South Carolina
Department of Labor, Licensing and Regulation

Division of Professional and Occupational Licensing
Office of Investigations and Enforcement

Nikki R. Haley
Governor

Richele Taylor
Director

110 Centerview Drive
Post Office Box 11329
Columbia, SC 29211-1329
Phone: (803) 896-4470
FAX: (803) 896-4656

July 27, 2015

**CONFIDENTIAL**

Mr. Thomas R. White
167 Bethlehem Cir.
Leesville, SC 29070

Re: Dr. Istvan Takacs

Dear Mr. White:

This correspondence is to advise you that the Office of Investigations and Enforcement has received your complaint. Complaints are investigated in the order in which received unless there is an immediate danger to the public/patient.

Your complaint has been assigned to Investigator Renee Bouye. In the course of the investigation, you may be contacted for clarification or additional information. If you have supporting documentation not previously submitted, please submit it as soon as possible.

Please be aware that all activities regarding this complaint are confidential.

Thank you for your initiative in this matter. If in the future you have questions regarding this complaint, please contact the above Investigator at (803) 896-4516.

Sincerely,

Althea B. Myers
Chief Investigator
Case # 2015-296

ABM

South Carolina
Department of Labor, Licensing and Regulation

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July 27, 2015

**CONFIDENTIAL**

Mr. Thomas R. White
167 Bethlehem Cir.
Leesville, SC 29070

Re: DR GONZALO JAVIER REVUELTA

Dear Mr. White:

This correspondence is to advise you that the Office of Investigations and Enforcement has received your complaint. Complaints are investigated in the order in which received unless there is an immediate danger to the public/patient.

Your complaint has been assigned to Investigator Renee Bouye. In the course of the investigation, you may be contacted for clarification or additional information. If you have supporting documentation not previously submitted, please submit it as soon as possible.

Please be aware that all activities regarding this complaint are confidential.

Thank you for your initiative in this matter. If in the future you have questions regarding this complaint, please contact the above Investigator at (803) 896-4516.

Sincerely,

Althea B. Myers
Chief Investigator
Case # 2015-295

ABM

MUSC Health
Medical University of South Carolina
Charleston, SC
843-792-2123

# Operative Note

**Patient:** **WHITE, THOMAS** **MRN:** **001756561**

Attending: Date: 1/25/11 12:00 AM

Status: FINAL

MUSC Medical Center
OPERATIVE NOTE
Patient Name: WHITE, THOMAS R
MRN: 001756561
Patcom. 104213798
Date of Surgery: 01/25/2011
Surgeon: Istvan Takacs, MD
Assistant(s):
PREOPERATIVE DIAGNOSIS: Essential tremor.
POSTOPERATIVE DIAGNOSIS: Essential tremor.
PROCEDURES: Implantation of deep brain stimulation electrode to the right thalamic ventralis intermedius nucleus with microelectrode recording.
INDICATIONS FOR PROCEDURE: A 74-year-old white male with essential tremor, who was previously implanted with a left-sided DBS system with very good results. He now returns to obtain control of his left-sided tremor. Consent was obtained.
DESCRIPTION OF PROCEDURE: On the morning of surgery, the patient was seen in the radiology department where he was fitted with a stereotactic head frame and underwent a head CT with DBS protocols. He was then transferred to preoperative holding. The images were sent from the CT scanner to the Stealth computer workstation where the images were fused with a previously obtained MRI. The target point for the right VIM was selected and the target coordinates calculated on the basis of this imaging. Once the planning had been completed, the patient was taken to the operating room. He was identified, placed supine on the operating table, and the head frame was clamped to the operating table with a Mayfield head clamp adapter. IV prophylactic antibiotics were given. Mild conscious sedation was administered. The C-arm was brought into position to allow us to take lateral images throughout the surgery to follow the position of the lead intracranially. The top of the patient's head was shaved and sterilely prepped and draped. The stereotactic coordinates were tested against the base phantom. The arc was then transferred to the head frame and secured in its receptacles. The entry point was marked on the patient's scalp with a marking pen and then infiltrated with local anesthetic. An arcuate incision was made in the skin, and the skin flap was reflected laterally. A single bur hole was taken up over the coronal suture with a 14-mm Codman bur. The dura was opened with monopolar cautery. The pia and the arachnoid were breached with

# Operative Note

**Patient:** WHITE, THOMAS **MRN:** 001756561

Attending: Date: 1/25/11 12:00 AM

Status: FINAL

fine-tip bipolar cautery. The burr hole cap was inserted into the bur hole and secured with the 2 micro screws provided in the kit. The arc was adjusted to the proper trajectory, and the micro drive base was placed on the arc. Three cannulas with a 2 mm anterior and posterior offset to the center track were inserted into the patient's brain to a depth 25 mm short of target depth. The micro drive was then mounted on the base, and 3 microelectrode recording probes were inserted through the frame depth and connected to the Alpha Omega computer workstation. These probes were then advanced in sub-millimeter increments with continuous monitoring of microelectric brain activity. A solid VIM registration was obtained along the center track as we approached target depth. The anterior and the posterior cannulas were removed. The center microelectrode probe was removed and replaced with a permanent macro lead, which was inserted to target depth. It was then connected to an external stimulator and on each of the 4 contacts on a different setting, the patient, whose sedation had been lifted, underwent various tasks to verify that his tremor was controlled. He was able to draw even figures and hold the laser probe light steady against a targeting on the ceiling. There were no side effects at increasing stimulation voltages. With the C-arm, target point image was taken. As the head frame and arc were disassembled around the lead, these images were repeated to make sure that no inadvertent motion in the lead position had occurred. The lead was locked into the bur hole cap with the lock mechanism provided in that kit. The stylet was removed from the permanent lead. The distal end of the lead was capped off with a protective cap and inserted under the galea ipsilaterally to a point behind and slightly above the ear. The excess lead was coiled around the bur hole cap, which was covered with a transparent plastic lead also provided in the kit. The incision was washed out with bacitracin solution and sprinkled with vancomycin powder. The galea was closed with 3-0 inverted interrupted Vicryl sutures, and the skin was closed with running 4-0 nylon. Sterile dressings were applied. The head frame was removed. The pin sites were treated with bacitracin ointment. The patient was taken to the PACU for postoperative observation. There were no intraoperative complications noted. I performed the above procedures myself.

This was done assessing my right not the hand controlled by the newly inserted electrode.

Dictated by: Istvan Takacs, MD

Istvan Takacs, MD

Surgeon

1437 / 44076 /

MUSC Health

Medical University of South Carolina

Charleston, SC

843-792-2123

# Operative Note

**Patient:** **WHITE, THOMAS** **MRN:** **001756561**

Attending: Date: 1/25/11 12:00 AM

Status: FINAL

JOB: 6025380
DD: 02/06/11 06:14 PM
DT: 02/07/11 11:31 AM
Additional CC:_____
Authenticated and Edited by ISTVAN TAKACS, MD On 2/23/11 9:54:52 AM





**Dr. Istvan Takacs MD (DBS Neurosurgeon) performed a Bilateral "Right" Deep Brain Stimulation (DBS) operation on me on January 25, 2010 that violated all directives.**

**Listed below is proof of the above statement:**

1. **Care of the Movement Disorder Patient with Deep Brain Stimulation**



Note: MUSC used and are still using Medtronic products and this book should have been available when I had my surgery on January 25, 2010.

**Bilateral VIM DBS** is associated with stimulation-induced dysarthria from well-placed leads. Dysarthria is produced by current spreading into adjacent motor or capsular fibers. This can be minimized in some patients by programming adjustments, but sometimes this is not possible and a choice must be made to tolerate dysarthria in exchange for better tremor control. Others may choose to deactivate one implant during speaking engagements and activate both sides for fine-motor tasks. Additionally, control of proximal ataxia or cerebellar symptoms is more difficult to treat (often refractory to VIM stimulation) than distal (hand/wrist) tremor (Hamel et al., 2007).

For unclear reasons, **some patients with implants develop a type of ataxic gait disorder or trouble with balance after bilateral implants (Koller et al., 1997).** It is unclear if this results from the spread of current/stimulation to other regions connecting with the thalamus (cerebellar fibers), or if this is related to a patient's underlying disease progression after implant (Hamel et al., 2007; Herzog et al., 2007).

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2. **Deep Brain Stimulation in Neurological and Psychiatric Disorders**

**A quote from the book "side effects are more frequent with Bilateral DBS and that Bilateral DBS is not recommended". This book was written in 2008.**

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3. **Bilateral thalamic stimulation for the treatment of essential tremor**

Neurology. 1999 Oct 22

**Bilateral thalamic stimulation is effective in reducing tremor and functional disability in ET; however, dysarthria is a possible complication.**

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## 4. Gait and Balance in Essential Tremor: Variable Effects of Bilateral Thalamic Stimulation

Mov Disord. Feb 15, 2009

**Our present results show significant differences between those with ET who have bilateral thalamic DBS during both tandem and standard walking. In fact, our results showed a greater number of significant differences between groups for standard walking than for tandem walking. We also reported significant differences between the ET and control groups on balance and functional mobility measures.**

---

## Listed below is what Dr. Takacs actually did:

The Medical University of South Carolina prides itself as an academic medical center leader in **quality** and **innovation**. **Our medical team is constantly striving to discover, learn, and understand new medical advancements and technology that can save lives**.

**NOTE: The Movement Disorder Team (Dr. Takacs and Dr. Revuelta) failed to constantly strive to discover, learn, and understand new medical advancements and technology that can save lives.**

Dr. Takacs should have read his own book (**Care of the Movement Disorder Patient with Deep Brain Stimulation)** published by Medtronic in 2009 (because he used Medtronic products) and learn the many pitfalls using Bilateral DBS and the other articles and documents stating the many pitfalls of Bilateral DBS.

**Dr. Istvan Takacs MD (DBS Neurosurgeon) performed a Bilateral "Right" Deep Brain Stimulation (DBS) operation on me on January 25, 2010.** That violated all directives.

**If Dr. Takacs had not install the second DBS, then I would not have the side effects that I suffered from (now over four years)and if or when the blood got on my brain then the two DBS's would not have arched – eating lesions around both tips of my brain making my side effects permanent.**

# Qualifications for Deep Brain Stimulation Surgery

http://essentialtremor.org/treatments/surgical-treatments/
Potential candidates for surgical procedures are ET patients who do not experience satisfactory tremor control with medications, and **who have disabling tremor that affects their ability to perform activities of daily living such as eating, writing, drinking, dressing, working, or enjoying their hobbies.**

http://www.medtronicdbs.com/essential-tremor/about/what-is-dbs/index.htm
You may be a candidate for this therapy if you have essential tremor not adequately controlled by medications **and the tremor is keeping you from what you need to do.**

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=279&ncdver=1&NCAId=21&NcaName=Deep+Brain+Stimulation+for+Parkinson%2527s+Disease&IsPopup=y&bc=AAAAAAAACAAAAA%3D%3D&
For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

> **Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.**

http://www.mountsinai.org/patient-care/service-areas/neurosurgery/areas-of-care/center-for-neuromodulation/conditions-we-treat/essential-tremor
Qualifications for Deep Brain Stimulation

> In general, however, the treatment is most successful in patients who have:
> Not responded to traditional therapies or medications
> Have severe side effects to medication
> **Have an advanced form of ET that is impairing**

http://www.muschealth.com/neurosciences/about/movementdisorders/forms/4%20Movement%20Disorders%20Program%20DBS%20expedited%20referral%20form%2012%2007%2011.pdf
**MUSC Medical Center**

> To be a surgical candidate for tremor or dystonia**, these conditions need to be disabling** and medically refractory.

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**Listed above are only five of the many sources that state the qualifications for DBS surgery for essential tremor. All of them state the qualifications are "conditions that are disabling or impairing" even the MUSC Medical Center.**

**********

Prior to my first DBS surgery, on Sept 28, 2010, I was thoroughly checked out to make sure tremors were severe enough and that I met all the other criteria. At that time my tremor in my right hand was about a 3 inch swing and my left hand had about a 2 inch swing, conditions were disabling and impairing.

I first was examined by Dr. Athar, a neurologist, On April 23, 2010. She tried me out on three different medicines and none done anything to stop my tremors. Then she said that I passed her step of the qualifications for DBS surgery and she referred me to Dr. Wagner.

On July 19, 2010 I was seen by Dr. Wagner PhD a Clinical Neuro-psychologist. In his report he wrote "The patient was ambulatory with a steady gait. He had a fine action tremor right greater than left. He had some minor tremor in his head and mouth. In a cognitive testing, the MMSE was replicated and he continued to score 30/30 which is no change from 2007. On the RBANS, he scored in the low average range with some difficulty for sustained concentration. Executive function was within normal limits. Perceptual function was above the average. Delayed recall was low average. Fine motor dexterity was impaired right greater that left. Impression: 1. Essential tremor. 2. Age- associated memory loss. 3. No neuropsychiatric contraindications to proceed with DBS therapy. Discussion: The patient has a history of essential tremor now about 30 years in duration. He has not responded to multiple medication trails. He is unable to do many of the hobbies that he normally has enjoyed in the past because of the tremor including working on cars and boats. There are no neuropsychiatric contraindications for him to move forward with DBs therapy for the tremor."

I was examined by Dr. Takacs, MD, Neuro Surgeon, on September 18, 2010, and He wrote in his report "I think he would be a good candidate for VIM stimulation bilaterally and we would begin with placing a left- sided stimulator to control his right-sided tremor."

They performed surgery by placing a left- sided stimulator (DBS) to control his right-sided tremor on September 28, 2010. After the operation my right hand tremor was gone (steady) and the tremor in my left hand was minor – about one inch swing.

Without and more testing of my left hand Dr. Takacs wanted to do DBS surgery for my left hand. I told him that the tremors of my left hand were not bad enough for a DBS operation. He told me that I would need it later in time and it would be best to do it now. I thought he knew best so I agreed to the operation. There is no record of this discussion.

This operation did not meet the requirements listed above for the second operation. The second DBS surgery was performed on January 25, 2011.

01/25/11 : 04:04pm
dbs mer

(RIGHT SIDED DBS SYSTEM)

**PROCEDURES:**

1. Identification of the Vim and surrounding structures bilaterally by microelectrode recording.
2. Intraoperative micro and macro stimulation of the target area with clinical examination for confirmation of placement for the quadripolar deep brain stimulating electrodes.

**CLINICAL INFORMATION:**

**Indication:** ET

74 year old man with treatment refractory ET

**Duration:** 2_hours _30__min for preparation, recording, on-line analysis, stimulation, and examination.

**Right:**

Number of electrodes used in Ben gun array: 2_
Trajectories: 2__
Final DBS lead placement relative to imaged target:

_0_ mm anterior posterior
_0_ mm medial lateral
_0_ mm ABOVE OR BELOW image based original target

**MICROELECTRODE RECORDING:**

Deep brain intra-operative, single and multi-cellular electrophysiological recording was performed in order to avoid vital brain structures, define the boundaries of the target nuclei for provide optimal deep brain stimulation (DBS) electrode placement, and determine initial parameters of clinical effectiveness.

Recording is performed under sterile OR conditions as part of stereotaxic functional neurosurgery. On each trajectory of the recording electrode in the brain, monitoring began 25 mm above the provisional target, as determined by image fusion of CT and MRI brain scans.

The Alpha Omega MicroGuide Pro physiological navigation system was used to coordinate single and multi unit microelectrode recording and analysis with depth measurements using a computerized clinical micropositioner that advances the electrodes by 0.01 mm increments. Continuous simultaneous measurement and recording was performed with monitoring of signal amplification and filtering. Visual, audio and numeric microelectrode data was displayed and selected portions of the case are recorded by a PC based system. On line signal analysis is performed at various intervals of the trajectory for amplitude and wave frequency distribution using frequency raster, wave form analysis, oscilloscope, and chart recorder functions. Microelectrode impedance monitoring was performed to determine integrity of the entire electrical circuit.

**MACRO STIMULATION AND DBS LEAD TESTING:**

Mono-polar macro stimulation is performed via the micro-electrode canula at multiple locations within the target nucleus. Poor clinical response or adverse stimulation effects determines the need for a different trajectory to target. In the case of GPi placement, the boundary of the visual tract is located by microrecording of activity induced by strobe light. After final optimal depth of the electrode placement is recorded for the target area (VIM, GPi or STN), the microelectrode assembly is removed and the quadripolar electrode is placed in the micropositioner. The bottom most electrode is then placed at the target depth for DBS lead testing.

Testing of the DBS lead is then performed using the four electrode regions of the quadripolar DBS electrode with test stimulus delivered by Medtronic Stimulation Tester Model 3625. The electrodes are stimulated in combination with a 60-90 microsecond duration pulse, delivered at 90 - 200 Hz, with amplitudes ranging from 0 to 10 volts, with clinical examination of efficacy and evidence of electrical spread outside the target zone producing paresthesiae, visual phosphors, tremor, or corticospinal tract signs. Final DBS lead placement is then determined. Either lack of efficacy, presence of deleterious electrical stimulation or inadequate traversing of the target nucleus may be reason for further stereotaxic trajectories with microelectrode recording, and is documented below.

**NOTES:**

Track length:

There was robust bursting activity in both tracks, see recordings for exact track length.

Somatotopy:

Posterior: we found arm and leg motor driving in 4 areas throughout the posterior track.

Monopolar thresholds with Macrostimulation through the canula:

Center: 75% efficacy at 2mAmps 2 and 4 mm above target. Transient paresthesias present, no motor or sensory threshold reached at 3 mAmps.

Posterior: lip paresthesias at 0.5 mAmps, permanent at 1 mAmp, could not reach therapeutic amplitudes

Comments:

Although we did not identify Vc in the posterior track, we were clearly close to it, since sensory thresholds were very low when testing. Based on these findings and clear efficacy with wide therapeutic window in the center track we implanted there. Of note, there was significant insertional effect after implanting the DBS lead, so determinations regarding efficacy were limited.

Monopolar thresholds with the DBS lead were as follows:

0. 3 V, motor, 50%
1. 3 V, motor, 15%
2. 3 V, motor, 80%
3. 4 V, motor, 90%

Gonzalo J. Revuelta, DO
Director, Deep Brain Stimulation
Movement Disorders Program

# Dr. Revuelta knowingly inserts the DBS electrode in the wrong position

## Listed below is proof of the above statement:

1. Care of the Movement Disorder Patient with Deep Brain Stimulation
   

Note: MUSC used and are still using Medtronic products and this book should have been available when I had my surgery on January 25, 2010.

Tremor remains a challenging symptom to manage with DBS. In patients with a clear diagnosis of ET who have **well-placed leads,** however, VIM DBS has proven effective for long-term control of distal limb tremor (Koller et al.).

**High-frequency electrical stimulation interferes with or modulates abnormal brain circuitry through unknown mechanisms of action. The effect lasts as long as stimulation continues and ceases when stimulation ends.**

**The key to successful surgery is precise placement of the head frame to identify the target and other landmarks within the brain.**

2. **Avoidance and Management of Surgical and Hardware-Related Complications of Deep Brain Stimulation**
   Issue release date: September 2010

**With increasing experience of surgeons, complete obedience to intraoperative surgical routines and reasonable application of the microelectrode recording technique, other complications could also be reduced.**

3. **Medtronic For Healthcare Professionals**

- The system components (DBS Electrode) may be completely removed, preserving options for future therapies

.....

## 4. Functional Connectivity Targeting for Deep Brain Stimulation in Essential Tremor

- Published online before print September 1, 2011

**Long-term failure rates for deep brain stimulation in essential tremor have been reported to be 13%–40%, due to a hypothesized physiologic tolerance or suboptimal lead placement.**

In 1 study, **even as little as a 2-mm error in placement resulted in only a 17% chance of producing essential tremor control. And a 83% of not producing essential tremor control.**

---

## 5. Patient-Specific Modeling and Simulation of Deep Brain Stimulation

**The clinical result from DBS is very dependent on the anatomical placement of the electrode in the brain, and thus the surgical implantation procedure as well as the stimulation parameter settings of the device. As DBS has become more commonly used, there are also an increasing number of reports of postoperative adverse events including speech disturbances, depression, mood changes and behavioral problems (Hariz et al., 2008). Such side disorders are often associated with electrode misplacement or the stimulation settings in relation to the pre-defined target area selected for electrode implantation.**

**DBS targets the target area for implantation of the DBS electrode is preselected depending on the symptom that should be reduced, and is usually only slightly larger than the DBS electrode itself. This makes the positioning of the electrode crucial. The targeting, together with optimization of the stimulation parameters are therefore of utmost importance for an effective clinical outcome with minimal side effects.**

**The clinical result from DBS is very dependent on the anatomical placement of the electrode in the brain, and thus the surgical implantation procedure as well as the stimulation parameter settings of the device.**

---

## 6. Neurology, North Shore University Heath Systems (Arif Dalvi)

**The most common malfunction of an implanted DBS device is spread of electrical current from the area want targeted to other areas. For example, spread of current to centers that control speech can cause slurred speech instead of improving tremors.**

# 7. Patient-Specific Modeling and Simulation of Deep Brain Stimulation

By Karin Wårdell, Elin Diczfalusy and Mattias Åström

**As DBS has become more commonly used, there are also an increasing number of reports of postoperative adverse events including speech disturbances, depression, mood changes and behavioral problems (Hariz et al., 2008).** Such side disorders are often associated with electrode misplacement or the stimulation settings in relation to the pre-defined target area selected for electrode implantation.

**Note:** For patients with Essential Tremors the DBS electrodes tips are placed in the thalamus region of the brain, about 1 1/8 inches apart. Each DBS electrodes radiates a signal. When bilateral (two) DBS electrodes are installed the radiation from each tip will interfere with each other causing both to not work correctly and can never be programmed with a substantial program causing many side effects.

## Listed below is what Dr. Gonzalo Revuelta's actually did:

**Dr. Gonzalo Revuelta's (DO Director DBS Program) responsibility was to make sure the electrode and wires were operational and were positioned exactly in the correct position.**

Dr. Revuelta wrote in his January 25, 2010 report (attached) during the DBS operation on the placement of the DBS electrode "There was robusting activity in both tracks".

Note: The "robusting activity in both tracks" was caused by the radiation from each tip that will interfere with each other causing both to not work correctly. This was an indication that something was definitely wrong with the installation and he should have stopped the operation and removed the DBS electrode.

But he continued on and wrote in his January 25, 2010 report during the DBS operation on the placement of the DBS electrode **"Although we did not identify VC in the posterior track, we were close to it. Since sensory thresholds were very low when testing. Based on these findings and clear efficacy with wide therapeutic windows in the center track we implanted there. Of note, there was significant insertional effect after implanting the DBS lead, so determinations regarding efficacy were limited".**

As stated above "even as little as a 2-mm error in placement resulted in only a 17% chance of producing essential tremor control. And an 83% of not producing essential tremor control. **Dr. Revuelta said he was close. Also, said above "The key to successful surgery is precise placement of the head frame to identify the target and other landmarks within the brain". Dr. Revuelta did not position the DBS electrode in a spot where he identified the target; he said "Although we did not identify VC in the posterior track, we were close to it".**

He committed **willful gross negligence** when he knew that he was not placing the electrode in the optimal position and he completed the operation knowing that it was wrong.

He let me go to many doctors and take many tests trying to find out what was wrong when he knew all along and did not do anything to correct it. He should have stopped the operation and removed the Bilateral Right DBS Electrode. By not placing the electrode in the proper place he performed an unnecessary operation.

******

From my side effects, Dr. Revuelta knew that he had not placed the DBS electrode in the optimal position, that he ignored the whole time that I saw him and made no effort to find out what was causing my side effects. He could have used the vast expertise there at MUSC.

******

## STATEMENT MEDICAL MALPRATICE Summary:

May 16, 2014

For Thomas R White and the January 25, 2011 operation

**1. Dr. Istvan Takacs MD (DBS Neurosurgeon) performed a Bilateral "Right" Deep Brain Stimulation (DBS) operation on me on January 25, 2010. He was responsible for the operation and to oversee the insertion of the DBS Electrode and its associated wires. I have recently found out that a bilateral DBS stimulation should not have been used. HE did not keep up with the latest directives and policies about the problems of Bilateral DBS use and advise not to use Bilateral DBS on a person (Me) with "Limb" essential tremor problems. I have "Limb" essential tremors (Arms and hands). Unilateral (one) Deep Brain Stimulation (DBS) is used to treat "Limb" essential tremors. Bilateral (two) DBS's is not recommended for "Limb" essential tremor patients because it creates many side effects. Bilateral DBS's is used to treat patients with "Midline" (head, voice, tongue, and trunk) essential tremor. But the side effects have to be tolerated or reduced with bipolar programing. Some expert opinions are for and against Bilateral DBS for essential tremors. But all agree if Bilateral DBS for limb essential tremors you can expect severe side-effects and you have to consider:**

**1. Using Bilateral DBS and having Sevier side-effects and some control of the severe tremors.**

**2. Not using Bilateral DBS and having little control of the severe tremors.**

I should have been informed of **this and they should have let me choose which method I wanted.**

**I did not have severe tremors of my left hand (Right DBS).**

**2. During the operation on January 25, 2011 it was Dr. Gonzalo Revuelta's DO (Director DBS Program)** responsibility to make sure the electrode and wires were operational and were positioned exactly in the correct position. He committed willful gross negligence when he knew **that he was not placing the electrode in the optimal position and he completed the operation knowing that it was wrong.** He should have stopped the operation and removed the Bilateral Right DBS Electrode**. By not placing the electrode in the optimal position he performed an unnecessary operation that was against all medical official standards.**

**3.** The operation on January 25, 2011 caused many problems (symptoms). Here is a list of these problems/ Symptoms:

1. Lethargic
2. Walking
3. Balance
4. Vision
5. Dragging left leg
6. Constipation
7. Speech
8. Choking
8. Drooling
9. Trouble urinating
9. Dysarthria
10. Sometimes hard to think
10. Tremors – both hands
12. Movement delay
13. Stooped posture
14. Spacey at times
15. Muscle weakness

**4. Dr. Gonzalo Revuelta's (Director DBS Program) is guilty of failure to provide a proper standard medical care. Dr. Revuelta totally disregarded all my symptoms when he was informed by my family doctor, Dr. John F. Mattei MD, that I was diagnosed as having "Advanced Parkinsonism". Every visit with Dr. Revuelta he noted my symptoms/problems but made no effort to discover what was causing them.** I was **repeatedly** told that they (MUSC) could solve the symptoms/problems with one more programming session. I had nine programming sessions and each one worked fine for a few days and then my symptoms/problems returned. They kept saying to wait. MUSC never made any effort to find out what was causing my symptom/problems.

**5.** I had ten programming sessions and each one worked fine for a few days and then my symptoms/problems returned. Each and every time they failed to follow the latest directives on how to program a Bilateral DBS installation. They should have had the Medtronic "Care of the movement patient with DBS" book (MUSC uses Medtronic products and this is a 50 page guide, revised December 2009, of recommendations for the practice in DBS management). In that book, on page 33 under a section labeled I-4 explains how to program a Bilateral DBS installation with bipolar programming.

***no one used this method of programming**

**6.** About June 2011 blood was discovered pooling around the tip off one of the DBS Electrodes. When the blood got deep enough to cover both DBS Electrode tips and both DBS Electrodes were turned on arcing occurred. This arcing ate out lesions in my brain around each tip. Failure to prevent the lesions around both DBS Electrodes in my brain caused my symptoms/problems to be permanent.

1. When the blood started MUSC could have turned both DBS Electrodes off preventing the arcing.
2. They could have not installed the "Right" bilateral DBS Electrode.

7. After the operation I went to many doctors and had many tests trying to find out what was causing my problems. No one could tell me what was wrong. As a last resort, to find out what was causing my symptoms, I finally went to the Mayo Clinic in Jacksonville. On November 13, 2011 I saw Dr. Van Gerpen. In his report he wrote **"I am concerned about sequelae from DBS placement (in particular, the natural history suggests that there have been major changes after placement of the right lead). Certainly, there are reports about bilateral DBS being associated with gait dysfunction, dysarthria, etc."** I was **finally told by Dr. Wharen, on November 21, 2011, that the January 25, 2011 DBS operation was causing my symptoms. Certified copies of Dr. Van Gerpen's report and a letter from Dr. Wharen are attached.**

8. **Informed Consent:**
I signed a "Consent" form that said "Although we have discussed the potential likelihood of success, no guarantees or assurances have been made or given by anyone as to the results that may be obtained: bleeding, infection, damage to surrounding tissue." Dr. Takacs talked me into having the operation on the "Right" DBS system (Bilateral DBS). I said my tremors where not too bad on my left hand. But he said that it was best to do it now and that we would have no problems, same as the first time.
**Documented Facts:** There may also be complications of surgery, such as bleeding within the brain. After surgery, swelling of the brain tissue, mild disorientation, and sleepiness are normal. Once implanted, device related infection, skin erosion and/or system migration may occur. Medtronic DBS Therapy could suddenly cease because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return. Medtronic DBS Therapy may cause worsening of some motor symptoms associated with the patient's movement disorder, and may cause speech and language impairments. Stimulation parameters may be adjusted to minimize side effects and attain maximum symptom control. In patients receiving Medtronic DBS Therapy, depression, suicidal ideations and suicide have been reported. Occurrence of "fall" has also been reported. **This was not listed on the consent form that I signed for the operation. I did not sign or consent for an operation that directives and policies said not to perform Bilateral DBS operations for "limb" essential tremors due to serious side effects/problems.**

## CHARGE

**Summary:**

**1. Dr. Istvan Takacs MD (DBS Neurosurgeon) performed a Bilateral "Right" Deep Brain Stimulation (DBS) operation on me on January 25, 2010. He was responsibe for the operation and to oversee the insertion of the DBS Electrode and its associated wires. I have recently found out that a bilateral DBS stimulation should not have been used. HE did not keep up with the latest directives and policies about the problems of Bilateral DBS use and advise not to use Bilateral DBS on a person (Me) with "Limb" essential tremor problems. I have "Limb" essential tremors (Arms and hands). Unilateral (one) Deep Brain Stimulation (DBS) is used to treat "Limb" essential tremors. Bilateral (two) DBS's is not recommended for "Limb" essential tremor patients because it creates many side effects. Bilateral DBS's is used to treat patients with "Midline" (head, voice, tongue, and trunk) essential tremor. But the side effects have to be tolerated or reduced with bipolar programing. Some expert opinion's are for and against Bilateral DBS for essential tremors. But all agree if Bilateral DBS for limb essential tremors you can expect severe side-effects and you have to consider:**

**1. Using Bilateral DBS and having Sevier side-effects and some control of the severe tremors.**

**2. Not using Bilateral DBS and having little control of the severe tremors.**

I should have been informed of **this and they should have let me choose which method I wanted.**

**I did not have severe tremors of my left hand (Right DBS).**

9. **Informed Consent:**

I signed a "Consent" form that said "Although we have discussed the potential likelihood of success, no guarantees or assurances have been made or given by anyone as to the results that may be obtained: bleeding, infection, damage to surrounding tissue." Dr. Takacs talked me into having the operation on the "Right" DBS system (Bilateral DBS). I said my tremors where not too bad on my left hand. But he said that it was best to do it now and that we would have no problems, same as the first time.

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