The Myxo File: Part X
Edition III

Exposing the Truth
Twelfth Year of Reporting
2007-2019

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Table of Contents

Edition III

Dedication:

To My Faith, My Family and My Patients

Acknowledgment:

Ms. Toni Vlahoulis gives permission to use the photo of her valve ring on the front cover removed at the time of her second heart surgery at the Cleveland Clinic in May 2007.

The McCarthy Annuloplasty Ring Model 5100

All evidentiary documents can be found in the Senate Finance and Senate Judiciary Investigations as part of the public domain as submitted to the FDA investigative officials on December 19, 2018 for the Fifth time now with a full summary of the experimental protocol, to the United States Senate HELP Committee, the United States Senate Committee on Homeland Security and the House Committee on Government Oversight

Chapter One

US Senate Investigations:

https://www.finance.senate.gov/ranking-members-news/grassley-seeks-answers-about-the-use-of-a-heart-device-in-clinical-research

https://www.grassley.senate.gov/news/news-releases/grassley-seeks-documents-northwestern-university-heart-valve-device

https://www.grassley.senate.gov/news/news-releases/continues-press-northwestern-university-heart-valve-disclosures

Chapter Two

Exposing the Truth

On December 4, 2008, Sen. Charles Grassley, ranking member and Chairman of the Senate Finance Committee, opened an investigation of a scientific publication regarding the clinical outcomes of a newly designed and patented heart valve (Patent Number: 10/834556). The Myxo ETlogix heart valve, Model 5100, was designed for patients with myxomatous mitral valve disease. The Senator's primary concern was for the health and welfare of the patients enrolled in the study without consent to receive the experimental ring, and the payments from Medicare and Medicaid to support the research and development of the device.[1]

At the time of the investigation, the device manufacturer, Edwards Lifesciences, (Irvine, CA) and Northwestern University, (Chicago, IL) believed that the heart valve was "FDA approved" via a Justification to File process without any Food and Drug Administration regulatory submissions.[2] The Justification to File is an Edwards Lifesciences document which was provided to the United States Senate Finance Committee.[3]

A Justification to File essentially is internal documentation justifying that design changes to a medical device do not need new regulatory submission. This strategy is sometimes used for very minor improvements to an approved device that have been evaluated extensively and determined not to present additional risk to patients. Bigger changes or any potential new risk that was not present in the cleared design requires a new 510(k) application to the FDA.

Edwards Lifesciences' and Northwestern University's response to the United States Senate investigation included emails, documents and a regulatory history confirming the communications between Edwards Lifesciences and the General Counsel for Northwestern from August to September 2007. The documentation confirmed that Edwards Lifesciences, LLC, claimed that the device was approved for sale using a justification to file, as of March 2006 and that no FDA documents were available.

The manufacturer believed that this document served as the basis for FDA approval, that no further FDA disclosure was needed for testing or marketing of the device, and that no patient consent was necessary to test device in the early feasibility study.[4-5] However, the first in human testing guidelines are very strict and require the highest level of FDA oversight and patient consent for testing significant risk heart valve rings.

Northwestern University in statements to the Senate Finance Committee and Northwestern Memorial Hospital in the case of Obermeier versus Northwestern Memorial Hospital etc, (08-L-012426) patients gave consent to participate in the study by signing an outcomes registry to release their health care record data for the research, but did not give specific consent to test and or study the Model 5100 device after the surgical implantation in their hearts.

As an eye-witness and former participant[6] in referring patients to the experimental surgery, I removed my participation from the study and the final publication after I learned there was no informed consent to test the model 5100 for the first time in humans.[5]

I immediately began reporting to the Chief of Cardiology, the University, the Hospital administration and the Dean's office as of May 2007 and continue to report the unauthorized surgical testing to this date. It was after my reporting that the University's Institutional Review Board (research ethics board) office began to inquire regarding the regulatory status of the Model 5100. This was in August of 2007, just over one year after the experimental surgery began in March 2006. The US Department of Health and Human Services regulations for human subject protections require validation of the status of an FDA device testing prior to the start of the study. According to the FDA FOIA released on December 19, 2018, there was no validation performed by Northwestern University IRB regarding the FDA status of the device.

In July 2008, the FDA first learned of the sales on the US market of the Myxo ETlogix Model 5100. A patient and I reported the testing and experimental use of the device in the clinical study to the FDA's Center for Device and Radiologic Health.

On October 14, 2008, the FDA convened a meeting between Edwards Lifesciences and the FDA's Office of Compliance. The meeting was summarized in a power point submitted by Edwards Lifesciences to the US Senate Finance Committee. The FDA cited that the company had made three major mistakes in following the FDA 510(K) guidance document to internally "approve the Model 5100."[7]

The issue that the FDA had with Edwards Lifesciences internal approval process stemmed from the major changes Edwards Lifesciences made to the model 5100, including the shape, biomaterials, indications for use, and directions for use in patients with myxomatous mitral valve disease. These major changes required the company to check the box "Yes" for question 8.3 of the 510(k) guidance regulations, and not the answer cited in the internal justification to file document, "No",[7] according to the power point summary of the meeting which was provided to the US Senate Finance Committee and released during meetings with the Senate Finance, Judiciary, HELP, Homeland Security Committee and House committee on Government Oversight to the FDA, and to the HHS Inspector General. Also released in letters sent by Senator Ron Johnson to the HHS IG and Congressman Glenn Grothman to the FDA.

Edwards Lifesciences placed the model 5100 and the model 4100 on an urgent recall, which began on December 5, 2008. The recall occurred the day after the Senate Finance Committee investigation was announced.[8] The recall was reported to investors of Edwards Lifesciences.

However, Edwards Lifesciences and Northwestern Memorial Hospital, did not inform the patients of the urgent recall.

The Director of the FDA compliance office further confirmed misbranding and failure to report adverse events as related to the Model 5100 in a warning letter to the device manufacturer Edwards Lifesciences in 2010, after a surprise inspection of the manufacture's plant facility in the fall of 2009.[9]

I had met with the Director of the FDA Compliance division, Mr. Timothy Ulatowski, three times in 2009 at the FDA, reporting my concerns regarding the violations of the patients' rights, several adverse events,

and the FDA regulations, which require informing the patients of the experimental surgeries.

Finally, on October 13, 2016 and January 25, 2017, I received the two letters from the FDA at my practice in Sheboygan WI, The Most Sacred Heart of Jesus Cardiology and Valvular Institute.

The FDA Office of Scientific Integrity confirmed that they would not inform the patients of the recall of not one but two heart valves, the Model 4100 and the Model 5100, during which Edwards Lifesciences pulled these valves from hospital shelves as of December 5, 2008. They also confirmed that they would not warn the patients of the potential safety issues as related to the device.

The FDA cited their 2009 letter to the Senate Finance Committee and Sen. Richard Lugar of Indiana, as the reason to deny my request to help the patients. In this letter, the FDA compliance office utilized only the results from the published clinical study, as reported by the FDA to the Senate Committee, [5] which excluded several adverse events, including heart attacks and deaths.

In fact, the FDA letter in response to the Senate Finance Committee's investigation, stated that the device caused no heart attacks and no deaths reported in the final scientific publication. That was despite the FDA's own MAUDE (Manufacturer and User Facility Device Experience) database reporting 2 heart attacks and 2 deaths related to the Myxo ETlogix device.

Relying upon the responses submitted to the Senate Committees, Sen. Grassley (Iowa) was led to believe that the device was not tested in any type of clinical trial. He also was led to believe that the registry consent was enough for the patients, who thought they had received an "FDA approved device" for sale on the US Market as of March 2006—something which was safe and fully ready for use in humans.

However, the documents attached to the responses told another story. In the regulatory history summary, Edward Lifesciences failed to mention to the United States Senate that there was a prototype which was undergoing months of testing in humans and in the Edwards Lifesciences own bioengineering testing facilities to determine the safety issues surrounding the new design, shape, and biomaterials for the Model 5100. A device which would require humans with the diagnosis of myxomatous mitral valve disease, since the FDA acknowledged to the company that there are no animal models with myxomatous mitral valve disease to test the device for safety and efficacy.

All of the above specifications noted by the FDA during the Compliance meeting on October 14, 2008 are the critical components necessary for prospective clinical trials:

1) pre-trial validation of the status of the device,
2) pre-trial application for an Investigational Device Exemption,
3) pre-trial submission of documentation to Northwestern University IRB for permission test in patients,
4) pre-operative informed consent from the patients before implantation into their hearts,
5) post-operative life-long follow-up of these patients to identify any complications, harm, adverse events all reportable to the FDA under the Federal Wide Assurance 00001549 signed by the Institute Officer for Northwestern University, who is the Vice President for Research.

None of the five components were completed under the Federal Laws to protect the US citizens.

In 2014, the Senate Judiciary committee reopened an investigation questioning Northwestern University, regarding failure to submit documents to the Senate Finance Committee. These related to the Institutional Review Board approval of the research supporting the use of the Myxo ETlogix device in patients.

The newly discovered documents from the public docket of the Circuit Court of Cook County,[10] revealed that prior to open heart surgery, patients signed either an atrial fibrillation outcomes registry or a clinical outcomes registry, as confirmed in the responses by Northwestern University to Sen. Grassley the chairman of the Senate Judiciary Committee in 2014.[11,12] He began investigating the testing and sales of the device in 2008, while he was the ranking member on the Finance Committee.[1]

This position was justified to the Senate Judiciary Committee by the University, and the device manufacturer, to publish the clinical test results in the Journal of Thoracic Cardiovascular Surgery, without patients' consent to receive the device while under general anesthesia. They believed the device to be "FDA approved" during the use of the device in the published study.[5]

The FDA decided that no consent was ever necessary to test the device, and that Edwards Lifesciences had made an honest mistake in determining when to submit a new 510(k).[13]

The court docket still did not have all of the IRB evidence and the IRB inspection records back in 2014.

EXPOSING THE TRUTH THE EVIDENCE SUBMITTED TO THE SENATE COMMITTEES

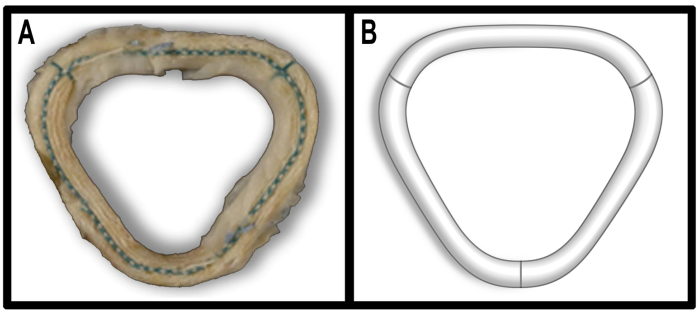
In 2015, I met with the Senate Finance Committee and the Senate HELP (Health, Education, Labor and Pensions) Committee. After reviewing hundreds of pages of documents with the committee staff, the evidence emerged regarding the true history of the research and development of the Model 5100.

Here is a brief outline:

1. October 13, 2005, a meeting was held at the Tommy Bahama's Restaurant in New Port Beach CA. Edwards Lifesciences and the inventor of the valve ring, Dr. Patrick McCarthy, met to decide which prototype would be used: an open or a closed ring. They also determined a surgical schedule, deciding that after the first ten implants, the device would be sent to other test hospitals.
2. The Senate Documents revealed that there were two versions of the model 5100. One was the prototype identified as the "McCarthy annuloplasty Ring" which at least 60+ patients received during the research and development phase the testing of the device. This version of the device was never discussed in the public, it was never disclosed to the FDA in an application for an Investigational Device exemption, and it was never disclosed to the patients who received the ring.[2]
3. The Senate documents revealed that Edwards Lifesciences categorized this model as "pre-production in human" phase. On March 3, 2006, Edwards Lifesciences regulatory officials signed a first in human use certificate for the initial implantation of the Model 5100, again without any notification or registration to the FDA. During the next several months, Edwards Lifesciences identified 122 failure modes or potential "product defects" as summarized in a Failure Model Effect Analysis (FMEA) document. [14]
4. On November 20, 2006, the manufacturer and inventor documented the modifications made to the

first version of the device several times to ensure safety and efficacy of the device, prior to the official sales on the US Market. Modifications including changes to the core of the ring, changes to the directions for use and an addition of a green marker to identify the front from the back of the ring,[14] **Figure 1**.

5. **Figure 1**



Panel A: McCarthy Annuloplasty Ring Model 5100, February 26, 2006 to November 20, 2006.

Panel B: Myxo ETlogix, Model 5100, November 20,2006-December 5, 2008.

A mark which in my graphic rendition is a slash mark at the bottom of the ring. This mark which in the actual device is "a green V Suture mark" that was needed in the second version of the device, on November 20, 2006 to guide surgeons, the front from the back of the ring before surgical placement of the ring.

Edwards Lifesciences then submitted an application to the US Trademark office and was awarded a certificate confirming that on or after January 24, 2007, the Myxo ETlogix would be used for the first time in human beings.[15]

The Myxo ETlogix, the second version of the valve, was available on the US market, which also corroborates with Edwards Lifesciences SEC disclosures, and an official release in a press release at the time of the Society of Thoracic Surgeons meeting in 2007.[16]

The design of the model 5100, both versions, the feasibility testing, the modifications and the US market press release, and SEC disclosures were all completed without FDA oversight. The FDA confirmed to Senator Grassley in March 2009 that the Myxo ETlogix annuloplasty ring is of significant risk and did not have a 510(k) or and IDE approval for the Myxo ETlogix Annuloplasty Ring. The FDA further confirmed to the Senator that any device which is not cleared or approved would be required to be studied under an Investigational Device Exemption.

The FDA Guidance on first in human use studies,[17] confirms the need for informed consent for feasibility testing prior to sales on the US market. The testing of the device during the limited release, first in human feasibility study was confirmed in the open court proceedings in the Circuit Court of Cook County.[10,18]

During cross-examination by the patient's attorney, valve ring inventor Dr. Patrick McCarthy confirmed under oath on March 31, 2016 that he was testing the model 5100 as a limited release in 2006. During depositions in the same case, he testified to the use of the calipers to size the device. He acknowledged he was the first surgeon to test the device before he gave the approval to Edwards Lifesciences to expand the

release of the limited release of the heart valve to a handful of other surgical testing sites. He also confirmed in 2011 responses to the third amended complaint in the court case[19] that the plaintiff did indeed suffer a myocardial infarction (heart attack) during the surgery.

This evidence was provided to the Northwestern University Board of Trustees and the Department of Justice in the Northern District of Illinois on May 25, 2016, with no response to the information regarding the IRB violations, and the testing.

On a related note, Boston Scientific, Maple Grove, MN, reported to investors on Feb. 23, 2017 via a Security Exchange Commission (SEC) filing a global recall of the Lotus Valve replacement system. During the testing, prior to the FDA pre-market approval process, Boston Scientific discovered an unexpected complication in the deployment technology.[20] Boston Scientific should be commended on following the FDA guidelines for reporting any identified problems of the valve pending future FDA approval, during feasibility testing for safety and efficacy. Boston Scientific confirmed that the patients provided informed consent prior to receiving the Investigational Device Exemption device, as documented on the FDA website with the posted IDE for the Lotus valve.

Boston Scientific's honest approach serves as an example for the steps the FDA should take in response to the testing, sales, recall and known safety issues related to the model 5100 and the 4100, another heart valve tested in patients in a clinical feasibility study.

Over the past 12 years, I reported the several adverse events in patients who received the Edwards Lifesciences device during the clinical testing, including heart attacks, deaths, infections, reoperations and other events to the FDA, the Federal Bureau of Investigation, the Office of Inspector General at HHS, the Department of Justice, the University, Senate and Congressional Committees.

Only Sens. Grassley and Lugar wrote letters seeking answers to the allegations from my eye-witness testimony and the FDA's failure to help the patients. Only aides and Congressman Grothman of Sheboygan, WI, met with me to discuss the experimental surgeries and violations of the FDA regulations, and contacted the FDA. Only aides for Senator Ron Johnson of WI, discussed the issues and contacted the HHS Inspector General. Only one FDA officer in the FDA's division of criminal investigations, Michael Redmond followed up via email confirming the issues, while he tried to get information to the senior officials at the FDA, spoke to the Senate Judiciary Committee and reviewed the Senate Documents to help the patients.

Still to this date, CDRH FDA has refused to report the testing, the recall and the safety issues to the patients who participated in the limited release-feasibility study without consent. Even after a meeting with the FDA officials in Minneapolis District office on December 19, 2018 to review the discoveries in the Senate documents and the patients' adverse events.

Still to this date, the Office for Human Research Protections (a small office within HHS that deals with ethical oversight of clinical research) refuses to help the patients who were enrolled in a feasibility study as of September 1, 2016. OHRP's Dr. Kristina Borror, in an email, cites that the ring was used for "clinical purposes and not research purposes" using a clinical database and not involving experimental surgeries despite the testing in patients of Medicare age. NIH's Dr. Lawrence Tabak, in an email, cites a similar

response with no further investigation despite the use of NIH funding for at least one of the investigator's salaries.

In 2019, I can confirm without hesitation, that the Model 5100 was tested in a limited release, first in human use study without informed consent and without FDA approval for an Investigational Device Exemption, to study the initial prototype and the second version the Myxo ETlogix, Model 5100. These 667 patients are at risk for serious safety issues as related to the biomaterials, shape and known outcomes of heart attack and deaths, which were never reported in the published clinical feasibility-first in human use Model 5100, in 2008.

To date, 667 patients who received the Model 5100 before it was FDA approved for sale in the United States still do not know the hidden safety issues, the recall and the illegal testing without informed consent of the early prototype, which underwent several modifications before the second version of the device was improved for safety and efficacy and prior to the official sales on the US market on or after January 24, 2007.[15]

As of today, there are no FDA regulations listed on the FDA website, confirming an FDA path to 510(k) approval using the approach of a "Justification to File." There is no law posted on the FDA website, which allows a device manufacturer to modify, test, sell and report to investors using Security Exchange Filings, a new device, with a new indication for use, without informing the FDA via a PMA (Pre-Market Approval), IDE (Investigational Device Exemption), and/or a 510(k) application.[21]

According to the October 14, 2008 FDA compliance meeting between the FDA and Edwards Lifesciences, the criteria noted for the novel changes in the Myxo ETlogix Ring, would require an IDE and a PMA not a 510(k) because the device had a new indication for use: to treat specifically myxomatous mitral valve disease.[7]

Instead of enforcing the CFR21 (federal regulations that govern food and drugs within the United States), which would have protected the patients immediately, the FDA gave the device manufacturer a pass regarding the mistakes made for testing, selling and failing to register the device in the FDA MAUDE database.

Instead of following the FDA laws, CFR21, the FDA allowed the company to change the indication for use, change the name of the device, and apply for a new 510(k) for the third version of the device. The DETOLOGIX[22] model 5100 is a 510(k) approved device for the use in patients with any type of mitral valve insufficiency.[23]

This new device, with a new name and an indication for use would comply with the FDA 510(k) path to approval, and give the company the legal right to sell the third version of the device in the United States. The company submitted the 510(k) application for this new device on October 29, 2008, and the FDA, senior scientist Dr. Bram Zuckerman, approved the device (K083191) on April 10, 2009.[23] Edwards Lifesciences has not been sold the third version of the device for several years.

In summary, all devices which are sold in the United States need to be registered for sale in the FDA database, so that the FDA can monitor the safety and adverse events using the MAUDE database since

1996.[24]

Finally, according to the FDA Compliance committee PMA regulations,[21] Edwards Lifesciences needed to submit an IDE application for the Model 5100, the Myxo ETLOGIX annuloplasty ring for myxomatous mitral valve disease prior to the testing in the patients. Edwards Lifesciences and Dr. McCarthy—the inventor, the surgeon and the principle investigator for the Myxo ETlogix "limited release," first in human use, feasibility trial—are required to inform the University prior to the start of the study, under the HHS laws to protect human subjects, for performing experimental studies.

All of the evidence presented in this report are documents which are now part of the public domain and part of the Senate Investigations of this device as listed in Chapter One.

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CHAPTER THREE

YEAR TWELVE OF REPORTING TO THE LOCAL AND FEDERAL ENTITITES AND THE NEW COURT FILING 2-1401 FRAUDULANT CONCEALMENT FAILURE TO OBTAIN CONSENT

On December 18, 2018, FOIA Documents were released by the FDA to Dr. Rajamannan. The documents reveal that the Cardiac Surgeon Implanted Experimental Devices without Consent

A years-old case involving non-FDA approved heart valve repair rings is back in court due to newly released records indicating a Northwestern Memorial Hospital cardiac surgeon and others may have fraudulently concealed evidence. The documents re-ignite questions about whether Dr. Patrick McCarthy, who implanted a device he invented into hundreds of patients, was simply recording outcomes after standard procedures or conducting a human research study/implanting investigational devices without their consent.

Maureen Obermeier, of Chicago, is asking for a new trial, based on records recently released under a Freedom of Information Act request. She alleges that the head of cardiac surgery at Northwestern and others withheld evidence critical to her original lawsuit, which was dismissed in 2016.

Obermeier's former cardiologist, Dr. Nalini Rajamannan, submitted a FOIA request for various documents that previously had not been released, including an FDA inspection report. She received those documents in December and has compiled a comprehensive report on what she believes to be a sweeping case of experimentation without patients' consent.

By the time the FDA approved the Myxo ETlogix heart valve ring, Model 5100 in 2009, the ring had been implanted into 667 patients. Rajamannan was practicing medicine and doing research at Northwestern in 2006 and 2007, including work on McCarthy's Myxo ring study. She was told that the patients enrolled in the study at Northwestern University and Northwestern Memorial Hospital in 2006 were receiving full consent to participate in the study.

One of the study patients told Rajamannan in 2007 that she hadn't given consent to test that heart valve. The patient needed a second heart surgery to remove the prototype device. Rajamannan immediately removed herself from any participation in the study. She has reported her concerns to the university, the FDA and Congress.

That patient and others suffered permanent damage to their hearts after their surgeries.

Obermeier contends that Northwestern did not tell her she had suffered a heart attack during a surgery to have her valve ring implanted in 2006. She later received a surgically implanted pacemaker and defibrillator and filed suit against McCarthy, Northwestern, Northwestern Medical Faculty Foundation and Edwards Lifesciences. Obermeier claims she had no idea McCarthy had invented the ring he implanted in her and that he might have had a financial incentive to use it on his patients.

McCarthy contended he didn't know the valve he was implanting didn't have FDA approval. The FOIA

documents indicate that McCarthy originally had applied to do a retrospective (back-looking) review of his patients through June 2006, which did not require their consent.

Later, he applied to do a study of later patients who received the valve ring, but the Institutional Review Board wrote that expanding the study would be prospective (forward looking) and therefore would require different protocols and patient consent.

The existence of the IRB inspection records were revealed only in an FDA Freedom of Information sent to Dr. Nalini Rajamannan on December 18, 2018 on the eve of the most recent FDA investigation meeting held at the Minneapolis District office on December 19, 2018.

The inspection record revealed that the Model 5100 was undergoing testing, but also a novel method to determine a caliper based sizing protocol was also part of the prospective 1532-004 clinical forward moving study.

McCarthy wrote that he had decided not to pursue the extended study and was terminating. But the FOIA documents show he continued to study patient outcomes on the valve at least through November 2007, as published in a 2008 report.

Obermeier's request for a new trial is pending in Cook County Circuit Court. A status hearing is scheduled on the petition for May 2, 2019 in the Circuit Court.

ONGOING VIOLATIONS OF NORTHWESTERN UNIVERSITY FDA HUMAN SUBJECT PROTECTIONS UNDER THE FWA 0001549

1) Not giving consent to patients

2) Northwestern University "1532-003" IRB protocol to enroll patients in a database, which allowed the surgeon to perform secret human experiments to test his inventions without FDA oversight and without patient consent and without HHS Medicare pre-authorization, funded under the Bluhm Institute.

3) Northwestern University waives patients' rights to know they were being tested upon at least for the first few months under the IRB study protocol 1532-004. A failure to inform the patients by using the expedited HIPPA waive, and failure by Northwestern University IRB to determine the FDA status of the Model 5100 at the time of the study dates.

4) Dr. McCarthy requests another waiver in 2007, but this time the University IRB recognizes the prospective future study of the Myxo Ring, and then issues a cease and desist order to test the device and to test the measurements.

5) Dr. McCarthy and colleagues continued the research trial after the cease and desist without consent for another 5 months and enrolled 75 more patients without the University IRB approval.

6) Dr. McCarthy and colleagues published the study in July 2008, failing to mention the serious

adverse events reported to the FDA on December 19, 2018.

https://www.scribd.com/document/396114790/FDAAffidavit-Investigation-and-Testimony-from-the-Victims-12-19-2018-JMJ

https://www.scribd.com/document/399069069/Final-FDA-MEETING-JMJ

7) Northwestern University leaders refuse to meet with the patients despite the harm, injuries and ongoing loss of life secondary to the experimental protocol.

8) There are 667 patients who received the Model 5100 prior to the recall of the device in December 2008, who have not been informed of the status of the model 5100 at the time of their open heart surgery.

2-1401 PETITION

On February 22, 2019 the plaintiff in the case 08-L-012426 Obermeier versus Northwestern Memorial Hospital, Northwestern Memorial Faculty Foundation, Edwards Lifesciences and Dr. Patrick McCarthy filed a 2-1401 Petition in the Circuit Court of Cook County.

The Myxo Report by Dr. Nalini Rajamannan as published on Amazon.com has a copy of the public court record of the petition.

The petition incorporates the facts as revealed in the FDA FOIA critical in the case of Obermeier versus Northwestern Memorial Hospital, Northwestern Memorial Faculty Foundation, Dr. Patrick McCarthy and Edwards Lifesciences, LLC.

Facts which were never disclosed as evidence during the court proceedings, motions and court trial.

Evidence only revealed in the case as filed in the petition 2-1401 on 2-22-2019 in the Circuit Court of Cook County, Chicago Illinois by the plaintiff Obermeier.

PLEASE REFER TO THE MYXO REPORT PUBLISHED ON AMAZON ON APRIL 22, 2019[25]

On May 2, 2019 at 9:30 am, during the status hearing Northwestern defendants requested permission to file a motion to dismiss the 2-1401 petition instead of acting upon the newly discovered evidence in the FDA FOIA to help the patients who received the experimental device. A requirement under the Federal Wide Assurance signed by the Institute Officer for Northwestern University.

REFERENCE

25. New evidence shines spotlight on old case over illegal heart valve implants , Fisher J. DOTMED.com Accessed May 1, 2019 https://www.dotmed.com/news/story/47115

This link has now been removed from the website similar to other stories, interviews etc over the years.

PERMISSION

Permission was obtained from Ms. Vlahoulis for her photo of the McCarthy Annuloplasty Device Model 5100 that was removed at the Cleveland Clinic for the cover of the Myxo Files Series.

About the author

Dr. Nalini Rajamannan is a heart valve expert in the field of cardiovascular medicine. She has been researching heart valve disease for 31 years. She earned her undergraduate science pre-professional degree from the University of Notre Dame, her Medical Doctorate from Mayo Medical School and her post-graduate training in Internal Medicine and Cardiology at the Mayo Clinic. She also worked at the Mayo Clinic as a staff consultant in Internal Medicine. Currently, she practices consultative medicine specializing in Cardiac Valvular Heart Disease at Most Sacred Heart of Jesus Cardiology and Valvular Institute, WI.