mr. Benson,

I am writing you to use your influence to keep electroshock therapy in Class III regulation...

I was a patient at University Hospital, Denver, Colorado, from early January to March 22, 1989. I was given 12 treatments and allowed to come home. A few days later, I was so desperate to get relief from anxiety and depression that I nearly died by a suicide attempt. I was asked to sign permission for further ECT...I had 20 electroshock treatments and I regret very much my decision to have any of the treatments.

I had to retire from part-time work as a paraprofessional in a local high school and I doubt I will ever be able to work again. I have forgotten how to weave, could not concentrate on anything, felt very little pleasure in life and still feel suicidal. I often don't remember people who speak to me, much of my past life is gone from my memory, I have cognitive thinking problems, fear being in any social situation, cannot spell, cannot remember factual information, and lead a rather hermit-like existence.

I believe I have permanent brain damage as a result of ECT and I do not think I will ever again be as intelligent a person as I was before the electroshock treatments...

Thank you,

Sincerely,

Theresa G. Blumen

FDA Docket #82P-0316, C450, June 14, 1990

James Benson was at the time the commissioner of the FDA. Blumen's letter to him was one of over a thousand comments sent to the FDA in response to the American

Psychiatric Association's petition to reclassify the ECT device.<sup>1</sup> The comments are filed under Docket #82P-0316 and like all dockets at the FDA, this is a public record which anyone can see on request.

I've chosen this letter from an ECT survivor because of its detail. It gives not only the name of the hospital but the number of treatments, twenty (a fairly typical number no one would consider excessive) and the date (1989, a date putting it unquestionably well into the mythical modern or improved era of ECT by anyone's calculations). It is also quite detailed as to the effects of ECT on memory and cognition and the consequences for the writer's social and economic life.

The opinions carefully stated at the end follow logically from the information in the preceding paragraphs. The writer has done all she can do to make her case by reporting her observations. She does not have access to the technology to do a brain scan or neuropsychological testing. She cannot ask the FDA to conduct a scan of her brain, because the agency has already said it will not do so.

If there were no other cases similar to Blumen's in Docket #82P-0316, her letter could be dismissed as anecdotal, and her bad outcome could be attributed to chance. The FDA could say hers was an isolated case, a random experience. Her conclusions might be dismissed as nothing more than unsubstantiated opinion. Her experience would have no meaning. Least of all would it constitute scientific evidence.

If there were no similar reports. As it happens, there are about two hundred. That's approximately how many letter writers identified themselves publicly as ECT survivors.

Dear Mr.Villforth:

As a former recipient of ECT, I have ongoingly suffered from memory loss. In addition to destruction of entire blocks of pre-ECT memories, I have continued to have considerable difficulty in memory recall with regard to academic pursuits.

To date, of embarrassing necessity, I have been forced to tape-record all education materials that require memorization. This has included basic classes in accounting and word processing materials. I was forced to "re-take" accounting in 1983. Now, I am again forced to "re-take" a basic one-semester course in computerized word processing.

Currently, I am finding it extremely embarrassing and hurtful when fellow classmates (however innocent) refer to my struggles in grasping my study materials, thusly: "You are an AIR-BRAIN!" How can I explain that my struggles are due to ECT?

As far as the loss of my childhood memories, I often feel as though a very vital part of my life "died" as a result of these treatments. In particular, when my family refers to specific earlier experiences, I feel a great sense of loss and grief because I cannot share their memories, as an ongoing testament of "life," in totality, as they can easily recall each vivid childhood happening.

In addition to feeling deeply grieved about my own memory loss, I am also grieved that countless other fellow citizens risk being needlessly victimized in a like manner due to ECT devices, and not being honestly apprised, by medical practitioners about the risk of permanent memory loss.

Thank you for the opportunity to submit this letter, urging that the "notice of intent" to reclassify ECT devices be rescinded.

Felicia McCarty Winter

May 23, 1988

Dear Mr. Villforth,

Nearly twenty years ago, I underwent 30 shock treatments at the Institute of Living in Hartford, Connecticut. As a result I lost two full years of memory. I have one child, a daughter, and the two years that were wiped out in my memory were the years when she was two and three years old; those memories are irreplaceable. Recently I have begun writing my autobiography...I found that my memories are clear and detailed back to age 2 1/2. But when it comes to those two critical years before I received shock treatments, my mind remains a blank. It is clear to me that I have suffered brain damage as a result of ECT treatments.

As an advocate for over 8000 mental health clients in Maine, I do have contact with many former ECT recipients. I have met many others who have lost over 20 years' worth of memory; I have talked with others who, after shock treatments, were unable to resume their former work and lifestyles because of short term memory damage. I am convinced that brain damage from ECT treatments is not only common, but that it is the rule rather than the exception.

In view of the frightening damage that has been reported as a result of ECT, doesn't it make sense at least to investigate the safety of such treatment? We spend millions testing artificial sweeteners to determine if they are potentially carcinogenic in rats; aren't our minds at least as precious?

Sincerely,

Sally Clay

November 9, 1987

Dear Mr. Villforth,

I understand that the FDA is undecided whether to take back the notice of intent regarding electric shock treatments.

In 1968 I had 19 shock treatments. I found out later that they were probably unnecessary and that I had severe thyroid and female hormone deficiencies. Needless to say the electric shocks didn't help my hormone deficiencies!

They did wreck my life however! I suffer severe memory loss which has never returned. It covers 8 to 10 years!

I also have a very deep inability to learn and comprehend things and this has led to problems with my own self understanding. It also has affected my relations with my own family and other people too.

Mr. Villforth, I urge you NOT to make ECT such an easy to use treatment.

Sincerely,

Dorothy Oimette

FDA Docket #82P-0316, C00230, January 29, 1988

Dear FDA,

I am a former recipient of ECT around the year 1976. They used the "Mecta" ECT device on my head. Dr. Paul Blachly (now deceased) was the inventor of this modern ECT device which is used world wide now.

The side effects I received were:

- A. Persistent memory loss
- B. Loss of ability to concentrate
- C. Pain in my head

Dr. Blachly said during that time:

1. "Signing for ECT actually scares the patient"
2. "There are side effects"
3. "It is a necessary evil."

I believe that the pros and cons of the ECT procedure be examined and that the "Mecta Machine" be classified as a "dangerous machine."

Thank you for your time and efforts.

Yours truly

Roy E. Jones

FDA Docket #82P-0316, C693, November 11, 1990

The 2 years of college I had before the shocks was gone. All I had was a vague memory of my art professor when I looked at the painting I'd done hanging on my wall. So the shock doctors were not only barbaric--they were thieves, robbing me of the one thing in life that brought me the most satisfaction. From day 1 I had dreamed and fantasized of being a teacher--they were my role models...I've been fired and asked to leave job after job in my profession due directly or indirectly to what was forced on me against my will...misdiagnosed, mistreated and now unable to perform I exist on less than \$300.00 a mo. SS disability. If it weren't for the ECTs I'd have my master's or PhD and

still be teaching. ECTs raped and robbed my brain. I'll go to my grave with this--the worst thing that ever happened to me in my whole life.

Betty Scoleri

FDA Docket #85P-0422, May 1, 1986

Dear Mr. Villforth,

During my last bout of suicidal depression, I received 2 courses of ECT treatments. As a result I now suffer from loss of memory, both long and short term, as well as dimunition of reasoning ability which renders it impossible for me to return to my previous occupation.

I firmly believe that ECT should be classified as a Class III, High Risk treatment and that physicians be required to inform patients in advance of all side effects and risks of ECT.

Jennifer Harmon

FDA Docket #82P-0316, C430, June 15, 1989

I received over 20 ECTs when I was 17 years old...I was told the memories would come back in 6 weeks. I was told the shock treatments were no more powerful than the batteries in a flashlight. This was 30 years ago.

I lost 95% of all my memories before the treatment. They never came back. I went back to high school. I did not remember my fellow students. I could not find my classes. It was awful. To this day I look at the school year books hoping some of the pictures will spark a memory. I used to play the violin. I had won 2nd place in duets in the city of

Cleveland. (The only reason I know this is because I have the medal in my drawer.) I could not remember how to play my violin after the first series of treatments. I was devastated...My doctor kept saying that one more series would make me well...

I have trouble with my memory today. I have been told I have permanent brain damage due to the ECT treatment. My IQ was 120 before treatments and it is not anywhere near that now. I have trouble just trying to cook a meal. I do not work. I make lists so that I can try to remember what I need to do.

ECTs changed my life forever--and not for the better. I wish no one would be given ECTs.

Sue Ann Kulcsar

November 9, 2000

Dear Mr. Benson,

As someone who was given shock "therapy" for depression after the death of a baby I can tell you with words of soberness that ECT causes permanent memory loss. For example, I was in beauty school right before my shocks. Before shock "treatments" I cut my friend's hair for them. After the shocks I picked up the scissors to cut my mother's hair. I had forgotten how. I realize that in my circumstances I could have relearned how to cut hair; however the point I'm trying to make is the memory of how to cut hair never returned. My loss, as far as remembering how to cut hair was a mild loss. But, what about the complicated careers and educations which have been totally obliterated by shock "treatments"?

If the FDA allows the shock doctors to pressure it into reclassifying the ECT machine then the FDA does a disservice to the people of this nation because no one is immune to having an emotional break!

With sincerity,

Sandra Everett

FDA Docket #82P-0316, C408, May 25, 1989

Permanent memory loss for the time of the treatments and some time before is usual, not unusual. If a person, even one feeling awful, realizes what this does is to divide life into a present and a past which cannot ever be reconciled psychologically, he or she will realize that ECT is unnatural and wrong.

Yours truly

Mark Fenton

FDA Docket #82P-0316, C802, February 1, 1994

Mr. Villforth:

The purpose of this letter is to express my opposition to the 1983 "notice of intent" to reclassify ECT devices to Class II.

As you might suspect, I am one of those many people who have been subjected to shock treatments in an attempt to alleviate a severe depression. Had I foreseen the damaging effect that these 24 treatments were to have on my brain, I never would have agreed to undergo them.. Because of the subsequent difficulties I have encountered as a

result of ECT (including a recurrence of the depression and a suicide attempt), I consider these treatments to have been a setback rather than a help in my recovery.

I was fortunate in that I was able to return to my job but the process of relearning my job and retaining what I learn has been an arduous process. It is extremely stressful for me to cope in many areas of life because of my altered mental capacity. In addition, I have suffered embarrassment because I am unable to remember many people that I had met before the treatment as well as many important events in my life. In school, I have tremendous difficulty recalling what I have read, and, as a consequence, do poorly on essay-type exams. This has limited my coursework in recent years to those subjects that do not use essay exams. I certainly can imagine that unless one has very supportive friends and co-workers, as I do, the effects of ECT would be devastating.

It is most frustrating to experience these changes in my capacity that affect almost everything I do and then listen to a psychiatrist say that it is all in my head.

I hope that the present classification of ECT devices as Class III does not change.

Sincerely,

Lucinda H. Frend

February 8, 1988

To Whom It May Concern:

I'm enclosing this letter with my petition, for the truth about ECT.

It's been 7-8 years since I had them, the long term damage is there and it's not coming back. At one time I never minded filling out job applications, I loved to read, my goal was to finish high school G.E.D. and become somebody.

I can no longer fill out applications. I'm not able to retain anything I might learn, I read and the next minute it's gone. I can't follow written instructions, I become confused. Just the other day I had to fill out an application for Food Stamps. I couldn't do it. I started to cry Something so simple and it deals with current things, I just couldn't handle it.

At one time I tried to file for Social Security. I could not remember places I worked or years, my mother tells me I was always good with dates, years, etc, not no more. I can't do any math, I've been tutored and helped and it won't sink in. I can read a page in a book and look up and not have any recollection of what I read. I have lost my ability to learn and better myself.

I feel doctors should tell people that are about to have ECT that sometimes, some of the brain is damaged and not all memory might come back. If I had thought for one min. I might of lost any of my memory forever, I would not of went through with it!

I'd also like to tell you that since the ECT I lost my first husband, I have hardly any memory of him, we were married 10 years.

I can no longer remember from day to day. When I'm lucky enough to find work, it's mass confusion and I usually don't last too long.

Thank you for your time.

PS I mean, I don't understand why no one at the FDA wants to find out the truth. So the FDA runs few simple tests, they find out the truth, they may save 50 people a day from a life of hell.

Doris Heikila

FDA Docket #82P-0316, C140, February 25, 1987

Dear Mr. Villforth:

I am one of many ECT patients who cannot help but suspect that ECT caused brain damage...I would like to think that someday, thanks to the FDA, the truth about ECT will be known, whatever that truth may ultimately be...

Mr. Villforth, I can write a pretty good letter, I think, but in this case it's what I can't do that counts. I am constantly reminded of what I can't do...although I could do it once. And what is "it"? I can't remember new information with the ease I could before ECT. Distractions and interruptions seriously interfere with information retention...any new bit of information may "cancel out" the bit that preceded it. My auditory and visual memory seem to function episodically...enough so I know they exist and how well they functioned before ECT.

How have these deficits, which developed immediately after ECT, affected my life?

1. When I returned to my 6th grade teaching job after ECT I could not remember how to teach. Therefore, 5 months after ECT, I attempted suicide.
2. For two and a half years I worked in a kitchen. The loss in income was dramatic but worse was the total loss of confidence and the perception that I was a complete failure.
3. When I dared to take a college course, even multiple readings of the same material yielded next to nothing.
4. In September of 1987, I matriculated. However, because the information was complex and largely theoretical, and because I found it hard to remember instructions, I withdrew from school. I am very fortunate that I survived the subsequent depression.

5. Why am I not making the \$40,000 I would be making if I'd remained in teaching. Why am I praying that I'll find a job that pays me \$16,000. Why am I likely to settle for less if it will make few demands on my memory. I'm sure I need not answer "why".

I had a high "B" average in college. I remembered ideas better than facts. I was not a slave to my studies. One year six months later functioning like that was just a bitter memory. If ECT must be used in spite of its damaging effects, can we not develop cognitive retraining programs to help people adapt to their new deficits.

I know in the first page of this letter I referred to my "brief" description of my experience. Is this brief? It is for someone who feels she struggles with the consequences of ECT still--after 20 years.

I do sincerely appreciate the time you or your staff have spent reading this letter.

Sincerely,

Pam Maccabee

Docket #82P-0316, C323, January 20, 1987

I've had three separate series of ECT (as far I can remember!) I spend time, as many other survivors, writing lists to remind myself of daily things--which I didn't do as a young teenager (I just passed exams that were required of me then.)

I'd like to see a firm warning of the danger to memory and the memory function in learning new skills and being able to retain them, plus severely slowing down reading by affecting concentration.

Charlotte Thornton

FDA Docket #82P-0316, C810, January 13, 1996

Dear Mr. Villforth:

I am requesting that as a senior official of the FDA you recommend that the "Notice of Intent" to reclassify the Electroconvulsive Treatment (ECT) device be rescinded...

It took me five years of hard work and frustration to restore my reading comprehension to the college level. And I had been a Reading Specialist. For some twenty years I could not play the piano. I doubt I'll ever reach the level I had been before I was subjected to ECT.

It has taken me the past twenty years, and will take me the rest of my life to approximate the education I lost. My career as an Intelligence Officer for the Federal Government was lost forever.

The effects of ECT not only ruined my life, but it nearly destroyed my family and my marriage...My personal belief is that an investigation is in order to prove that ECT is indeed beneficial and not brain damaging. How can I feel differently when that so-called therapy has wrecked a major portion of my life?

Respectfully yours,

Marjorie E. Faeder

FDA Docket #82P-0316, C314, January 21, 1988

Dear Sir:

It is with enormous horror that I view the pending action of the FDA to put the ECT device in a relatively non-damaging classification.

I myself, who was subjected to such "treatment" over forty years ago, have had a life very much reduced in participation in all social matters, whether it is viewing and remembering the movie just seen (almost immediately forgotten) to mastering what would be trivial details to virtually anyone, the small technicalities needed to be learned in every job.

Do not reclassify the ECT device to Class II. It is a terribly dangerous and damaging tool. Why don't you test it to ascertain just what are the effects of treatment?

Most sincerely,

Beatrice Rosenthal

FDA Docket #82P-0316, C566, October 30, 1990

Dear John Villforth,

It came to my attention that there is a move to reclassify Electric Shock Treatment from Class III to Class II...

When I was 19 years old my folks had me in the Hartford Retreat or the Institute of Living to get a series of about 18 shocks. Because of their complete trust in the psychiatrist who recommended I go to that place for my health, I was forced to submit to the hospital's best judgment. It was the hope of my parents that I would be able to resume college and study chemical engineering which I didn't do. In light of our present day knowledge that ECT destroys the brain, do you believe that I had a fair chance to compete with other college students? Is it not reasonable for our great country to provide that people should be informed of the brain damaging side reaction to ECT before they sign to approve of it as therapy?

Very truly yours,

Monroe Prussack

FDA Docket #82P-0316, C201, January 20, 1988

After I'd signed all the papers, including the "formality" of one giving the doctor permission to treat me (the admittance clerks words), I was taken to the psychiatric ward, given a bed and a sleeping pill. I slept soundly, knowing I was going to get help.

When I awoke the next morning, I met my room-mate...She said, "You know they give you shock treatments, don't you?" Dear God, No!...

I tried to run. They caught me and forced me onto the table. I don't remember ever fighting after that...

My family came to see me. I remember none of them, but my oldest son. I will remember that, from what I later learned, till the day I die. At that time, I was so "happy and excited." They had a gift wagon that came by and I had bought four gifts for the kids. Since my oldest son's birthday was Nov. sixteenth, I decided to let him have his pick of the gifts. He turned 13.

He came into the room with his father. He stopped and looked at me, then came in and kissed me. I got out the "gifts" and told him to take his pick and give the other kids the rest. He chose one and said he was going down to the waiting room for a few minutes. I didn't know for some years that he had gone down there to cry, holding the cheap plastic toy that would have been better suited for a five or six year old. He cried for me.

He said he had never been so terrified. I had also not known that he'd been there before. He said I had been very lethargic, eyes vacant. This day, I had seemed happy, but

I had acted as though he had been five or six years old. What a hell to put a young boy through...

Soon after that, I was pronounced "well." I could go home. My youngest aunt lived at home, and I asked her a million questions. Where do I live; in a house or an apartment; upstairs or down; what kind of car does my brother-in-law drive; where were the kids, on and on.

I knew nothing of where I kept anything, which bedroom or bed was mine, where did this or that come from.

But the heartbreaking part was my children. They were thirteen, eleven, ten and barely eight. They brought friends in and I would say, "What a nice boy, who is he?" They would look embarrassed and tell me I had known him since we'd moved there.

I don't really remember a lot of what went on in that time, either. I do remember deciding I was going to get a job. I went to a clothing store. They said they didn't need any help then, but would take my number and call me if they needed help. Where had I worked? I told them a dress shop and the town. Name of the shop? Nothing. Who did I work for? Nothing. Who owned the shop? Nothing. I went home, embarrassed and not so enthusiastic.

I remember my sons. They just looked sad or upset, most of the time. I couldn't figure it out. I felt so good, why weren't they happy?

Then, I came down. My problems? Right there, as they had been before the treatments. Only now, the kids were hurting. I couldn't remember things, my family was upset and worried about me...

I felt resentful and so terribly frustrated, and helpless. Because I'd found out the dangers after the fact. I couldn't go back and "un-do" the treatments.

I believe my body, my brain, was violated. By not telling me the type of treatments I would receive; by not telling me of the dangers and the unknown elements involved; by not even telling me of the short term effects, I feel not only myself but my innocent children and family suffered with me.

Cora Lee Ritchey

FDA Docket #82P-0316, C124, August 11, 1986

Dear Mr. Benson,

It is 5 and one-half years since my horrifying experience of awaking in a hospital after ECT, not knowing who I was, where I was, who my husband and children were, what were my likes and dislikes, what my family was all about, what classes my children excelled in, what the family liked and disliked, and where I stood in the life I was supposed to be living...The fear is a reality that I would never want to experience again in any way.

The consent form, which states that there may be some temporary memory loss is an understatement. It is an outright lie and I wish to bring this to your attention. The damage from ECT can be extreme and completely disabling, to a degree inconceivable except by those who have undergone this horror. A diagnosis of organic brain syndrome or senile dementia after ECT through neuropsychological testing is not taken lightly by a person who had once been an intelligent and fully functioning being.

...The heartache and striving for health following brain damage is an illness itself after the damage from ECT.

Pat Gabel

FDA Docket 82P-0316, C345, January 25, 1990

Dear Sir,

Please have mercy on people like me and keep shock treatment in class III...Shock torture is terrifying and brain damaging. My memory just comes and goes because of psychiatric torture.

What is needed is a law that says no human being can be given shock or drugs without the person's consent. No matter how sick a person seems to be or how crazy he should always have the right to refuse treatment and not be imprisoned.

Ralph Allred

FDA Docket #82P-0316, C409, May 9, 1990

Dear Mr. Villforth:

As a former recipient of Electro Convulsive Therapy, I write you urging that you (the FDA) rescind your "Notice of Intent" to reclassify the ECT device from Class III to Class II...

In my case, I have been left with permanent memory loss, which is strongly indicative of brain damage. My (emotional) condition before administration of ECT was not such, that the "side effects" were worth risking, for benefits that might have been derived. Had the risks of these "side effects" been discussed in advance with me and my family, I feel certain we would not have agreed to this treatment...

I appreciate the fact that the FDA is spending the time and energy to study the information that you have on this controversial matter.

Very sincerely,

Gail Landsmith

FDA Docket #82P-0315, C225, February 8, 1988

Dear Sir/Madam:

I was never warned of the possible damage to brain function which could happen from shock treatment. I was never warned of any potential risk to my health from the shock treatment...I appear to have lost the major portion of my ability as an LPN since that time. I cannot remember much of my theory and I had made a 92% on State Boards.

Sincerely,

Sharon Cotter Sasso, LPN

FDA Docket #82P-0316, C555, October 25, 1990

Greetings Mr. McRae:

If the ECT device is reclassified to Class II, it would deny the current call for a safety investigation, and the manufacturers would not be required to submit any clinical data regarding its safety and effectiveness.

In my opinion, ECT does have the potential for serious side effects--given that current "traumatic brain injury" guidelines state that: two weeks or more of post-trauma amnesia count as a severe brain injury...this effect is very common following ECT. I can personally testify to permanent memory loss--and I am one of many.

The APA's recent report on ECT instructs doctors that they "do not need to inform patients that brain damage is a possible risk." I am not an attorney, but I would sure question that omission if faced with any kind of lawsuit! The abuse of the patient's trust and untruthfulness of the implication that there is no risk of damage is blatant. I also question the motive for the omission of the statement.

Sincerely,

Kathy R. Linn

July 20, 1990

Dear Mr. Villforth,

I am writing this letter to urge you to rescind the 1983 "notice of intent" to reclassify the ECT device. Psychiatrists may insist that ECT is safe, but they only administer the treatments. The patients know better...

In 1972 I received 19 shock treatments because I was depressed. Without going into details, I can say that my life has been altered because of them and there isn't a day that goes by that I'm not aware of it...I am convinced that electroshock treatment causes brain damage.

Yours truly,

Barbara Richer

FDA Docket #82P-0316, C214, February 9, 1988

My doctor informed me that I would experience some short term memory loss, but reassured me that my memory would return to normal within six weeks following the end

of the treatments. He pronounced me "cured" and urged me to return to college. I had to drop out of school when I realized I could not remember what I had studied before entering the hospital, and I was totally unable to absorb new material. I suffered for many months from a complete inability to concentrate, and was not even able to read a newspaper or magazine. I have been left with permanent memory loss of events that preceded the ECT by several months. I continue to have difficulty concentrating for extended periods of time, which I believe is the result of ECT.

I believe that stringent regulations are needed to protect patients from being easily pressured into consenting to ECT. In my case, it could hardly have been called "informed consent" because I wasn't well informed of the risks involved.

Sharon Heim

FDA Docket #82P-0316, C650, November 2, 1990

Shock treatments are one of the most inhumane acts one person can give another!

I know because I had a bunch of them many years ago and I'm still having problems with my senses and the brain damage it did...

When you come out of this hellish treatment--you sometimes don't know your name--you've forgotten a lot of important events in your life. I forget my children year they were born--I forgot addresses and how to contact people etc.

And years later I'm having the same problems. When I finally got out of the hospital I had to be hand led around on buses, and when I went out.

I have watched many cases of people who had shock treatments and yet am waiting, so far no good results.

Jean Culligan

FDA Docket #82P-0316, C420, May 9, 1990

My personal experience as a patient, shock treatment is intrusive therapy...Blue Cross, Blue Shield pays for a quick fix. I had no after-care followup in the community. The experience of going back to work was horrendous. I could not remember names of fellow employees, code numbers for the computer department was wiped out of my mind.

Before this hospitalization, I was going to business school for accounting. All that I learned was wiped out of my mind. My vocal studies were brought to an abrupt halt. My repertoire of music was wiped out of my mind.

Followups of each and every patient who have had shock treatment should be a matter of necessity. A Pet-Scan or Cat-Scan would be a necessary, cautionary followup procedure. Pretesting with the Cat or Pet-Scan to have a view of the brain before and after treatment.

PLEASE DO NOT CHANGE SHOCK FROM CLASS III TO CLASS II

Rehabilitation should be included after shock treatment.

Please send me the documented evidence that the FDA has on the safety of shock.

Elizabeth Plasick

FDA Docket #82P-0316, C54, May 20, 1983

Before ECT, I studied math up through calculus. After ECT, I can just barely make change in a store. ECT gives a person a different brain from the one a person had. One

never feels sure about this strange new head. Some things come back. A great deal of memory never returns. And one cannot retain new information, so one's future is DEAD.

June Bassett

FDA Docket #82P-0316, C51, May 2, 1983

Dear Mr. Villforth,

I am writing to request the FD rescind their notice of intent to reclassify the ECT device.

I have suffered loss of jobs, family or friends' respect as a result of ECT treatments (in 1971). I was administered 26 treatments with the ECT device for endocrine glands malfunction "nervous breakdown". Five years later I realized I was brain damaged because of confused physiological functioning and continual depression on the job and in school (college). I am now 38 years old--and 3/4 of every day since those 26 ECT treatments I am bitter because I no longer feel vital and fit for life.

I do praise the FDA for its original Class III classification.

Yours truly,

Karen Whitehead

FDA Docket #82P-0316, C204, January 27, 1988

Over 30 years ago my brain was severely damaged by several medical sadists in the psychiatric "profession" using electroshock machines. I very strongly urge that shock machines remain in the "Class III" category...

Electroshock to the brain is not only extremely sadistic, but also results in the wiping out of the abused person's education, and normal memories of past experiences in the psychiatrically abused person's life. Electroshock also negates the victim's ability to acquire new knowledge, and even negates the victim's ability to relearn knowledge the victim had before the permanent amnesia which results from electroconvulsive "therapy".

Also I would like to remind you that any arguments by shock doctors, who might state that improvements have been made in the procedure, are exceedingly specious. Damage to the brain by electroshock remains the same...

Sincerely,

Donald A. Mattoon

FDA Docket #82P-0316, C18, October 6, 1982

Dear Mr. Villforth,

I was a victim of ECT when I was nineteen years old. I am now forty. The ECT was given to me against my will...Before the ECT I was a college student studying art and a springboard diver in training for the Olympics. After the treatments I tried to resume these things, but I could not remember people who knew me at school and lost my nerve for diving. I feel the shock treatment was responsible.

My parents never would have consented to the treatment if they had been informed it might hurt my memory and damage my brain...

I would like the 1983 "notice of intent" rescinded, and others allowed to know the truth about ECT and the damage it causes.

One last thing I want to mention is an example of the effect ECT had on me. I was a young girl, intelligent, athletic, diving, attending college making good grades. I took a trip with my parents after leaving the hospital and I can remember going in the bathroom, coming out carrying a roll of toilet paper. I didn't even realize I had it. I was very embarrassed when I realized I had it and left it sitting in a drinking fountain. That is an example of how I was affected.

Sincerely,

Suza Gaudino

FDA Docket #82P-0316, C203, January 24, 1988

Dear Sir,

Please add my name to those strongly urging you to thoroughly investigate the safety of electroconvulsive therapy.

From personal experience, I can vouch for the fact that ECT does permanent damage which inhibits the brain's facility for memory (particularly short-term) and concentration.

I know many others who have had ECT and there is not one who is positive about it.

Sincerely,

Edith G. Harris

FDA Docket #82P-0316, C180, November 28, 1987

To whom it may concern:

I was hospitalized, voluntarily, from January 30 to February 20, 1991, during which I had eight electroshock treatments. The second treatment was with bilateral electrode placement; the others were all unilateral right-hemisphere electrode placement...

ECT did work; it unquestionably saved my life...

Most medical research concludes that prolonged or severe adverse effects are very rare, but for those of us who do experience them--whether we represent one out of two or one out of two million ECT recipients--they are very real, debilitating, and even life-threatening.

### Effectiveness

The ECT got rid of my depression completely for three weeks. After that, my depression began returning intermittently, and by six weeks post-treatment, it was constant again.

### Short-term effects

The confusion I experienced immediately after each ECT treatment was different enough from routine confusion that it should probably have a different name. I'm not talking about not knowing whether it was morning or afternoon--I'm talking about not even knowing what I was, let alone who or where I was...

The "confusion" I continued to experience for about six weeks after my last treatment was another matter. I was unable to organize or conceptualize thoughts and feelings. I couldn't discern any logic, either internal or externally imposed, in my thoughts and perceptions. I was unable to perceive or create any hierarchy among thoughts, feelings, and physical sensations. Everything I thought, said, or wrote was an incoherent stream of

consciousness with the result that I was utterly unable to communicate appropriately or effectively. This amounted to a severe occupational and social disability...

"Memory" isn't just a data bank of pieces of information that we might or might not care to use at any given moment. Memory pretty much covers everything we know and feel, and need to know and feel, to function--on every level. I lost knowledge, skills, abilities, and feelings of all kinds, and these losses made it impossible to function in work, routine activities, self-care, relationships, etc.

My memory loss included, at various times for about six weeks following my ECT, not knowing who people were, let alone what their names were; not being able to figure out how to put on my clothes; not having even the most basic job skills necessary to perform my usual work; not being able to drive my car, let alone figure out where I was going; not knowing where anything was in my home; etc.

I found myself wondering such things as: What is that thing (the machine I later recognized as my vacuum cleaner), and what it is for? I wonder if there's any way I can get my floor clean? Is cleaning floors something that normal people do, or am I being strange to want to clean my floor? Who lives in that house across the street? Did I used to know who lives there? Am I the kind of person who would have known who lives there? What kind of person am I anyway? What did I used to believe, and would I believe the same things now?

I am also having to re-learn how to remember--I lost the process itself of remembering and learning...

At least a couple of times every day, I found myself screaming and writhing uncontrollably. When there was verbal content to my screams, it consisted of such things

as : "What have they done to me??" "They've destroyed me!" "My self is gone!" "I can't feel!" "They've turned me into a monster!" "They should have killed me instead!"

#### Six months later

I am now living with the deadly depression and the debilitating residual effects of the ECT. After the first six weeks post-treatment, my progress in recovering from the adverse effects came to a standstill.

In the six months since my ECT, I have been able to work only a few days altogether. There are still significant gaps in my memory of the past, and I am still often unable to learn and remember in the present. Since cognitive and memory impairments have also been symptomatic of my depression, I know that some of these difficulties may be attributable to the depression. However, I'm convinced that most of these dysfunctions are the result of the ECT, both because they are qualitatively different, and because they are far worse now than they were before the ECT.

#### Informed Consent

A psychiatrist who has been very active in fighting against regulation of the use of ECT has lamented that California's legal requirements on informed consent for ECT are the most restrictive for any medical procedure anywhere in the U.S...I shudder to think how unprotected consumers must be in other states if California's legal requirements are the strongest.

The content of the information given to me, on the basis of which I was to consent to ECT, was woefully inadequate. What I already knew, and recall being informed of, was that memory loss and confusion, usually of short duration, were common effects of ECT, and that other more serious adverse effects--such as cardiac arrhythmia, hypotension, and

death--were possible. I wasn't informed that the debilitating effects I have experienced from ECT were possible outcomes...

I especially wish that I had been forewarned that recuperation from the treatment can be a very difficult and time-consuming process. I wasn't prepared for the possibility that I might be disabled for months by the residual effects of the ECT...

Whenever I reported any of the adverse effects to my attending physician in the hospital, his response was to categorize all my experiences as manifestations of the predictable "memory loss and confusion," and to assure me that they would be of short duration. However, the worst of these effects didn't even become manifest until I left the hospital and tried to return to my life. Since my physician never did any followup on my progress after I left the hospital, he has no way of knowing what the longer-term effects of my ECT have been or how severely they have disabled me.

Much more specific information should be provided to clients on things like the average length and range of time it takes to recover memory; the percentage of people who never fully recover memory or other cognitive functioning; the percentage of people who experience affective impairments and the kinds and severity of these impairments; etc. I know that some of this information is not currently available, but it should be, and research should be done to find it...

No one, under any circumstances, should ever be subjected to ECT without his/her fully informed consent. I realize that not many people would agree with me on this point, but I would go so far to argue that ECT should not be administered without one's consent even if it is known with certainty that suicide will otherwise result. Having been myself in the position of suicide or ECT as the only options available to me, I feel entitled to

make that argument. And if I were faced with the choice today, I would unhesitatingly prefer death to ECT.

Karen Rian, Ph.D<sup>2</sup>

FDA Docket #82P-0316, Let. 24, September 6, 1991

Dr. Rian later chose to commit suicide rather than undergo more ECT.

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<sup>1</sup> Over the years, letters came in addressed to various officials: John Villforth, James Veale, James Benson, Philip White, Robert Munzner, James MacRae, David Kessler. (Villforth, director of the Center for Device Evaluation, is said to have been the man who made the actual decision to reclassify the ECT device.) Most but not all were collected in Docket #82P-0316; some sent directly to the official, not the docket, were not given comment numbers. The official tally was less than a thousand comments when last checked. However, in quite a few cases the FDA lumped similar comments (as in form letters, which were frequently written in in the margins) together as one comment, so that hundreds of comments were counted as only one. There are over 1500 of these forms, which the FDA considers as only a few comments.

<sup>2</sup> This letter has been edited for length from the original seven pages.