The Myxo Report

The FDA Evidence of Human Experimentation without Consent and without Northwestern University Approval

A decade later the FDA released the Health and Human Services Inspection Report of Northwestern University Human Subject Protections confirming that the Myxo Protocol Study "004" was closed as of June 2006 and no further testing was allowed at Northwestern University of the device.

Nalini M. Rajamannan, MD

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DEDICATION

“To one who has faith in God, no explanation is necessary.

To one without faith in God, no explanation is possible.”

— **St. Thomas Aquinas**

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ACKNOWLEDGMENTS

Court Records from the Public Docket Circuit Court of Cook County.

The Myxo Report is a 2019 summary of the Myxo Files.

CHAPTER ONE

FAILURE TO OBTAIN CONSENT

FOIA Documents: 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.

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.

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.

CHAPTER TWO

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.

Below is 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.

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

MAUREEN OBERMEIER,	)	
Plaintiff,	)	
v.	)	No. 08 L 12426
NORTHWESTERN MEMORIAL HOSPITAL,	)	
NORTHWESTERN MEDICAL FACULTY	)	
FOUNDATION; PATRICK MCCARTHY, M.D.;	)	
EDWARDS LIFESCIENCES, LLC.	)	
	)	
Defendants.	)	

PLAINTIFF'S PETITION PURSUANT TO 735 ILCS 5/2-1401

NOW COMES the Plaintiff, MAUREEN OBERMEIER, by her attorneys, NEWMAN, BOYER & STATHAM, LTD., and moves this court pursuant to 735 ILCS 5/2-1401 to vacate the judgment order of April 1, 2016 entered on the jury verdict in favor of Defendants, Northwestern Memorial Hospital, Northwestern Medical Faculty Foundation, and Patrick McCarthy, M.D. (herein collectively the "Northwestern Defendants") and to vacate the order of January 30, 2017 denying Plaintiff's post trial motion, and further, moves for a new trial and for such other relief requested herein or as the Honorable Court might deem appropriate. In support thereof, Plaintiff states as follows:

Introduction

1. Plaintiff brings this petition to vacate the April 1, 2016 judgment order on a jury verdict. (Ex. 1401-03)[1] and to vacate the order denying Plaintiff's post trial motion

[1] This motion cites new documents recently obtained by a witness through a FOIA request and recently provided to Plaintiff's counsel, as described herein. Aside from these new documents, all other documents and evidence are contained in the record of this case, now the record on appeal. Many of these documents were used during depositions, in motions, during summary judgment and at trial, and the documents thus have multiple bates and exhibit numbers, including records on appeal bates numbers. In this motion, plaintiff refers to the documents cited herein by new 1401 exhibit numbers, e.g., Ex. 1401-1, 1401-2, etc. Attached hereto as Ex. 1401-1 is a chart which cross-references each document with their record on appeal

entered on January 30, 2017. (Ex. 1401-04). Plaintiff seeks a new trial and other appropriate relief based on critically dispositive newly discovered evidence which was concealed by the Northwestern Defendants during the previous trial court proceedings.

2. Plaintiff filed a timely notice of appeal. Ex 1401-05. The appeal is fully briefed and is pending. *Obermeier v Edwards Lifesciences, LLC, et. al.*, No. 17-0553. Plaintiff intends to seek an order from the appellate court which stays the appeal pending the outcome of these §2-1401 proceedings before the trial court.

3. This Petition meets the requirements of Section 2-1401 (a) and (b). Section 2-1401 of the Illinois Code of Civil Procedure, 735 ILCS 5/2-1401 allows relief from final judgments or orders after 30 days from the entry thereof. Id. §2-1401(a). Section §2-1401 Petitions must be filed in the same proceeding in which the judgment order was entered. 5/2-1401(b). This Petition meets these requirements.

Timeliness

4. A §2-1401 Petition must be filed not later than 2 years after the entry of the order or judgment. §2-1401(c). However, where the ground for relief is fraudulently concealed from the Petitioner, the time of the concealment is excluded from computing the 2 year period. *Id.* This Petition sets forth facts which show that this petition is timely under the fraudulent concealment provision of subsection (c). *In re Marriage of Emerson*, 15 Ill.App.3d 712 (2nd Dist. 1983) (petitions filed more than two years after the entry of judgment must show that the grounds asserted for relief were fraudulently concealed from the petitioner).

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bates numbers. Exhibits which are designated confidential are referred to with an "R" prefix, e.g., Ex. R-1401 - ___.

5. The failure to comply with the obligation of full and truthful disclosure imposed on litigants by the rules of discovery constitutes fraudulent concealment for purposes of tolling the limitations period of §2-1401. *Ostendorf v. International Harvester Co.* (1982), 89 Ill. 2d 273 (1982) explained:

> As regards petitioners' diligence in discovering the ground for relief, we think a litigant exercises ordinary diligence in pretrial discovery when he poses interrogatories reasonably calculated to elicit the information important to his case. If his opponent then suppresses information within the scope of the interrogatories in such a way as to prevent the inquirer from realizing what has occurred, the failure to discover the information is the result of the former's fault, not of the latter's negligence.
>
> One of the guiding principles in the administration of section 72 (now 2-1401) relief is that the petition invokes the equitable powers of the court, which should prevent enforcement of a judgment when it would be unfair, unjust, or unconscionable. *Elfman v. Evanston Bus Co.* (1963), 27 Ill. 2d 609, 613; *Ellman v. De Ruiter* (1952), 412 Ill. 285, 292.) We note that in both these cases the unfair conduct of counsel was a factor in the court's determination that section 72 relief was warranted. As the court stated in *Elfman*, "'Something more than the morals of a medieval market may reasonably be expected in the conduct of litigation.'" 27 Ill. 2d 609, 615, quoting *Jansma Transport, Inc. v. Torino Baking Co.* (1960), 27 Ill. App. 2d 347, 354. *Ostendorf*, 89 Ill.2d at 284-285

6. Plaintiff filed this Section 2-1401 Petition within thirty (30) days of learning of the new FOIA evidence which was concealed by the Northwestern Defendants

Elements of 2-1401

7. To prevail on a §2-1401 petition, the petitioner must prove (1) that if the ground for relief had been known at trial it would have prevented the entry of judgment against him, and (2) that failure to discover and present the ground for relief was not the result of his own lack of diligence. *Ostendorf v. International Harvester Co.* 89 Ill. 2d 273, 283 (1982) (vacated order dismissing §1401 petition). Plaintiff's Petition meets

these burden of proof requirements.

Plaintiff's Informed Consent Claims

7. This case proceeded to trial on two claims; one charging Dr. McCarthy with professional negligence for failing to diagnose and treat Plaintiff's intra-operative heart attack (Ex. 1401-06, Plaintiff's Instruction No. 12); and two, charging Dr. McCarthy with the failure to inform Plaintiff that she was receiving a new medical device (the Myxo Ring) as part of a study Dr. McCarthy was conducting, and further failing to inform Plaintiff that the Myxo Ring was an investigational device (Ex.. 1401-07, Plaintiff's Instruction Nos. 21-13). See also, 1401-09, Plaintiff's Fourth Amended Complaint, Count VII (informed consent versus Dr. McCarthy).

8. Plaintiff's Jury Instruction No. 23 (Ex. 1401-07) states the burden of proof on Plaintiff's informed consent claim:

> As to Count II for Informed Consent, the plaintiff has the burden of proving each of the following propositions:
>
> First, that Dr. Patrick McCarthy conducted a human research study involving a medical device, that he failed to inform the plaintiff that he was conducting a human research study involving a medical device and that a reasonable physician would have disclosed this information to the plaintiff under the same or similar circumstances,
>
> OR
>
> First (dealing with an investigational device).....
>
> Second, that if Dr. Patrick McCarthy had disclosed the research study or the use of the investigational device, a reasonable person in the plaintiff's position would not have given her consent;
>
> Third, that the plaintiff was injured; and
>
> Fourth, that Dr. McCarthy's failure to disclose the research study or the likely use of an investigational device was a proximate cause of plaintiff's injury. *Id.*

9. Plaintiff's informed consent claim raised two independent theories. Plaintiff thus only needed to prove either that (a) Dr. McCarthy conducted a human research study involving his medical device (the Myxo Ring) on the Plaintiff without informing her; OR (b) that he used an investigational medical device on the Plaintiff without informing her. *Id.*

10. Dr. McCarthy's and the Northwestern Defendants' primary defense to the informed consent claim was that the study conducted by Dr. McCarthy did not constitute "research" for informed consent purposes. They claimed that Dr. McCarthy was simply doing a "retrospective" review of medical records included in the Northwestern Outcomes Registry which he then reported on his record reviews. As such, they claimed that patient consent was not needed.

11. The undisputed evidence established that Dr. McCarthy invented a new annuloplasty ring called the Myxo ETlogix ring (Myxo Ring). In 2006 through 2007, Dr. McCarthy implanted his new Myxo Ring into his patients at Northwestern Memorial Hospital. He published an interim abstract with the Society of Thoracic Surgeons (STS) on 6/30/06 entitled *Initial Experience with a Mitral Valve Repair Ring Designed for Myxomatous Mitral Valve Disease.* (Ex. 1401-15). He then published a second abstract with the American Association for Thoracic Surgery (AATS) entitled, *Novel Surgical Approach to Myxomatous Mitral Valve Repair*, reporting results of his Myxo Ring from 4/06 to 9/06. (Ex. 1401-16). Dr. McCarthy then in July 2008 published the final results of his Myxo Ring study in the Journal of Thoracic and Cardiovascular Surgery, entitled *Initial Clinical Experience with Myxo-ETlogix Mitral Valve Repair Ring* (Ex.1401-17). The first abstract in June 2006 reported results of the Myxo Ring in 18 patients as of

6/30/06. The second abstract in 9/06 reported the results of the Myxo Ring in 36 patients as of 9/06. Maureen Obermeier's surgery was on 11/6/06.

12. Dr. McCarthy's final Myxo Ring paper reported the results of the Myxo Ring in 100 patients as of November 19, 2007. Dr. McCarthy claimed he had the approval of Northwestern's Institutional Review Board (IRB) to perform this study. (Ex. 1401-17 at SUP E 10174 v7). The newly discovered FOIA documents establish that as of June 2006, Dr. McCarthy had limited IRB approval only to retrospectively review patient charts prior to June 2006. (FOIA Exs B-E). In May 2007, Dr. McCarthy then requested, but was denied approval to expand the time and number of patients in his study. (FOIA Exs. C-E).The FOIA documents were not disclosed to Plaintiff or her counsel during the trial court proceedings. Plaintiff will show below that the documents and information was requested during discovery and their disclosure was concealed, which affected the outcome of the trial court proceedings against Plaintiff.

13. Plaintiff conducted extensive written and oral discovery involving Dr. McCarthy's study, the scope and purpose of the study, and his need for IRB approval of his study, and the involvement of Northwestern's IRB. (Ex.1401-18, written discovery log). The discovery also included the consent forms that Plaintiff signed and approved. *Id.*

14. The documents produced by the Northwestern Defendants and used during discovery showed that Dr. McCarthy was performing his chart reviews under IRB No. 1532-003, in which he claimed to be using patient information from the Northwestern Outcomes Registry to review past surgical outcomes. (Ex. 1401-20).

15. Plaintiff Maureen Obermeier signed a consent to have her records included in the Northwestern Outcomes Registry. *Id.* The Outcomes Registry was approved by the Institutional Review Board under IRB Project Number 1532-003. (*Id.* at SEC C321). The Plaintiff claimed she was not informed that Dr. McCarthy was conducting a study and that she did not give her consent to be included in his study, or to have his new device used on her as part of a study.

Discovery Disputes and Rulings Involving Research Documents

16. Discovery disputes arose over Plaintiff's efforts to depose Northwestern witnesses involved in Dr. McCarthy's research study and for documents pertaining to the study.

17. The Northwestern Defendants (Dr. McCarthy, Northwestern Memorial Hospital, and Northwestern Medical Faculty Foundation) were represented by Anderson, Rasor & Partners, LLP throughout this litigation. (Ex. 1401-14).

18. The Anderson Rasor law firm, by attorney Patricia Foltz, also represented the Northwestern University witnesses, Anna Huskin (Ex. 1401-24), Ann Adams (Ex. 1401-25) and Eileen Yates (Ex. 1401-26).

19. Anderson Rasor filed Motions to Quash on behalf of these witnesses. (Ex. 1401-33 (Huskin Motion to Quash); Ex. 1401-25 (Adams Motion to Quash and Ex. 1401-34 (Yates Motion to Quash).

Plaintiff's Motion to Compel Research Documents

20. Plaintiff filed a Motion to Compel, for Protective Order and for Other Relief against the Northwestern Defendants (Dr. McCarthy, NMH and NMFF) and NU. Ex.

1401-33; Exhibits are restricted, Ex. 1401-33R-1 to 16).[2] See, log of exhibits attached hereto as Exhibit A.

21. In summary, Plaintiff's Motion to Compel stated:

> ¶1. This motion bears on issues relating to plaintiff's informed consent and battery claims, and to IRB materials. The Northwestern Defendants produced certain materials relating to these claims in the course of discovery. These include.....IRB Research protocol 1532-003 and related forms (attached motion exhibits 8-11)...and materials relating to a subsequent IRB 1532-004 (Ex. 15)..... *Id.*
>
> ¶3 These documents were produced by Northwestern Memorial Hospital and with NMH bates numbers. *Id.*
>
> ¶5. (Plaintiff's) consent form (for the outcomes registry) listed IRB 1532-003. *Id.* last page.

22. Plaintiff's Motion to Compel cited and included the following exhibits:

> Plaintiff's Consent Documents:
>
> Ex 5: IRB 1532-003 approved Outcomes Registry consent signed by plaintiff (3 pages, version date 8/26/06). Ex. 33R-5.
>
> Ex. 6: IRB 1532-003 approved Research Subject Authorization signed by plaintiff (2 pages, version date 8/25/06) Ex. 33R-6.
>
> IRB 1532-003 Documents :
>
> Ex 8: IRB 1532-003 Protocol dated 7/24/05 entitled, *Early and Late Outcomes Following Surgical Interventions for Atrial Fibrillation Database* (Form Version 11/1/04) (NMH 1462-NMH 1476) (15 pages) Ex. 33R-8.
>
> Ex 9: IRB 1532-003 New Project Submission Form dated 8/12/05 (NMH 1477 to NMH 1493) (17 pages) (Ex. 33R-9)

[2] The restricted exhibits in the motion to compel are cited herein as Ex 33R-__. All are part of the restricted portion of exhibit 1401-33.

Ex 10: IRB 1532-003 Request to Waive Consent (Version 11/1/04 dtd 8/12/04) (NMH 1494-1495) (Ex. 33-R-10).

Ex 11: IRB 1532-003 HIPPA Waiver Authorization Form (Version 9/1/04 dated 8/12/05) (NMH 1495 to NMH 1501) (Ex. 33R-11)

Ex 12: Dr. McCarthy's Myxo Ring study paper: Initial Clinical Experience with Myxo-ETlogix mitral valve repair ring, McCarthy, JTCS 2008; Vol 136: 73-81 (Ex. 33R-12).

IRB NO. 1532-004 Documents

Ex 15-B and C: 6/26/06 Letters E Yates to Dr McCarthy; Re: 1532-004 Subject: Mitral Valve Pathology: A Quantitative Assessment Pre and Post Repair (Study at NMH 12-NMH 26); (NMH 005, NMH 006) (Ex. 33R-15B-C).

Ex 15D: HIPPA WAIVER OF AUTHORIZATION FORM, Northwestern Office for Protection of Human Subjects, IRB 1532-004 (NMH 007 to NMH 0011); (Ex. 33R-15D).

Ex 15E: Protocol paper, dated 6/7/06, Mitral Valve Pathology, A Quantitative Assessment Pre and Post Repair, McCarthy, Principal Investigator, as Chief, Division of Cardiothoracic Surgery, Co-Director Bluhm Cardiovascular Institute, and Professor or Surgery, Northwestern University, dated 6/7/06 (NMH 0012 to NMH 0029), (SEC C 409-C 426)

Plaintiff's Written Discovery Requests/Responses

Exs15 and 16: NMH Discovery Responses. (Ex. 33R-15 and 16).

23. The documents attached to the Plaintiff's Motion to Compel establish that Dr. McCarthy was the Principal Investigator of a research project which the Institutional Review Board approved through project number IRB No. 1532-003, in the following respects:

a. The Outcomes Registry consent form signed by Maureen Obermeier (Ex. 1401-20) has a stamp that designates that the consent form had IRB approval under project 1532-003.

b. The Research Subject Authorization form signed by Maureen Obermeier (Ex. 1401-21) has a stamp that designates that the form was approved under IRB 1532-003.

c. The forms relating to IRB No. 1532-003 refer to the protocol for the Outcomes Registry. These include those documents described above as Exs Ex. 33R-8-11).

24. The Northwestern Defendants produced three documents relating to IRB 1532-004: (1) HIPPA Waiver of Authorization Form dated 6/20/06 (Ex. 33R-15D) in which Dr. McCarthy seeks the waiver of patient authorization to review records as part of a retrospective study through June 27, 2007. (2) Letters from Eileen Yates, Senior IRB Coordinator to Dr. McCarthy, approving the request (Ex. 33R-15C and D); and (3) the1532-003 protocol (Ex. 33R-15E).

25. The three IRB 1532-004 documents that the Northwestern Defendants produced to Plaintiff only showed that Dr. McCarthy was conducting a retrospective review of records that already existed as of June 2006. Plaintiff never received the new FOIA documents which showed that Dr. McCarthy never received IRB approval to continue his Myxo Ring study beyond June of 2006. *Id.*

26. The IRB 1532-004 documents that were produced to Plaintiff's counsel did not show or say that Dr. McCarthy intended to study or look at any records subsequent to the June 2006 date of his IRB request. The scope of IRB 15432-004 that was disclosed to Plaintiff's counsel was that, like 1532-003, the new 1532-004 was also limited to a request for a retrospective review of records. This was not a request to study surgical results of the new Myxo Ring going forward, i.e., it was not prospective.

The False and Misleading Representation by Northwestern

27. On 12/6/13, the trial court heard arguments on Defendants' Medical Studies Act claims, and on Plaintiff's Motion to Compel. (Ex. 1401-29). The following discussion took place:

> MR. BOYER: We also need rulings on the group of documents that were part of my Group (Exhibit) 15, and those involve -- Pat, we never got to these.
>
> MS. FOLTZ: Because I don't know what you're talking about.
>
> MR BOYER: These are IRB 004, and we were fighting over 003 during the deposition.
>
> MS. FOLTZ: Can you show me what you're talking about, Ardy (sic), because I honestly don't know what you're talking about?
>
> MR. BOYER: Can we just take a couple minutes?
>
> THE COURT: You want to take a couple minutes to go off.
>
> MR. BOYER: Yes.
>
> (Whereupon, a discussion was had off the record). (SUP R 4341 V5)
>
> ---
>
> THE COURT: And Schoenecker's dep we don't need.
>
> MS. FOLTZ: We've done that, and we don't need to supplement.
>
> THE COURT: What about Huskin?
>
> MR. BOYER: Huskin, Anna Huskin's deposition, given the Court's ruling, I have no need to purse that at this point, and I will give some thought to whether I need to do a motion to pursue appeal on that.
>
> I would like to add, your Honor, that as part of my motion, I have some materials on Exhibit 15 that were part of Northwestern Memorial Hospital's (response to) request to produce, amended No. 36, they're Exhibit E, dealing with NMH Bates numbers 1 through 29. **And these are dealing with IRB 1532-004, and Pat Foltz has just represented to me that these have no bearing on Dr. McCarthy's paper**.

THE COURT: **Or the Obermeier case.**

MR. BOYER: **Or the Obermeier case. And given that, I do not need to pursue discovery on those materials, and I will withdraw my motion as to these materials**.

MS. FOLTZ: **And I will affirm that representation**. (SUP R 4342 V5) (Plaintiff's bold).

28. Plaintiff's counsel withdrew his efforts to secure documents relating to IRB 1532-004 in reliance upon Ms. Foltz's affirmative representations that IRB 1532-004 had "no bearing on Dr. McCarthy's (Myxo Ring) paper" or on "the Obermeier case."

29. Fraud may be established where one party induced another party's detrimental reliance by knowing and material misrepresentation. *Ebersole v Ebersole*, 171 Ill.App.3d 632 (3rd Dist. 1988)

30. Documents relating to IRB 1532-004 are attached as part of Group Ex. 15 to Plaintiff's Motion to Compel (Ex. 1401-33, with restricted exhibits at 33R), so there is no reason for Ms. Foltz to claim that she "had no idea" what these documents were "about." This was a tactical maneuver to mislead the inquiry into IRB 1532-004. After the off-the-record discussion, the attorneys went back on the record, where Ms. Foltz's follow-up representation to Plaintiff's counsel and to the Court that IRB 1532-004 and its materials had no bearing on the Myxo Ring study and no bearing on the Obermeier case has now proven to be false. This is demonstrated through the newly discovered FOIA materials and explained below.

Newly Discovered Evidence withheld by Northwestern Defendants

31. Plaintiff recently learned of crucial new evidence which goes to the very heart of Plaintiff's informed consent claim. The Northwestern Defendants not only failed to

disclose this critical evidence, they withheld the evidence and represented that it had no bearing on Dr. McCarthy's study or on the Obermeier case.

32. On February 6, 2019, Nalini Rajamannan, M.D. contacted Plaintiff's counsel and informed him that she had received new information and documents on a Freedom of Information Request (FOIA) that she submitted to the F.D.A. Dr. Rajamannan forwarded the documents to Mr. Boyer, who then reviewed them and on February 12, 2019 consulted with Dr. Rajamannan on the documents. (Ex. 1401-01).

33. The new evidence described below shows that Dr. McCarthy knew that his study involving the Myxo Ring was, in fact, a prospective study which required independent IRB approval. We now know that Dr. McCarthy was fully aware of this because new documents establish that Dr. McCarthy was told by the head of the IRB that the study was prospective, that new permission to proceed with the study was needed, and that he was required to cease any further work on the study until he complied.

34. Attached hereto is Dr. Rajamannan's affidavit, which authenticates materials she received on 12/18/18 pursuant to an FDA FOIA request, which she provided to Obermeier's counsel, Mr. Boyer, on 2/6/19. (Ex. 1401-01). The attached FOIA documents are as follows:

> FOIA Exhibit A: December 18, 2018 U.S. Food and Drug Administration Letter responding to Dr. Rajamannan's FOIA request. (2 pages).
>
> FOIA Exhibit B: June 29, 2006 Letter from Ellen Yates, Senior IRB Coordinator, to Patrick McCarthy, MD, regarding IRB Project Number 1532-004 review dated 6/27/06 (2 pages, referenced as EI 8/8/08 LH Exhibit #11) [3]
>
> FOIA Exhibit C: Northwestern University Office for the Protection of Research Subjects, CONTINUING REVIEW OF RESEARCH FORM (CRRF) dated June

[3] The 6/29/06 Yates letters were produced to Plaintiff in this case. They are attached to Plaintiff's Motion to Compel as Exhibits 15 B and C. The other documents, Exhibits C, D, E and F were not disclosed to Plaintiff.

1, 2007 regarding IRB No. 1532-004 (8 pages, referenced as EI 8/8/08 LH Exhibit #12)

FOIA Exhibit D: Emails exchanged by Tasha Osafo (identified as Senior Coordinator Expedited/Periodic Review, Office for the Protection of Research Subjects, Northwestern University) and Patrick McCarthy, MD dated 6/19/07, 6/28/07 and 7/12/07 regarding IRB Project 1532-004 (4 pages, referenced as EI 8/8/08, LH Exhibit #14).

FOIA Exhibit E: 7/17/07 Received Stamp - Project Termination/Closure Form for IRB Project Number 1532-004 (2 pages, referenced as EI 8/8/08 LH Exhibit #15).

FOIA Exhibit F. 8/8/08 Establishment Inspection Report (EIR) by Lisa Hayka, investigator. (7 pages)

35. The FOIA documents pertain to an aspect of Dr. Patrick McCarthy's study involving his Myxo-ETlogix annuloplasty ring which he surgically implanted in his patients at Northwestern Memorial Hospital. Dr. McCarthy's published report on this study is attached hereto as Exhibit G. (Ex. 1401-01).

36. The FOIA exhibits cited above refer to Northwestern University IRB Project Number 1532-004. Id.

37. The documents show that on June 29, 2006, Dr. McCarthy received IRB approval for a waiver of HIPAA Compliance and written and verbal consent to conduct a retrospective review of records in the Northwestern Cardiac Surgery Outcomes Registry covering surgeries up through June 2006. He was permitted to retrospectively review these old charts until June 27, 2007. (FOIA Ex. B).

38. In FOIA Exhibit C, on May 27, 2007, Dr. McCarthy submitted a request to the Northwestern University Office for the Protection of Research Subjects entitled CONTINUING REVIEW OF RESEARCH FORM (CRRF). This document addresses the following:

Dr. McCarthy is identified as the "Principal Investigator" of the study (§3, page 1 of 8).

He reports that he is conducting a study at Northwestern University (NU), Northwestern memorial Hospital (NMH), and Northwestern Medical Faculty Foundation (NMFF) (§5, page 2 of 8). Dr. McCarthy reports that he his IRB submission for 1532-004 matured into his research of ring sizing techniques and leaflet measurements that bear on surgical techniques. (§6 at page 3 of 8).

Dr. McCarthy reports that as of this submission, only 25 patients had been consented or studied to date (§10, page 4 of 8), and that he was seeking IRB approval for 125 patients (*Id.*).

Dr. McCarthy summarized this revised request as follows: "At this time we are requesting an extension for review of medical records. Initial approved period was April 2004-June 2006 (with approximately 125 records to be reviewed). At this time we are requesting a review of records through May 2007 (approximately 250 records to be reviewed). Our abstract titled "Initial Experience with Mitral Valve Repair Ring Designed for Myxomatous Mitral Valve Disease" (copy attached) submitted to the Society for Thoracic Surgery (STS) was rejected. We believe with a larger patient population our results will be highly significant; thereby improving the likelihood of future abstract/manuscript acceptance." (§11, page 5 of 8).

The CRRF is signed on behalf of Northwestern Memorial Hospital by Charles Watts, MD, its Senior Vice President of Medical Affairs, (§18, page 7 of 8) and by Dr. Patrick McCarthy as the study's Principal Investigator. (§19, page 8 of 8).

39. FOIA Exhibit D is a series of emails exchanged by Dr. McCarthy and Tasha Osafo who served as NU's Senior IRB Coordinator, including:

On June 29, 2007, Osafo emailed Dr. McCarthy and notified him that Dr. McCarthy's study is no longer "retrospective" and is now "prospective" which requires additional documentation, including a new protocol. (page 3 of 4).

On June 28, 2007, Osafo emailed Dr. McCarthy advising that he had not submitted the materials and that "all study procedures must stop until approval is granted." (page 2 of 4).

On July 27, 2007, Dr. McCarthy emailed Osafo advising that he decided to "terminate this project. No further research has been done since the project expiration (June 27)." (page 2 of 4).

On July 12, 2007, Osafo emailed Dr. McCarthy confirming his intent to terminate this research project. (page 1 of 4).

40. FOIA Exhibit E is a July 13, 2007 Project Termination/Closure Form regarding IRB 1532-004 completed by Dr. McCarthy. This form establishes the following:

> Dr. McCarthy represented that he completed the project that is the subject of 1532-004. (§5, page 1 of 2).
>
> Dr. McCarthy reviewed only 25 charts to date as part of his study, and no subjects were withdrawn from it. (§6, page 1 of 2).
>
> Dr. McCarthy signed the termination form as Principal Investigator of the research project/study. (§10, page 2 of 2).

41. FOIA Exhibit F is an Establishment Inspection Report dated August 8, 2008, covering a for cause inspection of NU's Office for the Protection of Research Subjects (Institutional Review Board - IRB). The inspection was conducted by the FDA's Center for Devices and Radiological Health. This report investigated the Myxo Ring study conducted by Dr. McCarthy which is the subject of the Obermeier lawsuit. The report summarizes the documents and information outlined above in this Petition.

42. Dr. Rajamannan testified as a witness in Maureen Obermeier's case. She was practicing medicine and doing medical research at the Northwestern entities in 2006 and 2007, and was involved with Dr. McCarthy's Myxo Ring study in 2006 and early 2007.

43. The undisputed evidence at trial established that Dr. McCarthy did not provide his Myxo Ring patients with any information regarding his study or that he was using his new Myxo Ring as part of a patient study. This includes the Myxo Ring he used on Maureen Obermeier on 11/6/06.

44. Through trial, Plaintiff and her counsel were unaware of the specifics relating to IRB 1532-004, particularly of the information in the contents of the documents that recently provided to Plaintiff pursuant to Dr. Rajamannan's FOIA request cited above.

45. These FOIA documents show that IRB 1532-004 involved Dr. McCarthy's Myxo Ring study and that it covered the period of time Dr. McCarthy implanted his Myxo Ring into Maureen Obermeier on November 6, 2006. By concealing these 1532-004 materials, Plaintiff was not aware that Dr. McCarthy had been directed to "stop all study procedures" by Ms. Osafo, nor was Plaintiff aware that on behalf of NU's Office for the Protection of Research Subjects, Ms. Osafo had specifically informed Dr. McCarthy that his Myxo Ring study was a "prospective" study which required IRB a new protocol and approval. Nor was Plaintiff made aware that, in response to this information, Dr. McCarthy had informed the Office for the Protection of Research Subjects that he terminated his study, when he in fact did not terminate it but went forward with it through November 19. 2007. (Ex. 1401-02).

46. Dr. McCarthy and the Northwestern Defendants claimed at trial that Dr. McCarthy did not need to inform his patients of his Myxo Ring study on the grounds that he was not conducting "research" and so informed consent was not required. They based this claim on the theory that Dr. McCarthy was doing "retrospective" reviews of medical records. The new FOIA documents show that Dr. McCarthy's Myxo Ring study was, per the NU IRB, a "prospective" study which required independent IRB approval and the patient's informed consent. The new FOIA documents completely undermine Dr. McCarthy's defense of the informed consent case. Had these documents and the

information in them been available, Plaintiff's counsel could have used this information to controvert Dr. McCarthy's defenses to the informed consent claims.

47. Dr. Rajamannan sent Maureen Obermeier's attorney, Ardwin Boyer, a copy of the FOIA documents via email on February 6, 2019. She then discussed the new FOIA documents with Mr. Boyer on February 12, 2019. During this discussion, Dr. Rajamannan informed Mr. Boyer of those additional matters that are set forth in her attached affidavit. (Ex.1401-01).

48. The Northwestern Defendants claimed through this case and at trial that Dr. McCarthy did not require IRB approval of his Myxo Ring study or need to provide his patients with informed consent because his study did not constitute "research" involving human subjects. The newly discovered FOIA materials established that Dr. McCarthy, in fact, submitted an application for IRB approval of his Myxo Ring study in June of 2007, and the application was rejected on the grounds that he was conducting a prospective study which required a new protocol. He never received approval to continue his Myxo Ring study beyond June of 2006.

The Concealment of the Newly Discovered FOIA Documents and Information Affected the Outcome of the Trial Proceedings

50. At the time of the new FOIA documents, Northwestern University had in effect a Human Subject Protection Program (HSPP) (Ex. 1401-32) over which the Office for the Protection of Human Subjects (OPRS) has primary responsibility for maintaining its Human Subjects Protection Program. Moreover, all research conducted at Northwestern Memorial Hospital and through Northwestern Medical Faculty Foundation was governed by the policies of this program. The policy stated:

Policy for Human Subjects Research at Northwestern University

I. Preamble

> This document provides information on the policy of Northwestern University (NU...) relating to human subjects research. The information is intended for use by investigators, researchers, Institutional Review Board members,....or others who are involved with NU research involving human subjects. Research that is sponsored or conducted by Northwestern University, including research conducted at the University, Northwestern Memorial Hospital (NMH), Northwestern Medical Faculty Foundation (NMHH).....shall be conducted in accordance with this policy.

II. Overview of the IRB, OPRS and the Human Subject Protection Program (HSPP)

..The Office for the Protection of Research Subjects (OPRS) has immediate and primary responsibility for ensuring the ongoing development and maintenance of HSPP (the Human Subjects Protection Program). *Id.* at p 5 of 108.

> .....the *principal investigator* has immediate and primary responsibility for protecting research subjects by following the approved research procedures....*Id.* (emphasis ours)

51. The above policies establish that Dr. McCarthy was bound to follow the policies and procedures of the Northwestern Human Subjects Program in conducting any human subject research at Northwestern Memorial Hospital. They establish that the Office for the Protection of Research Subjects (OPRS) had primary responsibility for overseeing and maintaining compliance with these policies.

52. Dr. McCarthy was the "principal investigator" of his Myxo Ring study so he was primarily responsible for ensuring that his Myxo Ring study complied with the HSPP policy. Dr. McCarthy signed the CRRF for approval of his IRB 1532-004 project in his capacity as "Principal Investigator." (FOIA Ex. C at p 8).

81. Plaintiff also requests sanctions against the Northwestern Defendants pursuant to S. Ct. Rule 219.

WHEREFORE, Plaintiff, Maureen Obermeier, prays this Honorable Court pursuant to 735 ILCS 5/2-1401 to vacate the judgment order of April 1, 2016, to vacate the ordering denying Plaintiff's post-trial motion of January 30, 2017, to enter and order granting Plaintiff a new trial against Defendants Patrick McCarthy, M.D., Northwestern Memorial Hospital, and the Northwestern Medical Faculty Foundations, for appropriate sanctions, and for such other relief as this Honorable Court may deem proper.

Respectfully submitted,

/s/ Adwin E. Boyer

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CHAPTER THREE

NORTHWESTERN MEMORIAL HOSPITAL, ETC RESPONSE FILED ON MARCH 27, 2019

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Thomas D. Palella
Clerk of the Appellate Court
APPELLATE COURT 1ST DISTRICT

No. 17-0553

IN THE APPELLATE COURT OF ILLINOIS
FIRST JUDICIAL DISTRICT

MAUREEN OBERMEIER Plaintiff- Appellant, vs. NORTHWESTERN MEMORIAL HOSPITAL, NORTHWESTERN MEDICAL FACULTY FOUNDATION, PATRICK MCCARTHY, M.D., and EDWARDS LIFESCIENCES, L.L.C., Defendants -Appellees.	) On Appeal from the Circuit) Court of Cook County, Illinois) County Department)) Circuit Court No. 08 L 012426))) Trial Judge James M. McGing)))))

APPELLEES' OPPOSITION TO
APPELLANT'S MOTION TO STAY

COME NOW Appellees, **NORTHWESTERN MEMORIAL HOSPITAL ("NMH"), NORTHWESTERN MEDICAL FACULTY FOUNDATION ("NMFF"),**and **PATRICK MCCARTHY, M.D. ("Dr. McCarthy")**, by and through their attorneys, and hereby respond to Appellant's "Motion to Stay Limited Issues Pending on Appeal" state as follows:

I. APPELLANT'S MOTION TO STAY SHOULD BE DENIED BECAUSE THE § 2-1401 PETITION ON WHICH IT IS BASED IS INSUFFICIENT ON ITS FACE TO SUPPORT THE RELIEF REQUESTED

A. The petition is untimely because it fails to assert that any *party* fraudulently concealed evidence.

Appellant has lodged a § 2-1401 petition with the Circuit Court of Cook County alleging that "newly discovered evidence" was brought to Appellant's attention in February 2019 by his ostensible expert, Nalini Rajamannan, M.D. Although § 2-1401 requires that such a petition

must be filed no later than two years after the entry of the order or judgment in question, Appellant alleges that a prior "fraudulent concealment" of the alleged evidence by "the Northwestern Defendants" allows the filing beyond the two-year limitations. This representation by Appellant (which is critical to his ability to bring his petition) is, at best, highly misleading.

Appellant's "fraudulent concealment" argument relies entirely on statements made by attorney, Patricia Foltz, during a hearing on a motion to quash. The motion to quash had been brought by non-party deponents, Anna Huskin and Nancy Shoenecker, who were employees of Northwestern University – a non-party in the lawsuit. Ms. Foltz represented the deponents at the hearing. Edwards had separate counsel present at the hearing, and Northwestern Memorial Hospital, NMFF, and Dr. McCarthy were represented by separate counsel at the hearing. Although Ms. Foltz was a partner practicing at Anderson, Rasor & Partners (the same firm that represents NMH, NMFF, and Dr. McCarthy), the written motions and the transcript of all proceedings clearly reflect that Ms. Foltz represented only the deponents, not any party to the lawsuit.

Appellant cites no authority that stands for the proposition that the statements of an attorney who *does not represent* a party in that matter can be imputed to the party. Nor does Appellant cite any authority that stands for the proposition that because Ms. Foltz was a member of the law firm that represented NMH, NMFF, and Dr. McCarthy, any statement that she made could be imputed to NMH, NMFF, or Dr. McCarthy, notwithstanding that they were represented by different individual attorneys.

On its face, Appellant's § 2-1401 is meritless. Therefore, it does not constitute a basis to stay this appeal.

B. The statements alleged to be "misrepresentations" are not misrepresentations

To prove fraudulent concealment in a § 2-1401 petition, the petitioner must prove *by clear and convincing evidence* that the respondent intentionally misstated or concealed a material fact which the respondent had a duty to disclose and that the petitioner detrimentally relied on the respondent's statement or conduct. *In re Marriage of Himmel*, 285 Ill.App.3d 145, 148 (1996)

Appellant complains that statements made by Ms. Foltz at a hearing regarding a motion to quash filed by non-party deponents, Anna Huskin and Nancy Shoenecker caused him to forgo investigation into a Northwestern University IRB Project that was numbered "1532-004." Documents that Dr. Rajamannan obtained through her FOIA request describe a project that was limited to medical record reviews of patients who underwent mitral valve repair between April 2004 and June 2006. (Appellant's FOIA Exhibit C, page 3) The project involved no randomization and no interventions. *Id.* The focus of discussion at the hearing on the motion to quash pertained to Northwestern University IRB Project numbered 1532-003, which was the "Outcomes Registry" discussed during the trial of this matter. Throughout discovery and trial of this case, Appellant and the parties have referred to the paper that Dr. McCarthy published in the Journal of Thoracic and Cardiovascular surgery (SUP E 10173 - 10181 V7, Plaintiff's Trial Exhibit 84, and Exhibit 17 to Appellant's 1401 Motion) as Dr. McCarthy's "study" or "paper." This paper, on its face, states that information for the paper was obtained from the cardiac surgery outcomes registry of the Bluhm Cardiovascular Institute, which was approved by the Northwestern University Institutional Review Board for use in research. *Id.* at p. 2 (SUP E 10174). Hence, the stated source for the paper in question was IRB Project numbered 1532-003 – the Outcomes Registry.

The sole basis for Appellant's allegation of "fraudulent concealment" is that Ms. Foltz affirmed Appellant Counsel's representation at the hearing on the her motion to quash that she had represented to Appellant's counsel that requested materials from IRB 1532-004 had no bearing on Dr. McCarthy's paper or on the Obermeier case. It is difficult to understand how this representation could be interpreted as misleading, much less false. Dr. McCarthy's paper states explicitly that it is based upon data obtained from the Outcomes Registry – 1532-003. Appellant has alluded to no evidence that would contradict that proposition. Nor has Appellant alluded to any evidence that IRB 1532-004 has anything to do with the Obermeier case. Mrs. Obermeier's surgery occurred on November 6, 2006. IRB 1532-004 was a project that was limited to medical record reviews of patients who underwent mitral valve repair between April 2004 and June 2006. An effort was made to extend that time period beyond June 2006, which was denied. How does a study that was limited to a review of surgeries up to June 2006 have anything to do with the Obermeier case? Indeed, even after carefully reviewing Appellant's § 2-1401 Petition and all of its supporting materials, Appellees fail to perceive how IRB 1532-004 has anything to do with Dr. McCarthy's paper, Maureen Obermeier, or the Obermeier lawsuit.

Appellant's assertion that a misrepresentation occurred is specious on its face. A § 2-1401 petition that is specious on its face cannot constitute a basis to stay this appeal.

C. Appellant's § 2-1401 petition does not articulate a rational basis for suggesting how the contents of this ostensible ground for relief would have prevented the entry of judgment against him.

To prevail on a § 2-1401 petition, Appellant must prove *by a preponderance of evidence* that (1) if the ground for relief had been known at trial it would have prevented the entry of judgment against him; and (2) failure to discover and present the ground for relief was not the

result of his own lack of diligence. *Smith v. Airoom, Inc.*, 114 Ill.2d 209 (Ill. 1986); *Ostendorf v. International Harvester Co.*, 89 Ill.2d 273 (Ill. 1982). The petition is subject to dismissal for want of legal or factual sufficiency. *Brockmeyer v. Duncan*, 18 Ill.2d 502 (Ill. 1960). "Like a complaint, the petition may be challenged by a motion to dismiss for its failure to state a cause of action or if, on its face, it shows that the petitioner is not entitled to relief." *People v. Vincent,* 226 Ill.2d 1, 8 (Ill. 2007).

Appellant cites no fact that supports the proposition that the Plaintiff-Appellant, Maureen Obermeier, was part of the IRB Project designated IRB 1532-004. Indeed, her surgery was performed on November 6, 2006, and the original project only encompassed patients who underwent mitral valve repair between April 2004 and June 2006. No evidence has been cited that implies that data from her surgery was collected or utilized for the purposes of IRB 1532-004, so there is no basis to assert that she should have signed a consent form for that study. Indeed, she conceded at trial and on appeal that she signed a consent form for the Outcomes Registry – IRB 1532-003, which was the basis of Dr. McCarthy's paper.[1]

Appellant also seems to assert that by being deprived of materials pertaining to IRB 1532-004, she was deprived of rebutting a contention that Dr. McCarthy's study was prospective rather than retrospective. What Appellant fails to appreciate, however, is that Appellee's evidence at trial and argument to the jury was not based upon and did not depend upon whether Dr. McCarthy's study was labeled "prospective" or "retrospective." Defendant-Appellees' research/IRB expert at trial was Jeffrey Cooper, M.D. As Appellees' brief before this Honorable

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[1]Ironically, it was acknowledged by Appellant and Dr. Rajamannan at trial that data from Maureen Obermeier's surgery was *excluded* from Dr. McCarthy's paper, which Dr. Rajamannan attempted to criticize.

Court sets forth in great detail, this designation was not material to Dr. Cooper's unequivocal opinion that under FDA regulations, Ms. Obermeier was not a human subject involved in a clinical investigation when Dr. McCarthy utilized a Myxo ring in her care. (Appellee Brief, pp. 11- 14) He was not conducting a "clinical trial," a "clinical investigation," or "research" subject to regulation when he did so. *Id.* Nor was Dr. McCarthy conducting "research" under HHS regulations when he implanted a Myxo ring in Ms. Obermeier, so he was not required to obtain IRB clearance before he did so. *Id.*

Appellee maintained through trial and during this appeal that he utilized a Myxo ring during Ms. Obermeier's care because he felt that it was the best device to address her problems. There was no protocol or study that dictated what annular ring he would use with Ms. Obermeier or any other patient. And the ring was provided to him as a legally marketed device, not an investigational device, so he was entitled to assume that it was not an investigational device. The purported "evidence" that Dr. Rajamannan has obtained through a FOIA request has no impact on that position at all. Refusing to consent to a review of her medical records would not have affected which ring Dr. McCarthy utilized in repairing Ms. Obermeier's mitral valve. There was no study that dictated or controlled that decision.

The briefs and evidence that have already been submitted to this Honorable Court provide ample evidence that Dr. Rajamannan's "newly discovered evidence" is of little relevance to the matters that were adjudicated at trial. Appellant's bald assertion that it would somehow have overcome the evidence against her claims and the unanimous jury verdict in favor of Defendants is absurd. This Honorable Court should not stay these proceedings to permit Appellant to pursue a petition that on its face fails to satisfy the burden imposed by § 2-1401.

II. APPELLANT'S MOTION TO STAY CONCEDES THAT THE APPEAL SHOULD PROCEED AS TO ALL ISSUES THAT PERTAIN TO NMH, NMFF, AND DR. MCCARTHY.

In Paragraph 15 of Appellant's Motion to Stay, Appellant concedes that it is not necessary to stay the appeal with regard to the following issues:

> -Alleged error in dismissal of institutional informed consent claims against NMH (Count VI of the Third Amended Complaint);
>
> -Alleged error in dismissal of civil battery claims against NMH (Count VIII of the Third Amended Complaint);
>
> -Alleged error in holding that certain documents are privileged under the Medical Studies Act;
>
> -Alleged error in designating Dr. Rajamannan as a 213(f)(3) witness;
>
> -Alleged error in the scope of cross examination of Dr. Rajamannan;
>
> -Alleged error in permitting Dr. McCarthy to testify that he donated his Myxo ring royalties to a food shelter.

This laundry list encompasses the entirety of Appellant's alleged bases for obtaining a new trial. Therefore, it is unclear to Appellee what Appellant seeks to "stay."

III. THE CIRCUIT COURT LACKS JURISDICTION TO HEAR APPELLEE'S § 2-1401 PETITION

On March 18, 2019, the trial court, over Defendants-Appellees' jurisdictional objection, determined that it could preside over Plaintiff-Appellant's § 2-1401 Petition, notwithstanding that the relief sought in Plaintiff-Appellant's § 2-1401 Petition is identical to the issues currently pending before this Court.

The trial court lacks subject matter jurisdiction over Plaintiff-Appellant's § 2-1401 Petition, which directly seeks to alter the same issues encompassed in Plaintiff-Appellant's

Notice of Appeal, currently pending before this Court. "A notice of appeal is a procedural device . . . that, when timely filed, vests jurisdiction in the appellate court in order to permit review of the judgment such that it may be affirmed, reversed, or modified." *General Motors v. Pappas*, 242 Ill.2d 163, 173 (Ill. 2011). Once a notice of appeal is filed, appellate jurisdiction attaches *instanter*, which divests the trial court of the ability to substantively alter or vacate the appealed order. *General Motors*, 242 Ill. 2d at 173; *Dragon Construction, Inc. v. Parkway Bank & Trust*, 287 Ill. App. 3d 29, 34-35 (1st Dist. 1997)(it is a well-established rule that once an appeal is properly filed, the trial court does not have jurisdiction over the case). The effect of filing a notice of appeal is to restrain the trial court from either changing or modifying the order set for appellate review. *Lindsey v. Board of Educ. of City of Chicago*, 127 Ill.App.3d 413, 418 (1st Dist. 1984).

Illinois Supreme Court Rule ("Rule") 303 (b)(2) sets forth the applicable requirements for notices of appeal and provides, in pertinent part that a notice of appeal "shall specify the judgment . . . appealed from and the relief sought from the reviewing court." Therefore, in accordance with Rule 303 (b)(2), appellate jurisdiction over Plaintiff-Appellant's claims vested on March 11, 2017, when Plaintiff-Appellant timely filed her Notice of Appeal. Importantly, Plaintiff-Appellant's Notice of Appeal conferred jurisdiction on this Court "to only consider the judgments included in the notice of appeal," namely: (1) the April 1, 2016, jury verdict; and (2) the January 30, 2017, order denying Plaintiff-Appellant's post-trial motion seeking a new trial. *See General Motors*, 242 Ill. 2d at 176.

Despite the clear authority enunciating the divestment of the trial court's jurisdiction over issues pending on appeal, Plaintiff-Appellant proceeded headlong with her § 2-1401 Petition

seeking to alter the identical issues presented on appeal. As set forth above, Plaintiff-Appellant's March 1, 2017, Notice of Appeal seeks appellate review of the April 1, 2016, jury verdict and the January 30, 2017, order denying Plaintiff-Appellant's post-trial motion seeking a new trial. Now, Plaintiff-Appellant's § 2-1401 Petition seeks: (1) "to vacate the April 1, 2016, judgment order" entered following the jury verdict; and (2) to "vacate the order denying Plaintiff's post trial motion entered on January 30, 2017." Given the identical nature of the issues encompassing Plaintiff-Appellant's Notice of Appeal and her § 2-1401 Petition, the trial court lacks jurisdiction to preside, change, or modify the issues concurrently raised in Plaintiff-Appellant's Notice of Appeal and § 2-1401 Petition. *See Lindsey*, 127 Ill.App.3d at 418.

Despite the procedural uniqueness of the instant § 2-1401 Petition, the reasoning behind requiring exclusive appellate jurisdiction over issues on appeal stems from the mandate that only final orders are appealable, encompassed in Rule 303 (b)(2). The finality requirement needed for an appeal would be rendered meaningless if a party to an appeal could remove issues from appellate review to be refined in the trial court and then submitted anew on appeal again. *See Dragon Construction, Inc.*, 287 Ill. App. 3d at 34-35. Rule 303's finality requirement is enforced through the mechanism of divesting the trial court of jurisdiction upon the submission of a Notice of Appeal. Considered in unison, both Rule 303 and the divestment of a trial court's jurisdiction over issues raised in a Notice of Appeal, requires a finding that the trial court does not have subject matter jurisdiction over Plaintiff-Appellant's § 2-1401 Petition.

OBERMEIER v. NMH, et al.
APPELLATE COURT NO. 17-0553
ARP FILE NO.: 706002-000039

SERVICE LIST

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Missing from the Defense attorney's response to the court is the fact that Northwestern University Human Subjects Protections Board terminated the protocol to study the Myxo ETlogix Model 5100 device as of June 2006.

The termination agreement was between Northwestern University and the surgeon Dr. McCarthy. The doctor requested to terminate the study instead of filling out the IRB regulated paperwork needed to study the device prospectively and legally.

The defendants' brief fails to mention the fact that 1532-004 was terminated for failure to submit proper paperwork to Northwestern University's IRB human subjects' office.

The defendant's brief fails to mention the fact that Dr. McCarthy agreed not to study the Myxo ETlogix patients after June 2006, and that any use of the device during surgery was unauthorized under Northwestern University's Federal Wide Assurance 00001549.
The surgeon continued to perform the experimental surgeries until November 2007 and published the study in July 2008, trying to claim that the study protocol 003 was enough to publish the test results, despite his agreement with the Northwestern University's federal office of human subject protections not to publish the study.

The Federal Termination contract signed on July 13, 2007, is posted in the next two pages of the Myxo Report. The termination contract and other exhibits were produced as part of the FDA Freedom of Information Disclosures on December 18, 2018 on the eve of the FDA meeting at the Minneapolis District office on December 19, 2018.

Finally, the investigators failed to follow Northwestern University's IRB cease and desist order for the study as of June 2006, and continued to perform the study until November 2007, as published in the final scientific publication.

IRB Review - Office Use Only	IRB Date Stamp - Office Use Only	IRB Accession Number
Northwestern University Institutional Review Board IRB #: 1532-004 APPROVED: 07/17/2007	RECEIVED JUL 17 2007 OPRS	200707-0908 Office Use Only IRB Project Number: **1532-004**

Northwestern University – Office for the Protection of Research Subjects
Project Termination/Closure Form (Also use for studies that were never initiated)
Instructions: Please refer to the Termination Guidelines on when to terminate a project. http://www.northwestern.edu/research/OPRS/irb/handbook/guidance/termination guidelines.doc The Principal Investigator must sign this termination report. If this project involves the Robert H. Lurie Cancer Center, please give a copy of this report to the Clinical Research Director. If this project is conducted at RIC, please give a copy of this report to the Research Office.
Forward this submission to **OPRS, Rubloff, 7th Floor, 750 N. Lake Shore Drive, Chicago, IL 60611 or Hogan, G100-6th Floor, 2205 Tech Drive, Evanston, IL 60208**
Handwritten forms will not be accepted.

1. Date of Preparation: 7/13/2007 Date project is to be Terminated: **7/12/2007**
2. Principal Investigator Name: McCarthy, Patrick MD
Telephone Number: **312-695--3114** Fax Number: **5-1903** E-Mail Address: **pmccart@nmh.org**
Submission Prepared By: (b) (6) **RN**
Phone **5-4067** Fax **5-6854** E-Mail: (b) (6) **@nmh.org**
4. Project Title: Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair.

Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 15
Page 1 of 2

5. Project Status:[1]
A. Determined by Investigator (Check appropriate box (s) describing project status)
1. ☒ Project is completed—No Further Contact with Human Subjects is planned: no subjects are, or will be, treated or followed; all data are gathered and analyzed; and there are no further sponsor reports or publications to submit to the IRB.
2. ☐ Project terminated by the investigator: Reason:
3. ☐ Project terminated by the sponsor. If by the sponsor, please attach documentation.
4. ☐ Project Never Initiated--No human subjects were recruited. Work will not be done at this time.
5. ☐ OPRS Initiated Closure
6. ☐ Other: Give Reason(s):

B. Summary: Please attach a summary of your research findings written in lay language to aid the IRB in their review. Attach available research analysis, or reprints, include an overview of any recent literature, amendments or modifications to the research since the last full board review, reports from multi-center trials, Data Safety Committee reports, and any other relevant information. Also include information about findings (either good or bad) that should be disclosed to subjects in the study. Discuss the rationale for and method of notification to subjects. If the project was never initiated please explain why. **An abstract (attached) with project findings was submitted to the Society of Thoracic Surgery (STS); unfortunately it was not accepted.**

6. Enrolled Subjects:[2]
A. Total number of subjects/sample/charts approved for enrollment/to be studied in this project: **125**
B. Total number of subjects/samples/charts enrolled/studied to date: **25**
C. Have any subjects withdrawn from the study?: ☒ No ☐ Yes, Please explain on a separate sheet the reasons for withdrawal—give the subject initials, date enrolled, reason for withdrawal, and any other additional information. Reasons for withdrawal might include but not be limited to, lost to follow-up, moved from this area, serious adverse events, and non-compliance on the part of the subject.
D. Is there a fully executed consent form in the study file for each subject reported in 6B? ☐ Yes ☒ No, Please explain on a separate sheet. **N/A: Medical Record Review; Waiver of Consent granted**
E. Were more subjects enrolled than were IRB approved? ☒ No ☐ Yes, Please explain on a separate sheet.

[1] All pending issues must be resolved prior to closure of the project.
[2] Enrolled subjects are those who signed consent forms and are participating in (or completed) the study. (Participating = e.g., filling out questionnaires, answering questions, taking drugs, having surgery, being called on the telephone, having data collected.) Enrollment is a finite number usually dictated by the sponsor or by statistical methods.

7. **Serious Adverse Events:** Have anticipated or unanticipated, serious or fatal adverse event(s) occurred?
☒ No ☐ Yes, Please provide a final summary of all Serious Adverse Events for this project.

8. **Protocol Violations/Monitor Reports:** Please attach any protocol violations/deviations or monitor reports that have not been previously submitted to the IRB. None

9. **External Audits:** Has this project been audited by the FDA, DHHS, a sponsor or other external independent auditor?
☒ No
☐ Yes, provide a copy of all correspondence related to any audits and any applicable audit reports. (Do not include routine monitor reports.)

10. **Investigator/Faculty Advisor Assurance:**
Investigator's Assurance:
I certify that the information provided in this application is complete and accurate.

Patrick M. McCarthy, MD		7/12/2007
Principal Investigator's Name	Principal Investigator's Signature	Date

11. **VA Endorsement:**

VA ACOS Research and Development Name and Signature (if applicable) Date

Please return completed form to: **The Office for the Protection of Research Subjects (OPRS)**
E-Mail: irb@northwestern.edu **Website:** http://www.northwestern.edu/research/OPRS

Chicago Campus
Rubloff, 7th Floor, 750 N. Lake Shore Drive, Chicago, IL 60611
Telephone: (312) 503-9338 Fax: (312) 503-0555

Or

Evanston Campus
Hogan, G100-6th Floor, 2205 Tech Drive, Evanston, IL 60208
Telephone: (847) 467-1723 Fax: (847) 467-3112

Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 15
Page 2 of 2

CHAPTER FOUR

I began this journey when I first heard from a patient in 2007, that while she developed complications from her experimental surgery conducted by Dr. Patrick McCarthy, she was not given the opportunity to give consent to participate in the clinical trial to test Dr. McCarthy's unapproved medical heart valve device (The Myxo ETlogix heart valve ring, Model 5100) which was invented by him.

From 2006-2007, I had witnessed a clinical trial on patients who received a "first in human use" prototype heart valve. I was told by the senior investigators 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, Ms. Vlahoulis, confirmed in May 2007, " that I did not sign a consent form" to participate in the testing of the valve ring called the Myxo ETlogix heart valve ring. This patient needed a second heart surgery to remove the prototype device. Since that moment, I removed myself from any participation from the study and anything to do with the human experiments without consent.

In July 2008 after myself and the patient reported to the FDA of the clinical study to test the unapproved Model 5100, the FDA acknowledged in a short email to the patient that the "McCarthy myxoetlogix annuloplasty ring 5100 model" device was "not FDA approved".

From December 2008 to March 2014, I reported to the United States Senate Judiciary Committee and Senate Finance Committee. Senator Grassley(IA) began an investigation of the University, the hospital and the FDA by sending letters requesting answers. Northwestern University responded to the Senator's investigation and the most recent response April 2014, is attached.

STATEMENTS TO THE PRESS TO CONCEAL THE TRUTH

The Press tried, tried, and tried to get at the truth in several stories published to date including a front page story by the Wall Street Journal (WSJ):
The Wall Street Journal quoted Northwestern University on December 29, 2009,while calling the issue " a doctors' spat" reported the following quotes:

"The university says it didn't convene a review board or ask for special patient consent because there was no clinical trial."

"Dr. McCarthy says it is common for surgeons to try out tweaks to devices without going through the whole clinical-trial process. Asked whether he thought he should have asked for a review board, he said: "Not even remotely."

THE HISTORY OF FAILING TO CONSENT PATIENTS

THE BATISTA PROCEDURE

In 2002, Office of Human Research Protections (OHRP) cited the Cleveland Clinic Institutional Review Board (IRB) for similar violations for a study performed at the Cleveland Clinic:

Partial left ventriculectomy and mitral valve repair for end-stage congestive heart failure.

The final statement of the investigation of the Cleveland Clinic's IRB was that Dr. McCarthy and colleagues did not give consent for the prospective clinical trial as published in the above paper.

"OHRP finds that the above-referenced publications described prospective, nonexempt human subject research that was conducted without being reviewed and approved by the Clinic's IRB."

Dr. Michael A. Carome, Director, Division of Compliance Oversight

This is the Letter downloaded from the OHRP website.
Dr. Michael A. Carome now works for Public Citizen as a patient advocate.

RECIDIVISM?

ATRICURE

In 2005, the Wall Street Journal reported on another device, the Atricure, and the conflict of interest as it relates to the surgeons' failure to disclose the conflicts at the Cleveland Clinic. In 2006, the Journal of Thoracic and Cardiovascular Surgery (JTCVS) editor, Dr. Andrew S. Wechsler, published an editorial on the Atricure failure to disclose conflicts of interest. JTCVS is the same journal which published the prospective clinical testing of the Myxo Ring and the calipers Model 1155, testing the experimental measurements in patients without consent and without an IDE. Furthermore, In 2010, the Department of Justice DOJ had indicted Atricure for 3.76 million dollars to resolve Medicare Fraud.

The FDA confirmed to Ms. Vlahoulis in a 2009 FDA letter that the device was experimental, as reported by the Project on Government Oversight in 2011. **The narrative would be different if only the patients, the DOJ, and the Press had the FOIA.**

FOOD AND DRUG ADMINISTRATION

From 2008-2019, I have reported to the FDA of the unauthorized testing of the Model 5100, the Myxo ETlogix ring. I learned from the United States Senate Finance Investigation, there was not one but three versions of the design of the heart valve ring, the model 5100. The first

version was a prototype version, the McCarthy annuloplasty ring, Model 5100 tested in patients and in the research laboratory of Edwards Lifesciences, from February 27, 2006 to November 20, 2006 without an Investigational Device Exemption, the second version was the Myxo ETlogix ring, Model 5100 which was also tested in patients from November 20, 2006 to November 19. 2007.

Edwards Lifesciences, LLC, Irvine CA, reported to the United States Senate Finance committee of their analysis in November 2006, entitled FMEA number 6989, version C, Failure Mode Effects Analysis. In this document, the company disclosed over 120 failure modes in the prototype version of the device which required modifications of the prototype version to improve the safety and efficacy of the second version of the Model 5100. The second version of the device was sold on the US market sometime in 2007 as confirmed in disclosures by Edwards Lifesciences to the Security Exchange Commission.

In 2018, the FDA provided confirmation of an inspection of the IRB at Northwestern University dating back to 2008. This inspection occurred shortly after the FDA learned for the first time of the existence of the non-registered, non-approved significant risk device the Myxo ETlogix, Model 5100.

I requested the report from the FDA through a Freedom of Information Act (FOIA). The report included records of the inspection report and exhibits from Northwestern University IRB, the on campus FDA Office of Human Subject Protections. All of the exhibits arrived on December, 18, 2018, on the eve of an investigative meeting with the patients, their representatives, myself and the FDA investigators.

The records from the FDA's FOIA, reveal that there was no informed consent to test the Myxo ETlogix device in patients for the first time for safety and efficacy from 2006 to 2007. There was a HIPPA waiver 1532-004 to publish the date from March 2006 to June 2006, but no other approvals from Northwestern University's IRB office of human subject protections.

The most important exhibit is the request to the University's IRB senior coordinator Ms. Tasha Osafo by the inventor and senior investigator, Dr. Patrick McCarthy, to continue the ongoing testing, research and scientific publications of the Model 5100.

In the request, Dr. McCarthy specifically included in the protocol to use the specially designed calipers to measure for the first time valve leaflet heights. These measurements were important for the study of the newly designed ring the Model 5100. His hypothesis was to develop a novel specialized sizing technique (Model 1155) to be used in experimental surgical protocols for patients who had varying sizes of valve leaflet heights.

The inspection also revealed that there was not one IRB study protocol 1532-003, but a second IRB study protocol 1532-004. This discovery is contradictor to what Northwestern University reported on the record to the Wall Street Journal in 2009.

Finally, the most important revelation was that Northwestern University IRB coordinator, Ms. Tasha Osafo, determined that Dr. McCarthy's renewal for his protocol to measure the heart valve heights and to test the model 5100 was "prospective," meaning that it was an ongoing future clinical trial to include more patients to test, to study the device and to publish test the future test results.

Northwestern University IRB then requested from the inventor/surgeon to submit the proper federal paper work under HHS/NIH/FDA Common Rule to document the change in the status of the study.

Again Ms. Tasha Osafo allowed the investigator to terminate all experimental protocol measurements and device testing on July 13, 2007as long as the investigator agreed to cease and desist any future inclusion of patients, no new analysis of data, and no more scientific publications.

The surgeon signed the termination agreement on July 13, 2007 agreeing to cease and desist the protocol 1532-004.

Instead of ceasing the protocol, the surgeon and co-investigators at Northwestern University continued the study until November 2007, and the study was actually published in July 2008, despite agreeing to stop all protocols from being published after 2007. I requested from the FDA the Freedom of Information documents which arrived via email. The FOIA included records of the inspection report and exhibits from Northwestern University's IRB the on campus FDA Office of Human Subject Protections.

REPORTING TO NORTHWESTERN UNIVERSITY OFFICIALS

Since 2007, I have reported my eye-witness account of the clinical testing to the Dean's office for Northwestern University Fienberg School of Medicine, the general counsel, the President's office, the Board of Trustees and to the various entities responsible for the human subject protections of the patients who received the experimental prototype device.

I continue to inform all influential leaders at Northwestern University, and government officials in the USA and regulatory bodies including FDA, HHS OIG, FBI, DOJ to try and get help for the patients. The Northwestern University Board of Trustees, the VP for research, have been given notice of the exhibits, the injuries, and the death of the patients.

The University IRB, the VP for research, Dr. Jay Walsh, who is also the Institute Officer, Northwestern University President Shapiro, and the Board of Trustees have been informed of the harm, injuries and deaths for 12 years.

The VP for research, Dr. Jay Walsh has refused to meet with the victims and their families as per an email dated January 4, 2019 citing the statement:

"First, you mention two Northwestern University research studies. Study 1532-004 was a retrospective chart review (a historical look back at medical records to assess outcomes following certain standard of care surgeries) that was voluntarily closed by Dr. McCarthy in 2007. Study 1532-003 was an outcomes registry (a database relating to outcomes of certain standard of care surgical procedures). There were no research interventions, device testing, or experimental surgeries done as part of either of those studies. "

Dr. Walsh fails to mention in his email to the patients and myself, the fact that Northwestern

University's own IRB terminated the study and any future publications of the study results after June 2006 according to the FDA Inspection report.

REPORTING TO THE FDA

Since July 2008 I reported to the FDA the violations of the Human Subject Research Protections. In August of 2008, the FDA inspected Northwestern University human subject research files related to the study.

On December 18, 2018, the FDA released a Freedom of Information Act documents for the Inspection of Northwestern University.

On December 19, 2018, myself and several patient representatives and one patient testified to the FDA in Minneapolis Minnesota of the results of the experimental testing of the Model 5100 and the calipers during open heart surgery. The cover of this book is a photo of the FDA office taken by myself before entering the meeting.

EVIDENCE FOR PROTOTYPE TESTING:

On October 13, 2005, Dr. Patrick McCarthy and Edwards Lifesciences engineers met at Tommy Bahama's restaurant, New Hope Beach, CA. During the dinner meeting, Edwards Lifesciences engineers presented several "prototype models" and Dr. McCarthy chose the sample he would test in the first ten patients on or after the end of February 2006.

Edwards Lifesciences engineers also presented to Dr. McCarthy the specially designed calipers Model 1155 for his novel sizing technique to measure the 6 scallops of the front and back mitral valve leaflets.

The first in human use clinical testing began in March 2006 without FDA, and Northwestern University approval to test the prototype in the patients.

The second version of the Model 5100 was filed in the internal records of Edwards Lifesciences on November 20, 2006 after several modifications were made to the device during the design verification process to develop the model 5100, after over 120 design failures were identified during the human testing in 2006, as reported to the United States Senate Finance Committee by Edwards Lifesciences.

The Freedom of Information act exhibits which arrived via email on December 18, 2018, confirming these facts. The FDA met with myself and several patients to hear testimony of the ongoing use of protocol 1532-004 which was terminated in July 2007. The termination agreement clearly states no studies after June 2006 can be analyzed nor published in any future scientific publications.

The Northwestern evidence from the FOIA, validate my reporting to officials for 12 years, trying to help the patients. The exhibits concurrently confirm through an independent FDA determination by NU IRB officials working on behalf of the federal government under the FWA at Northwestern University. Furthermore, there was not one but two IRB's approved by Northwestern University, 003 and 004. The surgeon continued the study despite the termination of the contract by Northwestern University human subject research protections officer to stop the study.

Tasha Osafo

From: Tasha Osafo [t-osafo@northwestern.edu]
Sent: Thursday, July 12, 2007 2:50 PM
To: 'pmccart@nmh.org'
Subject: FW: IRB Project 1532-004

Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University
Rubloff Building,
750 North Lake Shore Drive
Suite 700
Chicago, IL 60611
Phone: 312-503-4225
Fax: 312-503-0555
-----Original Message-----
From: Tasha Osafo [mailto:t-osafo@northwestern.edu]
Sent: Thursday, July 12, 2007 2:48 PM
To: (b) (6)
Subject: RE: IRB Project 1532-004

(b) (6)

Since you wish to terminate this, I am going to officially withdraw your continuing review submission in our records. Please be sure to complete the Termination Form which is found at http://www.research.northwestern.edu/research/oprs/irb/forms/docs/Termination.doc

Thank you,

Tasha

Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University
Rubloff Building,
750 North Lake Shore Drive
Suite 700
Chicago, IL 60611
Phone: 312-503-4225
Fax: 312-503-0555
-----Original Message-----
From: (b) (6) [mailto:(b) (6) @nmh.org]
Sent: Thursday, July 12, 2007 2:02 PM
To: Tasha Osafo
Subject: RE: IRB Project 1532-004

Hi Tasha,

Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 14
Page 1 of 4

7/12/2007

I apologize for the delay in response, (b) (6) . After further consideration, we have decided to terminate this project. No further research has been done since the project expiration (June 27). I will forward the project termination to your attention once completed. Please let me know if you have any questions.

Regards,
(b) (6)

(b) (6) *RN, BSN, CCRC*
Research Design Manager
Clinical Trials Unit
Bluhm Cardiovascular Institute
Northwestern University
676 N. St. Clair, Suite 1700
Chicago, IL 60611-2969
Ph: (b) (6)
Fax:
(b) (6) *@nmh.org*

"To learn more about the Bluhm Cardiovascular Institute, please visit our web site at http://www.nmff.org/clinicaldepts/department.asp?id=66/"

From: Tasha Osafo [mailto:t-osafo@northwestern.edu]
Sent: Thursday, June 28, 2007 6:01 PM
To: (b) (6) @northwestern.edu; McCarthy, Patrick M.D.
Subject: FW: IRB Project 1532-004

Dear (b) (6)

I'm writing to remind you that we have not yet received a response to the issues below.

Also, this project expired on June 27. As such, please understand that all study procedures must stop until approval is granted.

Thank you,

Tasha

Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University
Rubloff Building,
750 North Lake Shore Drive
Suite 700
Chicago, IL 60611
Phone: 312-503-4225
Fax: 312-503-0555

-----Original Message-----
From: Tasha Osafo [mailto:t-osafo@northwestern.edu]
Sent: Tuesday, June 19, 2007 11:15 AM
To: (b) (6) @northwestern.edu'
Cc: 'pmccart@nmh.org'
Subject: IRB Project 1532-004

Dear (b) (6)

We have received the Continuing Review of Research Form (CRRF) for Dr. McCarthy's project 1532-004, "Mitral Valve Pathology: A Quantitative Assessment Pre and Post Repair".

The study has undergone expedited review and was considered incomplete. The reviewer noted that the PI was approved to conduct a retrospective chart review of records from April 2004 through June 2006. As the PI now wishes to expand the dates of the chart review to May 2007, the study is no longer considered retrospective but prospective in nature. This point, as well as the change of dates needs to be documented in several forms of which I have outlined below. Until we receive these forms, this submission is considered **incomplete** ..

1. **Waiver of Authorization Form:**
   a. Please submit an updated HIPAA Waiver of Authorization Form which reflects the expansion of the chart review to May 2007.
   b. Please clarify that the study is no longer retrospective, but now prospective in nature. As a reference, attached is a PDF of the version we currently have on record.

2. **Waiver of Consent Form:** The waiver of consent initially granted for this study was only for the review of data in the records from April 2004 through June 2006. Please complete the waiver of consent form and clarify why a waiver of consent is needed for this change to the study. The form is available at http://www.research.northwestern.edu/research/oprs/irb/informedConsent/docs/waiveConsent

3. **Protocol:**
   a. Please submit an updated study protocol which reflects the expansion of the chart review to May 2007 and
   b. Please revise the protocol to indicate this study is no longer retrospective in nature, but prospective. I have attached a copy of the last approved protocol for your reference.

4. **CRRF:**
   a. Please revise Section 7 to indicate that this is now a prospective study. Currently, the 1st sentence of the 2nd paragraph states that this is a retrospective study.
   b. Please note that your study expires on June 27, 2007. Your response is needed by then to avoid a lapsed protocol. If you cannot respond by then, please be sure to complete Section 8.1 of the CRRF

Please feel free to contact me with any questions. I suggest responding to me via e-mail for the fastest response.

Thank you,

Tasha
Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University
Rubloff Building,
750 North Lake Shore Drive
Suite 700

Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 14
Page 3 of 4

7/12/2007

Chicago, IL 60611
Phone: 312-503-4225
Fax: 312-503-0555

7/12/2007

CHAPTER FIVE

FOOD AND DRUG ADMINISTRATION HHS INSPECTION REPORT PERFORMED ON AUGUST, 8, 2008 OF NORTHWESTERN UNIVERSITY HUMAN SUBJECT PROTECTIONS FILES AND INTERVIEWS OF NORTHWESTERN UNIVERSITY IRB LEADERS INCLUDING MS. TICE AND MS. OSAFO

Establishment Inspection Report	FEI:	**1470178**
Northwestern University IRB	EI Start:	08/08/2008
Chicago, IL 60611-4579	EI End:	08/08/2008

SUMMARY

This is a directed for-cause inspection of the Northwestern University Office for the Protection of Research Subjects (Institutional Review Board) initiated by the Center for Devices and Radiological Health, Division of Bioresearch Monitoring, HFZ-310. This assignment, FACTS #882363, was originally issued as a routine IRB surveillance assignment, but was changed per e-mail from HFZ-310 on 8/5/08 to a for-cause inspection to obtain information on the IRB's review of studies involving the Edwards Lifesciences, Ltd., Myxo-ETlogix mitral valve repair ring after CDRH became aware of an article published by Patrick M. McCarthy, M.D., in which he reported on his clinical use of the device. The inspection was conducted in accordance with Compliance Program 7348.809, "Institutional Review Board" and the instructions from HFZ-310. The previous inspection of this IRB was conducted on 7/15/03-8/6/03 and was classified VAI due to deficiencies in documenting vote counts in meeting minutes and discrepancies in written procedures.

At the initiation of the inspection, credentials were presented and a Form FDA 482, Notice of Inspection, was issued to Debra Gibson Tice, Interim Director of IRB Operations, and most responsible individual present at the initiation of this inspection. This inspection was limited to coverage of Dr. McCarthy's studies involving the Myxo-ETlogix mitral valve repair ring.

The Center for Devices and Radiological Health became aware of an article titled, Initial Clinical Experience with Myxo-ETlogix Mitral Valve Repair Ring, published in the Journal of Thoracic and Cardiovascular Surgery, Volume 136, July 2008, by Patrick M. McCarthy, M.D., et al. The article reported that from March 15, 2006 through November 19, 2007, 129 patients underwent mitral valve surgery for pure myxomatous disease at Northwestern Memorial Hospital. The Myxo-ETlogix device was reported to have been used in 100 cases. The article states that the Myxo-ETlogix mitral valve repair ring is a new ring designed specifically for myxomatous disease. The article states that patient information and follow-up data were obtained from the prospectively maintained cardiac surgery outcomes registry of the Bluhm Cardiovascular Institute, which was approved by the Northwestern University Institutional Review Board for use in research. The article also reports that the ring is FDA approved for patients undergoing mitral valve repair.

This inspection revealed that the Cardiac Surgery Outcomes Registry (previous title: Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database) was originally approved in September 2005 as a patient database to be used for retrospective chart review. Evaluation of outcomes of mitral valve repair using the MyxoETlogix mitral valve repair ring was an objective of the Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair protocol. This protocol was reviewed and approved by the IRB as a retrospective chart review study. The IRB did not have any records for a prospective patient study involving the Myxo-ETlogix mitral valve repair ring or any information on the approval status of the device.

No refusals were encountered. No samples were collected. No Form FDA 483 was issued.

Establishment Inspection Report	FEI:	**1470178**
Northwestern University IRB	EI Start:	08/08/2008
Chicago, IL 60611-4579	EI End:	08/08/2008

FMD-145

The FMD-145 copy of this EIR and any correspondence should be sent to:

Dean M. Harrison, President and CEO
Northwestern Memorial Healthcare
251 East Huron Street
Chicago, IL 60611

ADMINISTRATIVE DATA

Inspected firm:	Northwestern University IRB
Location:	750 N Lake Shore Dr, 7th Floor Chicago, IL 60611-4579
Phone:	312-503-9338
FAX:	(312)503-0555
Mailing address:	750 N Lake Shore Dr, 7th Floor Chicago, IL 60611-4579
Dates of inspection:	8/8/2008
Days in the facility:	1
Participants:	Lisa Hayka, Investigator

At the initiation of the inspection, credentials were presented and a Form FDA 482, Notice of Inspection, was issued to Debra Gibson Tice, Interim Director of IRB Operations, and most responsible individual present at the initiation of this inspection.

HISTORY

The Northwestern University Institutional Review Board was previously inspected on 7/15/03-8/6/03 and was classified VAI due to deficiencies in documenting vote counts in meeting minutes

and discrepancies in written procedures. The IRB's responsibilities include reviewing all research involving human subjects at Northwestern University and Northwestern Memorial Hospital.

INTERSTATE COMMERCE

Not applicable.

JURISDICTION

This Institutional Review Board oversees research that is being conducted using FDA regulated articles that involve human subjects.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On 8/8/08, I presented credentials and issued a Form FDA 482, Notice of Inspection, to Debra Gibson Tice, Interim Director of IRB Operations, and most responsible individual present at the initiation of this inspection.

The following individuals were also present during the inspection:

Tasha K. Osafo, Manager, Continuing Review and Expedited Review

Eileen Yates, IRB Manager, Training and Quality Assurance

Cardiac Surgery Outcomes Registry

I obtained a list of all research projects conducted by Dr. Patrick McCarthy, closed and active. (Exhibit #1) Active studies include the Cardiac Surgery Outcomes Registry, the PARTNER IDE Trial: Placement of Aortic Transcatheter Valves Trial, sponsored by Edwards Lifesciences Corporation, and the study titled Can Cardiac Allograft Vasculopathy Be Predicted By Diastolic Dysfunction within 6 Months of Heart Transplantation?, a retrospective chart and database review. There was no project titled, Initial Clinical Experience with Myxo-ETlogix Mitral Valve Repair Ring.

The article titled, Initial Clinical Experience with Myxo-ETlogix Mitral Valve Repair Ring, published in the Journal of Thoracic and Cardiovascular Surgery, by Patrick M. McCarthy, M.D., et

Establishment Inspection Report	FEI:	**1470178**
Northwestern University IRB	EI Start:	08/08/2008
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al. states that patient information and follow-up data were obtained from the prospectively maintained cardiac surgery outcomes registry of the Bluhm Cardiovascular Institute at Northwestern Memorial Hospital. The IRB records for this study were reviewed. The project was originally titled, Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database, IRB #1532-003, and was approved by the IRB in a letter dated 9/13/05. (Exhibit #2) The IRB approved Consent Form for the Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database, Version dated 9/12/05, is included as Exhibit #3. The consent describes the research purpose is to "allow researchers to review and compare medical information including symptoms, treatments and complications that people undergoing procedures for atrial fibrillation have. It will also allow researchers to look at medical events that occur in people diagnosed with and receiving treatment for atrial fibrillation, including results of any procedures you have." The Northwestern University Research Subject Authorization Confidentiality & Privacy Rights for the Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database, Version dated 9/12/05, is included as Exhibit #4. The most current IRB approved version of the Cardiac Surgery Outcomes Registry of the Bluhm Cardiovascular Institute Clinical Trials Unit, Amendment 5, dated 7/13/07, is included as Exhibit #5. As of the date of this inspection, the project was most recently approved by the IRB on 8/20/07 through expedited review. The IRB approval letter, dated 8/21/07, is included as Exhibit #6. The current Northwestern University Department of Surgery, Consent Form and Authorization For Research, for the Cardiac Surgery Outcomes Registry, Version 5, dated 7/17/07, is included as Exhibit #7. This consent form describes the research purpose is to allow researchers to review and compare medical information including symptoms, complications and additional treatments that people undergoing cardiac surgery may have.

Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair

The closed study titled, Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair, IRB #1532-002, specifically involved the Myxo-ETlogix mitral valve repair ring. This study was described as a retrospective chart review of all patients who underwent mitral valve repair from April 2004 through June 2006. One of the primary objectives of the study was the evaluation of the results of myxomatous mitral valve repair using the Myxo-ETlogix annuloplasty ring in terms of reduction in mitral regurgitation, and a secondary objective is listed as comparing the outcomes of myxomatous valve repair using the Myxo ETlogix annuloplasty ring to other annuloplasty ring systems. The New Project (Medical Record Review) Form for this project is included as Exhibit #8.

The Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair protocol, Version 1.0, dated 6/7/06, is included as Exhibit #9. The protocol states that the Myxo ETlogix annuloplasty ring was specifically developed for patients with myxomatous mitral valves to help eliminate the need to perform the complex, time-consuming sliding-plasty procedure, and that the Myxo-ETlogix is the first ring designed to reshape the annulus to accommodate the larger leaflets. It further states that the 3-D design is elevated at the P2 segment; thereby, pulling the posterior leaflet away from the aortic outflow tract. The protocol also investigated the efficacy and safety of the Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring (CMA IMR Ring) in the surgical treatment of ischemic mitral regurgitation.

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The Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair protocol, Version 1.0, dated 6/7/06, is included as Exhibit #9. The protocol states that the Myxo ETlogix annuloplasty ring was specifically developed for patients with myxomatous mitral valves to help eliminate the need to perform the complex, time-consuming sliding-plasty procedure, and that the Myxo-ETlogix is the first ring designed to reshape the annulus to accommodate the larger leaflets. It further states that the 3-D design is elevated at the P2 segment; thereby, pulling the posterior leaflet away from the aortic outflow tract. The protocol also investigated the efficacy and safety of the Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring (CMA IMR Ring) in the surgical treatment of ischemic mitral regurgitation.

Establishment Inspection Report	FEI:	**1470178**
Northwestern University IRB	EI Start:	08/08/2008
Chicago, IL 60611-4579	EI End:	08/08/2008

Dr. McCarthy submitted a HIPAA Waiver of Authorization Form for this study. (Exhibit #10) The IRB approved this project on 6/29/06 with a waiver of authorization through expedited review procedures. The IRB approval letters are included as Exhibit #11. The Continuing Review of Research Form was received by the Office for the Protection of Research Subjects on 6/1/07. (Exhibit #12) The report stated that 25 medical records had been reviewed. The submission requested the review of records of patients who underwent mitral valve repair through May 2007. The report stated that an abstract with project findings was submitted to the Society of Thoracic Surgery but was not accepted. The abstract titled, Initial Experience with a Mitral Valve Repair Ring Designed for Myxomatous Mitral Valve Disease, printed from the Online Abstract Submission System, is dated 6/30/06. (Exhibit #13)

The Continuing Review of Research Form was reviewed by the IRB through expedited review procedures and was determined to be incomplete. The reviewer noted that because the Principal Investigator requested to expand the dates of the chart review to May 2007, the project was no longer considered retrospective in nature, and the IRB requested additional information from Dr. McCarthy. An email, dated 6/19/07, was sent to Dr. McCarthy's office informing him of the reviewer's findings. (Exhibit #14, pp. 3-4) The IRB sent another email, dated 6/28/07, informing Dr. McCarthy that he had not responded to the IRB's request for more information and that the project approval had expired. Dr. McCarthy's office responded that they had decided to terminate the project. (Exhibit #14, pp.1-2) The Project Termination/ Closure Form is included as Exhibit #15.

Ms. Tice, Ms. Yates, and Ms. Osafo could not find any information in the IRB files concerning the approval status of the Myxo-ETlogix Mitral Valve Annuloplasty Ring. During the inspection, the IRB contacted Dr. McCarthy's study coordinator, (b) (6) RN, BSN, CCRC. (b) (6) reported that she believed the device was FDA approved

REFUSALS

No refusals were encountered.

SAMPLES COLLECTED

No samples were collected.

VOLUNTARY CORRECTIONS

Not applicable.

EXHIBITS COLLECTED

1. IRB List of Studies Conducted by Dr. Patrick McCarthy
2. Original IRB Approval Letter for Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database, IRB #1532-003
3. Consent Form for the Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database, Version dated 9/12/05
4. Research Subject Authorization Confidentiality & Privacy Rights for Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database, Version 9/12/05
5. Cardiac Surgery Outcomes Registry, Amendment 5, dated 7/13/07
6. Cardiac Surgery Outcomes Registry IRB Reapproval Letter dated 8/21/07
7. Consent Form and Authorization For Research, for the Cardiac Surgery Outcomes Registry, Version 5, dated 7/17/07
8. IRB #1532-002, Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair New Project (Medical Record Review) Form
9. IRB #1532-002, Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair protocol, Version 1.0, dated 6/7/06
10. IRB #1532-002 HIPAA Waiver of Authorization Form
11. IRB #1532-002, IRB Approval Letters
12. IRB #1532-002, Continuing Review of Research Form
13. Abstract titled, Initial Experience with a Mitral Valve Repair Ring Designed for Myxomatous Mitral Valve Disease
14. Emails Regarding the Continuing Review of IRB #1532-002
15. IRB #1532-002, Project Termination/ Closure Form

ATTACHMENTS

Form FDA 482
Assignment

Establishment Inspection Report	FEI:	**1470178**
Northwestern University IRB	EI Start:	08/08/2008
Chicago, IL 60611-4579	EI End:	08/08/2008

Lisa Hayka

Lisa Hayka, Investigator

Dr. Nalini M. Rajamannan's Background

The primary purpose of this book is to make public the willful negligent actions of Dr. Patrick McCarthy of Northwestern University who implanted a heart valve ring into patients that were not FDA approved and did so without receiving consent from his patients in a clinical trial which was then later published without the University Office of Human Subject Research Protections Approval. These facts are confirmed in December 2018, as they are revealed in an FDA report obtained through the Freedom of Information Act (FIOA). The fact that in 2007 Dr. Patrick McCarthy agreed to stop testing the novel experimental protocol on patients and agreed to no longer publish the study. This did not happen. As a matter of fact, evidence shows the use of the experimental protocol continued until at least 2014.

Other federal violations and misconduct by **Northwestern University** discussed in this book include:

- Unauthorized Human Experiments
- Failure to follow-up on the outcomes of the Human Experiments
- Failure to provide proper health care for the victims
- Failure to report evidence to the Senate Finance, and Senate Judiciary Committee of the evidence
- Failure to report evidence during the court proceedings as related to Obermeier versus Northwestern Memorial Hospital, Northwestern Faculty Foundation, Edwards Lifesciences, and Dr. Patrick McCarthy.

My name is Dr. Nalini M. Rajamannan, and I am a heart valve expert in the field of cardiovascular medicine. I was born and raised in the great state of Minnesota. I have been researching heart valve disease for 31 years after I receiving my undergraduate science pre-professional degree from the University of Notre Dame, my Medical Doctorate from Mayo Medical School and my post-graduate training in Internal Medicine and Cardiology at the Mayo Clinic. I also worked at the Mayo Clinic as a staff consultant in Internal Medicine. For 19 years, I have held a visiting scientist position in Biochemistry and Molecular Biology at the Mayo Clinic. I was also an adjunct professor at the University of Notre Dame in bioengineering. I practice consultative medicine specializing in Cardiac Valvular Heart Disease at Most Sacred Heart of Cardiology and Valvular Institute, WI.

> *During my time as a witness to these events, I was recruited to Northwestern University in 2000 and I worked as a cardiologist at Northwestern University as a National Institute Health funded K08/R01/ARRA researcher in the molecular biology of valvular heart disease, VA Echo Lab Director for five years, and the*

Northwestern Valve Director from the years 2006-2011. I continued working at NU before removing herself from this study and anything associated with the study once I learned that the inventor/surgeon was not giving informed consent for the testing of his invention. An invention which he would receive future Royalties as revealed to the Senate Finance Committee during Senator Charles Grassley(IA).

At the time of my termination from Northwestern University in 2011, I was funded under the American reinvestment and recovery act grant from the NIH which provides me with lifelong protections under the federal whistleblower laws. I has been working in Sheboygan, WI as a heart valve specialist since 2010, and I have been a clinical valve researcher at Corvita for the past 2 years.

For the past 12 years, as part of my commitment and federal legal obligations as a medical doctor, I have been advocating for patients who have been enrolled in unauthorized human experiments since at least 2006 at Northwestern University. As a doctor, it is my sworn duty to bring this information to light and to help these patients and their cause.